

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



Cambridge Healthtech Institute
250 First Avenue, Suite 300
Needham, MA 02494
www.healthtech.com

Cambridge Healthtech Institute's 22nd International



Molecular Med TRI-CON 2015

February 15-20, 2015
Moscone North Convention Center
San Francisco, CA

**REGISTER BY JANUARY 16
AND SAVE UP TO \$200!**

PREMIER SPONSORS



COVER

EVENT-AT-A-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



2015 EVENT-AT-A-GLANCE

EVENTS AT THE MOSCONE NORTH CONVENTION CENTER

Sunday, February 15

1:00 pm Registration
2:00 – 5:00 pm Afternoon Short Courses
5:30 – 8:30 pm Dinner Short Courses

Monday, February 16

7:00 am Registration and Morning Coffee
8:00 – 11:00 am Morning Short Courses
11:50 – 1:00 pm Conference Programs
1:15 – 2:15 pm Luncheon Presentations or Lunch on Your Own
2:30 – 4:40 pm Conference Programs
5:00 – 6:00 pm Plenary Session
6:00 – 7:30 pm Grand Opening Reception in the Exhibit Hall with Poster Viewing

Tuesday, February 17

7:00 am Registration and Morning Coffee
8:00 – 9:00 am Plenary Session
9:00 – 10:05 am Refreshment Break in the Exhibit Hall with Poster Viewing
10:05 am – 12:15 pm Conference Programs
12:25 – 1:25 pm Luncheon Presentations or Lunch on Your Own
1:25 – 2:00 pm Refreshment Break in the Exhibit Hall with Poster Viewing
2:00 – 4:10 pm Conference Programs
4:10 – 5:00 pm
Mardi Gras Celebration in the Exhibit Hall with Poster Viewing
5:00 – 6:00 pm Breakout Discussions in the Exhibit Hall



Wednesday, February 18

7:00 am Registration and Morning Coffee
7:00 am Breakfast Presentations
8:00 – 9:45 am Plenary Session
9:45 – 10:35 am Refreshment Break & Poster Competition Winner Announced in the Exhibit Hall
10:35 am – 12:15 pm Conference Programs
12:25 – 1:00 pm Luncheon Presentations or Lunch on Your Own
1:00 – 1:40 pm Refreshment Break in the Exhibit Hall with Poster Viewing
1:40 – 5:40 pm Conference Programs

EVENTS AT THE INTERCONTINENTAL HOTEL

Thursday, February 19

7:30 am Registration and Morning Coffee
9:00 am – 5:00 pm Symposia

Friday, February 20

8:00 am Morning Coffee
8:25 am – 12:30 pm Symposia

CONFERENCE PROGRAMS

DIAGNOSTICS CHANNEL

Molecular Diagnostics
Personalized Diagnostics
Cancer Molecular Markers
Circulating Tumor Cells
Digital Pathology
Companion Diagnostics
PCR for Molecular Medicine
Genomic Sample Prep & Biospecimen Science
Epigenomics in Disease
Genome and Transcriptome Analysis
Genomic Technologies for Patient Stratification -NEW

CLINICAL CHANNEL

Epigenomics in Disease
Genomic Technologies for Patient Stratification -NEW
Translational to Clinical R&D
Clinical Sequencing
Technology-Driven Oncology Clinical Development -NEW

CANCER CHANNEL

Cancer Molecular Markers
Circulating Tumor Cells
Translational to Clinical R&D
Technology-Driven Oncology Clinical Development -NEW
Predictive Preclinical Models in Oncology

INFORMATICS CHANNEL

Genome and Transcriptome Analysis
Bioinformatics for Big Data
Integrated Pharma Informatics & Data Science

SYMPOSIA

New Frontiers in Gene Editing -NEW
Circulating Cell-Free DNA
Genomics in Medicine
Point-of-Care Diagnostics
Clinical Cancer Immunotherapy -NEW
Genomics & Sequencing Data Integration, Analysis & Visualization

STAY CONNECTED

.inked in



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



MEDIA PARTNERS

OFFICIAL MEDIA SPONSORS



SPONSORING PUBLICATIONS



WEB PARTNERS



SPONSORING ORGANIZATIONS



LOCAL SUPPORTING ORGANIZATIONS



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



Plenary Session

MONDAY, FEBRUARY 16

5:00 – 6:00 pm

Plenary Session Introduction:

Robert Penny, M.D., Ph.D., CEO, Paradigm



Integrating the Digital Universe of Data with Consumer-Driven Mobile Apps and Large-Scale Panomics Data to Better Understand, Treat, and Prevent Disease



Andrew Kasarskis, Ph.D., Co-Director, Icahn Institute for Genomics and Multiscale Biology; Vice Chairman, Department of Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai

The digital universe of data continues to grow at an exponential pace, now comprising more than 1 zettabyte of useable data. Contributing to this big data revolution are panomic technologies, which have made possible the routine sequencing of whole genomes and transcriptomes, and wearable and implantable sensors that make the acquisition of real-time physiologic data across many dimensions a reality in populations of individuals. With extensive molecular, cellular, and physiologic data generated on individuals in a longitudinal fashion, the potential exists to characterize the health of an individual at a far deeper level than has been possible before. Better characterization of an individual's health will lead to more precise diagnoses, treatments, and preventative strategies for disease at a highly personalized level. Towards this end, we have developed a predictive, multiscale framework that enables us to understand the health of an individual at the molecular, cellular, organ, organism and community scales so that we can better diagnose, treat, and prevent disease.

TUESDAY, FEBRUARY 17

8:00 – 9:00 am

Plenary Session Introduction:

Peter Heseltine, CMO, Singulex, Inc.



The Dawn of a New Research Model: The Case for Parent - Clinician - Researcher Collaboration Matthew Wilsey, President, Grace Wilsey Foundation

Matthew Wilsey, President, Grace Wilsey Foundation

Matt is a Silicon Valley angel investor and advisor. His investments include Nimble Storage, Practice Fusion, Pinterest, Virtual Instruments, Bonobos, LYFE Kitchen, Caveman Foods, Frontier Snacks, Juicero, Rinse, Moment, Tout, Pinrose, Interior Define, Gear Launch, and Weddington Way. In addition to consumer products and services, Matt invests in and advocates for biomedical research, drug development, and genetic sequencing technologies. Before moving to the investment side, he spent many years as a front-line operator. Most recently, Matt was Co-Founder and Chief Revenue Officer of CardSpring, a payment infrastructure company that was acquired by Twitter. Previously, Matt ran West coast sales and business development for Howcast.com. He was responsible for building Howcast's instructional content library, distribution network, and strategic relationships. Before Howcast, Matt worked for Kohlberg Kravis Roberts (KKR) on the Capital Markets team focused on new product development, capital raising, and investor relations. Prior to that, Matt spent five years as Co-Founder and Vice President of Business Development at Zazzle.com, where he was responsible for all content and distribution deals. He started his career serving in various roles at the White House and the Department of Defense. Matt became a rare disease hunter and advocate after his daughter, Grace, was born with NGLY1 Deficiency. He has since funded over 40 scientists at 10 medical centers in 3 countries with the sole purpose of treating the disease. Matt holds a B.A. from Stanford University and a M.B.A. from Stanford's Graduate School of Business. Matt sits on the Board of Directors of the Grace Wilsey Foundation where he is also President, Global Genes, The Lucile Packard Foundation for Children's Health, the EveryLife Foundation for Rare Diseases, and Perlstein Lab.

TUESDAY, FEBRUARY 17, 4:10 – 5:00 PM

Join us for a fun Mardi Gras Celebration. Come network with fellow delegates, exhibitors, sponsors, poster presenters and speakers at this informal fun celebration.



Refreshments will be served.

WEDNESDAY, FEBRUARY 18

8:00 – 9:45 am

Plenary Session Panel: Emerging Technologies and Industry Perspectives

Panelists:

Bernard Andruss, Ph.D., Vice President, CDx Development and Regulatory Affairs, Asuragen, Inc.

Yuling Luo, Ph.D., CEO and Founder, Advanced Cell Diagnostics

Rudi Pauwels, Ph.D., Founder, CEO & Executive Chairman, Biocartis

Puneet Sarin, MBA, Vice President & General Manager, Pathology Imaging Business, Leica Biosystems

Joe Beechman, Ph.D., Senior Vice President, R&D, NanoString Technologies

Lynn Zieske, Ph.D., Principal Scientist, Life Science, Singulex, Inc.

Mark Hughes, Senior Product Manager, Systems Biology & Analytics, Thomson Reuters Addition
Panelists to be Announced

Sponsored by:



NEW



EARN POINTS WITH THE NEW TRICON PERKS REWARDS!

STEP 1: Register online at TriConference.com/TRICON-Perks for your Perks Reward

STEP 2: Start earning perks Mention MMTCF when you complete the "Perks Registration" for your first perk

STEP 3: Visit the Cambridge Healthtech Institute Booth in the Tri-Conference Exhibit Hall and you will receive your TRICON Perks Reward (Starbucks Gift Card).

For more information, visit: TriConference.com/TRICON-Perks

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com

SHORT COURSES*

SUNDAY, FEBRUARY 15
AFTERNOON COURSES | 2:00 – 5:00 pm

SC1: Translating CTCs to Clinical Use

Joshua M. Lang, M.D., MS, Assistant Professor of Medicine, Carbone Cancer Center, University of Wisconsin, Wisconsin Institutes for Medical Research
Allison Welsh, Ph.D., CTC Scientist, Foundation Medicine, Inc.
Benjamin Casavant, Ph.D., Vice President, Tasso

SC2: Latest Advances in Molecular Pathology

Michael H.A. Roehrl, M.D., Ph.D., Director, UHN Program in BioSpecimen Sciences, University of Toronto
Xu Li, M.D., Ph.D., Director, Cytogenetics Lab, Genetics, Kaiser Permanente San Jose Medical Center
Carlos J Suarez, M.D., Assistant Professor, Pathology, Molecular Pathology, Stanford University Medical Center, Stanford Health Care

SC3: Validation and Compliance Considerations for an NGS Lab

Victoria M. Pratt, Ph.D., FACMG, Director, Pharmacogenomics Laboratory, Medical and Molecular Genetics, Indiana University School of Medicine
Monica J. Basehore, Ph.D., FACMG, Lead Director, Molecular Diagnostic Laboratory; Associate Director, Medical Genetics Training Program, Greenwood Genetic Center

SC4: Sequencing 101

Ryan Kim, Ph.D., Director, UC Davis Genome Center, DNA Technologies and Expression Analysis Cores, University of California, Davis

SC5: PCR Part I: Primer Design for PCR Experiments

Jian Han, Ph.D., Faculty Investigator, iCubate, HudsonAlpha Institute for Biotechnology
Carl T. Wittwer, M.D., Ph.D., Professor, Pathology, University of Utah

SC6: Reimbursement for Advanced Diagnostics: From Clinical Value Establishment to Coverage and Pricing

Catherine Schnabel, Ph.D., Senior Vice President, Research & Development, bioTheragnostics, Inc.
Macey Johnson III, Vice President, Managed Care and Reimbursement, bioTheragnostics, Inc.

SUNDAY, FEBRUARY 15
DINNER COURSES | 5:30 – 8:30 pm

SC9: Clinical Informatics Needs of an NGS Lab

Alexis B. Carter, M.D., Assistant Professor, Pathology and Laboratory Medicine; Member, Center for Comprehensive Informatics; Director, Pathology Informatics, Emory University School of Medicine; Chair, AMP Informatics Interest Group; President, Association of Pathology Informatics
Federico A. Monzon, M.D., FCAP, Director, Oncology, InVita; Adjunct Faculty, Baylor College of Medicine
Mark J. Routbort, M.D., Ph.D., Director, Computational and Integrational Pathology; Associate Professor, Hematopathology; Medical Director, Laboratory Informatics, UT MD Anderson Cancer Center



SC10: Knowing Your NGS Analysis Upstream: Alignments and Variants

Gabe Rudy, Vice President, Product Development, Golden Helix

SC11: Regulatory Compliance in Molecular Diagnostics

Melina Cimler, Ph.D., Vice President, Head, Global Quality, Illumina, Inc.
Maham Ansari, MS, RAC, Senior Manager, Regulatory Affairs, Focal Healthcare, Inc.

SC12: Introduction to Hadoop for Bioinformatics

Martin Gollery, CEO, Tahoe Informatics

SC13: PCR Part II: Digital PCR Applications and Advances

Alison Devonshire, Ph.D., Science Leader, Nucleic Acid Metrology, LGC Genomics
Robert Palais, Ph.D., Associate Professor, Math Dept, Utah Valley University; Research Professor, Pathology Dept, University of Utah

MONDAY, FEBRUARY 16
MORNING COURSES | 8 – 11:00 am

SC17: Commercialization Boot Camp: Manual for Success in Molecular Diagnostics

Harry Glorikian, Healthcare Consultant
Elaine Cheung, Business & Corporate Development, Illumina

SC18: Next-Generation Sequencing as a Diagnostics Platform

Karl Voelkerding, M.D., Associate Professor, Pathology, University of Utah; Medical Director, Advanced Technology and Bioinformatics, ARUP Laboratories
Additional Instructors to be Announced

SC19: Isolation and Characterization of Cancer Stem Cells

Leslie Crews, Ph.D., Assistant Project Scientist, Catriona Jamieson Laboratory, Sanford Consortium for Regenerative Medicine and MooresUCSD Cancer Center
Kristen M. Smith, Ph.D., Scientist II, Bionomics, Inc.

SC20: Using Preclinical Models in Oncology to Inform First-Man-Trial Design: Tools and Techniques

Arijit Chakravarty, Ph.D., Director, Modeling & Simulation (DMPK), Takeda Pharmaceutical International Co.

SC21: Best Practices in Personalized and Translational Medicine

Erik Bierwagen, Principal Programmer Analyst, Genentech
Sergio Rotstein, Ph.D., Director, Research Business Technology, Pfizer, Inc.
Jean Yuan, Senior Programming Analyst, Genentech
Doug Garrett, Software Engineer, Genentech

SC22: NGS for Infectious Disease Diagnostics

Charles Chiu, M.D., Ph.D., Assistant Professor, Lab Medicine and Medicine, Infectious Diseases, University of California San Francisco

SHORT COURSES MAXIMIZE YOUR PRODUCTIVITY

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

Short Courses are held prior to the main conference events so you won't miss a moment of TRI-CON 2015.



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



DIAGNOSTICS CHANNEL

Molecular technologies are essential to accurately understand and effectively diagnose disease and guide therapy. The Diagnostics Channel will bring together industry leaders to discuss best practices in the creation and implementation of tools to enable personalized medicine.

- Molecular Diagnostics
- Personalized Diagnostics
- Cancer Molecular Markers
- Circulating Tumor Cells
- Digital Pathology
- Companion Diagnostics
- PCR for Molecular Medicine
- Genomic Sample Prep and Biospecimen Science
- Epigenomics in Disease
- Genome and Transcriptome Analysis
- Genomic Technologies for Patient Stratification - **NEW**

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



The Industry Leader's Networking Event

Cambridge Healthtech Institute's Twelfth Annual

MOLECULAR DIAGNOSTICS

Executive Strategies for Success

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

KEYNOTE FORUM

Co-Organized with

11:50 Moderator's Opening Remarks

*Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP
(AMP 2014 President and Member, AMP Professional Relations
Committee)*



12:00 pm **PANEL DISCUSSION: The Value of Molecular Diagnostics: A Discussion on Clinical Utility**

The number and complexity of clinical molecular diagnostic tests (MDx) are increasing at a rapid rate. The health care professional asks: When does MDx make sense for my patient? What scientific evidence is needed to establish the clinical utility of a particular MDx? This keynote session will focus on the clinical utility of MDx in cancer and inherited disease. It is an outgrowth of ongoing discussions on this issue among members of the Association for Molecular Pathology. We will address the contribution of MDx to the care of patients at the present time, and anticipated progress in the near future.

- Defining and measuring clinical utility from the point of view of both the clinician and the patient
- MDx of malignancies to offer prognostic and predictive information useful for selecting the optimal therapy
- Halting the "diagnostic odyssey" by selecting the appropriate genomic MDx for people, often children, with diseases that are difficult or sometimes seemingly impossible to diagnose
- Establishing the value of MDx as a modality that will not only improve health-care, but do so in a way that will lower costs in the long run

Panelists:

Loren Joseph, M.D., Medical Director, Molecular Diagnostics & Cancer Genetics, Pathology, Laboratory Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School (2014 Chair, AMP Clinical Practice Committee)

Paul G. Rothberg, Ph.D., Professor, Pathology & Lab Medicine, University of Rochester Medical Center (AMP Clinical Practice Committee, Genetics Subdivision Representative)

1:00 Session Break

1:15 Luncheon Presentation I: Rising to the Challenge of Liquid Biopsies using PointMan DNA Enrichment

*Andrew Webb, CEO, EKF Molecular
Diagnostics*

Sponsored by



Personalised cancer therapies based on tumour genotype have led to unparalleled progress in treatment. Genotype at diagnosis using solid biopsies is standard, routine monitoring of patient genotype during treatment presents an unmet clinical need. Here we present data utilising PointMan DNA enrichment using cfDNA and circulating tumour cells and how this rapid and cost effective sample enrichment can be incorporated into routine and next generation sequencing assays for patient monitoring.

1:45 Luncheon Presentation II (*Sponsorship
Opportunity Available*)

2:15 Session Break

PANEL DISCUSSION: Generating and Communicating Evidence for Payer Coverage

2:30 Moderator's Remarks

John W. Hanna, Vice President, Endocrinology, Veracyte

Medical policy is a complex multi-factor decision-making process. In addition to the objective assessment of medical evidence, plans may consider input from their network providers, employers, patients, and their peers. However, labs can be challenged with getting their medical evidence in front of medical policy review committees and decision makers. Obtaining medical policy coverage requires convincing data, but it also requires active participation of other influencers that drive medical policy review and decision making. This session will discuss how to harness some of those influencers in the medical policy review process.

- Harnessing local providers and KOLs
- Empowering patients to advocate for coverage
- Formally communicating medical evidence to medical policy committees

Panelists:

Robin Harper Cowie, Director, Reimbursement, Biondesix, Inc.

Jeffrey P. Bush, MBA, Vice President, Payer Markets & Reimbursement, AssureX Health

Marijke Annis, MSPH, Independent Consultant, Reimbursement and Market Access Strategy Development, CardioDx, Inc.

4:10 Leveraging New Automated Ultra-Sensitive Detection Technologies for Novel LDTs

Sponsored by
Quanterix

*Mark Roskey, Ph.D., Vice President & General Manager,
Applications & Reagents, Quanterix*

With the rapid growth of personalized medicine and the resulting proliferation of novel tests offered in private labs as LDTs, more powerful and efficient tools are required. We will introduce and discuss how Simoa, an ultra-sensitive protein detection platform, meets the specific needs of LDT providers.

4:25 2015 is Here! Reimbursement Lessons for Another Year

Sponsored by
XIFIN

*Rina Wolf, Vice President, Commercialization
Strategies, Consulting and Industry Affairs, XIFIN, Inc.*

This session will highlight any updates on PAMA, Medicare and commercial payor trends in coverage and pricing, and what labs should be looking out for this year, and beyond.

4:40 Break and Transition to Plenary Session

» **5:00 PLENARY SESSION (PLEASE SEE PAGE
5 FOR DETAILS)**

**6:00 Grand Opening Reception in the Exhibit Hall
with Poster Viewing**

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» **8:00 PLENARY SESSION (see page 5 for
details)**

**9:00 Refreshment Break in the
Exhibit Hall with Poster Viewing**

Sponsored by
SLONEPARTNERS

NEW INSIGHTS INTO DISEASE FROM NON-CODING RNA

10:05 Chairperson's Remarks

Dalia Cohen, Ph.D., Head, Research, Beryllium

MOLECULAR DIAGNOSTICS

CONTINUED ON NEXT PAGE

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



MOLECULAR DIAGNOSTICS

continued

10:15 About Noam Chomsky, DNA Patterns, Noncoding RNAs and Cancer Patients

George Calin, M.D., Ph.D., Professor, Experimental Therapeutics and Leukemia, MD Anderson Cancer Center

This talk will review the newly discovered differential expression in numerous tissues, key cellular processes and multiple diseases for several families of long and short non-coding RNAs (ncRNAs, RNAs that do not codify for proteins but for RNAs with regulatory functions), including the already famous class of microRNAs (miRNAs). These strongly suggest that the scientific and medical communities have significantly underestimated the spectrum of ncRNAs whose altered expression has significant consequences in diseases. This talk will review the recent studies on miRNAs and non-coding genes.

10:45 Journeys through Space and Time: Ultra High-Resolution Expression Profiling of Long Noncoding RNAs

Marcel E. Dinger, Ph.D., Head, Clinical Genomics, Kinghorn Center for Clinical Informatics, Garvin Institute of Medical Research

Long noncoding RNAs (lncRNAs) are increasingly recognized as having key regulatory roles in development and disease. However, these regulatory molecules often have short half lives and are expressed only in specific tissues or cell types, resulting in the poor representation of lncRNAs in transcriptomic datasets. Using novel detection and sampling approaches, we reveal a high-resolution spatiotemporal view of the long noncoding transcriptome that provides fresh insights into their roles in development and disease.

11:15 Exosomal microRNAs Orchestrate the Biology of the Tumor Microenvironment

Muller Fabbri, M.D., Ph.D., St. Baldrick's Foundation Scholar; Assistant Professor, Pediatrics and Molecular Microbiology & Immunology, Norris Comprehensive Cancer Center, University of Southern California- Keck School of Medicine; Children's Hospital Los Angeles

MicroRNAs (miRNAs) are secreted by cells within microvesicles called exosomes. Cancer cells are selective in defining the miRNA cargo within their exosomes. The function of exosomal miRNAs within the Tumor Microenvironment is currently not completely understood. We discovered that in addition to their "traditional" gene expression regulatory mechanism of action, exosomal miRNAs can also function as ligands of miRNA receptors in surrounding cells, leading to a pro-tumoral response. These findings identify a new mechanism of action of miRNAs and lead to the identification of new targets.

11:45 Sponsored Presentations (Opportunities Available)

12:15 pm Session Break

12:25 Luminex: Setting a New Standard of Care with ARIES™ and NxTAG™

Sherry Dunbar, Ph.D., Director, Scientific Affairs, Luminex Corporation

Sponsored by
Luminex

12:55 Luncheon Presentation II : CLIA Waived Molecular Diagnostics: A Ripe Opportunity in the Age of Affordable Health Care

Ihor Boszko, Vice President, Business Development, Xagenic Inc. Katherine Tynan, Ph.D., President, Tynan Consulting LLC Fran White, President, MDC Associates

Sponsored by
Xagenic

The molecular diagnostic industry has been evolving toward point-of-care diagnostics for the past decade. However, because most MDx systems rely on PCR and similar enzymatic methods, no system has been simple enough to attain CLIA-waived status. Emerging MDx technologies enable simpler engineering and workflows, broadening access to POC diagnostics to larger markets like physicians' offices. This session will explore commercial, regulatory, reimbursement and health economic aspects of CLIA-waived MDx testing.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

MOLECULAR DIAGNOSTIC TESTS: IMPROVING PATIENT CARE AND SAVING COSTS

Co-Organized with



2:00 Moderator's Remarks

Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

- What are the new tests?
- Why are they important?
- How are they transforming care?
- Do they save money?
- Current obstacles to medical adoption

Panelists:

Mark Monane, M.D., MS, Chief Medical Officer, CardioDx, Inc. David Jansen, Vice President, Marketing, Vermillion, Inc. Albert A. Luderer, Ph.D., Chief Executive Officer, Integrated Diagnostics (IndiDx)

3:40 Discovery, Development and Commercialization of Multiplex Diagnostics

Austin Tanney, Ph.D., Marketing Manager, Almac Discovery and Diagnostics, Almac

Sponsored by
ALMAC

This presentation will highlight Almac's experience and expertise in the discovery, development and commercialization of multiplex diagnostics and companion diagnostics. Detail will be shown on the discovery and

development of Almacs test for Angiogenesis drug response (AADx).

3:55 Sponsored Presentation (Opportunity Available)

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (see website for details)

6:00 Close of Day

WEDNESDAY, FEBRUARY 18

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

8:00 PLENARY SESSION PANEL (see page 5 for details)

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall



10:35 Moderator's Remarks

Alan B. Carter, President, MDx Consulting

Start-up companies selected from a pool with product ideas for Assays, Reagents, Platforms, Computation and Data for the molecular diagnostics industry will compete to be chosen for a longer presentation in front of a panel of judges.

Qualifying Criteria:

Start-up companies will be judged on the following: 1) Clinical utility 2) Investor readiness 3) Healthcare impact

Panel of Judges:

Mark Boguski, M.D., Ph.D., Founder & CMO, Genome Health Solutions Paul D. Grossman, Ph.D., Venture Partner, Telegraph Hill Partners Stan Rose, Ph.D., CEO, Transplant Genomics Enrico Picozza, MS, Venture Partner, HLM Venture Partners

MOLECULAR DIAGNOSTICS

CONTINUED ON NEXT PAGE

- COVER
- EVENT-ATA-GLANCE
- PLENARY SESSION
- SHORT COURSES
- DIAGNOSTICS CHANNEL
- CLINICAL CHANNEL
- CANCER CHANNEL
- INFORMATICS CHANNEL
- SYMPOSIA
- SPONSOR & EXHIBIT OPPORTUNITIES
- HOTEL & TRAVEL INFORMATION
- REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!
TriConference.com

MOLECULAR DIAGNOSTICS

continued

Enter for your start-up to compete at:
www.triconference.com/evaluating-start-ups

12:15 pm Session Break

12:25 Luncheon Presentation: From Biomarkers to Business Success: Strategies to Maximize Clinical Impact and Market Uptake



Scott Marshall, Ph.D., Managing Director, Precision Analytics, Precision for Medicine
David Parker, Ph.D., Vice President, Market Access, Precision for Medicine

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

1:40 Competition by Finalists

2:40 Summary and Award for Top Start-Up

Presented by the Judges Panel

3:20 Sponsored Presentations (Opportunities Available)

3:50 Refreshment Break

WHAT DO YOU HAVE TO DO TO GET A TEST COVERED AROUND HERE?

Insights from Proponents, Payers, and the PMC

4:00 Moderator's Remarks

Lon Castle, M.D., CMO, Molecular Genetics and Personalized Medicine, CareCore National, LLC

Diagnostic companies, health systems, and payers have all been impacted in different ways by the advent of genomics. Their views on how to best incorporate these emerging tests stem from their unique roles within the healthcare system. Insights on how they assess when a test provides enough value to include it as a covered benefit for their members will be explored. The metrics for getting a molecular diagnostic test covered continue to evolve. Hearing from payers on how they evaluate tests and what factors are most important in demonstrating value would provide good insights into the process for the conference attendees

- Determine how health systems evaluate data to determine benefits of a genomic test
- Appreciate the key elements that determine success (or failure) when creating new genomic tests
- Understand how payers think about the inclusion of new genomic tests into the medical benefit
- Hear how organizations like the Personalized Medicine Coalition are working to guide diagnostic companies in their evidence development process

Panelists:

Fiona Wilmot, M.D., M.P.H., Healthcare Consultant
Sherie Smalley, M.D., Chief, Medical Policy & Benefits Branch, UPMC Health Plan
Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

5:40 Close of Conference Program



PERSONALIZED DIAGNOSTICS

Impacting Care and Improving Outcomes

Sponsored by



4:10 Changing The Landscape of Non-Invasive Prenatal Testing: The IONA Test

Peter Collins, CCO, Premaitha Health

4:25 Sponsored Presentation (Opportunity Available)

4:40 Break and Transition to Plenary Session

5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by



CASE STUDIES OF AN INTEGRATED APPROACH TO PATIENT CARE

10:05 Chairperson's Remarks

Karl V. Voelkerding, M.D., Professor, Pathology, University of Utah; Medical Director, Genomics and Bioinformatics, ARUP Laboratories

10:15 Clinical Exome Sequencing for the Diagnosis of Neurodegenerative Disorders

Rong Mao, M.D., Associate Professor, Pathology, ARUP Lab, University of Utah

Clinical exome sequencing is a new genome-based technology for demystifying undiagnosed illnesses - particularly rare childhood diseases. It has proven remarkably successful in identifying the causes of Mendelian diseases with a reported detection rate for deleterious mutations ranged from 25 to 30%. Herein I will present exome cases, and illustrate exome sequencing as an efficient diagnostic tool for complex neurodegenerative disorders.

PERSONALIZED DIAGNOSTICS

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

KEYNOTE FORUM

Co-Organized with



11:50 Moderator's Opening Remarks

Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP (AMP 2014 President and Member, AMP Professional Relations Committee)

12:00 pm PANEL DISCUSSION: The Value of Molecular Diagnostics: A Discussion on Clinical Utility

The number and complexity of clinical molecular diagnostic tests (MDx) are increasing at a rapid rate. The health care professional asks: When does MDx make sense for my patient? What scientific evidence is needed to establish the clinical utility of a particular MDx? This keynote session will focus on the clinical utility of MDx in cancer and inherited disease. It is an outgrowth of ongoing discussions on this issue among members of the Association for Molecular Pathology. We will address the contribution of MDx to the care of patients at the present time, and anticipated progress in the near future.

- Defining and measuring clinical utility from the point of view of both the clinician and the patient
- MDx of malignancies to offer prognostic and predictive information useful for selecting the optimal therapy
- Halting the "diagnostic odyssey" by selecting the appropriate genomic MDx for people, often children, with diseases that are difficult or sometimes seemingly impossible to diagnose
- Establishing the value of MDx as a modality that will not only improve health-care, but do so in a way that will lower costs in the long run

Panelists:

Milena Cankovic, Ph.D., D(ABMLI), Director, Molecular Pathology and Genomic Medicine, Pathology, Henry Ford Hospital, Adjunct Assistant Professor, Wayne State University School of Medicine (AMP Clinical Practice Committee)

Paul G. Rothberg, Ph.D., Professor, Pathology & Lab Medicine, University of Rochester Medical Center (AMP Clinical Practice Committee, Genetics Subdivision Representative)

1:00 Session Break

1:15 Luncheon Presentation I: Multiplexed Fusion Gene

Detection with the nCounter Elements™ Reagents

Sponsored by
nanoString
TECHNOLOGIES

Gino Somers, Ph.D., Division Head, Pathology, The Hospital for Sick Children

nCounter Elements reagents enable the development of highly multiplexed assays capable of detecting fusion events. Assays can be developed which target a given fusion gene without knowledge of the partner gene. Alternatively, assays can be developed that target the unique sequence formed at the fusion junction. These methods can be combined to develop robust, comprehensive assays for virtually any gene fusion. Data will be presented demonstrating the performance of a comprehensive fusion gene assay based on nCounter Elements reagents.

1:45 Luncheon Presentation II (Sponsorship Opportunity Available)

2:15 Session Break

CASE STUDIES IN PRENATAL DIAGNOSTICS

2:30 Chairperson's Remarks

Allan T. Bombard, M.D., MBA, Chief Medical Officer, Progenity, Inc.

2:40 History Before NIPT

Mark I. Evans, M.D., Professor, Obstetrics & Gynecology, Mount Sinai School of Medicine; Director, Comprehensive Genetics PLLC

The past 50 years have seen a pendulum of screening and testing for prenatal diagnosis with increasing rounds of sophistication, better statistics, and increasing acceptance. The "goal posts" have kept moving rendering sweeping conclusions as to primacy of any approach having a very short shelf life. The economics and science are intertwined in trying to determine optimal protocols and standards.

3:10 Case Studies in Prenatal Diagnostics; End-User of Prenatal Testing in Clinical Practice

Edward Wolf, M.D., President, New Jersey Perinatal Associates

To review the impact that rapid changes in prenatal testing options have had on the delivery of healthcare to pregnant women, from screening tests, ultrasound and cell free fetal DNA in maternal serum to invasive needle based testing options.

3:40 Lessons from NIPT: Interesting Cases, Complex Issues

Nicole Teed, MS, CGC, CEO, Integrity Genomics

In the few years since NIPT emerged as an advanced prenatal screening technology, a number of lessons have been learned, both biological and ethical. This presentation will use case studies to illustrate considerations for NIPT, with broader applications for other NGS technologies making their way into routine medical practice.

COVER

EVENT-AT-A-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



PERSONALIZED DIAGNOSTICS

continued

10:45 Clinical Utility of Multiple-Gene Sequencing Panels for Hereditary Cancer Risk Assessment

James M. Ford, M.D., Associate Professor, Medicine & Genetics, Division of Oncology, Stanford University School of Medicine

Panels assaying multiple hereditary cancer risk genes are entering clinical use, however little is known about their yield or effect on clinical management of patients. We sequenced germline DNA samples from 400 patients with personal and family histories of breast and/ovarian cancer, but without BRCA1/2 mutations, and found ~10% carry potentially pathogenic mutations in other cancer susceptibility genes.

11:15 Applying Next-Generation Sequencing to Mutation Detection in Hematologic Malignancies with an Emphasis on Value Added to Patient Care

Jennifer J.D. Morrisette, Ph.D., FACMG, Scientific Director, Clinical Cancer Cytogenetics; Clinical Director, Center for Personalized Diagnostics; Pathology, University of Pennsylvania

Genomic testing in hematologic malignancies reliably detects somatic mutations and can provide insight into disease development, prognosis and therapeutic options. This talk will discuss our approach to mutation detection in hematological malignancies, including capture of difficult to sequence regions (e.g. CEBPA and large FLT3-ITDs), and mutation profiles with respect to conventional cytogenetic findings. An overview of clinical impact of testing and case studies where our NGS-heme panel influenced treatment will be discussed.

11:45 Metagenomic Next-Generation Sequencing for Clinical Diagnosis of Infectious Diseases

Charles Chiu, M.D., Ph.D., Assistant Professor, Laboratory Medicine and Medicine/Infectious Diseases; Director, UCSFAbbott Viral Diagnostics and Discovery Center; Associate Director, UCSF Clinical Microbiology Laboratory, UCSF School of Medicine

Metagenomic next-generation sequencing (NGS) is a powerful approach to diagnose infectious diseases by comprehensively detecting all potential pathogens in a single assay. We have validated an NGS assay for infectious diseases in a CLIA-certified laboratory setting that leverages a rapid, cloud-compatible bioinformatics pipeline for pathogen identification. We will discuss case studies applying this assay for diagnosis of challenging clinical cases in infectious disease.

12:15 pm Session Break

12:25 Luncheon Presentation I: Information Innovation for Clinical Implementation of Next-Generation Sequencing

Shelly Gunn, M.D., Ph.D, CMO, MolecularHealth, Inc. David Jackson, Ph.D, CSO, MolecularHealth, Inc.

In-depth discussion of innovative clinico-molecular informatics platform that applies proprietary text analytics, biomedical curation, genome and proteome informatics and chemoinformatics methodologies to the analysis of patientspecific clinical and molecular information to identify the safest and most effective cancer treatment options. Case studies will be presented that demonstrate the translation of genetic tumor data to actionable information using HER2 positive early stage breast cancer cases.

12:55 Luncheon Presentation II

(Opportunity Available)

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

TAKING A SNAPSHOT OF BLOOD/PLASMA/SERUM TO LEARN ABOUT THE HEALTH OF THE PATIENT

2:00 Chairperson's Remarks

Daniel H. Farkas, Ph.D., HCLD, FACB, Laboratory Director, Sequenom Center for Molecular Medicine

2:10 Translating a Trillion Points of Data into Therapies, Diagnostics, and New Insights into Disease

Atul Butte, M.D., Ph.D., Division Chief and Associate Professor, Stanford University School of Medicine; Director, Center for Pediatric Bioinformatics, Lucile Packard Children's Hospital; Co-Founder, Personalis and NuMedii

Dr. Butte's lab at Stanford builds and applies tools to translate more than a trillion points of molecular, clinical, and epidemiological data – measured by researchers and clinicians over the past decade and now commonly called “big data” – into diagnostics, therapeutics, and new insights into disease. Dr. Butte will highlight his lab's work on using publicly-available molecular measurements to discover new diagnostics and treatment mechanisms for type 2 diabetes and the evaluation of patients presenting with whole genomes sequenced.

2:40 Adventitious Maternal Cancer Detection during Non-Invasive Prenatal Testing of Circulating Fetal DNA

Nilesh Dharajiya, M.D., Director, Clinical Lab, Sequenom Laboratories

Non-invasive prenatal testing of cell free DNA (cfDNA) provides a novel tool to detect chromosomal abnormalities prenatally. Maternal cfDNA is also sequenced, and therefore, we may learn about the mother's genome or other medical conditions. Here, we provide an overview of cfDNA aneuploidy testing and present clinical cases where testing serendipitously detected cell free tumor DNA, resulting in an earlier diagnosis of a neoplastic process.

3:10 Liquid Biopsy Approaches For Detecting and Characterizing Human Cancer

Victor Velculescu, M.D., Ph.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Cancer Center

Analyses of cancer genomes have revealed mechanisms underlying tumorigenesis and new avenues for therapeutic intervention. In this presentation, I will discuss lessons learned through the characterization of cancer genome landscapes, challenges in translating these analyses to the clinic, and new technologies that have emerged to analyze molecular alterations in the circulation of cancer patients as cell-free tumor DNA. These approaches have important implications for non-invasive detection and monitoring of human cancer, therapeutic stratification, and identification of mechanisms of resistance to targeted therapies.

3:40 The Hunt for Blood-Based Biomarkers for Diagnosis of Neurodegenerative Diseases

Robert M. Umek, Meso-Scale Diagnostics

While cerebrospinal fluid biomarkers and brain imaging have advanced our understanding of neurodegenerative diseases, there is considerable demand for blood-based biomarkers for diagnostics and use in clinical trials owing to the ease of sample acquisition and cost. The status of the field as well as the challenges remaining will be considered.

3:55 Sponsored Presentation (Opportunity Available)

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (see website for details)

6:00 Close of Day

WEDNESDAY, FEBRUARY 18

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

8:00 PLENARY SESSION PANEL (see page 5 for details)

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

STRATEGIC ISSUES IN NGS-ENABLED CANCER CARE

10:35 Chairperson's Remarks

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

10:45 Advancing Clinical Outcomes with Targeted Therapies for Patients with Solid Tumors Using the Next Generation Sequencing Assay

Jo-Anne Vergilio, M.D., Associate Medical Director, Foundation Medicine, Inc.

The FoundationOne™ assay for solid tumors has been validated as a sensitive comprehensive next generation sequencing assay that can detect all classes of genomic alterations at extremely low mutant allele frequencies. This presentation will highlight clinical applications of FoundationOne that have impacted disease outcomes in a variety of common and rare solid tumors.

PERSONALIZED DIAGNOSTICS

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



Cambridge Healthtech Institute
250 First Avenue, Suite 300
Needham, MA 02494
www.healthtech.com

PERSONALIZED DIAGNOSTICS

continued

11:15 High-Impact Applications of Liquid Biopsies

Luis A. Diaz, M.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

Novel technologies to evaluate tumor burden in blood have opened the doors for several new clinical applications that will address unmet clinical needs in Oncology. This lecture will discuss these high-impact applications in the context of the most recent technologies.

11:45 The NGS Cost Equation in Cancer Care: Are We at the Tipping Point?

German Pihan, M.D., Staff Pathologist & Director, Hematopathology Lab, Pathology, Beth Israel Deaconess Medical Center

The cost-effectiveness of exome sequencing (WES) in the diagnosis, risk assessment and, particularly, therapy of cancer remains undetermined. This talk will address this very important issue and propose guidelines for the development of data-driven algorithms predicting cost-effective implementation of WES.

12:15 pm Session Break

12:25 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

WHAT IS NEEDED FOR TRANSLATION IN THE CLINICAL SETTING?

1:40 Chairperson's Remarks

Paul R. Billings, M.D., Ph.D., CMO, Omicria, Inc.

1:50 KEYNOTE PRESENTATION: Challenges Encountered Using NGS in Common Clinical Settings

Paul R. Billings, M.D., Ph.D., CMO, Omicria, Inc.

NGS is evolving to become a common part of oncology and obstetric practices as well as in the evaluation of pediatric and adult cases that are difficult to diagnose. A variety of challenges have been encountered in the high quality implementation of NGS in these settings. What do doctors and patients understand is the value of these tests and how does this impact consent for testing? What types of tests are ordered? What results are reported? What services optimize delivery? What interpretative support is required immediately and over time? Consultants will increasingly bring already captured NGS data to routine clinical encounters. This talk will discuss these issues as NGS is standardized and integrates in to professional medical practice.

2:20 Precision Prevention

Dietrich A. Stephan, Ph.D., Professor & Chairman, Human Genetics, University of Pittsburgh; Associate Director, Population Genetics and Translational Acceleration, Institute for Personalized Medicine of UPMC & University of Pittsburgh Health

New molecular diagnostics are allowing us not only stratify individuals for therapies when sick (personalized medicine),

but also now to allow pre-symptomatic molecular diagnosis. Precision prevention promises to significantly impact individual outcomes and improve public health.

2:50 Delivering Diagnostic and Predispositional Genomic Findings in the Clinic

Robert C. Green, M.D., MPH, Associate Professor, Medicine & Genetics, Brigham & Women's Hospital and Harvard Medical School

This talk will describe empirical efforts to use genomic information from germline sequencing in the clinical practice of medicine. Evidence will be presented emphasizing distinctions between sequencing for diagnosis and predispositional or predictive testing. New data will be presented supporting the penetrance of incidental findings in unselected populations.

3:20 The Clinical and Diagnostic Advantages of Genome-Wide Sequencing Based MDx

Sponsored by
gh GENOMIC HEALTHCARE INNOVATIONS

Elizabeth Worthey, Ph.D., Vice President, Informatics, Genomic Healthcare Innovations

Many patients with suspected genetic disorders remain undiagnosed and at risk for inappropriate, costly therapies that may negatively impact quality of life. We will discuss how genome-wide sequencing based tests can significantly increase the definitive diagnosis rate for these patients.

3:35 Sponsored Presentation (Opportunity Available)

3:50 Refreshment Break

TRANSLATING DATA TO PATIENT CARE

4:00 Chairperson's Remarks

4:10 KEYNOTE PRESENTATION: Global Exchange of Human Genetic Data for Medicine and Research

David Haussler, Ph.D., Distinguished Professor and Scientific Director, UC Santa Cruz Genomics Institute, University of California Santa Cruz

Every human disease is a rare disease at the molecular level. No single institute has enough patients to understand any particular molecular subtype. For genomics to benefit medicine and science, we must share data. This presentation outlines the data standards and Application Programming Interfaces developed by the Global Alliance for Genomics and Health that are intended to address this issue, and highlight a few global genomics projects that use them.

4:40 Data Linking and Warehousing to Support Evaluation of Pathogenicity of Genes and Genetic Variants by the Clinical Genome Resource Project

Xin Feng, Ph.D., Assistant Professor, Bioinformatics Research Lab and Department of Molecular and Human Genetics, Baylor College of Medicine

The Clinical Genome Resource (ClinGen) is an NIH-funded program dedicated to creating a database of clinically relevant genomic variants to inform genome interpretation in a

DIAGNOSTICS CHANNEL

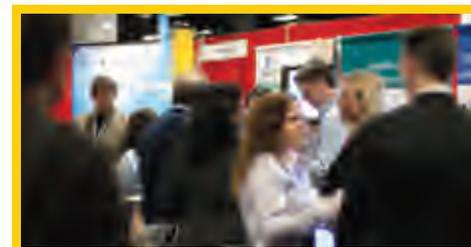
variety of clinical contexts. A core component of ClinGen is ClinGenDB, an integration point for data about variants that supports their computational and manual evaluation by experts. In this presentation, we compare the two approaches by going through a number of use cases of data integration in ClinGenDB for the purpose of evaluating pathogenicity of genetic variants.

5:10 XPRIZE: Transforming Science Fiction into Science Reality through Incentivized Competition

Grant Campamy, Senior Director, XPRIZE

Imagine a portable, wireless device in the palm of your hand that monitors and diagnoses your health conditions. That's the technology envisioned by the \$10 million Qualcomm Tricorder XPRIZE competition, and it will allow unprecedented access to personal health metrics. The end result: Radical innovation in healthcare that will give individuals far greater choices in when, where, and how they receive care.

5:40 Close of Conference Program



CHI's
INTRONET
Networking at its Best

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

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

Cambridge Healthtech Institute's Eighth Annual

CANCER MOLECULAR MARKERS

Guiding Cancer Management

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

» KEYNOTE SESSION: MARKER OF CHOICE FOR CLINICAL USE?

11:50 Chairperson's Opening Remarks

Stefanie Jeffrey, M.D., John and Marva Warnock Professor, Surgery; Chief of Surgical Oncology Research, Stanford University School of Medicine and Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University, Medical Center Hamburg-Eppendorf, University of Hamburg

12:00 pm CTC: Current Clinical Utility and Future Prospects

Jeffrey Smerage, M.D., Ph.D., Clinical Associate Professor, Division of Hematology and Oncology, University of Michigan
CTC enumeration is clearly associated with poor prognosis in several epithelial malignancies. A prospective randomized clinical trial in metastatic breast cancer (S0500) demonstrated that failure to clear CTC harbors a terrible prognosis, but that switching to a different chemotherapy is of no value. Future studies will focus on molecular characterization of CTC and investigating genomic, targeted therapies based on these results.

12:30 Qualifying Blood-Based Molecular Assays for Targeted Therapies in Cancer

Daniel C. Danila, M.D., Assistant Attending, Medicine, Memorial Sloan Kettering Cancer Center

Unmet needs in cancer drug development and patient management are the ability to monitor treatment benefit and to identify the target of interest in a tumor at the time treatment is being considered. Given the effort and cost to new blood biomarkers, it is essential to develop metrics to determine which promising assays warrant prospective testing in large-scale phase III trials to establish qualification in the context of use.

1:00 Session Break

1:15 Luncheon Presentation I: High Sensitive Detection of Circulating Tumor Cells Including EMT-CTCs in NSCLC Patients by TelomeScan F35

Shinsaku Togo, M.D., Ph.D., Associate Professor, Division of Respiratory Medicine, Faculty of Medicine & Graduate School of Medicine, Juntendo University

We established a unique CTC-detecting platform using TelomeScan F35, a telomerase-specific replication-selective



adenovirus expressing GFP. In clinical feasibility studies, we demonstrated that TelomeScan F35 is useful to detect alive and EMT-induced CTCs from patients of various types of cancer. In NSCLC, CTCs were sensitively detected from patients with early clinical stage (Stage I) and it suggests TelomeScan F35 is a powerful surrogate indicator and liquid biopsy for cancer diagnosis.

1:45 Luncheon Presentation II

Speaker to be Announced

2:15 Session Break

CHARACTERIZING CTCs

2:30 Chairperson's Remarks

Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University, Medical Center Hamburg-Eppendorf, University of Hamburg

2:40 Circulating Tumor Cells in Lung Cancer, Biomarkers, Biology, and Mouse Models

Caroline Dive, B.Pharm, Ph.D., Professor & Senior Group Leader, Clinical and Experimental Pharmacology Group, Cancer Research UK Manchester Institute

Dr. Dive will discuss the current utility of CTCs in lung cancer in early clinical trials and the challenges associated with use of new marker independent CTC enrichment platforms in clinical trial samples. She will also focus on the development of patient derived CTC explant models that now offer unique opportunities to study lung cancer biology, discover new drug targets, understand drug resistance mechanisms and test novel therapies.

3:10 Novel Approaches to Enable Molecular Characterization of CTCs

Nikolas H. Stoecklein, M.D., Professor, General Visceral and Pediatric Surgery, University Hospital of the Heinrich-Heine, University of Düsseldorf

The talk will cover a recently established workflow to enable high-resolution genomic analysis of single CTCs and will discuss the concept of diagnostic leukapheresis (DLA) to increase the detection rate of CTCs by screening larger blood volumes.

3:40 Deep Sequencing of Circulating Tumor Cells as a Window into Disseminated Cancer

Jens Lohr, M.D., Ph.D., Instructor in Medicine, Medical Oncology, Cancer Program, Dana-Farber Cancer Institute; Broad Institute

We have developed targeted and whole exome sequencing frameworks to explore the genomics of circulating tumor cells (CTCs), with a focus on defining somatic mutations in single CTCs. We are investigating how the genetics of CTCs

evolve over time and how they compare to primary tumors and metastases.

4:10 Characterization and Molecular Profiling of CTCs using DEPAArray™ and Ampli1™ Technologies

Farideh Z. Bischoff, Ph.D., Executive Director, Scientific Affairs, Silicon Biosystems

DEPAArray™ allows sorting and recovery of target cells using image-based identification of specific markers. Enriched cell suspensions can be used to recover rare cells with 100% purity. Using this approach, CTCs have been successfully recovered for downstream molecular profiling and NGS.

4:25 Clinical Impact and Future Developments of Circulating Cancer Cells

Patrizia Paterlini-Brechot, M.D., Ph.D., Professor, University Paris Descartes, Inserm Unit 1151 and Rarecells Diagnostics SAS

Circulating Cancer Cells are tumor cells which are extracted from blood without any bias and identified through a diagnostic approach, cytopathology. They are the basis for clinical and molecular studies avoiding the classical troubles which affect Circulating Tumor Cells.

4:40 Break and Transition to Plenary Session

» 5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» 8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by
SLONEPARTNERS

CANCER MOLECULAR
MARKERS

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CANCER MOLECULAR MARKERS

continued

CELLS VS. CIRCULATING BIOMARKERS

10:05 Chairperson's Remarks

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

10:15 Platforms for CTC Isolation and Analysis

Z. Hugh Fan, Ph.D., Professor, Mechanical and Aerospace Engineering, University of Florida

We will present our recent results on integrating aptamers, antibodies, nanoparticles, and multivalent binding mechanisms with microfluidics for the isolation of cancer cells, as well as on the correlation between CTC enumeration and therapy responses of pancreatic cancer patients. Other platforms for CTC isolation and analysis will be reviewed and examined. Parameters for platform comparison will be discussed.

10:45 Circulating Tumor DNA: Opportunities and Challenges on the Road to Clinical Utility

Mark Lee, M.D., Ph.D., Google[x] Life Sciences

The advent of new technologies for sensitive and specific detection of cell-free, circulating tumor DNA (ctDNA) in plasma has generated considerable enthusiasm for this new class of biomarkers to improve clinical decision-making in oncology. Emerging evidence suggests a number of promising potential clinical applications. Considerations and strategies to establish clinical utility of ctDNA will be discussed.

11:15 Biology and Function of Exosomes

Raghu Kalluri, M.D., Ph.D., Professor & Chair, Cancer Biology, MD Anderson Cancer Center

The lecture will discuss the biology and function of exosomes in cancer detection and progression of cancer. DNA, RNA and protein profiles will be discussed with specific emphasis on early detection of cancer.

11:45 Microfluidic Isolation of Microvesicles and Circulating Tumor Cells from Cancer Patients

Shannon L. Stott, Ph.D., Assistant Professor, Medicine, Massachusetts General Hospital and Harvard Medical School

Circulating tumor cells (CTCs) and microvesicles (MVs) are found in the bloodstream of cancer patients and have the potential to help guide cancer treatment. Through a collaborative effort between bioengineers, biologists, and clinicians, our group at MGH has developed microfluidic devices to isolate these rare circulating biomarkers from whole blood. I will describe our recent efforts to molecularly characterize CTCs and MVs, and the insights gained from our analysis.

12:15 pm Session Break**12:25 Luncheon Presentation I: Circulating Tumor Cells: From Enumeration to Comprehensive Characterization**

Sponsored by



Mark Connelly, Ph.D., Site Director & Scientific Director, Cellular Research, Janssen

This presentation will describe a novel platform for the capture and analysis of circulating tumor cells (CTC). The platform is antibody independent and delivers viable CTCs in suspension. This novel platform enables routine enumeration of all tumor derived cells, ex vivo propagation of the CTCs, and comprehensive molecular and protein analyses using single cell analytical methods to characterize tissue of origin, epithelial-mesenchymal transition, stem cells and functional biomarkers.

12:55 Luncheon Presentation II: Exosomes and cfDNA: Complete Nucleic Acid Analysis from a Liquid Biopsy

Sponsored by



Johan Skog, Ph.D., CSO, Exosome Diagnostics

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing**TAKING A SNAPSHOT OF BLOOD/PLASMA/SERUM TO LEARN ABOUT THE HEALTH OF THE PATIENT****2:00 Chairperson's Remarks**

Daniel H. Farkas, Ph.D., HCLD, FACB, Laboratory Director, Sequenom Center for Molecular Medicine

2:10 Translating a Trillion Points of Data into Therapies, Diagnostics, and New Insights into Disease

Atul Butte, M.D., Ph.D., Division Chief and Associate Professor, Stanford University School of Medicine; Director, Center for Pediatric Bioinformatics, Lucile Packard Children's Hospital; Co-Founder, Personalis and NuMedii

Dr. Butte's lab at Stanford builds and applies tools to translate more than a trillion points of molecular, clinical, and epidemiological data – measured by researchers and clinicians over the past decade and now commonly called “big data” – into diagnostics, therapeutics, and new insights into disease. Dr. Butte will highlight his lab's work on using publicly-available molecular measurements to discover new diagnostics and treatment mechanisms for type 2 diabetes and the evaluation of patients presenting with whole genomes sequenced.

2:40 Adventitious Maternal Cancer Detection during Non-Invasive Prenatal Testing of Circulating Fetal DNA

Nilesh Dharajiya, M.D., Director, Clinical Lab, Sequenom Laboratories

Non-invasive prenatal testing of cell free DNA (cfDNA) provides a novel tool to detect chromosomal abnormalities prenatally. Maternal cfDNA is also sequenced, and therefore, we may learn about the mother's genome or other medical conditions. Here, we provide an overview of cfDNA aneuploidy testing and present clinical cases where testing serendipitously detected cell free tumor DNA, resulting in an earlier diagnosis of a neoplastic process.

3:10 Liquid Biopsy Approaches For Detecting and Characterizing Human Cancer

Victor Velculescu, M.D., Ph.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Cancer Center

Analyses of cancer genomes have revealed mechanisms underlying tumorigenesis and new avenues for therapeutic intervention. In this presentation, I will discuss lessons learned through the characterization of cancer genome landscapes, challenges in translating these analyses to the clinic, and new technologies that have emerged to analyze molecular alterations in the circulation of cancer patients as cell-free tumor DNA. These approaches have important implications for non-invasive detection and monitoring of human cancer, therapeutic stratification, and identification of mechanisms of resistance to targeted therapies.

3:40 The Hunt for Blood-Based Biomarkers for Diagnosis of Neurodegenerative Diseases

Robert M. Umek, Meso-Scale Diagnostics

While cerebrospinal fluid biomarkers and brain imaging have advanced our understanding of neurodegenerative diseases, there is considerable demand for blood-based biomarkers for diagnostics and use in clinical trials owing to the ease of sample acquisition and cost. The status of the field as well as the challenges remaining will be considered.

3:55 Sponsored Presentation (Opportunity Available)**4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing****5:00 Breakout Discussions in the Exhibit Hall (see website for details)**

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CANCER MOLECULAR MARKERS

*continued***6:00 Close of Day****WEDNESDAY, FEBRUARY 18****7:00 am Breakfast Presentation** (*Sponsorship Opportunity Available*) or **Morning Coffee****8:00 PLENARY SESSION PANEL** (see page 5 for details)**9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall****DNA METHYLATION BIOMARKERS IN CANCER****10:35 Chairperson's Remarks***Michelle M. Hanna, Ph.D., CEO & Scientific Director, RiboMed***10:45 DNA Methylation as Cancer Biomarkers in Clinical Development***David Shames, Ph.D., Senior Scientist, Genentech***11:15 Development of DNA Methylation Markers for Early Lung Cancer Detection***Ite A. Laird-Offringa, Ph.D., Associate Professor, Surgery and of Biochemistry and Molecular Biology, Norris Cancer Center, Keck School of Medicine, University of Southern California*

We are developing DNA methylation as a lung cancer marker. Cancer DNA is shed into the blood and can in principle be used to non-invasively detect a cancer signature in bodily fluids. We have mined our own and publicly available data to identify DNA methylation markers present with high penetrance in lung cancer tumors. Given that low-dose spiral computed tomography, the state-of-the-art and only tool currently available for lung cancer early detection, has a false positive rate of 96%, there is a great need for additional complementary biomarkers.

11:45 Simultaneous Glioma Grading and Drug Response Testing with DNA Methylation Profiling*Michelle M. Hanna, Ph.D., CEO & Scientific Director, RiboMed Biotechnologies, Inc.*

Unfortunately, there are significant inter-observer and intra-observer variability in the grading of Gliomas, and, many patients do not respond to the chemotherapy they receive. We have developed a sensitive, quantitative, bisulfite-free, fluorescent Glioma stratification test based on DNA methylation profiling of 6 genes using FFPE Glioma samples. The status of all 6 genes can be determined with a single FFPE sample with a tumor cross section as small as 2 μm, providing physicians with a new tool for the diagnosis and treatment of brain cancer.

12:15 pm Session Break**12:25 Luncheon Presentation** (*Sponsorship Opportunity Available*) or **Lunch on Your Own****1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing****CLINICAL USE OF CTCs****1:40 Chairperson's Remarks***Stuart S. Martin, Ph.D., Associate Professor, Physiology, Greenebaum Cancer Center, University of Maryland School of Medicine***1:50 Detection and Molecular Characterization of CTCs in Glioma Patients***Klaus Pantel, M.D., Professor & Chairman, Tumor Biology, University Medical Center Hamburg-Eppendorf*

Glioblastoma multiform (GBM) is the most frequent and aggressive brain tumor in adults. The dogma that GBM spread is restricted to the brain was challenged by reports on extracranial metastases after organ transplantation from GBM donors. The CTC detection approach developed in this study is easily applicable as a companion diagnostic to identify patients with extracranial tumor cell spread, and it might be advisable to exclude these patients as organ donors.

2:20 Single Cell Genomic Analyses of Circulating Tumor Cells*Sunney Xie, Ph.D., Mallinckrodt Professor, Chemistry and Chemical Biology, Harvard University*

We have demonstrated whole genome sequencing of circulating tumor cells (CTCs) with multiple annealing and looping-based amplification cycles (MALBAC). We discovered that CTCs of the same patient exhibit reproducible CNV gain and loss patterns, which are similar to the patterns of metastatic sites. Patients with the same cancer type have similar patterns while patients with different cancers have dissimilar patterns. The fact that CTC's CNV patterns are tissue and cancer dependent offers prospects for noninvasive cancer diagnostics.

2:50 Targeting Microtentacles on Circulating Tumor Cells to Reduce Metastasis*Stuart S. Martin, Ph.D., Associate Professor, Physiology, Greenebaum Cancer Center, University of Maryland School of Medicine*

Tumor cells generate dynamic membrane microtentacles (McTNs) in free-floating microenvironments, that promote the reattachment of circulating tumor cells in distant tissues. These McTNs arise from imbalances between microtubule extension and contraction of the actin cortex, and are detectable in freshly-isolated tumor cells from patients. By defining the cytoskeletal mechanisms underlying McTNs, we are clarifying how existing chemotherapies affect CTCs and identifying new therapeutic opportunities.

3:20 Sponsored Presentations (*Opportunities Available*)**3:50 Refreshment Break****UNLOCKING NEW MARKERS FOR STRATIFICATION****4:00 Chairperson's Remarks***Jae Lee, Ph.D., Chair and Senior Member, Biostatistics and Bioinformatics, Moffitt Cancer Center***4:10 Identifying and Overcoming Markers of Chemoresistance***Jason Baum, Ph.D., Associate Director, Companion Diagnostics, Research, Merrimack Pharmaceuticals*

This talk will focus on the understanding of cancer cell survival networks to identify key biomarkers of resistance to chemotherapy. This includes initial proof-of-concept in a pre-clinical setting and translation into the clinic through the development of both tissue and blood-based diagnostic assays. Data from phase II clinical studies will illustrate the resistance of biomarker positive patients to chemotherapies across multiple indications, and the potential for targeted therapies to overcome this resistance.

4:40 The Impact of Tumor Heterogeneity on Clinical Biomarker Development using FFPE Tissue*Ken Chang, Ph.D., Senior Principal Scientist, Molecular Biomarkers and Diagnostics, Merck Clinical Labs*

We have developed a "Concordance Calculator" to quantify reproducibility of multi-variant calls among Next Generation Sequencing replicates. This novel approach also allowed us to eliminate many different technical artifacts including Post Tissue Collection Modifications such as deamination and oxidation artifacts. Our most recent studies suggest that DNA mutation signatures as novel biomarkers for cancer diagnosis and prognosis are likely to be less sensitive to the impact of tumor heterogeneity than RNA-based expression signatures.

5:10 Prognostic Surrogate Markers for Survival, A Case Series for a Novel Antiangiogenic Therapy*M.A. Nezami, M.D., President, Cancer Epigenetics, Pacific Medical Center of Hope*

Establishing the prognosis in majority of patients, especially with heterogeneous tumors, has been extremely challenging. One area of most recent attention in identifying surrogate markers for survival has been the vasculogenesis and its related serum markers. Here we present a series of cases treated with a novel antiangiogenic therapy and monitored through these markers to identify response that translated to prognosis and survival.

5:40 Close of Conference Program

CLICK HERE TO REGISTER ONLINE!

TriConference.com



Cambridge Healthtech Institute's Fifth Annual

CIRCULATING TUMOR CELLS

Future of Cancer Care

MONDAY, FEBRUARY 16
10:30 am Conference Program Registration
**» KEYNOTE SESSION:
MARKER OF CHOICE FOR CLINICAL USE?**
11:50 Chairperson's Opening Remarks

Stefanie Jeffrey, M.D., John and Marva Warnock Professor, Surgery; Chief of Surgical Oncology Research, Stanford University School of Medicine and Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University, Medical Center Hamburg-Eppendorf, University of Hamburg

12:00 pm CTC: Current Clinical Utility and Future Prospects

Jeffrey Smerage, M.D., Ph.D., Clinical Associate Professor, Division of Hematology and Oncology, University of Michigan

CTC enumeration is clearly associated with poor prognosis in several epithelial malignancies. A prospective randomized clinical trial in metastatic breast cancer (S0500) demonstrated that failure to clear CTC harbors a terrible prognosis, but that switching to a different chemotherapy is of no value. Future studies will focus on molecular characterization of CTC and investigating genomic, targeted therapies based on these results.

12:30 Qualifying Blood-Based Molecular Assays for Targeted Therapies in Cancer

Daniel C. Danila, M.D., Assistant Attending, Medicine, Memorial Sloan Kettering Cancer Center

Unmet needs in cancer drug development and patient management are the ability to monitor treatment benefit and to identify the target of interest in a tumor at the time treatment is being considered. Given the effort and cost to new blood biomarkers, it is essential to develop metrics to determine which promising assays warrant prospective testing in large-scale phase III trials to establish qualification in the context of use.

1:00 Session Break
**1:15 Luncheon Presentation I:
High Sensitive Detection of
Circulating Tumor Cells Including
EMT-CTCs in NSCLC Patients by TelomeScan F35**

Shinsaku Togo, MD, Ph.D., Associate Professor, Division of Respiratory Medicine, Juntendo University Faculty of Medicine & Graduate School of Medicine

We established a unique CTC-detecting platform using TelomeScan F35, a telomerase-specific replication-selective adenovirus expressing GFP. In clinical feasibility studies, we demonstrated that TelomeScan F35 is useful to detect

alive and EMT-induced CTCs from patients of various types of cancer. In NSCLC, CTCs were sensitively detected from patients with early clinical stage (Stage I) and it suggests TelomeScan F35 is a powerful surrogate indicator and liquid biopsy for cancer diagnosis.

1:45 Luncheon Presentation II

Speaker to be Announced

2:15 Session Break
CHARACTERIZING CTCs
2:30 Chairperson's Remarks

Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University, Medical Center Hamburg-Eppendorf, University of Hamburg

**2:40 Circulating Tumor Cells in Lung Cancer,
Biomarkers, Biology, and Mouse Models**

Caroline Dive, B.Pharm, Ph.D., Professor & Senior Group Leader, Clinical and Experimental Pharmacology Group, Cancer Research UK Manchester Institute

Dr. Dive will discuss the current utility of CTCs in lung cancer in early clinical trials and the challenges associated with use of new marker independent CTC enrichment platforms in clinical trial samples. She will also focus on the development of patient derived CTC explant models that now offer unique opportunities to study lung cancer biology, discover new drug targets, understand drug resistance mechanisms and test novel therapies.

**3:10 Novel Approaches to Enable Molecular
Characterization of CTCs**

Nikolas H. Stoecklein, M.D., Professor, General Visceral and Pediatric Surgery, University Hospital of the Heinrich-Heine, University of Düsseldorf

The talk will cover a recently established workflow to enable high-resolution genomic analysis of single CTCs and will discuss the concept of diagnostic leukapheresis (DLA) to increase the detection rate of CTCs by screening larger blood volumes.

**3:40 Deep Sequencing of Circulating Tumor Cells
as a Window into Disseminated Cancer**

Jens Lohr, M.D., Ph.D., Instructor in Medicine, Medical Oncology, Cancer Program, Dana-Farber Cancer Institute; Broad Institute

We have developed targeted and whole exome sequencing frameworks to explore the genomics of circulating tumor cells (CTCs), with a focus on defining somatic mutations in single CTCs. We are investigating how the genetics of CTCs evolve over time and how they compare to primary tumors and metastases.

**4:10 Characterization and
Molecular Profiling of CTCs
using DEPAArray™ and Ampli1™
Technologies**

Farideh Z. Bischoff, Ph.D., Executive Director, Scientific Affairs, Silicon Biosystems

DEPAArray™ allows sorting and recovery of target cells using image-based identification of specific markers. Enriched cell suspensions can be used to recover rare cells with 100% purity. Using this approach, CTCs have been successfully recovered for downstream molecular profiling and NGS.

**4:25 Clinical Impact and Future
Developments of Circulating
Cancer Cells**

Patrizia Paterlini-Brechot, M.D., Ph.D., Professor, University Paris Descartes, Inserm Unit 1151 and Rarecells Diagnostics SAS

Circulating Cancer Cells are tumor cells which are extracted from blood without any bias and identified through a diagnostic approach, cytopathology. They are the basis for clinical and molecular studies avoiding the classical troubles which affect Circulating Tumor Cells.

4:40 Break and Transition to Plenary Session
**» 5:00 PLENARY SESSION (see page 5 for
details)**
**6:00 Grand Opening Reception in the Exhibit Hall
with Poster Viewing**
7:30 Close of Day

Sponsored by
 Silicon Biosystems

Sponsored by
 Leica Biosystems

Sponsored by
 Rarecells Diagnostics

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



CIRCULATING TUMOR CELLS

continued

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» 8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing *Sponsored by*
SLONEPARTNERS

CELLS VS. CIRCULATING BIOMARKERS

10:05 Chairperson's Remarks

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

10:15 Platforms for CTC Isolation and Analysis

Z. Hugh Fan, Ph.D., Professor, Mechanical and Aerospace Engineering, University of Florida

We will present our recent results on integrating aptamers, antibodies, nanoparticles, and multivalent binding mechanisms with microfluidics for the isolation of cancer cells, as well as on the correlation between CTC enumeration and therapy responses of pancreatic cancer patients. Other platforms for CTC isolation and analysis will be reviewed and examined. Parameters for platform comparison will be discussed.

10:45 Circulating Tumor DNA: Opportunities and Challenges on the Road to Clinical Utility

Mark Lee, M.D., Ph.D., Google[x] Life Sciences

The advent of new technologies for sensitive and specific detection of cell-free, circulating tumor DNA (ctDNA) in plasma has generated considerable enthusiasm for this new class of biomarkers to improve clinical decision-making in oncology. Emerging evidence suggests a number of promising potential clinical applications. Considerations and strategies to establish clinical utility of ctDNA will be discussed.

11:15 Biology and Function of Exosomes

Raghu Kalluri, M.D., Ph.D., Professor & Chair, Cancer Biology, MD Anderson Cancer Center

The lecture will discuss the biology and function of exosomes in cancer detection and progression of cancer. DNA, RNA and protein profiles will be discussed with specific emphasis on early detection of cancer.

11:45 Microfluidic Isolation of Microvesicles and Circulating Tumor Cells from Cancer Patients

Shannon L. Stott, Ph.D., Assistant Professor, Medicine, Massachusetts General Hospital and Harvard Medical School
Circulating tumor cells (CTCs) and microvesicles (MVs) are found in the bloodstream of cancer patients and have

the potential to help guide cancer treatment. Through a collaborative effort between bioengineers, biologists, and clinicians, our group at MGH has developed microfluidic devices to isolate these rare circulating biomarkers from whole blood. I will describe our recent efforts to molecularly characterize CTCs and MVs, and the insights gained from our analysis.

12:15 pm Session Break

12:25 Luncheon Presentation I: Circulating Tumor Cells: From Enumeration to Comprehensive Characterization

Mark Connelly, Ph.D., Site Director & Scientific Director, Cellular Research, Janssen

This presentation will describe a novel platform for the capture and analysis of circulating tumor cells (CTC). The platform is antibody independent and delivers viable CTCs in suspension. This novel platform enables routine enumeration of all tumor derived cells, ex vivo propagation of the CTCs, and comprehensive molecular and protein analyses using single cell analytical methods to characterize tissue of origin, epithelial-mesenchymal transition, stem cells and functional biomarkers.

12:55 Luncheon Presentation II: Exosomes and cfDNA: Complete Nucleic Acid Analysis from a Liquid Biopsy

Johan Skog, Ph.D., CSO, Exosome Diagnostics

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

BEYOND SELECTION: Single Cell Analysis on CTCs

2:00 Chairperson's Remarks

Steven A. Soper, Ph.D.

2:10 Drug-Induced Damage of Genomic DNA Harvested from Circulating Tumor Cell Sub-Populations

Steven A. Soper, Ph.D., William H. Pryor Emeritus Professor, Biomedical Engineering and Chemistry, University of North Carolina, Chapel Hill

An innovative assay combined with groundbreaking hardware for the isolation and processing of distinct sub-populations of circulating tumor cells (CTCs) for a patient's cancer will be discussed. The assay quantifies response to therapy using three pieces of information for different CTC sub-populations; (1) CTC number; (2) CTC viability; and (3) frequency of DNA abasic (AP) sites in the CTCs' genomic DNA.

2:40 Isolation and Downstream Analysis of Circulating Tumor Cells

Daniel T. Chiu, Ph.D., A. Bruce Montgomery Professor, Chemistry & Bioengineering, University of Washington, Seattle

This presentation will describe advances we have made with the eDAR platform for the isolation of rare cells, with emphasis on employing eDAR for the downstream analysis of circulating tumor cells.

3:10 Single-Cell Analysis Using Drop Based Microfluidics

David A. Weitz, Ph.D., Mallinckrodt Professor, Physics, School of Engineering & Applied Sciences, Harvard University

Drop-based microfluidics have enabled large numbers of cells to be encapsulated in individual drops, a few picoliters in volume, immersed in an inert carrier oil. Each drop can be precisely controlled and analyzed, enabling large numbers of cells to be screened and specific cells identified for further analysis using either PCR or next generation sequencing. This technology has great potential for studies of circulating tumor cells.

3:40 Isolation and Characterization of Circulating Melanoma Cancer Cells by Size Filtration and Fluorescent in Situ Hybridization

Masahiko Yanagita, M.D., Ph.D., Research Fellow, Translational Research Laboratory, Dana Farber Cancer Institute

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (see website for details)

6:00 Close of Day

CIRCULATING TUMOR CELLS

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CIRCULATING TUMOR CELLS

*continued***WEDNESDAY, FEBRUARY 18****7:00 am Breakfast Presentation** (Sponsorship Opportunity Available) or Morning Coffee**8:00 PLENARY SESSION PANEL** (see page 5 for details)**9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall****TECHNOLOGY STRIDES FOR CTCs****10:35 Chairperson's Remarks***Dino Di Carlo, Ph.D., Associate Professor, Bioengineering, California NanoSystems Institute, Jonsson Comprehensive Cancer Center, University of California, Los Angeles***10:45 Vortex Technology for CTC Collection and Automated Image Cytometry for CTC Detection***Dino Di Carlo, Ph.D., Associate Professor, Bioengineering, California NanoSystems Institute, Jonsson Comprehensive Cancer Center, University of California, Los Angeles*

Dr. Di Carlo will introduce the vortex cell isolation and concentration technology and discuss the latest results in isolating and characterizing circulating tumor cells using label-free imaging approaches.

11:15 Nanoroughened Surfaces for Efficient Capture of Circulating Tumor Cells without Using Capture Antibodies*Jianping Fu, Ph.D., Mechanical Engineering & Biomedical Engineering, University of Michigan, Ann Arbor*

Circulating tumor cells (CTCs) detached from both primary and metastatic lesions represent a potential alternative to invasive biopsies as a source of tumor tissue for the detection, characterization and monitoring of cancers. Here we report a simple yet effective strategy for capturing CTCs without using capture antibodies. Our method uniquely utilized the differential adhesion preference of cancer cells to nanorough surfaces when compared to normal blood cells and thus did not depend on their physical size or surface protein expression, a significant advantage compared to other techniques.

11:45 Geometrically Enhanced Differential Immunocapture (GEDI): Informing Surgical and Medical Cancer Treatment via Capture of Circulating Tumor Cells*Brian J. Kirby, Ph.D., Associate Professor, Mechanical and Aerospace Engineering, Cornell University*

We will present results for early-stage circulating cell capture and its use to stage surgical decisions, as well as late-stage circulating tumor cell capture and its use to inform choice of chemotherapy. CTC capture is performed with Geometrically Enhance Differential Immunocapture, a microfluidic systems that uses both immunocapture and size-based cell trajectories to optimize efficiency and purity.

12:15 pm Session Break**12:25 Luncheon Presentation** (Sponsorship Opportunity Available) or Lunch on Your Own**1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing****CLINICAL USE OF CTCs****1:40 Chairperson's Remarks***Stuart S. Martin, Ph.D., Associate Professor, Physiology, Greenebaum Cancer Center, University of Maryland School of Medicine***1:50 Detection and Molecular Characterization of CTCs in Glioma Patients***Klaus Pantel, M.D., Professor & Chairman, Tumor Biology, University Medical Center Hamburg-Eppendorf*

Glioblastoma multiform (GBM) is the most frequent and aggressive brain tumor in adults. The dogma that GBM spread is restricted to the brain was challenged by reports on extracranial metastases after organ transplantation from GBM donors. The CTC detection approach developed in this study is easily applicable as a companion diagnostic to identify patients with extracranial tumor cell spread, and it might be advisable to exclude these patients as organ donors.

2:20 Single Cell Genomic Analyses of Circulating Tumor Cells*Sunney Xie, Ph.D., Mallinckrodt Professor, Chemistry and Chemical Biology, Harvard University*

We have demonstrated whole genome sequencing of circulating tumor cells (CTCs) with multiple annealing and looping-based amplification cycles (MALBAC). We discovered that CTCs of the same patient exhibit reproducible CNV gain and loss patterns, which are similar to the patterns of metastatic sites. Patients with the same cancer type have similar patterns while patients with different cancers have dissimilar patterns. The fact that CTC's CNV patterns are tissue and cancer dependent offers prospects for noninvasive cancer diagnostics.

2:50 Targeting Microtentacles on Circulating Tumor Cells to Reduce Metastasis*Stuart S. Martin, Ph.D., Associate Professor, Physiology, Greenebaum Cancer Center, University of Maryland School of Medicine*

Tumor cells generate dynamic membrane microtentacles (McTNs) in free-floating microenvironments, that promote the reattachment of circulating tumor cells in distant tissues. These McTNs arise from imbalances between microtubule extension and contraction of the actin cortex, and are detectable in freshly-isolated tumor cells from patients. By defining the cytoskeletal mechanisms underlying McTNs, we are clarifying how existing chemotherapies affect CTCs and identifying new therapeutic opportunities.

3:20 Sponsored Presentations (Opportunities Available)**3:50 Refreshment Break****CTCs FOR COMPANION DIAGNOSTICS****4:00 Chairperson's Remarks***Steven A. Soper, Ph.D., William H. Pryor Emeritus Professor, Biomedical Engineering and Chemistry, University of North Carolina, Chapel Hill***4:10 CTCs in Mouse Models***Jen Jen Yeh, M.D., Associate Professor, Surgery and Pharmacology, UNC Chapel Hill Lineberger Comprehensive Cancer Center*

This presentation will provide an overview of the data on CTCs in mouse models and their possible uses as biomarkers.

4:40 Challenges and Opportunities in the Use of CTCs for Companion Diagnostic Development*Elizabeth Punnoose, Ph.D., Senior Scientist, Oncology Biomarker Development, Genentech, Inc.*

Circulating tumor cells offer promise as a surrogate source of cancer cells that can be obtained in real time and may provide opportunities to evaluate predictive biomarkers that can guide treatment decisions. In this review, we consider some of the technical hurdles around CTC numbers and suitability of various CTC capture and analysis platforms for biomarker evaluation. In addition, we consider the potential regulatory hurdles to development of CTC-based diagnostics. Finally, we suggest a path for co-development of anticancer therapeutics with CTC-based diagnostics that could enable clinical validation and qualification of CTC-based assays as companion diagnostics.

5:10 Circulating Tumor Cells: What Is in It for the Patient? A Vision Towards the Future*Paul A. van de Wiel, Ph.D., Senior Director, Precision and Decentralized Diagnostics, Philips Research*

Knowledge on signal transduction pathways as drivers of cancer growth has fuelled development of targeted therapy. However, good companion diagnostic tests to determine the tumor driving pathways are still lacking. We will discuss novel approaches of assessing active tumor pathways based on advanced staining of CTCs in combination with automated image interpretation on a digital pathology platform, and by PCR-based analysis of isolated CTCs.

5:40 Close of Conference Program

CLICK HERE TO REGISTER ONLINE!

TriConference.com



DIGITAL PATHOLOGY

Transforming Medicine in a Digital World

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

DIGITAL PATHOLOGY PREDICTIONS: MARKET ANALYSIS & TRENDS

11:50 Chairperson's Opening Remarks

Sharon Moulis, Ph.D., Director, Tissue Diagnostics Alliances, Definiens

12:05 pm Mobile Industry: Exploiting Smartphones for Digital Pathology

Douglas J. Hartman, M.D., Assistant Professor, Pathology, University of Pittsburgh Medical Center

Smartphones are rapidly being expanded with new and greater functionalities. The emerging field of mobile health (mHealth) has led to changes in all areas of healthcare. Many of these functionalities are directed to consumers, however, some can be exploited within pathology. Applications of smartphones for digital pathology (such as QA, educational, tumor boards, etc) and emerging image analysis capabilities will be discussed.

12:35 DIGITAL PATHOLOGY – Where We Have Been and the Future

Kim Dickinson, M.D., MBA, MPH, Medical Director, Lab Corp Clinical Trials; President, Digital Pathology Association

Digital pathology is a vital and important component in the future delivery of health care and will become increasingly more integral to pathologists and the patient's care team. The discussion will provide a historical perspective of digital pathology, followed by a discussion of the future of digital pathology. The talk will also cover the current regulatory environment for digital imaging.

1:05 Session Break

1:15 Luncheon Presentation I: How to Develop Fit-for-Purpose IHC Assays to Enable Clinical Trial Patient Stratification

Sharon Moulis, Ph.D., Director, Tissue Diagnostics Alliances, Definiens

This presentation will discuss how to devise a method of IHC assay design that increases the chance of finding the optimal cutpoint of biomarker expression and maximizing the chance of success for companion diagnostic use. Through use of standard curves and quantitative image analysis, the required target expression level can be determined and IHC assays re-optimized for more uniform and consistent scoring by a pathologist.

Sponsored by
DEFINIENS
the tissue phenomics company

1:45 Luncheon Presentation II (Opportunity Available)

2:15 Session Break

IN VIVO MICROSCOPY

2:30 Chairperson's Remarks

Eric F. Glassy, M.D., FCAP, Medical Director, Affiliated Pathologists Medical Group

2:40 Gastrointestinal *in vivo* Microscopy: One Step Closer to Achieving the Fantastic Voyage

Gregory Y. Lauwers, M.D., Professor & Vice Chair, Pathology, Massachusetts General Hospital

Advances in *in vivo* microscopy technologies provide a unique opportunity for the pathologist and the gastroenterologist to evaluate large segments of the gastrointestinal tract *in vivo*. Although multiple challenges remain, it is certain that this technology will impact the clinical care of patients with gastrointestinal pathologies. Cooperation between clinicians, pathologists, and engineers will be cardinal in realizing this fantastic voyage.

3:10 No More Glass: Optical Coherence Tomography (OCT) Permits Pathologist-Ready Photomicrographs without Microscope Slides

Jeffrey Fine, M.D., Assistant Professor, Pathology, University of Pittsburgh School of Medicine

Optical Coherence Tomography (OCT) is an advanced imaging technique that permits rapid non-destructive microscopic tissue imaging. We will provide a pathologist-friendly overview of OCT, followed by a summary of our early ex-vivo imaging of breast and endometrial specimens. This work aims toward clinical application and toward OCT expertise that can support future *in vivo* applications. We will end with discussion of future trends for this technology.

3:40 26 Easy Steps to Implementing an *in vivo* Microscopy Service in Pathology

Andrew Quinn, M.D., Fellow, Cytology, Pathology, Brigham and Women's Hospital

This talk will address one institution's experiences implementing a clinical *in vivo* microscopy (IVM) service with particular attention paid to informatics and workflow considerations as well as potential pitfalls. It will additionally emphasize the rapidly evolving nature of the field and the growing need for participation by pathologists in all practice settings in this undertaking.

4:10 Collaboration Across Multi Disciplinary Teams

Chrystal Adams, Associate Vice President, Marketing, XIFIN

Sponsored by
XIFIN

Data show that when physicians across multiple disciplines (pathology, radiology, and oncology) collaborate, diagnoses are changed as much as 25% of the time. XIFIN's collaborative medicine portal enables communication across physician specialties in a secure cloud environment.

4:25 Sponsored Presentation (Opportunity Available)

4:40 Break and Transition to Plenary Session

» 5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» 8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by
SLONEPARTNERS

LARGE SCALE DEPLOYMENT OF DIGITAL PATHOLOGY

10:05 Chairperson's Remarks

Iron Pantanowitz, M.D., University of Pittsburgh Medical Center

10:15 Large Scale Deployment of Digital Pathology: The Importance of Color

Elizabeth A. Krupinski, Ph.D., Professor, Medical Imaging, University of Arizona

Digital Pathology is growing – slowly. Although it is clearly feasible and likely has numerous benefits, there are some challenges that have limited large-scale deployment. One of those is color – from acquisition through display. This talk will discuss some of the challenges with color rendering with WSI as well as the potential impact on the pathologists and the interpretation task.

DIGITAL PATHOLOGY
CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



CLICK HERE TO
REGISTER ONLINE!

TriConference.com



TRICON
PERKS

DIGITAL PATHOLOGY

continued

10:45 How Digital Pathology Enables New Business and Clinical Models in Pathology

Robert Michel, Editor-In-Chief, The Dark Report

Swift improvements to digital pathology technologies and systems—in tandem with healthcare's evolution toward integrated clinical care—are creating opportunities for nimble anatomic pathology laboratories to deliver value in new ways. This presentation will identify how early-adopter pathologists are utilizing digital pathology to improve patient outcomes and describe some of the emerging pathology business models that utilize digital pathology.

11:15 Digital Pathology Patent Landscape: Insights into Emerging Trends and Opportunities

Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, Office of Intramural Research, Office of Technology Transfer, NIH

Digital pathology has been increasingly used for education, clinical practice and research, and according to a recent market report, the global digital pathology market is expected to reach an estimated \$437 million by 2018. The rapid development of digital pathology is made possible by innovations across a variety of specialties such as information management systems and imaging and visualization technologies, and a majority of these innovations are patented. This presentation will highlight emerging trends in digital pathology technologies based on a systematic review of the patenting activity and will use these trends to discuss potential new opportunities.

11:45 Digital Pathology: Regulatory Barriers to Adoption

Eric F. Glassy, M.D., FCAP, Medical Director, Affiliated Pathologists Medical Group

Widespread adoption of Digital Pathology is hampered by an uncertain regulatory landscape. This talk will canvass the key legal issues associated with integrating telepathology and whole slide imaging into a pathology practice.

12:15 pm Session Break

12:25 Luncheon Presentation I: Bio-Formats & Omero: Open Source, Enterprise Solutions for Managing, Sharing, Analysing, and Integrating Digital Pathology Data

Jason Swedlow, Ph.D., President & CEO, Glencoe Software Inc.
Glencoe Software's Omero Data Management Engine is an enterprise-proven software platform that integrates digital pathology image data, metadata, analytics and annotations into a single system. Omero enables data integration, large-scale analysis, and private or public data sharing. Based on a proven open source foundation, Omero reads all major WSI formats with no data duplication and is the ideal system for delivering knowledge, discovery and diagnoses from image-based data.



12:55 Luncheon Presentation II: (Opportunity Available)

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

QUANTITATIVE DETECTION OF BIOMARKERS FOR NEXT-GEN IMMUNOHISTOCHEMISTRY

2:00 Chairperson's Remarks

David L. Rimm, M.D., Ph.D., Yale University School of Medicine

2:10 Next-Generation Immunohistochemistry Using Multiplexed Ion Beam Imaging

Michael Angelo, M.D., Ph.D., Instructor, Pathology, Stanford University

Multiplexed ion beam imaging (MIBI) is a new method for simultaneously analyzing dozens of antigens in a single tissue section using primary antibodies that are labeled with mass reporters. This talk will review the working principles of MIBI and present potential applications in clinical diagnostics and basic research.

2:40 Multiplexed Immunofluorescence in Translational Research and Clinical Applications

Michael D. Feldman, M.D., Ph.D., Associate Professor, Pathology and Laboratory Medicine, Hospital of the University of Pennsylvania

In this presentation, we will review the use of multiplexed immunofluorescence staining and imaging methods to extract cellular level information from FFPE samples. In specific clinical trial examples as well as applications to clinical use cases will be discussed.

3:10 Domain Specific Antibodies as Biomarkers

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

Biological processing of transmembrane ligands and receptors can provide information on tumor behavior. Differential outcome as a function of measurement of extracellular vs. the cytoplasmic domain of HER2 is shown as an example.

3:40 Reproducibility in Digital Pathology – The Last Step or the First in Standardization

Pawan Singh, Director, Workflow Solutions, Executive Management, Leica Biosystems

Increasing usage of digital pathology is promoting greater sharing of slides between organisations, often highlighting the different staining patterns and preferences between laboratories. Is this inherent variability in slide preparation something we should adjust for with digital pathology, or eliminate before slide scanning? We will look at a study measuring haematoxylin and eosin variation in serial sections and the challenges and benefits of utilising digital pathology, despite this variability.



4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (see website for details)

6:00 Close of Day

WEDNESDAY, FEBRUARY 18

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

8:00 PLENARY SESSION PANEL (see page 5 for details)

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

SPECIALIZED ADOPTION OF DIGITAL PATHOLOGY

10:35 Chairperson's Remarks

Beverly E. Faulkner-Jones, M.D., Ph.D., Staff Pathologist, Pathology, Beth Israel Deaconess Medical Center

10:45 Remote Eye Tracking to Assess Pathologist Interaction with Digital Whole Slide Images

Sharon Fox, M.D., Ph.D., Staff Pathologist, Pathology, Beth Israel Deaconess Medical Center; Resident, Pathology, LSU Health Sciences Center

Digital whole slide images (WSIs) are increasingly being used in pathology for teaching and diagnosis. Although it is important to understand the visual process by which pathologists arrive at image-based diagnoses, little is known about this form of visual expertise. Using remote eye-tracking visualization of gaze patterns we are evaluating the way pathologists interact with WSIs to optimize presentation of digital image data.

11:15 Advancing from Two to Three Dimensions in Digital Pathology

Beverly E. Faulkner-Jones, M.D., Ph.D., Staff Pathologist, Pathology, Beth Israel Deaconess Medical Center

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



DIGITAL PATHOLOGY

continued

11:45 Google Glass for Pathology

Liron Pantanowitz, M.D., Associate Professor, Pathology, University of Pittsburgh Medical Center

Google Glass is a head-mounted, wearable computer that can connect to the Internet and display information in a smartphone-like, hands-free format. Glass has great potential in healthcare. Recent studies have demonstrated utility for this novel device in Pathology, such as for telepathology. This talk will address the opportunities and challenges with using Google Glass in Pathology.

12:15 pm Session Break

12:25 Luncheon Presentation (*Sponsorship Opportunity Available*) or **Lunch on Your Own**

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

BIG DATA AND THE CLOUD

1:40 Chairperson's Remarks

Metin N. Gurcan, Ph.D., Associate Professor, Biomedical Informatics, The Ohio State University

1:50 Whole Slide Imaging Data Storage: A "Dickens" of a Tale -- "Please Sir, Can I Have Another Petabyte?"

Michael W. Riben, M.D., Medical Director, Laboratory Informatics; Associate Professor, Pathology, MD Anderson Cancer Center

As the penetration of whole slide imaging devices in pathology continues to expand, the challenge of managing, optimizing, and securing the imaging data and its storage becomes a high priority for successful integration into pathology clinical and research workflows. This presentation will highlight these challenges, look at potential strategies employed, and provide a framework for evaluating what is the best approach for your use cases.

WSI, BIOIMAGING & BIOINFORMATICS RESEARCH

2:20 Hot Spot Detection for Histopathological Images

Metin N. Gurcan, Ph.D., Associate Professor, Biomedical Informatics, The Ohio State University

Hotspot detection plays a key role in the diagnosis of several diseases including breast cancer and neuroendocrine tumors of the digestive system. In the Clinical Image Analysis Laboratory at the Ohio State University, we have been developing computerized image analysis algorithms for the detection of hot spots from Ki-67 stained slides. These methods rely on visually meaningful segmentation of images and novel clustering techniques.

2:50 Reimagining Cancer: The Opportunities and Challenges of Biomarker-Driven, Targeted Therapy

Mark Boguski, M.D., Ph.D., Founder & CMO, Genome Health Solutions

Biomarkers for precision medicine hold great promise for improving the outcomes of patients with cancer and other diseases. However there is a huge education gap among healthcare professionals in regional and community settings where >80% of cancer care is delivered. Traditional routes for the diffusion of knowledge and innovation are proving to be inadequate to close this gap. Furthermore the value propositions supporting the adoption of biomarker-driven, precision medicine are very unclear among healthcare executives and payers. These obstacles can be overcome by new platforms for molecular education and clinical decision support, but only if properly designed and deployed for the audiences that need them most.

3:20 Microscopy with UV Surface Excitation (MUSE): Towards Slide-Free Pathology

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

A new, inexpensive microscopy technique that allows for diagnostic-quality images to be obtained from tissues without fixation, freezing, paraffin-embedding or sectioning will be presented. In addition to recapitulating conventional histology, it can also reveal topographical features. MUSE should be useful for typical diagnostic applications, pre-clinical/basic research tissue characterization, and in global health settings.

3:50 Refreshment Break

NEXT STEPS FOR INTEGRATION: MOVING DIGITAL PATHOLOGY INTO REAL PRACTICE

4:00 Chairperson's Remarks

Kenneth J. Bloom, M.D., GE Healthcare

4:10 Using Digital Imaging to Select Tumor Cells for NGS

Kenneth J. Bloom, M.D., Chief Medical Officer, Laboratory and Genomic Services, GE Healthcare

NGS holds the promise to allow precision medicine to become a reality in oncology management. Tumor heterogeneity is a major impediment that must be understood and overcome before this is possible. The use of digital imaging will allow the pathologist to select the most appropriate cells for analysis, to better understand the composition of the nucleic acids in the sample analyzed and to more precisely interpret the sequencing data.

4:40 Data Intensive Modeling of Biomedical Processes in Computational Pathology

Jonas S. Almeida, Ph.D., Professor and Division Director, Pathology, University of Alabama Birmingham

Fast growing public biomolecular Big Data resources provide a comprehensive context to the comparatively small data produced by individual experiments, or describing individual patients. The patient-derived cancer genomics data resources of the TCGA and ICGC initiatives are a prime example. This new data intensive Computational Pathology landscape includes both a new emphasis on real-time Machine Learning and on physician/patient-facing software development for personalized medicine.

5:10 Clinical Performance and Regulatory Considerations for *in vitro* Diagnostic Use of Whole Slide Imaging in the U.S.

Michael C. Montalto, Ph.D., Senior Vice President, Clinical, Medical & Scientific Affairs, GE Healthcare

This presentation will give a high level overview of the regulatory frame work for *in vitro* diagnostic devices in the United States specifically as it relates to whole slide imaging (WSI) technology, including the FDA's current thoughts regarding WSI device classifications. Additionally, considerations for validating device performance for both manufactures and laboratories will be discussed.

5:40 Close of Conference Program

COMPANION DIAGNOSTICS

Strategies for Guiding Treatment and Improving Health

Sponsored by



1:15 Luncheon Presentation I: Rising to the Challenge of Liquid Biopsies using PointMan DNA Enrichment

Andrew Webb, CEO, EKF Molecular Diagnostics

Personalised cancer therapies based on tumour genotype have led to unparalleled progress in treatment. Genotype at diagnosis using solid biopsies is standard, routine monitoring of patient genotype during treatment presents an unmet clinical need. Here we present data utilising PointMan DNA enrichment using cfDNA and circulating tumour cells and how this rapid and cost effective sample enrichment can be incorporated into routine and next generation sequencing assays for patient monitoring.

1:45 Luncheon Presentation II (Sponsorship
Opportunity Available)

2:15 Session Break

PANEL DISCUSSION: COMMERCIALIZATION DYNAMICS OF COMPANION DIAGNOSTICS: ONE SIZE DOES NOT FIT ALL

2:30 Moderator's Remarks

Jonathan Pan, Ph.D, MBA, Director, Oncology Companion Diagnostic and Disease Strategy, GlaxoSmithKline

- Perspective on Global Market
- Companion Diagnostics Assessment and Approval in Ontario; Insights from a Publicly Funded System
- Defining Commercialization Requirements Lead by Engineering

Panelists:

Kenneth J. Bloom, M.D., Chief Medical Officer, Clariant, Inc.
Suzanne Kamel-Reid, Ph.D., DABMG, FACMG, Head, Clinical Laboratory Genetics; Director, Molecular Diagnostics, Pathology, The University Health Network; The University of Toronto
Jonathan Pan, Ph.D, MBA, Director, Oncology Companion Diagnostic and Disease Strategy, GlaxoSmithKline
Omar Perez, Ph.D., Director, Diagnostics Oncology, Worldwide R&D, Biotechnology Clinical Development, Development Operations, Pfizer Inc.

Sponsored by



4:10 Biomarker Partnerships from Feasibility through Commercialization of Personalized Multiplex Tests

Pankaj Oberoi, Vice President, Commercial Assays, Meso Scale
MESO SCALE DISCOVERY® offers a comprehensive service to screen, select, and validate custom biomarker tests. Examples of different stages of Biomarker development and partnerships will be presented.

4:25 Partnerships to Develop and Commercialize Complex Diagnostic and Companion Diagnostic Tests

Sponsored by
MYRIAD RBM

Samuel LaBrie, Ph.D., Vice President, Corporate Development,
Myriad RBM

Myriad has unique expertise in the development and commercialization of complex diagnostic tests based on panels of genes, RNAs, and proteins. We are developing new tests in areas of unmet medical need in chronic disease, often in partnership with drug development groups. Scientific and commercialization challenges will be discussed.

4:40 Break and Transition to Plenary Session

» 5:00 PLENARY SESSION (see page 5 for
details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» 8:00 PLENARY SESSION (see page 5 for
details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by
SLONEPARTNERS

RNA SEQ FOR PATIENT STRATIFICATION

10:05 Chairperson's Remarks

Michael C. Little, Ph.D., Senior Advisor, Popper & Co

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

» KEYNOTE FORUM

Co-Organized with



11:50 Moderator's Opening Remarks

Elaine Lyon, Ph.D., Medical Director, Molecular Genetics, ARUP
(AMP 2014 President and Member, AMP Professional Relations
Committee)

12:00 PM PANEL DISCUSSION: THE VALUE OF MOLECULAR DIAGNOSTICS: A DISCUSSION ON CLINICAL UTILITY

The number and complexity of clinical molecular diagnostic tests (MDx) are increasing at a rapid rate. The health care professional asks: When does MDx make sense for my patient? What scientific evidence is needed to establish the clinical utility of a particular MDx? This keynote session will focus on the clinical utility of MDx in cancer and inherited disease. It is an outgrowth of ongoing discussions on this issue among members of the Association for Molecular Pathology. We will address the contribution of MDx to the care of patients at the present time, and anticipated progress in the near future.

- Defining and measuring clinical utility from the point of view of both the clinician and the patient
- MDx of malignancies to offer prognostic and predictive information useful for selecting the optimal therapy
- Halting the "diagnostic odyssey" by selecting the appropriate genomic MDx for people, often children, with diseases that are difficult or sometimes seemingly impossible to diagnose
- Establishing the value of MDx as a modality that will not only improve health-care, but do so in a way that will lower costs in the long run

Panelists:

Loren Joseph, M.D., Medical Director, Molecular Diagnostics & Cancer Genetics, Pathology, Laboratory Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School (2014 Chair, AMP Clinical Practice Committee)

Paul G. Rothberg, Ph.D., Professor, Pathology & Lab Medicine, University of Rochester Medical Center (AMP Clinical Practice Committee, Genetics Subdivision Representative)

1:00 Session Break

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



TRICON
PERKS

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



COMPANION DIAGNOSTICS

continued

10:15 Genetic Profiling of Hematologic Malignancies

Omar Abdel-Wahab, M.D., Assistant Member, Human Oncology and Pathogenesis Program and Leukemia Service, Medicine, Memorial Sloan Kettering Cancer Center

Clinical, cytogenetic, and gene-based studies have been used to inform biology and improve prognostication for acute myeloid leukemia (AML) patients. We and others have shown somatic mutations can be used to improve risk stratification in AML. We have more recently worked to develop assays for genomic profiling of leukemia, lymphoma and myeloma patients and demonstrated how these assays can be used to inform clinical care.

10:45 Sequencing Approaches for Personalized Cancer Therapy Selection and Monitoring

Daniela Starcevic, Ph.D., Director, Diagnostic Sequencing; Assistant Professor, Genomics and Multiscale Biology; Assistant Professor, Pathology; Icahn School of Medicine at Mount Sinai

The Personalized Cancer Therapy program is aimed at developing molecular diagnostics for better disease management: therapy selection and monitoring. Patients' samples undergo state of the art sequencing and bioinformatics towards molecular level understanding of disease and a comprehensive/integrated approach for finding alternate, innovative and more effective treatment options. The opportunities and challenges of sequencing and analyzing tumor samples will be addressed and illustrated with examples.

11:15 Precision Oncology through Genomic Testing Strategies and Clinical Trials

Sameek Roychowdhury, M.D., Ph.D., Assistant Professor, Internal Medicine, Ohio State University Comprehensive Cancer Center
Dr. Roychowdhury will present on evolving use of genomic testing strategies for clinical decision making and eligibility, followed by challenges and approaches for application in clinical trials.

11:45 Accelerating the Velocity of Therapeutic Approval and Adoption

Kathryn Becker, Ph.D., Director, Global Marketing, CDx, Abbott Molecular

Abbott employs a variety of partnership models that support pre-clinical biomarker studies, complete development, indication expansion, and commercialization of CDx products. One core competency employed in all partnerships is the ability to simplify complex technologies, like multiplex molecular analysis, to enable adoption within the local clinical communities and support reproducible, reliable results on a global scale.

12:15 pm Session Break**12:25 Luncheon Presentation I: Innovative Targeted RNA-Seq Method for Identifying Known and Novel Gene Fusion Events in Tumor Cells**

Sponsored by



Jonathan Scolnick, Ph.D., Scientist, Research, NuGEN Technologies
The novel Single Primer Enrichment Technology (SPET) and how it differs from existing target enrichment methods will be described. Sensitive variant detection from genomic DNA derived from fresh and FFPE tissues using 344 cancer-related genes will be demonstrated as well as utilization of SPET as a rapid, cost-effective screening tool for discovery of novel fusions and detection of known fusions with a panel of 500 cancer genes implicated in fusions events.

12:55 Luncheon Presentation II (Opportunity Available)**1:25 Refreshment Break in the Exhibit Hall with Poster Viewing****PANEL DISCUSSION: PRACTICAL ASPECTS OF IMPLEMENTING THE MASTER PROTOCOL****2:00 Moderator's Remarks**

Glenn A. Miller, Ph.D., CTO & Executive Vice President, MolecularMD

- Predictive biomarkers and translational medicine in the S1400 lung-mAP trial
- Implementing the MATCH protocol
- Opportunities and challenges in designing and conducting basket trials

Panelists:

Philip C. Mack, Ph.D., Associate Adjunct Professor, Internal Medicine, Hematology and Oncology, University of California Davis Medical Center

Jason Lih, Ph.D., Principal Scientist, Molecular Characterization Group, Leidos Biomedical Research, Inc./Frederick National Laboratory for Cancer Research

Steffan N. Ho, M.D., Ph.D., Senior Director, Translational Oncology, Pfizer, Inc.

3:40 Enabling Advances in Cancer Genomics with NGS

Sponsored by



Frank S. Ong, M.D., Associate Director, Medical Affairs, Illumina, Inc.

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing**5:00 Breakout Discussions in the Exhibit Hall (see website for details)****6:00 Close of Day****WEDNESDAY, FEBRUARY 18**

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

8:00 PLENARY SESSION PANEL (see page 5 for details)

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

PANEL DISCUSSION: HOW THE BUSINESS MODEL IS CHANGING FOR ONE DRUG, ONE DIAGNOSTIC

10:35 Moderator's Remarks

Hakan Sakul, Ph.D., Executive Director and Head, Diagnostics, Worldwide R&D, Development Operations, Pfizer, Inc.

- How the paradigm for companion diagnostics is changing with the development of multi-gene panels and NGS coming into commonplace use
- How regulators view companion diagnostic tests
- Assessment of companion diagnostic technologies at NICE

Panelists:

Sarah Byron, Ph.D., Diagnostics Assessment Program, National Institute for Health and Care Excellence

Mara Aspinall, MBA, former CEO, Ventana Medical Systems
Garret Hampton, Ph.D., Senior Director, Oncology Biomarker Development, Genentech, Inc.

12:15 pm Session Break

12:25 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



COMPANION DIAGNOSTICS

continued

IMPLEMENTATION STRATEGIES FOR NGS-BASED COMPANION DIAGNOSTICS

1:40 Chairperson's Remarks

Seth D. Crosby, M.D., Director, Partnerships, Genetics, Washington University

1:50 The Devil is in the Details: Clinical Realities of NGS-based Tests as Companion Diagnostics

Seth D. Crosby, M.D., Director, Partnerships, Genetics, Washington University

NGS-based approaches make it possible to evaluate several thousand genes in a single assay, which provides the opportunity to stratify patients with many different diseases into many different treatments based on the results of a single lab test. However, the utility of an NGS-based Companion Diagnostic model will depend on several factors, including the scope of testing (genes and range of variants), test metrics, and medical evidence of better patient outcomes.

2:20 Companion Dx, LDTs, NGS and the MolDx Perspective – How Can We Get from Here to There?

Dane J. Dickson, M.D., Director, Clinical Science, MolDx, Palmetto GBA

Technology often outpaces clinical application. Yet, in some cases, waiting for clinical medicine to catch up before payer coverage may deprive patients of new and promising therapeutics. Finding an appropriate balance of “faith” and “science” is necessary to bridge the scientific gaps. This presentation discusses the MolDX approach to this complex balancing act, including a well-defined process of moving promising technology forward.

2:50 PANEL DISCUSSION: IMPLEMENTATION STRATEGIES FOR NGS-BASED COMPANION DIAGNOSTICS

Panelists:

Edgar Braendle, M.D., Ph.D., Senior Vice President & Global Head, Companion Diagnostics, Novartis

Dane J. Dickson, M.D., Director, Clinical Science, MolDx, Palmetto GBA

Seth D. Crosby, M.D., Director, Partnerships, Genetics, Washington University

3:20 Sponsored Presentations (Opportunities Available)

3:50 Refreshment Break

CTCs FOR COMPANION DX

4:00 Chairperson's Remarks

Steven A. Soper, Ph.D.

4:10 Circulating Tumor Cells: What Is in It for the Patient? A Vision Towards the Future

Paul A. van de Wiel, Ph.D., Senior Director, Precision and Decentralized Diagnostics, Philips Research

Knowledge on signal transduction pathways as drivers of cancer growth has fuelled development of targeted therapy. However, good companion diagnostic tests to determine the tumor driving pathways are still lacking. We will discuss novel approaches of assessing active tumor pathways based on advanced staining of CTCs in combination with automated image interpretation on a digital pathology platform, and by PCR-based analysis of isolated CTCs.

4:40 Challenges and Opportunities in the Use of CTCs for Companion Diagnostic Development

Elizabeth Punnoose, Ph.D., Senior Scientist, Oncology Biomarker Development, Genentech, Inc.

Circulating tumor cells offer promise as a surrogate source of cancer cells that can be obtained in real time and may provide opportunities to evaluate predictive biomarkers that can guide treatment decisions. In this review, we consider some of the technical hurdles around CTC numbers and suitability of various CTC capture and analysis platforms for biomarker evaluation. In addition, we consider the potential regulatory hurdles to development of CTC-based diagnostics. Finally, we suggest a path for co-development of anticancer therapeutics with CTC-based diagnostics that could enable clinical validation and qualification of CTC-based assays as companion diagnostics.

5:10 Close of Conference Program

PCR FOR MOLECULAR MEDICINE

Integrating Approaches for Clinical Success

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

» KEYNOTE SESSION

11:50 Chairperson's Opening Remarks

12:00 pm Are There Limits to the Performance and Speed of PCR?

Carl T. Wittwer, M.D., Ph.D., Professor, Pathology, University of Utah

By increasing primer and polymerase concentrations, high yield, efficient and specific PCR can be performed in less than 30 seconds with short products. With cycling overhead reduced to less than one second, product size and the polymerase extension rate determine depressors. Will advances in this foundational technology ever stop?

12:30 Pathogen Detection by Proximity Ligation Assay

Stephen Bustin, BA(Mod), Ph.D., FSB, Professor, Molecular Medicine, Faculty of Medical Science, Anglia Ruskin University

Detection of pathogen-specific proteins can be physiologically more relevant than detection of nucleic acids and is more sensitive than ELISAs or lateral flow devices. We describe the development of proximity ligation assays (PLA) targeting *Aspergillus* spp and *Clostridium difficile*, allowing earliest possible diagnosis of infectious or toxin-producing microorganisms.

1:00 Session Break

1:15 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own

2:15 Session Break

FDA-APPROVED PCR IN THE CLINIC

2:30 Chairperson's Remarks

Carl T. Wittwer, M.D., Ph.D., Professor, Pathology, University of Utah

2:40 Lab Quality Point-of-Care: 15 Minute Sample-to-Result Nucleic Acid Test for Strep A

Shuqi Chen, Ph.D., Vice President, Point-of-Care R&D, Roche Molecular System, Inc.

Point-of-care testing must combine speed, ease-of-use, and

accuracy to make patient care more efficient. cobas® Strep A is a nucleic acid test performed on the cobas® Liat that detects Strep A in only 15 minutes. Studies show that this molecular test, when used by untrained operators at the point-of-care, delivers accurate results compared to gold-standard culture, and significantly higher sensitivity compared to rapid antigen-based tests.

3:10 How Film Array Almost Killed Its Creators: Overcoming Regulatory and Developmental Challenges with an Integrated Product Team

Kirk M. Ririe, CEO & Founder, BS, BioFire Defense

The FilmArray diagnostic platform from BioFire offers hospital laboratories an easy-to-use syndrome-focused approach. FilmArray tests for dozens of viral, bacterial, or other pathogens in a one-hour test. Three panels are now CE and FDA-cleared with more in the pipeline. Together with our new partners at bioMérieux, we are making a difference in patient care. How did a small team in Salt Lake City do this?

3:40 Extended Q&A with Session Speakers: Preparing for FDA Approval

Moderator: Carl T. Wittwer, M.D., Ph.D., Professor, Pathology, University of Utah

Panelists: Shuqi Chen, Ph.D., Vice President, Point-of-Care R&D, Roche Molecular System, Inc.

Kirk M. Ririe, CEO & Founder, BS, BioFire Defense

4:10 One-Step PCR System as a Genetic BioSensor in Molecular Medicine

Sabrina Li, CEO, Coyote Bioscience Company

Coyote Bioscience is dedicated to making break-through innovations in molecular diagnostics that brings complex clinical testing directly to the patient. We would like to introduce our novel method of one-step gene test without nucleic acids extraction. The system can be as fast as 10min from blood sample to the result, and thus can be used as a Genetic Biosensor in Molecular Medicine.

4:25 Sponsored Presentation

Speaker to be Announced

Sponsored by



4:40 Break and Transition to Plenary Session

» 5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» 8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing *Sponsored by SLONEPARTNERS*

TECHNOLOGY AND ASSAY ADVANCES

10:05 Chairperson's Remarks

Kirk M. Ririe, BS, CEO & Founder, BioFire Defense

10:15 A Handheld qPCR Device for Use in the Field

Jo-Ann Stanton, Ph.D., Senior Research Fellow, Anatomy, University of Otago

We have invented a Handheld Quantitative PCR device (Freedom4) that can operate on battery for up to six hours. The Freedom4 was tested using World Health Organization and IANZ accredited assays for *E. coli* O157 STEC, influenza, adenovirus, enterovirus, norovirus, and astrovirus. In side-by-side tests with larger laboratory based instruments and clinical samples the Freedom4 was comparable to, and in one case better than, in-laboratory technology.

10:45 Implementation and Transition of Digital PCR from Discovery Applications to Clinical Diagnostic Tools

Andrew Brooks, Ph.D., COO, RUCDR Infinite Biologics, Rutgers University

The use of digital PCR technologies is rapidly evolving for a number of applications. As the technology transitions from being used as discovery tool to diagnostic applications there are many components and benchmarks that need to be established in order to accomplish these goals. This talk will look address the operational considerations for such a transition.

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



PCR FOR MOLECULAR MEDICINE

continued

11:15 Not All Primers Are Created Equal: Priming Efficiency Bias Uncovered by NGS

Jian Han, Ph.D., Faculty Investigator, iCubate, HudsonAlpha Institute for Biotechnology

TM-based primer design software has been used for over 30 years. However, if the same primer is subject to different TM evaluation equations, the obtained value could be 8-10 degrees different! We have designed a simple experiment to measure DNA polymerase bias. From these results, a mathematical model of the bias was developed and utilized in a software to guide primer design. This PPI (polymerase preference index) method can be used to improve PCR success rates.

11:45 Techniques for Cell-Free DNA Analysis

Alison Devonshire, Ph.D., Science Leader, Nucleic Acid Metrology, LGC Genomics

12:15 pm Session Break

12:25 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

PCR FOR PATIENT STRATIFICATION

2:00 Chairperson's Remarks

Andrew Brooks, Ph.D., COO, RUCDR Infinite Biologics, Rutgers University

2:10 Digital PCR for Patient Monitoring and Stratification in Clinical Trials

Reinhold Pollner, Ph.D., Director, Clinical Trial Assay Development, Genoptix Medical Laboratory, a Novartis Company

My presentation will focus on how digital PCR is used in the validation of clinical trial assays with respect to patient monitoring and stratification in a CLIA/CAP laboratory setting. A variety of different applications of digital PCR will be discussed ranging from the determination of DNA copy numbers in FFPE samples, absolute quantitation of a transgene in whole blood and bone marrow samples, identification of a fusion gene at the mRNA level in FFPE specimens, and rare allele detection using circulating tumor DNA.

2:40 Evaluation of EGFR Mutations in Plasma from NSCLC Patients: Utility in Managing Patients on TKI Therapy

Chris Karlovich, Ph.D., Principal Scientist, Molecular Diagnostics, Clovis Oncology

We are utilizing blood-based molecular testing in patients who have become resistant to first generation tyrosine kinase inhibitors with the goal of enabling subsequent therapy without need for repeat lung biopsy. The utility of plasma-based EGFR mutational analysis will be described in the context of CO-1686, a novel third-generation TKI that selectively inhibits the EGFR activating and T790M resistance mutations in NSCLC patients.

3:10 NGS-Assisted DNA-Based Digital PCR for the Detection and Quantification of Residual Disease in CML Patients with Undetectable BCR-ABL1 Transcripts

Mary Alikian, MSc, Clinical Scientist, Imperial Molecular Pathology, Imperial College

The presentation will describe a DNA-based method of detecting and quantifying low levels of BCR-ABL1 positive disease that improves on previous methodologies in two key areas: Identifying the patient-specific genomic BCR-ABL1 fusion junctions using targeted next generation sequencing allowing the rapid generation of high-performing DNA based qPCR assays. The second area is: Use of a DNA-based approach by optimizing the technique for use on a digital PCR (dPCR) platform, which provides absolute molecular quantification without the need for standard curve.

3:40 Precision Molecular Profiling of Cancer using ddPCR

Jennifer Berman, Ph.D., Staff Scientist, Digital Biology Center, Bio-Rad Laboratories

Cutting-edge, personalized cancer care requires ultra-sensitive detection and monitoring of actionable mutations from limited patient samples. The high sensitivity and precision of droplet digital PCR (ddPCR) offers critical advantages when clinical samples are limiting, degraded, and contain PCR inhibitors. We highlight use of ddPCR for quantification of KRAS mutations in FFPE and plasma cfDNA, as well as detection of copy number alterations of oncogenes like MYC, HER2, and EGFR.

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (see website for details)

6:00 Close of Day

WEDNESDAY, FEBRUARY 18

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

8:00 PLENARY SESSION PANEL (see page 5 for details)

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

APPLICATION CASE STUDIES

10:35 Chairperson's Remarks

10:45 PANEL DISCUSSION: Future Directions for PCR

Panelists: David Godler, Ph.D., Senior Research Fellow, Cyto-molecular Diagnostics Research and Victorian Clinical Genetics Services; Head, The FMR1 Related Disorders Group, Murdoch Children's Research Institute, Royal Children's Hospital

DIAGNOSTICS CHANNEL

*Stephanie I. Fraley, Ph.D., Assistant Professor, Bioengineering, University of California San Diego Johns Hopkins
Leonora Balaj, Ph.D., Researcher, Massachusetts General Hospital, Harvard Medical School*

GENETIC DIAGNOSTICS

11:45 An Automated Genetic Analysis Instrument That Boasts High Multiplexing Capabilities and Low Hands-On Time

Hanyoung Kim, Ph.D., Senior Scientist, Canon U.S. Life Sciences, Inc.

The development of an automated genetic analyzer instrument using liquid handling robots and pre-loaded custom reagent plates to run multiplexed genotyping panels on proprietary microfluidic cartridges is described. The microfluidic cartridge that rapidly amplifies and detects via high-resolution melting provides a simple, flexible test workflow. The instrument allows panels of >20 genetic targets to be tested sequentially on a single sample under different PCR conditions, while reducing hands-on time.

12:15 pm Session Break

12:25 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

1:40 Chairperson's Remarks

Mary Alikian, MSc, Clinical Scientist, Imperial Molecular Pathology, Imperial College

1:50 Droplet Digital PCR and Methylation Specific Quantitative Melt Analysis – Applications in Fragile X Related Disorders and Beyond

David Godler, Ph.D., Senior Research Fellow, Cyto-molecular Diagnostics Research and Victorian Clinical Genetics Services; Head, The FMR1 Related Disorders Group, Murdoch Children's Research Institute, Royal Children's Hospital

The first part of the talk will focus on a droplet digital PCR method for absolute quantification of FMR1 RNA toxicity. The second part will focus on a novel FMR1 methylation test utilizing combination of real-time PCR and high resolution melt, named methylation specific quantitative melt analysis or MS-QMA. The presentation will cover applications of both methods in Fragile X Related Disorders in multiple cohorts.

INFECTIOUS DISEASE

PCR FOR MOLECULAR MEDICINE

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



PCR FOR MOLECULAR MEDICINE

continued

2:20 Universal Digital High-Resolution Melt: A Rapid Molecular Approach for Accurately Resolving Mixed Infections

Stephanie I. Fraley, Ph.D., Assistant Professor, Bioengineering, University of California San Diego Johns Hopkins

Nucleic acid amplification with universal primers against microbial nucleic acids can achieve broad-based amplification, but resolving a mixture of amplified sequences, resulting from background contaminating DNA or polymicrobial infections, has proven to be a major challenge for rapid molecular diagnostics. We developed Universal Digital High Resolution Melting, a single microbe sensitive, rapid, and broad-based diagnostic technology to overcome these limitations and have demonstrated its utility in the context of diagnosing bacteremia.

2:50 "Salvage Microbiology" and the Infectious Diseases Physician

Robert A. Bonomo, M.D., Chief, Medical Service, Louis Stokes Cleveland VA Hospital; Vice Chair, Veterans Affairs, Medicine, University Hospital Case Medical Center

The timely and accurate diagnosis of pathogens is critical to choosing appropriate therapy and for informing antimicrobial stewardship measures. In many cases, bacterial cultures are unrevealing due to improper handling of samples, previous use of antibiotics, or low colony counts. We present a case series describing how PCR coupled with electrospray ionization mass spectrometry (PCR/ESI-MS) can be used to guide choices for therapy. We illustrate how unsuspected pathogens can be discovered, thereby improving decisions for therapy and increasing our understanding of disease processes.

3:20 Evaluation of Manufacture and QC Controls for PCR Components

Sponsored by



Used in Molecular Diagnostic Assays

Doug Storts, Ph.D., Head, Nucleic Acid Technologies, Promega Corporation

PCR-based molecular diagnostic assays rely on high quality reaction components to yield robust and reliable results. Gain a better understanding of the impact that PCR component manufacture and QC controls have on molecular diagnostic assay design and performance.

3:35 Sponsored Presentation (Opportunity Available)

3:50 Refreshment Break

4:00 Chairperson's Remarks

G. Mike Makrigiorgos, Ph.D., Professor, Radiation Oncology, Dana Farber and Harvard Medical School

4:10 HIV RNA Detection and Quantification by Nucleic Acid Testing-PNA Enzyme Linked Assay (NAT-PELA) for Viral Load Assays

Daniel Appella, Ph.D., Senior Investigator, LBC, NIDDK, NIH

This presentation will demonstrate how to engineer peptide nucleic acids (PNAs) to detect HIV RNA at levels competitive with standard PCR assays. Since PNA is resistant to degradation by enzymes, diagnostic devices using PNA probes are very stable. With the proper PNA probes, standard ELISA platforms can be used to directly detect HIV RNA and may be used to quantify viral load in plasma at clinically useful levels.

CANCER

4:40 Single-Tube Enrichment of Mutations in Cancer Gene Panels Using COLD-PCR Prior to

Targeted Amplicon Resequencing

G. Mike Makrigiorgos, Ph.D., Professor, Radiation Oncology, Dana Farber and Harvard Medical School

Targeted re-sequencing of mutations in cancer-relevant genes provides opportunities for fine-tuning cancer therapy and treatment follow-up, by examining mutations in tumors and bio-fluids. We present a new adaptation of COLD-PCR, fast-TT-COLD-PCR, via which mutations in numerous amplicons are first enriched in a single-tube reaction, prior to targeted re-sequencing. Modified nucleotides are employed in the reaction to enable detection of all mutations. Using this approach, sub-clonal mutations of 0.01-0.1% abundance are first converted to clonal mutations and then detected via NGS.

5:10 Evaluation of Biofluid Derived Extracellular Vesicles in Brain Tumors

Leonora Balaj, Ph.D., Researcher, Massachusetts General Hospital, Harvard Medical School

Extracellular vesicles (EVs) are lipid rafts released by all cells. They end up in biofluids where they can be captured and further characterized. Their cargo represents a molecular snapshot of the primary tumor, and have great potential to report these molecular changes over time. We have isolated EVs from plasma and CSF of patients with brain tumors, and have shown that they are a powerful source of genetic changes present in the primary tumor.

5:40 Close of Conference Program

Student Fellowships Are Available!

Full-time graduate students and PhD candidates are encouraged to apply for the Molecular Medicine Tri-Conference Student Fellowship. Twenty fellowship award winners will receive a poster presentation slot and a \$780 savings on their registration fee. Applications are due by November 14, 2014.

See TriConference.com/tricon/Student-Fellowship for details.

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



GENOMIC SAMPLE PREP AND BIOSPECIMEN SCIENCE

Assuring Development of Robust and Accurate Omics Assays

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

STANDARDIZING SAMPLE QUALITY AND PREANALYTICAL PROCESSING

11:50 Chairperson's Opening Remarks

Daniel Chelsky, Ph.D., CSO, Caprion Proteomics USA, LLC

**12:00 pm Pre-Analytical Variation in Human
Biospecimens: The Ultimate "Sample Preparation"
Challenge for Diagnostics**

Carolyn Compton, M.D., Ph.D., Professor, Life Sciences, Arizona State University; Professor, Laboratory Medicine and Pathology, Mayo Clinic School of Medicine; CMO, National Biomarker Development Alliance

The biomarker qualification program of the Center for Drug Evaluation and Research at the Food and Drug Administration emphasizes the need to document the biospecimen quality of diagnostic biomarkers used for drug development, and the Center for Devices and Radiologic Health has similar requirements for approval of diagnostic devices. It is imperative that the diagnostics development community address the need for standardized processes and fit-for-purpose biospecimens to accelerate the delivery of accurate, reproducible, clinically relevant molecular diagnostics for precision medicine.

**12:30 Comparison of Various Preanalytical
Strategies in Molecular Testing for Infectious
Diseases**

David R. Hillyard, M.D., Medical Director, Molecular Infectious Diseases, Arup Laboratories

Molecular infectious disease testing places unique demands on pre-analytic methods for organismal disruption, nucleic acid release, purification, and concentration. For both high-throughput core platforms and the increasing number of near point-of-care devices, nucleic extraction is a key pre-analytic step for good test performance. This presentation will review both currently available and emerging approaches to pathogen nucleic acid extraction, and issues relevant to its integration with downstream amplification and analysis technologies.

1:00 Session Break

FFPE vs. FROZEN SAMPLES

**1:15 Luncheon Presentation I:
Recovery and Analysis of FFPE
Derived Pure Tumor Cells Using the
DEPArray System: Enabling
Molecular Profiling and NGS Applications**

Sponsored by



Farideh Z. Bischoff, Ph.D., Executive Director, Scientific Affairs, Silicon Biosystems

Silicon Biosystems has combined the ability to manipulate individual cells using DEPArray™ technology. Molecular testing of FFPE tissue can often be compromised due to specimen size, heterogeneity, and presence of normal cells. The DEPArray™ platform enables identification and recovery of pure cell populations of interest from these complex, heterogeneous samples that are now amenable to downstream molecular profiling and NGS.

**1:45 Luncheon Presentation II
(Opportunities Available)**

2:15 Session Break

2:30 Chairperson's Remarks

**2:40 National Cancer Institute Resources to Guide
Fit-For-Purpose Biospecimen Collection and
Utilization**

Helen Moore, Ph.D., Branch Chief, Biorepositories & Biospecimen Research Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute

The National Cancer Institute has led the way in developing Best Practices for Biospecimen Resources, sponsoring new research in Biospecimen Science, and building groundbreaking research biospecimen collections including postmortem biospecimens for the NIH GTEx program. New projects to build evidence-based best practices for frozen and FFPE tissues will be described.

**3:10 Overcoming Challenges of Working with FFPE
Samples**

W. Fraser Symmans, M.D., Professor & Director, Research Operations, Pathology, UT MD Anderson Cancer Center

This presentation will discuss several important issues, such as: RNA detection in cancer tissues stored in FFPE samples; Profiling microRNA expression; FFPE DNA quality control and its correlation with NGS data; Understanding pre-analytic effects on RNA gene expression

**3:40 Impact of Preanalytical Variables on the Total
Proteome and Phosphoproteome of Cancer Tissue
Specimens**

Daniel Chelsky, Ph.D., CSO, Caprion Proteomics USA, LLC

**4:10 Standardizing Molecular
Pathology with Fully Automated
Nucleic Acid Isolation
from FFPE and FF Tissue**

Sponsored by
SIEMENS

Guido Hennig, Ph.D., Senior Global Scientific Affairs Manager, BU Molecular Global Marketing, Siemens Healthcare Diagnostics

Molecular analysis in FFPE/FF tissue is important in retrospective biomarker studies, biobanking and molecular pathology. The discussed Siemens Tissue Preparation System (TPS) fully automates and standardizes extraction of high quality DNA and RNA from any tissue for PCR and sequencing applications.

4:25 Sponsored Presentation (Opportunity Available)

4:40 Break and Transition to Plenary Session

**» 5:00 PLENARY SESSION (see page 5 for
details)**

**6:00 Grand Opening Reception in the Exhibit Hall
with Poster Viewing**

GENOMIC SAMPLE PREP
AND BIOSPECIMEN SCIENCE

CONTINUED ON NEXT PAGE

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



GENOMIC SAMPLE PREP AND BIOSPECIMEN SCIENCE

continued

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» **8:00 PLENARY SESSION** (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing *Sponsored by SLONEPARTNERS*

NOVEL TECHNOLOGIES

10:05 Chairperson's Remarks

David R. Hillyard, M.D., Medical Director, Molecular Infectious Diseases, Arup Laboratories

» **10:15 KEYNOTE PRESENTATION: New Technologies for Diagnostics**

Ronald W. Davis, Ph.D., Professor of Biochemistry and Genetics, Director, Stanford Genome Technology Center, Stanford University

The need to interrogate an expanding number of clinical biomarkers including host and pathogen nucleic acid sequence using tests that are rapid, accurate, and cost effective is a fundamental challenge for laboratory medicine. Advances in electronics, chemistry, fabrication, and informatics, allow for development of new test formats with dramatically improved performance and cost profiles. This presentation will highlight emerging technologies for detection and characterization of protein and nucleic acid biomarkers.

NGS ASSAYS: PREANALYTICAL CONSIDERATIONS, ASSAY DEVELOPMENT AND VALIDATION

11:15 Development and Validation of Clinical NGS tests: the Requirements and the Challenges Presented by the Various Clinical Applications

Martin Siaw, Ph.D., Associate Scientific Director, Advanced Sequencing, Quest Diagnostics Nichols Institute

The use of NGS in clinical laboratories has come of age. NGS tests for different sub-specialties (e.g., Infectious Diseases, Genetics, Oncology, etc.) involve a wide variety of clinical targets with varying requirements for sample preparation, sequence target size, target enrichment, depth of coverage, data analysis and clinical reporting. My presentation will focus on the requirements for the various tests and the challenges for developing and validating these tests for use in CLIA certified clinical laboratories.

11:45 A Microfluidic DNA Library Preparation Platform for Next-Generation Sequencing

Kamlesh Patel, Ph.D., Manager, Advance Systems Engineering and Deployment, Sandia National Labs

DNA sequencing is advancing at an unprecedented rate, but sample preparation methods rely on manual bench-top processes, which are labor-intensive. The introduction of fast, low-throughput sequencers warrants a need to automate

these protocols. We report on our work to integrate novel digital microfluidic technology to automate DNA library preparation workflows for characterization of novel and emerging pathogens from clinical samples.

12:15 pm Session Break

12:25 Luncheon Presentations (*Sponsorship Opportunities Available*) or **Lunch on Your Own**

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

NGS ASSAYS CONTINUED

2:00 Chairperson's Remarks

Jamie L Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.

2:10 Validation Challenges for Panels and Exomes

Josh Deignan, Ph.D., Associate Director, UCLA Molecular Diagnostics Laboratories, Department of Pathology and Laboratory Medicine, David Geffen School of Medicine, UCLA

Guidelines for the validation of molecular diagnostic tests have existed for some time, but guidelines for NGS testing have only recently emerged. Moreover, the approach required for the validation of a NGS mutation panel is different than the one required for an exome sequencing test, both of which are now offered clinically at UCLA. This talk will discuss our experiences with the validations of these two types of NGS tests.

2:40 FDA-Approved Versus LDT-Based NGS Systems: Preanalytical Issues and Validation

Jamie L Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.

As NGS technologies have matured and their utility in clinical diagnostics has been embraced, the evolution of RUO-based Laboratory Developed Processes (LDPs) to FDA-Cleared *In Vitro* Diagnostic Tests has followed. The major considerations around Preanalytical issues for these two categories of systems will be compared and discussed. In addition, the key validation or verification challenges will be contrasted and discussed within the context of a CLIA Lab experience using both types of systems. The objective of the presentation is to provide sufficient information, drawn from experience, to enable labs to choose the path that best suits their environment, goals and objectives.

3:10 PANEL DISCUSSION: Comparing Major NGS Instruments: Technical Differences, Application Preferences

Moderator: Jamie L Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.

Panelists: Shelly Gunn, M.D., Ph.D., CMO, Molecular Health

Martin Siaw, Ph.D., MB (ASCP), Associate Scientific Director, Advanced Sequencing, Quest Diagnostics Nichols Institute

Jennifer J.D. Morrisette, Ph.D., FACMG, Scientific Director, Clinical Cancer Cytogenetics; Clinical Director, Center for Personalized Diagnostics; Pathology, University of

Pennsylvania

Selecting the NGS platform or platforms that best address the pre-analytical and technical considerations of the assay objectives given the specific environment can be a challenging undertaking. Platform throughput, chemistry, and error modality vary greatly and are tightly tied to overall assay performance. This discussion will focus on the strengths and capabilities of the different commercially available NGS platforms from the perspective of users with experience on multiple platforms.

3:40 A Novel Method for Efficient and Hands-Free Purification of Circulating, Cell-Free DNA (ccfDNA) from Human Plasma

Sponsored by



Douglas Horejsh, Ph.D., Senior Research Scientist, Promega Corporation

The Promega Maxwell® RSC circulating DNA kit allows parallel purification of ccfDNA from 1-16 plasma samples. This method purifies high-quality DNA suitable for use in qPCR and NGS. The absence of pre-processing steps improves reproducibility and lowers risk of contamination.

3:55 Can You Handle a Million Tests per Year? Transitioning from Clinical Trials to a Validated, High-Throughput Diagnostics Operation

Sponsored by
sample minded

Daniel Steenblik, Vice President of Technology and Operations, Engineering, sampleminded

We will discuss the challenges of transitioning a lab from clinical trials to a high throughput diagnostic organization. How we employ a simple and sleek mission critical LIS, including tablets, monitoring and workflow metrics to capture quality indicators, while maintaining traditional LIS/LIMS functionality.

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (see website for details)

6:00 Close of Day

WEDNESDAY, FEBRUARY 18

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

GENOMIC SAMPLE PREP
AND BIOSPECIMEN SCIENCE

CONTINUED ON NEXT PAGE

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



GENOMIC SAMPLE PREP AND BIOSPECIMEN SCIENCE

continued

» **8:00 PLENARY SESSION PANEL (see page 5 for details)**

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

BEST BIOSPECIMEN AND BIOPREPOSITORY PRACTICES

10:35 Chairperson's Remarks

10:45 Preparing Research Samples for Future Use: Innovative Methods for Assessing Functional Quality Control and Biobanking Best Practices

Andrew Brooks, Ph.D., COO and Director, Technology Development, Technology, RUCDR Infinite

Variable DNA sample quality and the lack of standardized sample tracking in biorepositories perpetuates sample ID errors caused by mishandling during sample collection, storage or use. The RUCDR finds that greater than 98 percent of biorepository errors occur from issues during sample collection and are not errors in sample processing once they arrive at the biorepository. Sample qualification and verification prevents erroneous use of misidentified samples in downstream experiments and also ensures high-quality data from samples being analyzed.

11:15 Transformative Systems Pathology: Moving Omics to Clinics

Michael H.A. Roehrl, M.D., Ph.D., Director, UHN Program in BioSpecimen Sciences, University of Toronto

We will discuss latest advances in proteomic cancer biomarker discovery, cancer genome sequencing, and metabolomic discovery in human disease. We will highlight that ultra-rapid tissue biobanking and preservation in the frozen state are critically important for faithful physiome preservation in next gen diagnostics and specimen-driven molecular clinical trials.

11:45 MUSE: A Fast, Inexpensive and Informative Method for Slide-Free Microscopy

Richard Levenson, M.D., Professor, Vice Chair for Strategic Technologies, Pathology and Laboratory Medicine, UC Davis Medical Center

12:15 pm Session Break

12:25 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

RNA TESTING AND SAMPLE TO RESULT TECHNOLOGY

1:40 Chairperson's Remarks

1:50 Circulating RNA - Is it a Blessing or a Curse?

Kai Wang, Ph.D., Principal Scientist, Institute for Systems Biology

Cell free circulating RNA has attracted a great deal of attention in recent years as specific physiopathological conditions have been linked to varying concentrations of various RNA species. However, there are a number of challenges in accurately assessing levels of specific circulating RNA sequence. Standardized sample preparation protocols and new measurement approaches are clearly needed. In the meantime caution should be exercised when interpreting circulating RNA based results.

2:20 Human Cerebrospinal Fluid (CSF) miRNA Analysis: Critical Factors in Sampling Preparation and Detection

Wang-Xia Wang, Ph.D., Senior Scientist, Sanders-Brown Center on Aging, University of Kentucky

Human cerebrospinal fluid (CSF) microRNAs (miRNAs) have been proposed as potential biomarkers for disease conditions, specially, neurodegenerative diseases; however, technical challenges related to RNA sample preparation and detection has hindered the establishment of reproducible miRNA signatures. This talk will focus on the overview of technical aspects of CSF RNA sample preparation and detection, and will discuss the recent advance including several commercially developed extracellular miRNA/RNA sample preparation and analysis platforms.

2:50 RNAssist Fixative and Stabilizer for Immunohistochemistry and the Recovery of High Quality RNA, DNA and Proteins

Andrew Goldsborough, Ph.D., CEO, RNA Stability, RNAssist Ltd

The RNAssist reagent has been developed to efficiently fix tissue samples whilst preserving RNA, DNA, proteins as well as tissue histology for IHC analysis. It does not contain alcohol or formaldehyde, has very low volatility and is biodegradable. RNA stabilisation is superior to both standard fixatives and dedicated RNA stabilisation solutions. Results will be shown demonstrating RNA, DNA and protein stabilisation, and IHC in RNAssist fixed tissues.

3:20 Extending The Reach Of Molecular Diagnostics: Sample-To-Result Infectious Disease Tests

Barry Lutz, Ph.D., Research Assistant Professor, Department of Bioengineering, University of Washington

We are developing tests for DNA and RNA that can be performed outside conventional laboratory settings. All steps from sample preparation to visual readout are carried out automatically without an instrument. Data collection by a cell phone will allow transmission of results to a healthcare provider and medical record. Project goals include commercializable tests as well as broad platform capabilities for future tests. We are also collaborating to develop simplified drug resistance tests based on detection of single-base mutations in HIV and other infectious diseases.

3:50 Refreshment Break

ENABLING CANCER RESEARCH AND DEVELOPMENT

4:00 Chairperson's Remarks

4:10 Isolation of DNA/RNA Biomarkers and the Quest for Liquid Biopsy Cancer Diagnostics

Michael J. Heller, Ph.D., Professor, Nanoengineering & Bioengineering, University of California San Diego

The isolation of circulating cell free (ccf) DNA and ccf-RNA directly from blood and/or plasma remains a complex and time consuming procedure, which is impeding process toward liquid biopsy and point of care (POC) cancer diagnostics. We have now demonstrated the rapid isolation and detection of ccf-DNA/RNA from a number of different hematological and solid tumor samples.

4:40 Antibody Validation to Prevent Error

David L. Rimm, M.D., Ph.D., Professor, Pathology; Executive Director, Translational Pathology; Director, Yale Pathology Tissue Services, Yale University

Antibodies are an extremely broadly used and valuable tool, both in discovery research, translational research and in the clinic. However, some of the data produced and published in the literature is flawed, or misleading due to non-specificity or cross-reactivity. Here we will look at the use of antibodies, both in the research and clinical setting and show how lack of rigorous validation can produce flawed data. We will also provide guidelines for antibody validation that can be used to avoid flawed, but publishable results.

5:10 Managing Quality in Biorepository Operations to Support Translational Research- Experiences of the OHSU Knight BioLibrary

Devon Kelly, Director, OHSU Knight BioLibrary, Knight Cancer Institute, Oregon Health and Science University

Methods by which human research specimens are consented, collected, stored and distributed varies greatly from repository to repository. This variation is a large contributing factor in the ability of researchers to generate high-quality data from specimens acquired from multiple repositories into a single research project. Therefore, it is important to manage the quality of biobanking activities to maximize the utility of banked specimens collected for future research projects. Experiences in assessing and standardizing practices across a large cancer repository network will be discussed.

5:40 Close of Conference Program

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



EPIGENOMICS IN DISEASE

Above the Genome - Underlying Disease

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

INTERROGATING DISEASE (EPI)GENOMES

11:50 Chairperson's Opening Remarks

Susan Clark, Ph.D., Professor & Director, Epigenomics Centre, The Kinghorn Cancer Centre, Garvan Institute of Medical Research

12:00 PM KEYNOTE PRESENTATION: REGULATORY GENOMICS AND EPIGENOMICS OF COMPLEX DISEASE

Manolis Kellis, Ph.D., Professor, Computer Science, MIT; Director, Computational Biology Group, Computer Science and Artificial Intelligence Lab (CSAIL), Broad Institute of MIT and Harvard

12:30 Epigenome-Wide Landscape of Melanoma Progression to Brain Metastasis

David Hoon, Ph.D., Chief, Scientific Intelligence, Director, Molecular Oncology, John Wayne Cancer Institute

Although epigenomic aberrations in different primary tumors are well studied, their influence on tumor progression to brain metastasis (BM) still remains largely unexplored. By integrating genome-wide DNA methylation, gene expression, copy number variation, single nucleotide polymorphisms, DNase I hypersensitive sites, and chromatin immunoprecipitation analyses, we identified epigenome-wide alterations that contribute to the melanoma progression to BM. I will discuss the key role of epigenomic aberrations on the extraordinarily dynamic gene expression reprogramming and progression to BM.

1:00 Session Break

1:15 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own

2:15 Session Break

EPIGENETIC DRIVERS IN NEURO-ONCOLOGY

2:30 Chairperson's Remarks

Joseph Costello, Ph.D., Professor in Residence, Neurological Surgery; Director, Epigenetics Division, Cell Cycling and Signaling Program, Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco

2:40 Co-Dependency of the Genome and Epigenome during Tumor Evolution

Joseph Costello, Ph.D., Professor in Residence, Neurological Surgery; Director, Epigenetics Division, Cell Cycling and Signaling Program, Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco

Tumor epigenetic states are reversible and sensitive to the tumor microenvironment. We recently used mutation patterns to learn how low grade gliomas evolve over time. Here we examined the spatial and temporal dynamics of DNA methylation in our clinically and genetically characterized cohort of IDH1-mutant low-grade gliomas and their patient-matched recurrences. We constructed phylogenetic and phyloepigenetic relationships among co-evolving tumor cell populations. Despite the plasticity of tumor epigenetic states, phyloepigenetic relationships robustly recapitulated phylogenetic patterns.

3:40 Genetic-Epigenetic Interactions in Cis and Trans: Relevance to the Human Brain and Immune System

Benjamin Tycko, M.D., Ph.D., Professor, Pathology and Cell Biology, Institute for Cancer Genetics & Taub Institute for Research on Alzheimer's Disease and the Aging Brain, Columbia University

4:10 Sponsored Presentations (Opportunities Available)

4:40 Break and Transition to Plenary Session

5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by
SLONEPARTNERS

MECHANISMS UNDERPINNING DISEASE: CHROMATIN DYNAMICS AND LONG-RANGE REGULATORY CONTROL

10:05 Chairperson's Remarks

David Hoon, Ph.D., Chief, Scientific Intelligence; Director, Molecular Oncology, John Wayne Cancer Institute

10:15 FEATURED PRESENTATION: Epigenome Remodelling and DNA Replication Timing: What are the Implications in Cancer?

Susan Clark, Ph.D., Professor & Director, Epigenomics Centre, The Kinghorn Cancer Centre, Garvan Institute of Medical Research

By an integrative epigenome-wide sequencing analysis of prostate cancer and normal cells, we found the epigenetic deregulated domains are characterised by an exchange of active chromatin marks, and repressive marks. Here, I will discuss our latest data to inform the mechanism(s) involved in epigenome remodelling and the spatial and temporal dynamics associated with deregulated domains of the cancer epigenome. These findings have wide ramifications for cancer diagnosis, progression and epigenetic-based gene therapies.

10:45 Linking Histone Recognition to the Epigenetic Inheritance of DNA Methylation

Brian Strahl, Ph.D., Associate Professor & Director, Graduate Studies of Biochemistry & Biophysics, University of North Carolina School of Medicine

We have shown that UHRF1, a DNA- and histone-binding E3 ubiquitin ligase, functions in the DNA methylation program through constitutive multivalent recognition of a heterochromatic signature found on H3. We now show that hemi-methylated DNA recognition by UHRF1 is directly coupled to H3 recognition by this protein. Data will be presented that reveal how these domains are communicating with each other to mediate a highly coordinated histone-DNA binding event in chromatin.

11:15 Remodeling the Remodelers: BAF Complex Structure and Function in Human Malignancy

Cigall Kadoch, Ph.D., Assistant Professor, Pediatric Oncology, Dana-Farber Cancer Institute and Harvard Medical School

Recent genome-wide exon sequencing studies have revealed that over 20% of human cancers bear mutations in the genes encoding subunits of mammalian SWI/SNF (or BAF) ATP-dependent chromatin remodeling complexes, making them the most frequently and broadly mutated chromatin

EPIGENOMICS IN DISEASE

CONTINUED ON NEXT PAGE

COVER

EVENT-AT-A-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

EPIGENOMICS IN DISEASE

continued

regulator. Our studies focus upon cancers with genomically well-defined BAF complex aberrations, such as synovial sarcoma, malignant rhabdoid tumors, and others to uncover the structural and functional consequences of BAF complex perturbation, and to catalyze the identification of therapeutics for this class of tumors.

11:45 Extensive Variation in Chromatin States across Humans

Maya Kasowski, Ph.D., Fellow, Synder Lab, Genetics, Stanford University

We studied differences in chromatin states using five histone modifications, cohesin, and CTCF in lymphoblastoid lines from 19 individuals of diverse ancestry. We found extensive signal variation in regulatory regions, which often switch between active and repressed states across individuals. Enhancer activity is particularly diverse among individuals, whereas gene expression remains relatively stable. Chromatin variability shows genetic inheritance in trios, correlates with genetic variation and population divergence, and is associated with disruptions of transcription factor binding motifs.

12:15 pm Session Break

12:25 Luncheon Presentations (*Sponsorship Opportunities Available*) or **Lunch on Your Own**

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

TECHNOLOGICAL ADVANCES ENABLING (EPI)GENOMIC RESEARCH

2:00 Chairperson's Remarks

Ido Amit, Ph.D., Associate Professor, Immunology; Principal Investigator, Laboratory for Immuno-Genomics, Weizmann Institute of Science

2:10 FEATURED PRESENTATION: Shaping the Blood: Lessons from Chromatin and Single Cell RNA Dynamics

Ido Amit, Ph.D., Associate Professor, Immunology; Principal Investigator, Laboratory for Immuno-Genomics, Weizmann Institute of Science

Using a novel high-sensitivity indexing-first chromatin immunoprecipitation approach, we profiled the dynamics of four chromatin modifications across 16 stages of hematopoietic differentiation. We found that lineage commitment involves *de novo* establishment of thousands of lineage-specific enhancers. These enhancer repertoire expansions foreshadow transcriptional programs in the differentiated cells. Combining our enhancer catalog with single cell gene expression profiles, we elucidated the transcription factor network controlling chromatin dynamics and lineage specification in hematopoiesis.

2:40 Highly Sensitive Methods for Analysis of the "Accessible Genome"

William James Greenleaf, Ph.D., Assistant Professor, Department of Genetics, Stanford University School of Medicine

Eukaryotic genomes are hierarchically packaged into chromatin, and the nature of this packaging plays a central role in gene regulation. We have developed an Assay for Transposase Accessible Chromatin using sequencing (ATAC-seq) – based on direct *in vitro* transposition of sequencing adapters into native chromatin – as a rapid and sensitive method for integrative, high-resolution epigenomic analysis. With this method, we have investigated the chromatin changes associated with aging in T cells, as well as regulatory variation at the single-cell level.

3:10 Hybridization-Based Epigenotyping Using Methyl Binding Domains for Routine Clinical Analyses

Hadley D. Sikes, Ph.D., Joseph R. Mares Assistant Professor, Chemical Engineering, Massachusetts Institute of Technology

Basic and translational studies suggest that knowledge of the CpG methylation status of particular promoters has utility for predicting response to therapy and perhaps for diagnosis of several cancers. However, the techniques used to make these discoveries are not well suited for routine use in the clinical setting. We are quantitatively investigating hybridization-based epigenotyping using methyl binding domain proteins as an approach that eliminates bisulfite treatment steps and may be well suited for everyday use in pathology labs.

3:40 Sponsored Presentations (*Opportunities Available*)

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (*see website for details*)

6:00 Close of Day

WEDNESDAY, FEBRUARY 18

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

» 8:00 PLENARY SESSION PANEL (*see page 5 for details*)

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

DNA METHYLATION BIOMARKERS IN CANCER

10:35 Chairperson's Remarks

Michelle M. Hanna, Ph.D., CEO & Scientific Director, RiboMed

10:45 DNA Methylation as Cancer Biomarkers in Clinical Development

David Shames, Ph.D., Senior Scientist, Genentech

11:15 Development of DNA Methylation Markers for Early Lung Cancer Detection

Ite A. Laird-Offringa, Ph.D., Associate Professor, Surgery and of Biochemistry and Molecular Biology, Norris Cancer Center, Keck School of Medicine, University of Southern California

We are developing DNA methylation as a lung cancer marker. Cancer DNA is shed into the blood and can in principle be used to non-invasively detect a cancer signature in bodily fluids. We have mined our own and publicly available data to identify DNA methylation markers present with high penetrance in lung cancer tumors. Given that low-dose spiral computed tomography, the state-of-the-art and only tool currently available for lung cancer early detection, has a false positive rate of 96%, there is a great need for additional complementary biomarkers.

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-AT-A-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

EPIGENOMICS IN DISEASE

*continued***11:45 Simultaneous Glioma Grading and Drug Response Testing with DNA Methylation Profiling***Michelle M. Hanna, Ph.D., CEO & Scientific Director, RiboMed Biotechnologies, Inc.*

Unfortunately, there are significant inter-observer and intra-observer variability in the grading of Gliomas, and, many patients do not respond to the chemotherapy they receive. We have developed a sensitive, quantitative, bisulfite-free, fluorescent Glioma stratification test based on DNA methylation profiling of 6 genes using FFPE Glioma samples. The status of all 6 genes can be determined with a single FFPE sample with a tumor cross section as small as 2 μ m, providing physicians with a new tool for the diagnosis and treatment of brain cancer.

12:15 pm Session Break**12:25 Luncheon Presentation** (*Sponsorship Opportunity Available*) or **Lunch on Your Own****1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing****IMPROVING DISEASE-RELEVANT ANALYSIS OF (EPI)GENOMES****1:40 Chairperson's Remarks***Yijun Ruan, Ph.D., Professor and Director, Genome Sciences, Jackson Laboratory Genomic Medicine***1:50 New Avenues for Studying Gene Regulation in Clinical Cancer Research using DNA Methylation Sequencing***Benjamin P. Berman, Ph.D., Assistant Professor, Bioinformatics, Preventive Medicine; Member, USC Epigenome Center, University of Southern California*

By sequencing complete tumor methylomes, we have found that DNA methylation patterns can reveal a number of important gene regulatory processes, such as nucleosome organization, transcription factor binding, and 3D nuclear topological domains. We are also exploiting the unique properties of bisulfite sequencing to develop a "single molecule epistate" method to decompose complex tissue mixtures into their constituent cell types. These approaches open new avenues for studying chromatin changes and gene regulation in primary patient samples.

2:20 Interactive and Exploratory Visualization of Epigenome-Wide Data*Héctor Corrada Bravo, Ph.D., Assistant Professor, Computer Science, UM Institute for Advanced Computer Studies & Center for Bioinformatics and Computational Biology, University of Maryland*

We will introduce epigenomics data visualization tools that provide tight-knit integration with computational and statistical modeling and data analysis. Epviz permits interactive visualization within a state-of-the-art functional genomics analysis platform. The web-based design of our tools facilitates the reproducible dissemination of interactive data analyses in a user-friendly platform. We will illustrate these tools via analyses of the colon cancer epigenome, in particular, the relationship between clonal and population heterogeneity as inferred from DNA.

2:50 3D Genome Conformation and Gene Transcription Regulation in Human Diseases*Yijun Ruan, Ph.D., Professor and Director, Genome Sciences, Jackson Laboratory Genomic Medicine*

Although most of our current understandings of the human genome functions are based on linear explanations, it has been speculated that the 3D conformation and high-order organization of the genome must play important roles in shaping the mechanisms of nuclear processes such as transcription regulation and DNA replication. Recent advances in DNA sequencing has allowed the development of high-throughput technologies for mapping genome-wide chromatin interactions, and sophisticated computational programs are able to reconstitute the 3D structure of the genome.

3:20 Sponsored Presentations (*Opportunities Available*)**3:50 Refreshment Break****MECHANISMS UNDERPINNING DISEASE: DNA METHYLATION****4:00 Chairperson's Remarks***Lucy A. Godley, M.D., Ph.D., Associate Professor, Medicine, Hematology/Oncology, Cancer Research Center, The University of Chicago***4:10 Control of Cell Differentiation and Phenotype by 5-Hydroxymethylcytosine***Lucy A. Godley, M.D., Ph.D., Associate Professor, Medicine, Hematology/Oncology, Cancer Research Center, The University of Chicago*

We now appreciate that there are multiple covalently-modified cytosine species within mammalian DNA- 5-methylcytosine (5-mC), 5-hydroxymethylcytosine (5-hmC), 5-formylcytosine (5-fC), and 5-carboxylcytosine (5-caC). My laboratory is particularly focused on deciphering the functions of 5-hmC, especially during cellular differentiation and in response to the microenvironment. We find that 5-hmC levels change dramatically as the hematopoietic stem cell differentiates into erythrocytes, with gains of 5-hmC occurring near the binding sites for erythroid transcription factors in concert with activating histone marks, suggesting that 5-hmC contributes to chromatin accessibility.

4:40 DNA Methylation in Cancer and Other Human Diseases*Taijing Chen, Ph.D., Associate Professor, Department of Molecular Carcinogenesis, Division of Basic Science Research, The University of Texas MD Anderson Cancer Center*

Aberrant DNA methylation patterns are associated with human diseases, including cancer. The importance of DNA methylation is further highlighted by the identification of mutations in DNA methylation machinery, including DNMTs, TETs and MeCP2, in various human disorders. In this presentation, I will discuss recent progress in understanding the mechanisms by which DNMT mutations and aberrant DNA methylation contribute to disease phenotypes.

5:10 Heritability of Epimutations in Cancer-Prone Families*Megan Hitchins, Ph.D., Associate Professor, Department of Medicine, Division of Oncology, Stanford School of Medicine*

Epimutation, defined as an epigenetic error that results in altered gene expression within normal cells, has been identified as an alternative cause to genetic mutation for high-risk cancer syndromes. Some epimutations are associated with underlying cis-acting genetic defects and thus conform to Mendelian inheritance patterns, whilst others appear to have no genetic basis, and are either erased between generations, or demonstrate non-Mendelian vertical transmission. The role and inheritance patterns of MLH1 epimutation in Lynch syndrome will be the focus of this presentation.

5:40 Close of Conference Program**CLICK HERE TO REGISTER ONLINE!**

TriConference.com



Cambridge Healthtech Institute's Sixth Annual

GENOME AND TRANSCRIPTOME ANALYSIS

Disease-Relevant Analysis of NGS 'Omics Data

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

» KEYNOTE SESSION: ADVANCES IN GENOME AND TRANSCRIPTOME ANALYSIS

11:50 Chairperson's Opening Remarks

Todd M. Lowe, Ph.D., CSO, Maverix Biomics, Inc.

12:00 pm Shaping the Blood: Lessons from Chromatin and Single Cell RNA Dynamics

Ido Amit, Ph.D., Associate Professor, Department of Immunology; Principal Investigator, Laboratory for Immunogenomics, Weizmann Institute of Science

Using a novel high-sensitivity indexing-first chromatin immunoprecipitation approach we profiled the dynamics of four chromatin modifications across 16 stages of hematopoietic differentiation. We found that lineage commitment involves *de novo* establishment of thousands of lineage-specific enhancers. These enhancer repertoire expansions foreshadow transcriptional programs in the differentiated cells. Combining our enhancer catalog with single cell gene expression profiles, we elucidated the transcription factor network controlling chromatin dynamics and lineage specification in hematopoiesis.

12:30 The Biology of CRISPRs: From Genome Defense to Genetic Engineering

Jennifer Doudna, Ph.D., Professor, Molecular and Cell Biology, Chemistry, University of California, Berkeley; Investigator & Professor, Biochemistry, Biophysics & Structural Biology, Howard Hughes Medical Institute

The advent of facile genome engineering using the bacterial RNA-guided CRISPR-Cas9 system in animals and plants is transforming biology. I will present a brief history of CRISPR biology, providing the foundation for remarkable developments using this technology to modify, regulate or mark genomic loci in a wide variety of cells and organisms. These results highlight a new era in which genomic manipulation is no longer a bottleneck to experiments, paving the way to both fundamental discoveries in biology, with applications in all branches of biotechnology, and strategies for human therapeutics.

1:00 Session Break

1:15 Luncheon Presentation I: Developing Standard Computational Analytic Kits Matched to Sample Preparation Methods for Single Cell Analysis

Sponsored by
Maverix
BIOMICS

Todd M. Lowe, Ph.D., CSO, Maverix Biomics, Inc.

In spite of the rapid progress in RNA- and DNA-sequencing of single cells, robust standard analytics have yet to be established to meet the needs of the broadening research community. We have integrated the best methods and visualizations being used today into one, easy to use analytic kit that is accessible to any researcher. Because multiple technologies exist for sample preparation, we specifically optimize our kits to "match" these methods.

1:45 Luncheon Presentation II (Sponsorship Opportunity Available)

2:15 Session Break

RNA INNOVATIONS: SINGLE CELL ANALYSIS, GENOME AND TRANSCRIPTOME EDITING

2:30 Chairperson's Remarks

Cole Trapnell, Ph.D., Assistant Professor, Genome Sciences, University of Washington

2:40 Pseudotemporal Ordering of Single Cells Reveals Regulators of Cell Differentiation and Reprogramming

Cole Trapnell, Ph.D., Assistant Professor, Genome Sciences, University of Washington

Cell differentiation is governed by a vast and mostly unknown gene regulatory program. Each cell makes fate decisions independently by integrating a wide array of signals from other cells, executing a complex choreography of gene regulatory changes. Experiments performed on bulk populations of differentiating cells mask this variation. Single-cell genomics promises to expose this circuitry, revealing the key genes and interactions that determine cell fate. I will discuss our recent efforts to map cell fate circuits through single-cell transcriptomic analysis.

3:10 Expansion of the CRISPR-Cas9 Genome Targeting Space through the Use of H1 Promoter-Expressed Guide RNAs

Donald Jeffrey Zack, M.D., Ph.D., Guerrieri Professor, Genetic

Engineering & Molecular Ophthalmology; Professor, Molecular Biology & Genetics, Neuroscience, and the Institute of Genetic Medicine, John's Hopkins School of Medicine

3:40 Comparative Transcriptomics Analysis Reveals Regulatory and Functional Landscape of RNA Editing

Jin Billy Li, Ph.D., Assistant Professor, Genetics, Stanford University

Adenosine-to-inosine RNA editing diversifies the transcriptome and promotes functional diversity. A plethora of editing sites has been recently identified; however, how they are selected and regulated and which are functionally important are largely unknown. We find that the establishment of editing and variation in editing levels are largely explained and predicted by cis-regulatory elements. Furthermore, we are able to identify a large number of editing sites that are very likely functional.

4:10 Sponsored Presentations (Opportunities Available)

4:40 Break and Transition to Plenary Session

» 5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» 8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by
SLONEPARTNERS

NON-CODING RNA FUNCTIONAL ANALYSIS

10:05 Chairperson's Remarks

Dalia Cohen, Ph.D., Head of Research, Beryllium

GENOME AND TRANSCRIPTOME ANALYSIS

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

GENOME AND TRANSCRIPTOME ANALYSIS

*continued***10:15 About Noam Chomsky, DNA Patterns, Non-Coding RNAs and Cancer Patients***George Calin, M.D., Ph.D., Professor, Experimental Therapeutics, Division of Cancer Medicine, MD Anderson Cancer Center*

MicroRNA and other short or long non-coding RNAs alterations are involved in the initiation, progression and metastases of human cancer. Differential expression of non-coding RNAs in malignant compared with normal cells can be explained by the location of these genes in cancer-associated genomic regions, by epigenetic mechanisms and by alterations in the processing machinery. Expression profiling of human tumors has identified signatures associated with diagnosis, staging, progression, prognosis and response to treatment, as well as identification of targets of activated oncogenic pathways.

10:45 Journeys through Space and Time: Ultra High-Resolution Expression Profiling of Long Non-Coding RNAs*Marcel E. Dinger, Ph.D., Head, Clinical Genomics, Kinghorn Center for Clinical Informatics, Garvin Institute of Medical Research*

Long noncoding RNAs (lncRNAs) are increasingly recognized as having key regulatory roles in development and disease. However, these regulatory molecules often have short half lives and are expressed only in specific tissues or cell types, resulting in the poor representation of lncRNAs in transcriptomic datasets. Using novel detection and sampling approaches, we reveal a high-resolution spatiotemporal view of the long noncoding transcriptome that provides fresh insights into their roles in development and disease.

11:15 Exosomal microRNAs Orchestrate the Biology of the Tumor Microenvironment*Muller Fabbri, M.D., Ph.D., St. Baldrick's Foundation Scholar, Assistant Professor, Pediatrics and Molecular Microbiology & Immunology, Norris Comprehensive Cancer Center, University of Southern California- Keck School of Medicine; Children's Hospital Los Angeles*

MicroRNAs (miRNAs) are secreted by cells within microvesicles called exosomes. Cancer cells are selective in defining the miRNA cargo within their exosomes. The function of exosomal miRNAs within the Tumor Microenvironment is currently not completely understood. We discovered that in addition to their "traditional" gene expression regulatory mechanism of action, exosomal miRNAs can also function as ligands of miRNA receptors in surrounding cells, leading to a pro-tumoral response. These findings identify a new mechanism of action of miRNAs and lead to the identification of new targets.

11:45 Sponsored Presentations (*Opportunities Available*)**12:15 pm Session Break****12:25 Luncheon Presentations** (*Sponsorship Opportunities Available*) or **Lunch on Your Own****1:25 Refreshment Break in the Exhibit Hall with Poster Viewing****LARGE-SCALE RNA-SEQ DATA: INTEGRATION, ANALYSIS, AND DISCOVERY****2:00 Chairperson's Remarks***Marcel E. Dinger, Ph.D., Head, Clinical Genomics, Kinghorn Center for Clinical Informatics, Garvin Institute of Medical Research***2:10 Large-Scale, Cross-Site Sequencing Using Eight NGS Platforms***Christopher E. Mason, Ph.D., Assistant Professor, Computational Biomedicine, Weill Cornell Medical College*

Here we will describe the results of the FDA's SEQC (Sequencing Quality Control) study and the ABRF's NGS study on RNA-seq, where we have examined standardized samples across Illumina's HiSeq and MiSeq, Life Technologies SOLiD, PGM, and Proton, PacBio's RSII, 454, and some newer data from Oxford Nanopore's MinION system. We show that relative gene quantification is robust across platforms, but that splicing analysis clearly benefits from longer reads. We also present methods for cross-site normalization and quantification. These results suggest that clinical grade RNA-seq is ready for expanded use

2:40 Integrating Transcriptome and Genome Sequencing to Understand Functional Variation in Human Genomes*Tuuli Lappalainen, Ph.D., Principal Investigator & Core Member, New York Genome Center; Assistant Professor, Systems Biology, Columbia University*

Detailed characterization of cellular effects of genetic variants is essential for understanding biological processes that underlie genetic associations to disease. Integration of genome and transcriptome data has allowed us to characterize regulatory and loss-of-function genetic variants as well as imprinting both at the population and individual level, as well as their tissue-specificity and role in disease associations.

3:10 Exploring exRNAs Using Web-Based RNA-Seq Pipelines and Public Data Resources: exRNA Communication Consortium (ERCC)*Matthew E. Roth, Ph.D., Assistant Professor & Co-Director, Bioinformatics Research Lab, Baylor College of Medicine*

The extracellular RNA Communication Consortium (ERCC) consortium brings together a wide variety of experts to better understand the basic biology of exRNAs and their potential applications in the clinic. Large-scale RNA-Seq analyses of human exRNAs in the ERCC is a key focus and requires the development of novel analytical pipelines, custom public data sources, and their integration. How these resources are developed and applied to exRNA analyses, and their utility to the broader scientific community will be presented.

3:40 West Nile Virus Case Study — Example of Infectious Disease Research Using Ingenuity Pathway Analysis (IPA) and CLC Cancer Research WorkBench, the Qiagen Bioinformatics Solution*Jean-Noel Billaud, Principal Scientist, QIAGEN Bioinformatics*

Sponsored by

**4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing****5:00 Breakout Discussions in the Exhibit Hall** (*see website for details*)**6:00 Close of Day****WEDNESDAY, FEBRUARY 18****7:00 am Breakfast Presentation** (*Sponsorship Opportunity Available*) or **Morning Coffee****8:00 PLENARY SESSION PANEL** (*see page 5 for details*)**9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall****LARGE-SCALE GENOMIC DATA TRANSFER, ANALYSIS AND STORAGE****10:35 Chairperson's Remarks***Francisco M. De La Vega, D.Sc., Visiting Instructor, Department of Genetics, Stanford University School of Medicine***10:45 FEATURED PRESENTATION: Stable Reference Structures for Human Genome Analysis***David Haussler, Ph.D., Distinguished Professor and Scientific Director, UC Santa Cruz Genomics Institute, University of California Santa Cruz*

Currently there are many different ways to map individual patient DNA and call genetic variants relative to the human reference genome GRCh38. When an expanded version GRCh39 arrives, quite a bit of remapping and recalling turmoil will be created. I describe a new scheme being developed with assistance from the Global Alliance for Genomics and Health in which mapping to the reference genome and calling variants would become a precisely defined and relatively stable process, with a well-defined incremental update when the reference genome expands to a more comprehensive version.

11:15 Supporting a Biomedical Commons with the**GENOME AND TRANSCRIPTOME ANALYSIS**

CONTINUED ON NEXT PAGE

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

GENOME AND TRANSCRIPTOME ANALYSIS

*continued***Bionimbus Protected Data Cloud**

Robert Grossman, Ph.D., Chief Research Informatics Officer (CRIO); Director, Center in Data Intensive Science; Professor, Biological Sciences, University of Chicago; Core Faculty and Senior Fellow, Institute for Genomics and Systems Biology (IGSB) and the Computation Institute

11:45 Collaborating and Data Sharing When the Author List Goes Beyond 250 with an Eye to Re-Usability and Reproducibility

Larsson Omberg, Ph.D., Principal Scientist and Head of Data Science, Sage Bionetworks

Life science research projects are getting larger and more integrated across institutional boundaries requiring new paradigms for collaboration and sharing. This has become especially evident when speaking of results and data stemming from genomic technologies where data is often in flux as new samples are processed and existing samples fail quality control. I will discuss methodologies and tools that we have developed in conjunction with several large research communities to evolve active research projects into reusable resources for the broader community.

12:15 pm Session Break**12:25 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own****1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing****LARGE-SCALE GENOMIC DATA TRANSFER, ANALYSIS AND STORAGE (CONT.)****1:40 Chairperson's Remarks**

Francisco M. De La Vega, D.Sc., Visiting Instructor, Department of Genetics, Stanford University School of Medicine

1:50 Cloud Genomics at Scale: The Future of Drug Discovery and Development

Jeffrey Reid, Ph.D., Director & Head, Genome Informatics, Regeneron Pharmaceuticals

The Regeneron Genetics Center (RGC) has partnered with the Geisinger Health System to produce 100,000 exome sequences on patient volunteers over the next five years. Bringing together health-record information and exome sequence data at this scale will provide new insights into biology and genetics. The RGC's total commitment to cloud computing has been essential in bringing such an ambitious sequence production and analysis project to life in less than a year, and plays a pivotal role in data sharing with

research partners.

2:20 Accessible and Reproducible Large-Scale Analysis with Galaxy

James Taylor, Ph.D., Ralph S. O'Connor Associate Professor, Biology; Associate Professor, Computer Science, Johns Hopkins University

I will discuss the Galaxy framework for accessible genomic data analysis. I will particularly highlight new features of Galaxy which are enabling analysis at increasingly larger scales, including UI and backend improvements, as well as other recent improvements to Galaxy.

2:50 Genome Data Aggregation and Exchange across Distributed Genomic Data Repositories

Francisco M. De La Vega, D.Sc., Visiting Instructor, Department of Genetics, Stanford University School of Medicine

As sequencing technologies continue to evolve and the cost of genome sequencing drops, several large-scale population sequencing projects with sizes ranging from tens to hundreds of thousand samples are now being started. In a world where genomic data is distributed across many repositories around the world together with each patient's phenotype/clinical information, it will become impossible to amass the data in a single location/cloud for analysis. Instead, sharing of genomic data across networks for research and clinical applications will be necessary. We will discuss new paradigms to orchestrate global data sharing while maintaining secure access and privacy for patients.

3:20 Sponsored Presentations (Opportunities Available)**3:50 Refreshment Break****ADVANCES IN COMPUTATIONAL CANCER GENOMICS****4:00 Chairperson's Remarks**

Andreas Scherer, Ph.D., President and CEO, Golden Helix

4:10 Bioinformatics of Cancer Gene Panels: Challenges to Creating Effective Testing Workflows

Andreas Scherer, Ph.D., President and CEO, Golden Helix

In the transition of NGS to a clinical setting, the cancer gene panel is leading with a clear value proposition of clinically actionable results in a simple package. Except it's not so

simple. In this presentation I will cover the bioinformatics tools and best practices to achieve the goal of a reproducible workflow for analyzing NGS gene panel data. From amplicon and sample QC, to annotation sources and filtering thresholds, to summary of therapeutic targets and gene level reports, I will cover the methods and edge cases that go into setting up a gene panel test.

4:40 Maximizing the Utility of TCGA Genomic Data: Tools, Analysis and Discovery

Han Liang, Ph.D., Assistant Professor, Department of Bioinformatics and Computational Biology, Division of Quantitative Sciences, The University of Texas, MD Anderson Cancer Center

A central question for the cancer research community is how to use these genomic and proteomic data. I will first introduce two useful bioinformatics tools we recently developed for effectively analyzing and visualizing TCGA data: SurvNet and TCPA. Then I will present a systematic evaluation of the power of diverse TCGA molecular data with or without clinical variables in predicting patient survival and discuss the potential utility of cross-tumor analysis. Finally, I will focus on the biomedical significance and clinical relevance of expressed pseudogenes in human cancer.

5:10 Characterization of Cancer Genomes

Sohrab Shah, Ph.D., Assistant Professor, Pathology and Computer Science, University of British Columbia; Scientist, BC Cancer Agency

5:40 Close of Conference Program

Sponsored by



CLICK HERE TO REGISTER ONLINE!

TriConference.com

TRICON PERKS

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



Cambridge Healthtech Institute's Inaugural

GENOMIC TECHNOLOGIES FOR PATIENT STRATIFICATION

Unlocking New Markers to Ensure Successful Treatment

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

NGS-DRIVEN STRATIFIED CANCER TRIALS

11:50 Chairperson's Opening Remarks

Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

12:00 pm LungMAP/S1400: A Unique Public-Private Master Protocol for Drug-Biomarker Registration

David Gandara, M.D., Professor of Medicine, Division of Hematology/Oncology, University of California, Davis School of Medicine; Director, Thoracic Oncology Program, Senior Advisor to the Director, UC Davis Comprehensive Cancer Center; Chair, Lung Committee, Southwest Oncology Group (SWOG)

Despite rapid advances in deciphering the complex genomics of non-small cell lung cancer (NSCLC), clinical translation into approvable biomarker-drug combinations has been problematic, due in part to the relative rarity of genomically-defined subsets. Lung-MAP (S1400) is a one-of-a-kind public-private partnership designed to speed up development of targeted therapies for NSCLC of squamous cell histology (SCCA). Here we describe development of this registration-compliant biomarker-driven Phase II/III multi-arm "master" protocol, employing next generation sequencing to identify actionable molecular abnormalities, followed by patient randomization to biomarker-driven targeted therapy versus standard of care.

12:30 The Evolving Genotype-to-Phenotype Paradigm in Oncology Drug Development

Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

The clinical application of multiplexed molecular profiling technologies offers unprecedented opportunities to enhance the drug development process by directing treatment to patients who are more likely to benefit. However, molecular profiling technologies are in the early stages of clinical application as companion diagnostic tests. Future success will require close integration between not only biology and technology, but also between clinical and diagnostic development strategies.

1:00 Session Break

1:15 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own

2:15 Session Break

2:30 Chairperson's Remarks

Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

2:40 Clinical Trials for Predictive Biomarker Discovery and Validation in Oncology Drug Development

Eric Peters, Ph.D., Companion Diagnostics Leader, Oncology Biomarker Development, Genentech

3:10 Universal Testing for Actionable Genomic Variants in Cancer: a Paradigm Shift in Precision Oncology

Karen Gutekunst, Vice President, Diagnostic Development, Illumina, Inc.

Rapid technological progress allowing for broad interrogation of genomic variation in cancer, and a parallel expansion in knowledge regarding the actionability of an ever-growing number of germline and somatic variants, are revolutionizing the management of the disease. A paradigm shift is currently under way from drug-centered to patient-centered precision oncology, enabled by the advent of high-throughput, widely accessible NGS-based "universal" cancer genomic testing and featuring the emergence of "companion therapeutics".

3:40 PANEL DISCUSSION: Challenges in Developing Oncology Therapy with the Complexity of Cancer Heterogeneity

Panel Moderator: Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

Panelists: David Gandara, M.D., Professor of Medicine, Division of Hematology/Oncology, University of California, Davis School of Medicine; Director, Thoracic Oncology Program, Senior Advisor to the Director, UC Davis Comprehensive Cancer Center; Chair, Lung Committee, Southwest Oncology Group (SWOG)

Eric Peters, Ph.D., Companion Diagnostics Leader, Oncology Biomarker Development, Genentech

Karen Gutekunst, Vice President, Diagnostic Development, Illumina, Inc.

4:10 Evolving Clones and Detection Technology: Role in Cancer Management

Alison Todd, Ph.D., CSO and General Manager, SpeedX Pty Ltd.

The growing need to understand tumor heterogeneity and clonal evolution, and their potential significance for tailoring and monitoring therapy, reinforces the necessity for highly sensitive, rapid and accurate analytical tools. This presentation will outline novel approaches useful for clinical implementation.

Sponsored by
SpeedX

4:25 Sponsored Presentation (Opportunity Available)

4:40 Break and Transition to Plenary Session

» 5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» 8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by
SLONEPARTNERS

RNA SEQ FOR PATIENT STRATIFICATION

10:05 Chairperson's Remarks

Michael C. Little, Ph.D., Senior Advisor, Popper & Co

10:15 Genetic Profiling of Hematologic Malignancies

Ross L. Levine, M.D., Associate Member, HOPP; Associate

GENOMIC TECHNOLOGIES
FOR PATIENT STRATIFICATION

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

GENOMIC TECHNOLOGIES FOR PATIENT STRATIFICATION

*continued**Attending, Leukemia Service; Memorial Sloan-Kettering Cancer Center*

Clinical, cytogenetic, and gene-based studies have been used to inform biology and improve prognostication for acute myeloid leukemia (AML) patients. We and others have shown somatic mutations can be used to improve risk stratification in AML. We have more recently worked to develop assays for genomic profiling of leukemia, lymphoma and myeloma patients and demonstrated how these assays can be used to inform clinical care.

10:45 Sequencing Approaches for Personalized Cancer Therapy Selection and Monitoring*Daniela Starcevic, Ph.D., Director, Diagnostic Sequencing; Assistant Professor, Genomics and Multiscale Biology; Assistant Professor, Pathology; Icahn School of Medicine at Mount Sinai*

The Personalized Cancer Therapy program is aimed at developing molecular diagnostics for better disease management: therapy selection and monitoring. Patients' samples undergo state of the art sequencing and bioinformatics towards molecular level understanding of disease and a comprehensive/integrated approach for finding alternate, innovative and more effective treatment options. The opportunities and challenges of sequencing and analyzing tumor samples will be addressed and illustrated with examples.

11:15 Precision Oncology through Genomic Testing Strategies and Clinical Trials*Sameek Roychowdhury, M.D., Ph.D., Assistant Professor, Internal Medicine, Ohio State University Comprehensive Cancer Center*

Dr. Roychowdhury will present on evolving use of genomic testing strategies for clinical decision making and eligibility, followed by challenges and approaches for application in clinical trials.

11:45 Accelerating the Velocity of Therapeutic Approval and Adoption*Kathryn Becker, Ph.D., Director, Global Marketing, CDx, Abbott Molecular*

Abbott employs a variety of partnership models that support pre-clinical biomarker studies, complete development, indication expansion, and commercialization of CDx products. One core competency employed in all partnerships is the ability to simplify complex technologies, like multiplex molecular analysis, to enable adoption within the local clinical communities and support reproducible, reliable results on a global scale.

12:15 pm Session Break**12:25 Luncheon Presentation I: Innovative Targeted RNA-Seq Method for Identifying Known and Novel Gene Fusion Events in Tumor Cells**

Jonathan Scolnick, Ph.D., Scientist, Research, NuGEN Technologies
The novel Single Primer Enrichment Technology (SPET) and how it differs from existing target enrichment methods will be described. Sensitive variant detection from genomic DNA

derived from fresh and FFPE tissues using 344 cancer-related genes will be demonstrated as well as utilization of SPET as a rapid, cost-effective screening tool for discovery of novel fusions and detection of known fusions with a panel of 500 cancer genes implicated in fusions events.

12:55 Luncheon Presentation II (Opportunity Available)**1:25 Refreshment Break in the Exhibit Hall with Poster Viewing**

PCR FOR PATIENT STRATIFICATION

2:00 Chairperson's Remarks*Andrew Brooks, Ph.D., COO, RUCDR Infinite Biologics, Rutgers University***2:10 Digital PCR for Patient Monitoring and Stratification in Clinical Trials***Reinhold Pollner, Ph.D., Director, Clinical Trial Assay Development, Genoptix Medical Laboratory, a Novartis Company*

My presentation will focus on how digital PCR is used in the validation of clinical trial assays with respect to patient monitoring and stratification in a CLIA/CAP laboratory setting. A variety of different applications of digital PCR will be discussed ranging from the determination of DNA copy numbers in FFPE samples, absolute quantitation of a transgene in whole blood and bone marrow samples, identification of a fusion gene at the mRNA level in FFPE specimens, and rare allele detection using circulating tumor DNA.

2:40 Evaluation of EGFR Mutations in Plasma from NSCLC Patients: Utility in Managing Patients on TKI Therapy*Chris Karlovich, Ph.D., Principal Scientist, Molecular Diagnostics, Clovis Oncology*

We are utilizing blood-based molecular testing in patients who have become resistant to first generation tyrosine kinase inhibitors with the goal of enabling subsequent therapy without need for repeat lung biopsy. The utility of plasma-based EGFR mutational analysis will be described in the context of CO-1686, a novel third-generation TKI that selectively inhibits the EGFR activating and T790M resistance mutations in NSCLC patients.

3:10 NGS-Assisted DNA-Based Digital PCR for the Detection and Quantification of Residual Disease in CML Patients with Undetectable BCR-ABL1 Transcripts*Mary Alikian, MSc, Clinical Scientist, Imperial Molecular Pathology, Imperial College*

The presentation will describe a DNA-based method of detecting and quantifying low levels of BCR-ABL1 positive disease that improves on previous methodologies in two key areas: Identifying the patient-specific genomic BCR-ABL1 fusion junctions using targeted next generation sequencing allowing the rapid generation of high-performing DNA based

qPCR assays. The second area is: Use of a DNA-based approach by optimizing the technique for use on a digital PCR (dPCR) platform, which provides absolute molecular quantification without the need for standard curve.

3:40 Precision Molecular Profiling of Cancer using ddPCR*Sponsored by***BIO-RAD***Jennifer Berman, Ph.D., Staff Scientist, Digital Biology Center, Bio-Rad Laboratories*

Cutting-edge, personalized cancer care requires ultra-sensitive detection and monitoring of actionable mutations from limited patient samples. The high sensitivity and precision of droplet digital PCR (ddPCR) offers critical advantages when clinical samples are limiting, degraded, and contain PCR inhibitors. We highlight use of ddPCR for quantification of KRAS mutations in FFPE and plasma cfDNA, as well as detection of copy number alterations of oncogenes like MYC, HER2, and EGFR

3:55 Sponsored Presentation (Opportunity Available)**4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing****5:00 Breakout Discussions in the Exhibit Hall (see website for details)****6:00 Close of Day****WEDNESDAY, FEBRUARY 18****7:00 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee****8:00 PLENARY SESSION PANEL (see page 5 for details)****9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall****PATIENT RECRUITMENT USING BIOMARKER ANALYSIS TOOLS****10:35 Chairperson's Remarks***Jaya Goyal, Ph.D., Director, Value Based Medicine, Biogen Idec***10:45 Demonstration of the Utility of Point-of-Care Genotyping Technologies to Actively Recruit into Genotype Stratified Studies***Charles Cox, Ph.D., Head, Genetics Experiment Design and Delivery, GlaxoSmithKline*

GENOMIC TECHNOLOGIES FOR PATIENT STRATIFICATION

CONTINUED ON NEXT PAGE

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

GENOMIC TECHNOLOGIES FOR PATIENT STRATIFICATION

continued

We describe the design of an innovative experimental medicine study to assess the impact of a variant in the OPRM1 gene on a novel mu opioid receptor antagonist, with recruitment stratified by genotype. This study highlights the challenges of recruitment of individuals from Biobanks, and how we were able to rapidly design and test point of care genotype assays from 3 manufacturers and use them to successfully recruit into this study.

11:15 Survival Improvement by Personalized Genomic Diagnostics for Ovarian Cancer Chemotherapy

Jae Lee, Ph.D., Chair and Senior Member, Biostatistics and Bioinformatics, Moffitt Cancer Center

We have developed co-expression extrapolation (COXEN) biomarker models for simultaneously predicting patient response to three standard chemotherapy drugs used to treat advanced EOC: paclitaxel, cyclophosphamide, and topotecan. Our study has retrospectively, yet independently, showed a potential for genomic biomarker-based personalized chemotherapy selection to significantly improve survival of patients in the heterogeneous EOC population when using standard chemotherapies.

11:45 Presentation to be Announced

12:15 pm Session Break

12:25 Luncheon Presentation (*Sponsorship Opportunity Available*) or **Lunch on Your Own**

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

LOOKING BEYOND THE DIRECT MOLECULAR TARGETS OF DRUGS

1:40 Chairperson's Remarks

Ken Chang, Ph.D., Senior Principal Scientist, Molecular Biomarkers and Diagnostics, Merck Clinical Labs

1:50 Molecular and Clinical Predictors of Disease Status, Trajectory and Treatment Response Enabling Patient Stratification

Jaya Goyal, Ph.D., Director, Value Based Medicine, Biogen Idec

Identification of subgroups of patients with shared disease characteristics by using a combination of molecular, clinical, biochemical and imaging testing to select the optimal therapy for individual patient will result in optimal treatment outcome. Approaches for the post-hoc analysis of clinical trial data and samples to identify baseline clinical, radiographic and molecular variables associated with disease status, disease trajectory and outcome will be presented.

2:20 Contextualization of Individualized Patient Molecular Profiles Enabling Patient Stratification and Association with Distinct Clinical Characteristics

Ahmed Enayetallah, M.D., Ph.D., Senior Scientist, Value Based Medicine, Biogen Idec

Post-hoc analysis of molecular data collected from two large phase III clinical trial data to identify and characterize disease heterogeneity with the goal of uncovering patient subpopulations that are defined by their active molecular signals. Individualized patient molecular profiling and contextualization of observed molecular changes enabled molecularly-defined patient stratification and revealed subpopulations associated with distinct clinical characteristics. The analysis also characterized the molecular mechanisms potentially driving the clinical characteristics.

2:50 Orion Bionetworks, a Novel Cooperative Partnership for Systems Modeling and Biomarker Discovery for Brain Diseases

Magali Haas, M.D., Ph.D., Founder and CEO, Orion Bionetworks

This talk will describe a new Cooperative Alliance founded to accelerate time to cure for brain disorders by harnessing the power of big data and predictive analytics to build systems models of brain diseases, starting with multiple sclerosis and prodromal schizophrenia. Specifically, we will describe the development of prognostic diagnostic tools for multiple sclerosis and other neurodegenerative disorders through the application of high performance computing and predictive analytics on phenotypic, biosensor, clinical and biomarker data.

3:20 Genomic Predictors for Recurrence Patterns of Hepatocellular Carcinoma: Model Derivation and Validation

Ju-Seog Lee, Ph.D., Associate Professor, Systems Biology, Division of Cancer Medicine, UT MD Anderson Cancer Center

3:50 Refreshment Break

UNLOCKING NEW MARKERS FOR STRATIFICATION

4:00 Chairperson's Remarks

Jae Lee, Ph.D., Chair and Senior Member, Biostatistics and Bioinformatics, Moffitt Cancer Center

4:10 Identifying and Overcoming Markers of Chemoresistance

Jason Baum, Ph.D., Associate Director, Companion Diagnostics, Research, Merrimack Pharmaceuticals

This talk will focus on the understanding of cancer cell survival networks to identify key biomarkers of resistance to chemotherapy. This includes initial proof-of-concept in a pre-clinical setting and translation into the clinic through the development of both tissue and blood-based diagnostic assays. Data from phase II clinical studies will illustrate the resistance of biomarker positive patients to chemotherapies across multiple indications, and the potential for targeted therapies to overcome this resistance.

4:40 The Impact of Tumor Heterogeneity on Clinical Biomarker Development using FFPE Tissue

Ken Chang, Ph.D., Senior Principal Scientist, Molecular Biomarkers and Diagnostics, Merck Clinical Labs

We have developed a "Concordance Calculator" to quantify reproducibility of multi-variant calls among Next Generation Sequencing replicates. This novel approach also allowed us to eliminate many different technical artifacts including Post Tissue Collection Modifications such as deamination and oxidation artifacts. Our most recent studies suggest that DNA mutation signatures as novel biomarkers for cancer diagnosis and prognosis are likely to be less sensitive to the impact of tumor heterogeneity than RNA-based expression signatures.

5:10 Prognostic Surrogate Markers for Survival, A Case Series for a Novel Antiangiogenic Therapy

M.A. Nezami, M.D., President, Cancer Epigenetics, Pacific Medical Center of Hope

Establishing the prognosis in majority of patients, especially with heterogeneous tumors, has been extremely challenging. One area of most recent attention in identifying surrogate markers for survival has been the vasculogenesis and its related serum markers. Here we present a series of cases treated with a novel antiangiogenic therapy and monitored through these markers to identify response that translated to prognosis and survival.

5:40 Close of Conference Program

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



CLINICAL CHANNEL

As the biopharma industry faces the challenge of increasing costs and high probability of clinical failures, more emphasis is placed on strategies to de-risk and innovate drug development. The wide availability of genomic technologies acts as the prime driver of innovation in the clinical development field. The Clinical Channel will explore strategies, tools and technologies to improve translation and clinical development.

- Epigenomics in Disease
- Genomic Technologies for Patient Stratification- **NEW**
- Translational to Clinical R&D
- Clinical Sequencing
- Technology-Driven Oncology Clinical Development - **NEW**



TRANSLATIONAL TO CLINICAL R&D

Strategies and Technologies to Reduce Attrition and Improve Clinical Outcomes

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

IMPROVING TRANSLATION & SUCCESS OF ADCs IN THE CLINIC

11:50 Chairperson's Opening Remarks

Lynn Zieske, Ph.D., Principal Scientist, Life Science, Singulex Inc.

12:00 pm FEATURED PRESENTATION: Development of ADCs at Seattle Genetics

Nancy Whiting, PharmD, BCOP, Executive Director and Head, Medical Affairs, Seattle Genetics

In this presentation I will highlight the strategy for testing ADCETRIS in earlier lines of therapy & new indications for lymphoma. I will also discuss recent preclinical discoveries that may potentially increase ADC stability and potency in the future.

12:30 Target, Drug and Linker Selection Strategies for Antibody-Drug Conjugates

Puja Sapra, Ph.D., Senior Director, BioConjugates Discovery & Development, Oncology Research Unit East, Pfizer Worldwide Research and Development

1:00 Session Break

1:15 Luncheon Presentations (*Sponsorship Opportunities Available*) or **Lunch on Your Own**

2:15 Session Break

IMPROVING TRANSLATION & SUCCESS OF ADCs IN THE CLINIC (CONT.)

2:30 Chairperson's Remarks

Puja Sapra, Ph.D., Senior Director, BioConjugates Discovery & Development, Oncology Research Unit East, Pfizer Worldwide Research and Development

2:40 Emerging Strategies to Improve Success with ADCs in Oncology

Robert Lutz, Ph.D., Vice President, Translational Research and Development, ImmunoGen

Our growing clinical experience with antibody-maytansinoid conjugates is leading to an enhanced understanding regarding critical attributes for their success. This presentation will highlight some recent efforts to incorporate this translational knowledge into the future development of these compounds.

3:10 Improved Efficacy of Antibody-Drug Conjugates via Site-Specific Incorporation of Linkable Amino Acids

Alan Wahl, Ph.D., Vice President, Research and Discovery, Ambrx, Inc.

The recent approvals of CD30 (Adcetris) and Her2 (Kadcyla) antibody-drug conjugates signal significant milestones in targeted drug technology. The efficacy of ADCs has dramatically improved over the past three decades with better understanding of antibody engineering, linker technology and appropriately potent warheads, yet what appears as significant therapeutic window in rodent models remains nominal in man. This presentation will describe production cell lines engineered to incorporate reactive, non-natural amino acids into selected sites in the antibody structure.

3:40 Translational Safety of Immunostimulatory and ADC Cancer Biologics

Rakesh Dixit, Ph.D., DABT, Vice President, R&D; Global Head Biologics Safety Assessment, Pathology and LAR, MedImmune (AstraZeneca Biologics)

With technological advances in generation of immunostimulatory and chemically armed biologics, the translational safety and toxicology predictions face unprecedented challenges. There is now renewed focus on a better understanding of translational immune-pharmacology associated toxicities (both on-target and off-target).

Translational case studies with major considerations such as target distribution, target pharmacology, and systemic pharmacokinetics, early screening, both traditional and non-traditional (e.g., transgenic models), and *in vitro* safety assessments will be addressed.

4:10 The Search for Mutant HTT Protein in Huntington's Disease Patient CSF using the Erenna Immunoassay System

Sponsored by Singulex

Douglas Macdonald, Ph.D., Director, Drug Discovery and Development, CHDI Foundation / CHDI Management

Huntington protein (HTT) suppression is a key therapeutic strategy for Huntington's disease (HD). We have developed a sensitive and selective assay that measures polyglutamine-expanded HTT protein using the Singulex Single Molecule Counting technology that displays increased sensitivity over other assays.

4:25 Sponsored Presentation (*Opportunity Available*)

4:40 Break and Transition to Plenary Session

» **5:00 PLENARY SESSION** (see page 5 for details)

details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» **8:00 PLENARY SESSION** (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing *Sponsored by SLONEPARTNERS*

CONSIDERATIONS FOR DEVELOPMENT OF IMMUNOTHERAPIES AND COMBINATIONS

10:05 Chairperson's Remarks

James F. Smothers, Ph.D., Senior Director & Head, Discovery, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

10:15 Biomarkers in Cancer Immunotherapy

Ira Mellman, M.D., Vice President, Cancer Immunology, Genentech

Recent advances in cancer immunotherapy differ from other developments in oncology therapeutics in several respects. Not only have immunotherapies proved remarkably promising, but also the underlying science promises to be largely driven by findings in the clinic. Thus, both patient selection and the discovery of new therapeutic opportunities will be dependent on the ability to identify, collect, and understand biomarkers and immunobiology of patient response and lack of response.

TRANSLATIONAL TO CLINICAL R&D

CONTINUED ON NEXT PAGE



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

TRANSLATIONAL TO CLINICAL R&D

*continued***10:45 Strategies for Clinical Development of Cancer Immunotherapy***Roy Baynes, M.D., Senior Vice President, Global Clinical Development, Merck*

It has been established that autoimmunity against a number of malignancies can be revealed by pharmacologic modulation of checkpoint inhibitors and co-stimulatory molecules. A strategic imperative is comprehensive definition of the efficacy and safety of monotherapy across tumor types. This has required understanding the limitations of standard response evaluations and the need to identify and appropriately manage immune mediated adverse events. Patient selection and study enrichment approaches are emerging. Informative biology will be required to evaluate the array of potential therapeutic combinations.

11:15 Translational Approaches for the Development of Intratumoral Immunotherapies*Robert Pierce, M.D., CMO, OncoSec Medical, Inc.*

Intratumoral therapies are capable of reversing local immunosuppressive mechanisms and driving systemic anti-tumor immune responses. Given the safety and potential systemic efficacy of this approach, intratumoral therapies will likely play a growing role in future combination immunotherapy regimens. The pros and cons of current syngeneic mouse models will be addressed with particular emphasis on unique aspects of intratumoral therapies.

11:45 Preclinical Validation of Immunotherapies and Combination Strategies for Cancer*James F. Smothers, Ph.D., Senior Director, Head, Discovery, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline*

Recent clinical strategies to modulate T cell checkpoint pathways have demonstrated significant patient benefit in melanoma, renal cell carcinoma and non-small cell lung cancer indications. Clinical successes with immuno-oncology medicines greatly depend upon animal disease model studies and other pre-clinical rationale for their development. Translational data coupled with pre-clinical results can further bridge understanding of what patient populations might gain the most benefit from an immuno-oncology experimental medicine alone or in combination with another agent(s).

12:15 pm Session Break**12:25 Luncheon Presentation: GE Miniature Swine Preclinical Oncology Models***John Swart, Ph.D., President and CEO, Exemplar Genetics*

Current model systems of cancer have been informative but present challenges to translating therapies to the clinic. We have developed genetically modified miniature swine models

of cancer expressing mutations in the TP53, KRAS, and ATM genes. TP53 mutant pigs have been demonstrated to develop lymphomas and osteogenic tumors. The KRAS mutation is conditional and can be activated in a tissue specific manner. These pigs provide a novel large animal tumor model that replicates the human condition.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing**T-CELL IMMUNOTHERAPY SPOTLIGHT****2:00 Chairperson's Remarks***Richard A. Morgan, Ph.D., Vice President, Immunotherapy, Bluebird Bio***2:10 CART Cell Therapy: Target Antigen Discovery and Clinical Translation***Richard A. Morgan, Ph.D., Vice President, Immunotherapy, Bluebird Bio*

This talk will emphasize the importance of tumor antigen discovery in the selection of targets in CART cell therapy. As examples, I will compare and contrast Her2/neu and EGFRvIII as solid tumor targets. I will also discuss the clinical translation of these two CAR-based therapies and discuss options for building the next generation of CART cell technologies.

2:40 The Emerging Role of Autologous Tumor-Infiltrating Lymphocytes (TIL) as a Superior Immunotherapy Option for Patients with Solid Tumors*Laszlo Radvanyi, Ph.D., CSO, Lion Biotechnologies*

Although a number of T-cell based therapies are being developed for solid tumors, autologous TIL therapy has the longest clinical experience and is still the one of the most powerful immunotherapy options for patients with advanced solid tumors. This presentation will describe TIL therapy for solid tumors, its advantages compared to other current cell therapy options, its strategic role as part of a growing immunotherapy "toolbox" for personalized care of metastatic cancer, and the development of predictive biomarkers to identify resistance mechanisms as novel targets for combination therapies

3:10 Translational Strategies for Bispecific T Cell Engager (BiTE) Antibodies*Stanley R. Frankel, M.D., Medical Sciences Executive Medical Director, Oncology Early Development, Therapeutic Area Head, Amgen***3:40 Sponsored Presentations (Opportunities Available)****4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing****5:00 Breakout Discussions in the Exhibit Hall (see website for details)****6:00 Close of Day****WEDNESDAY, FEBRUARY 18****7:00 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee****8:00 PLENARY SESSION PANEL (see page 5 for details)****9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall****ADVANCES IN IMAGING FOR TRANSLATABLE BIOMARKERS****10:35 Chairperson's Remarks***Paul J. McCracken, Ph.D., Director, Imaging Biomarkers and Personalized Medicine, Eisai***10:45 Imaging for Decision Making in Drug Discovery and Early Development***Paul McCracken, Ph.D., Director of Imaging, Biomarkers and Personalized Medicine CFU, Eisai*

In this presentation, I will discuss improving the quality of compounds and decision making in discovery and early development with fit-for-purpose imaging biomarkers. I will provide case studies in neurology and oncology for application of imaging biomarkers to the discovery pipeline, including molecular target engagement, antibody-drug conjugate imaging, proof of mechanism, efficacy, stratification and drug safety.

11:15 Using Zr-89 ImmunoPET in the Selection, Understanding, and Early Clinical Development of Antibody-Drug Conjugates*Simon Williams, Ph.D., Principal Scientist, Biomedical Imaging, Genentech*

This presentation will review the development of Zr-89 immunoPET as a technology that is particularly well-suited to demonstrating, in patients, the combination of target presence, tissue penetration and internalization which are

CLICK HERE TO REGISTER ONLINE!

TriConference.com



TRANSLATIONAL TO CLINICAL R&D

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

TRANSLATIONAL TO CLINICAL R&D

continued

three requirements for effective antibody-drug conjugates. The use of immunoPET in quantifying drug delivery to tumor tissue will be discussed along with limitations of immunoPET and a discussion of complementary experiments.

11:45 Advances in Preclinical Imaging to Enable the Translation of Novel Therapies

Charles Glaus, Ph.D., Senior Scientist, Research Imaging Sciences, Amgen

12:15 pm Session Break

12:25 Luncheon Presentation (*Sponsorship Opportunity Available*) or **Lunch on Your Own**

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

PREDICTIVE PRECLINICAL MODELS

1:40 Chairperson's Remarks

Jennifer Brogdon, Ph.D., Senior Investigator, Oncology Cell and Immunotherapies, Novartis Institutes for BioMedical Research, Inc.

1:50 CART Therapy: Preclinical Approaches to Assess Specificity and Efficacy

Jennifer Brogdon, Ph.D., Senior Investigator, Oncology Cell and Immunotherapies, Novartis Institutes for BioMedical Research, Inc.
Due to the unique sensitivity of CAR therapy to low levels of antigen, understanding the specificity of a given CAR is critical to managing the safety and potential toxicity risk in patients. In this presentation, I will discuss our efforts to understand the safety and specificity of an EGFRvIII-specific CAR therapy that is being developed for Glioblastoma Multiforme. Highlights will include our *in vitro* and *in vivo* preclinical assessment of our humanized EGFRvIII CAR as well as the study design of the Phase I trial.

2:20T Cell Biology in a 3D Cell Culture System

David Colter, Ph.D., Principal Scientist, Biologics Research, Janssen
We have developed a high-throughput, 3D lung tumor model system for target discovery and drug screening applications. Specifically, we characterized the phenotypic, functional and drug response differences between lung tumor cells grown as 2D monolayer cultures, versus cells grown as 3D spheroids. We are currently extending the utility of this 3D model system towards evaluating antibody-mediated T cell recruitment and subsequent T cell-mediated cytotoxicity.

2:50 Mechanisms of Resistance to Antibody-Drug Conjugates

Frank Loganzo, Ph.D., Director, ADC Biochemistry, Oncology, Pfizer
The molecular mechanisms of drug resistance vary significantly across cancer indications, and there are limited data on the acquisition of resistance to ADCs. We have generated pre-clinical models of ADC resistance by chronic

exposure of cancer cell lines with ADCs. Leveraging the modular nature of ADCs, we have observed that changes to the linker and/or payload can overcome acquired resistance to some ADCs, both *in vitro* and *in vivo*, suggesting that patients whose tumors become refractory to one therapy may respond to other ADCs, or to chemotherapeutics with similar mechanisms of action.

3:20 Sponsored Presentations (*Opportunities Available*)**3:50 Refreshment Break**ADVANCES IN BIOMARKER DEVELOPMENT
IN ONCOLOGY**4:00 Chairperson's Remarks**

Jae Lee, Ph.D., Chair and Senior Member, Biostatistics and Bioinformatics, Moffitt Cancer Center

4:10 Identifying and Overcoming Markers of Chemoresistance

Jason Baum, Ph.D., Associate Director, Companion Diagnostics, Research, Merrimack Pharmaceuticals

This talk will focus on the understanding of cancer cell survival networks to identify key biomarkers of resistance to chemotherapy. This includes initial proof-of-concept in a preclinical setting and translation into the clinic through the development of both tissue and blood-based diagnostic assays. Data from phase 2 clinical studies will illustrate the resistance of biomarker positive patients to chemotherapies across multiple indications, and the potential for targeted therapies to overcome this resistance.

4:40 The Impact of Tumor Heterogeneity on Clinical Biomarker Development Using FFPE Tissue

Ken Chang, Ph.D., Senior Principal Scientist, Molecular Biomarkers and Diagnostics, Merck Clinical Labs

We have developed a "Concordance Calculator" to quantify reproducibility of multi-variant calls among Next Generation Sequencing. Recently we applied this approach to study the impact of tumor heterogeneity among consecutive FFPE tissue sections across entire tumor block and found no heterogeneity among different sections/regions of tumors in terms of mutation profiles using NGS. These studies suggest that DNA mutation signatures as novel biomarkers for cancer diagnosis and prognosis are likely to be less sensitive to the impact of tumor heterogeneity than RNA-based expression signatures.

5:10 Prognostic Surrogate Markers for Survival, A Case Series for a Novel Antiangiogenic Therapy

M.A. Nezami, M.D., President, Cancer Epigenetics, Pacific Medical Center of Hope

Establishing the prognosis in majority of patients, especially with heterogeneous tumors, has been extremely challenging. One area of most recent attention in identifying surrogate

markers for survival has been the vasculogenesis and its related serum markers. Here we present a series of cases treated with a novel antiangiogenic therapy and monitored through these markers to identify response that translated to prognosis and survival.

5:40 Close of Conference Program

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



CLINICAL SEQUENCING

Translating NGS to Practice

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

NGS-DRIVEN STRATIFIED CANCER TRIALS

11:50 Chairperson's Opening Remarks

Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

12:00 pm LungMAP/S1400: A Unique Public-Private Master Protocol for Drug-Biomarker Registration

David Gandara, M.D., Professor of Medicine, Division of Hematology/Oncology, University of California, Davis School of Medicine; Director, Thoracic Oncology Program, Senior Advisor to the Director, UC Davis Comprehensive Cancer Center; Chair, Lung Committee, Southwest Oncology Group (SWOG)

Despite rapid advances in deciphering the complex genomics of non-small cell lung cancer (NSCLC), clinical translation into approvable biomarker-drug combinations has been problematic, due in part to the relative rarity of genomically-defined subsets. Lung-MAP (S1400) is a one-of-a-kind public-private partnership designed to speed up development of targeted therapies for NSCLC of squamous cell histology (SCCA). Here we describe development of this registration-compliant biomarker-driven Phase II/III multi-arm "master" protocol, employing next generation sequencing to identify actionable molecular abnormalities, followed by patient randomization to biomarker-driven targeted therapy versus standard of care.

12:30 The Evolving Genotype-to-Phenotype Paradigm in Oncology Drug Development

Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

The clinical application of multiplexed molecular profiling technologies offers unprecedented opportunities to enhance the drug development process by directing treatment to patients who are more likely to benefit. However, molecular profiling technologies are in the early stages of clinical application as companion diagnostic tests. Future success will require close integration between not only biology and technology, but also between clinical and diagnostic development strategies.

1:00 Session Break

1:15 Luncheon Presentations (Sponsorship Opportunities Available)

2:15 Session Break

CASE STUDIES IN PRENATAL DIAGNOSTICS

2:30 Chairperson's Remarks

Allan T. Bombard, M.D., MBA, Chief Medical Officer, Progenity, Inc.

2:40 History Before NIPT

Mark I. Evans, M.D., Professor, Obstetrics & Gynecology, Mount Sinai School of Medicine; Director, Comprehensive Genetics PLLC

The past 50 years have seen a pendulum of screening and testing for prenatal diagnosis with increasing rounds of sophistication, better statistics, and increasing acceptance. The "goal posts" have kept moving rendering sweeping conclusions as to primacy of any approach having a very short shelf life. The economics and science are intertwined in trying to determine optimal protocols and standards.

3:10 Case Studies in Prenatal Diagnostics; End-User of Prenatal Testing in Clinical Practice

Edward Wolf, M.D., President, New Jersey Perinatal Associates

To review the impact that rapid changes in prenatal testing options have had on the delivery of healthcare to pregnant women, from screening tests, ultrasound and cell free fetal DNA in maternal serum to invasive needle based testing options.

3:40 Lessons from NIPT: Interesting Cases, Complex Issues

Nicole Teed, MS, CGC, CEO, Integrity Genomics

In the few years since NIPT emerged as an advanced prenatal screening technology, a number of lessons have been learned, both biological and ethical. This presentation will use case studies to illustrate considerations for NIPT, with broader applications for other NGS technologies making their way into routine medical practice.

Sponsored by



4:10 Changing The Landscape of Non-Invasive Prenatal Testing: The IONA Test

Peter Collins, CCO, Premiaitha Health

4:25 Sponsored Presentation (Opportunity Available)

4:40 Break and Transition to Plenary Session

5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by
SLONEPARTNERS

CASE STUDIES OF AN INTEGRATED APPROACH TO PATIENT CARE

10:05 Chairperson's Remarks

Karl V. Voelkerding, M.D., Professor, Pathology, University of Utah; Medical Director, Genomics and Bioinformatics, ARUP Laboratories

10:15 Clinical Exome Sequencing for the Diagnosis of Neurodegenerative Disorders

Rong Mao, M.D., Associate Professor, Pathology, ARUP Lab, University of Utah

Clinical exome sequencing is a new genome-based technology for demystifying undiagnosed illnesses - particularly rare childhood diseases. It has proven remarkably successful in identifying the causes of Mendelian diseases with a reported detection rate for deleterious mutations ranged from 25 to 30%. Herein I will present exome cases, and illustrate exome sequencing as an efficient diagnostic tool for complex neurodegenerative disorders.

10:45 Clinical Utility of Multiple-Gene Sequencing Panels for Hereditary Cancer Risk Assessment

James M. Ford, M.D., Associate Professor, Medicine & Genetics, Division of Oncology, Stanford University School of Medicine

Panels assaying multiple hereditary cancer risk genes are entering clinical use, however little is known about their yield or effect on clinical management of patients. We sequenced germline DNA samples from 400 patients with personal and family histories of breast and/or ovarian cancer, but without BRCA1/2 mutations, and found ~10% carry potentially pathogenic mutations in other cancer susceptibility genes.

11:15 Applying Next-Generation Sequencing to

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLINICAL SEQUENCING

*continued***Mutation Detection in Hematologic Malignancies with an Emphasis on Value Added to Patient Care**

Jennifer J.D. Morrisette, Ph.D., FACMG, Scientific Director, Clinical Cancer Cytogenetics; Clinical Director, Center for Personalized Diagnostics; Pathology, University of Pennsylvania

Genomic testing in hematologic malignancies reliably detects somatic mutations and can provide insight into disease development, prognosis and therapeutic options. This talk will discuss our approach to mutation detection in hematological malignancies, including capture of difficult to sequence regions (e.g. CEBPA and large FLT3-ITDs), and mutation profiles with respect to conventional cytogenetic findings. An overview of clinical impact of testing and case studies where our NGS-heme panel influenced treatment will be discussed.

11:45 Metagenomic Next-Generation Sequencing for Clinical Diagnosis of Infectious Diseases

Charles Chiu, M.D., Ph.D., Assistant Professor, Laboratory Medicine and Medicine/Infectious Diseases; Director, UCSFAbbott Viral Diagnostics and Discovery Center; Associate Director, UCSF Clinical Microbiology Laboratory, UCSF School of Medicine

Metagenomic next-generation sequencing (NGS) is a powerful approach to diagnose infectious diseases by comprehensively detecting all potential pathogens in a single assay. We have validated an NGS assay for infectious diseases in a CLIA-certified laboratory setting that leverages a rapid, cloud-compatible bioinformatics pipeline for pathogen identification. We will discuss case studies applying this assay for diagnosis of challenging clinical cases in infectious disease.

12:15 pm Session Break**12:25 Luncheon Presentation I: Information Innovation for Clinical Implementation of Next-Generation Sequencing**

Shelly Gunn, M.D., Ph.D, CMO, MolecularHealth, Inc. David Jackson, Ph.D, CSO, MolecularHealth, Inc.

In-depth discussion of innovative clinico-molecular informatics platform that applies proprietary text analytics, biomedical curation, genome and proteome informatics and cheminformatics methodologies to the analysis of patientspecific clinical and molecular information to identify the safest and most effective cancer treatment options. Case studies will be presented that demonstrate the translation of genetic tumor data to actionable information using HER2 positive early stage breast cancer cases.

12:55 Luncheon Presentation II (Opportunity Available)**1:25 Refreshment Break in the Exhibit Hall with Poster Viewing****NGS ASSAYS****2:00 Chairperson's Remarks****2:10 Validation Challenges for Panels and Exomes**

Josh Deignan, Ph.D., Associate Director, UCLA Molecular Diagnostics Laboratories, Department of Pathology and Laboratory Medicine, David Geffen School of Medicine, UCLA

Guidelines for the validation of molecular diagnostic tests have existed for some time, but guidelines for NGS testing have only recently emerged. Moreover, the approach required for the validation of a NGS mutation panel is different than the one required for an exome sequencing test, both of which are now offered clinically at UCLA. This talk will discuss our experiences with the validations of these two types of NGS tests.

2:40 FDA-Approved Versus LDT-Based NGS Systems: Preanalytical Issues and Validation

Jamie L Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.

As NGS technologies have matured and their utility in clinical diagnostics has been embraced, the evolution of RUO-based Laboratory Developed Processes (LDPs) to FDA-Cleared *In Vitro* Diagnostic Tests has followed. The major considerations around Preanalytical issues for these two categories of systems will be compared and discussed. In addition, the key validation or verification challenges will be contrasted and discussed within the context of a CLIA Lab experience using both types of systems. The objective of the presentation is to provide sufficient information, drawn from experience, to enable labs to choose the path that best suits their environment, goals and objectives.

3:10 PANEL DISCUSSION: Comparing Major NGS Instruments: Technical Differences, Application Preferences

Moderator: Jamie L Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.

Panelists: Shelly Gunn, M.D., Ph.D., CMO, Molecular Health Jennifer J.D. Morrisette, Ph.D., FACMG, Scientific Director, Clinical Cancer Cytogenetics; Clinical Director, Center for Personalized Diagnostics; Pathology, University of Pennsylvania

Martin Siaw, Ph.D., MB (ASCP), Associate Scientific Director, Advanced Sequencing, Quest Diagnostics Nichols Institute
Selecting the NGS platform or platforms that best address the pre-analytical and technical considerations of the assay objectives given the specific environment can be a challenging undertaking. Platform throughput, chemistry, and error modality vary greatly and are tightly tied to overall assay performance. This discussion will focus on the strengths and capabilities of the different commercially available NGS platforms from the perspective of users with experience on multiple platforms.

3:40 A Novel Method for Efficient and Hands-Free Purification of Circulating, Cell-Free DNA (ccfDNA) from Human Plasma

Douglas Horejsh, Ph.D., Senior Research Scientist, Promega Corporation

Sponsored by



The Promega Maxwell® RSC circulating DNA kit allows parallel purification of ccfDNA from 1-16 plasma samples. This method purifies high-quality DNA suitable for use in qPCR and NGS. The absence of pre-processing steps improves reproducibility and lowers risk of contamination.

3:55 Can You Handle a Million Tests per Year? Transitioning from Clinical Trials to a Validated, High-Throughput Diagnostics OperationSponsored by **sample minded**

Daniel Steenblik, Vice President of Technology and Operations, Engineering, *sampleminded*

We will discuss the challenges of transitioning a lab from clinical trials to a high throughput diagnostic organization. How we employ a simple and sleek mission critical LIS, including tablets, monitoring and workflow metrics to capture quality indicators, while maintaining traditional LIS/LIMS functionality.

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing**5:00 Breakout Discussions in the Exhibit Hall (see website for details)****6:00 Close of Day****WEDNESDAY, FEBRUARY 18****7:00 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee****8:00 PLENARY SESSION PANEL (see page 5 for details)****9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall****STRATEGIC ISSUES IN NGS-ENABLED CANCER CARE****10:35 Chairperson's Remarks**

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

10:45 Advancing Clinical Outcomes with Targeted Therapies for Patients with Solid Tumors Using the Next Generation Sequencing Assay

Jo-Anne Vergilio, M.D., Associate Medical Director, Foundation Medicine, Inc.

The FoundationOne™ assay for solid tumors has been

CLICK HERE TO REGISTER ONLINE!

TriConference.com



TRICON PERKS

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



CLINICAL SEQUENCING

continued

validated as a sensitive comprehensive next generation sequencing assay that can detect all classes of genomic alterations at extremely low mutant allele frequencies. This presentation will highlight clinical applications of FoundationOne that have impacted disease outcomes in a variety of common and rare solid tumors.

11:15 High-Impact Applications of Liquid Biopsies

Luis A. Diaz, M.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

Novel technologies to evaluate tumor burden in blood have opened the doors for several new clinical applications that will address unmet clinical needs in Oncology. This lecture will discuss these high-impact applications in the context of the most recent technologies.

11:45 The NGS Cost Equation in Cancer Care: Are We at the Tipping Point?

German Pihan, M.D., Staff Pathologist & Director, Hematopathology Lab, Pathology, Beth Israel Deaconess Medical Center

The cost-effectiveness of exome sequencing (WES) in the diagnosis, risk assessment and, particularly, therapy of cancer remains undetermined. This talk will address this very important issue and propose guidelines for the development of data-driven algorithms predicting cost-effective implementation of WES.

12:15 pm Session Break

12:25 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

WHAT IS NEEDED FOR TRANSLATION IN THE CLINICAL SETTING?

1:40 Chairperson's Remarks

Paul R. Billings, M.D., Ph.D., CMO, Omicia, Inc.

1:50 KEYNOTE PRESENTATION: Challenges Encountered Using NGS in Common Clinical Settings

Paul R. Billings, M.D., Ph.D., CMO, Omicia, Inc.

NGS is evolving to become a common part of oncology and obstetric practices as well as in the evaluation of pediatric and adult cases that are difficult to diagnose. A variety of challenges have been encountered in the high quality implementation of NGS in these settings. What do doctors and patients understand is the value of these tests and how does this impact consent for testing? What types of tests are ordered? What results are reported? What services optimize delivery? What interpretative support is required immediately and over time? Consultees will increasingly bring already captured NGS data to routine clinical encounters. This talk will discuss these issues as NGS is standardized and integrates in to professional medical practice.

2:20 Precision Prevention

Dietrich A. Stephan, Ph.D., Professor & Chairman, Human Genetics, University of Pittsburgh; Associate Director, Population Genetics and Translational Acceleration, Institute for Personalized Medicine of UPMC & University of Pittsburgh Health

New molecular diagnostics are allowing us not only stratify individuals for therapies when sick (personalized medicine), but also now to allow pre-symptomatic molecular diagnosis. Precision prevention promises to significantly impact individual outcomes and improve public health.

2:50 Delivering Diagnostic and Predispositional Genomic Findings in the Clinic

Robert C. Green, M.D., MPH, Director, G2P Research Program; Associate Director, Research, Partners Personalized Medicine, Division of Genetics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

This talk will describe empirical efforts to use genomic information from germline sequencing in the clinical practice of medicine. Evidence will be presented emphasizing distinctions between sequencing for diagnosis and predispositional or predictive testing. New data will be presented supporting the penetrance of incidental findings in unselected populations.

3:20 Sponsored Presentation

Speaker to be Announced

Sponsored by



3:35 Sponsored Presentation (Opportunity Available)

3:50 Refreshment Break

ADVANCES IN COMPUTATIONAL CANCER GENOMICS

4:00 Chairperson's Remarks

Andreas Scherer, Ph.D., President and CEO, Golden Helix

CLINICAL CHANNEL

4:10 Bioinformatics of Cancer Gene Panels: Challenges to Creating Effective Testing Workflows

Andreas Scherer, Ph.D., President and CEO, Golden Helix



In the transition of NGS to a clinical setting, the cancer gene panel is leading with a clear value proposition of clinically actionable results in a simple package. Except it's not so simple. In this presentation I will cover the bioinformatics tools and best practices to achieve the goal of a reproducible workflow for analyzing NGS gene panel data. From amplicon and sample QC, to annotation sources and filtering thresholds, to summary of therapeutic targets and gene level reports, I will cover the methods and edge cases that go into setting up a gene panel test.

4:40 Maximizing the Utility of TCGA Genomic Data: Tools, Analysis and Discovery

Han Liang, Ph.D., Assistant Professor, Department of Bioinformatics and Computational Biology, Division of Quantitative Sciences, The University of Texas, MD Anderson Cancer Center

A central question for the cancer research community is how to use these genomic and proteomic data. I will first introduce two useful bioinformatics tools we recently developed for effectively analyzing and visualizing TCGA data: SurvNet and TCPA. Then I will present a systematic evaluation of the power of diverse TCGA molecular data with or without clinical variables in predicting patient survival and discuss the potential utility of cross-tumor analysis. Finally, I will focus on the biomedical significance and clinical relevance of expressed pseudogenes in human cancer.

5:10 Characterization of Cancer Genomes

Sohrab Shah, Ph.D., Assistant Professor, Pathology and Computer Science, University of British Columbia; Scientist, BC Cancer Agency

5:40 Close of Conference Program

TECHNOLOGY-DRIVEN ONCOLOGY CLINICAL DEVELOPMENT

Biomarkers and Strategies for Combination Therapy and Immunotherapy

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

NGS-DRIVEN STRATIFIED CANCER TRIALS

11:50 Chairperson's Opening Remarks

Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

12:00 pm LungMAP/S1400: A Unique Public-Private Master Protocol for Drug-Biomarker Registration

David Gandara, M.D., Professor of Medicine, Division of Hematology/Oncology, University of California, Davis School of Medicine; Director, Thoracic Oncology Program, Senior Advisor to the Director, UC Davis Comprehensive Cancer Center; Chair, Lung Committee, Southwest Oncology Group (SWOG)

Despite rapid advances in deciphering the complex genomics of non-small cell lung cancer (NSCLC), clinical translation into approvable biomarker-drug combinations has been problematic, due in part to the relative rarity of genomically-defined subsets. Lung-MAP (S1400) is a one-of-a-kind public-private partnership designed to speed up development of targeted therapies for NSCLC of squamous cell histology (SCCA). Here we describe development of this registration-compliant biomarker-driven Phase II/III multi-arm "master" protocol, employing next generation sequencing to identify actionable molecular abnormalities, followed by patient randomization to biomarker-driven targeted therapy versus standard of care.

12:30 The Evolving Genotype-to-Phenotype Paradigm in Oncology Drug Development

Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

The clinical application of multiplexed molecular profiling technologies offers unprecedented opportunities to enhance the drug development process by directing treatment to patients who are more likely to benefit. However, molecular profiling technologies are in the early stages of clinical application as companion diagnostic tests. Future success will require close integration between not only biology and technology, but also between clinical and diagnostic development strategies.

1:00 Session Break

1:15 Luncheon Presentations (Sponsorship

Opportunities Available) or Lunch on Your Own

2:15 Session Break

2:30 Chairperson's Remarks

Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

2:40 Clinical Trials for Predictive Biomarker Discovery and Validation in Oncology Drug Development

Eric Peters, Ph.D., Companion Diagnostics Leader, Oncology Biomarker Development, Genentech

3:10 Universal Testing for Actionable Genomic Variants in Cancer: a Paradigm Shift in Precision Oncology

Karen Gutekunst, Vice President, Diagnostic Development, Illumina, Inc.

Rapid technological progress allowing for broad interrogation of genomic variation in cancer, and a parallel expansion in knowledge regarding the actionability of an ever-growing number of germline and somatic variants, are revolutionizing the management of the disease. A paradigm shift is currently under way from drug-centered to patient-centered precision oncology, enabled by the advent of high-throughput, widely accessible NGS-based "universal" cancer genomic testing and featuring the emergence of "companion therapeutics".

3:40 PANEL DISCUSSION: Challenges in Developing Oncology Therapy with the Complexity of Cancer Heterogeneity

Panel Moderator: Steffan N. Ho, M.D., Ph.D., Senior Director, Early Development and Translational Oncology, Pfizer Oncology

Panelists: David Gandara, M.D., Professor of Medicine, Division of Hematology/Oncology, University of California, Davis School of Medicine; Director, Thoracic Oncology Program, Senior Advisor to the Director, UC Davis Comprehensive Cancer Center; Chair, Lung Committee, Southwest Oncology Group (SWOG)

Eric Peters, Ph.D., Companion Diagnostics Leader, Oncology Biomarker Development, Genentech

Karen Gutekunst, Vice President, Diagnostic Development, Illumina, Inc.

4:10 Evolving Clones and Detection Technology: Role in Cancer Management

Alison Todd, Ph.D., CSO and General Manager, SpeedX Pty Ltd.

Sponsored by
SpeedX

The growing need to understand tumor heterogeneity and clonal evolution, and their potential significance for tailoring and monitoring therapy, reinforces the necessity for highly sensitive, rapid and accurate analytical tools. This presentation will outline novel approaches useful for clinical implementation.

4:25 Sponsored Presentation (Opportunity Available)

4:40 Break and Transition to Plenary Session

» **5:00 PLENARY SESSION** (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» **8:00 PLENARY SESSION** (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by SLONEPARTNERS

TRANSLATIONAL APPROACHES IN CANCER IMMUNOTHERAPY DEVELOPMENT

10:05 Chairperson's Remarks

James Smothers, Ph.D., Senior Director, Head, Discovery, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

10:15 Biomarkers in Cancer Immunotherapy

Ira Mellman, M.D., Vice President, Cancer Immunology, Genentech

Recent advances in cancer immunotherapy differ from other developments in oncology therapeutics in several respects. Not only have immunotherapies proved remarkably promising, but also the underlying science promises to be largely driven

TECHNOLOGY-DRIVEN ONCOLOGY
CLINICAL DEVELOPMENT

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

TECHNOLOGY-DRIVEN ONCOLOGY CLINICAL DEVELOPMENT

continued

by findings in the clinic. Thus, both patient selection and the discovery of new therapeutic opportunities will be dependent on the ability to identify, collect, and understand biomarkers and immunobiology of patient response and lack of response.

10:45 Strategies for Clinical Development of Cancer Immunotherapy

Roy Baynes, M.D., Senior Vice President Global Clinical Development, Merck

It has been established that autoimmunity against a number of malignancies can be revealed by pharmacologic modulation of checkpoint inhibitors and co-stimulatory molecules. A strategic imperative is comprehensive definition of the efficacy and safety of monotherapy across tumor types. This has required understanding the limitations of standard response evaluations and the need to identify and appropriately manage immune mediated adverse events. Patient selection and study enrichment approaches are emerging. Informative biology will be required to evaluate the array of potential therapeutic combinations.

11:15 Translational Approaches for the Development of Intratumoral Immunotherapies

Robert Pierce, M.D., CMO, OncoSec Medical, Inc.

Intratumoral therapies are capable of reversing local immunosuppressive mechanisms and driving systemic anti-tumor immune responses. Given the safety and potential systemic efficacy of this approach, intratumoral therapies will likely play a growing role in future combination immunotherapy regimens. The pros and cons of current syngeneic mouse models will be addressed with particular emphasis on unique aspects of intratumoral therapies.

11:45 Preclinical Validation of Immunotherapies and Combination Strategies for Cancer

James Smothers, Ph.D., Senior Director, Head, Discovery, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

Recent clinical strategies to modulate T cell checkpoint pathways have demonstrated significant patient benefit in melanoma, renal cell carcinoma and non-small cell lung cancer indications. Clinical successes with immuno-oncology medicines greatly depend upon animal disease model studies and other preclinical rationale for their development. Translational data coupled with preclinical results can further bridge understanding of what patient populations might gain the most benefit from an immuno-oncology experimental medicine alone or in combination with another agent.

12:15 pm Session Break**12:25 Luncheon Presentation: Sponsored by GE Miniature Swine Preclinical Oncology Models**

EXEMPLAR GENETICS

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

Current model systems of cancer have been informative but present challenges to translating therapies to the clinic. We have developed genetically modified miniature swine models of cancer expressing mutations in the TP53, KRAS, and ATM genes. TP53 mutant pigs have been demonstrated to develop lymphomas and osteogenic tumors. The KRAS mutation is conditional and can be activated in a tissue specific manner. These pigs provide a novel large animal tumor model that replicates the human condition.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing**PANEL DISCUSSION: PRACTICAL ASPECTS OF IMPLEMENTING THE MASTER PROTOCOL****2:00 Moderator's Remarks**

Glenn A. Miller, Ph.D., CTO & Executive Vice President, MolecularMD

- Predictive biomarkers and translational medicine in the S1400 lung-mAP trial
- Implementing the MATCH protocol
- Opportunities and challenges in designing and conducting basket trials

Panelists:

Philip C. Mack, Ph.D., Associate Adjunct Professor, Internal Medicine, Hematology and Oncology, University of California Davis Medical Center

Jason Lih, Ph.D., Principal Scientist, Molecular Characterization Group, Leidos Biomedical Research, Inc./Frederick National Laboratory for Cancer Research

Steffan N. Ho, M.D., Ph.D., Senior Director, Translational Oncology, Pfizer, Inc.

3:40 Enabling Advances in Cancer Genomics with NGS

Sponsored by
illumina™

Frank S. Ong, M.D., Associate Director, Medical Affairs, Illumina, Inc.

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing**5:00 Breakout Discussions in the Exhibit Hall (see website for details)****6:00 Close of Day****WEDNESDAY, FEBRUARY 18**

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

» **8:00 PLENARY SESSION PANEL (see page 5 for details)**

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

PDX MODELS TO INFORM CLINICAL TRIALS**10:35 Chairperson's Remarks**

Neal Goodwin, Ph.D., Vice President, Corporate Research and Development, Champions Oncology

10:45 Towards Personalized Medicine: Companion Therapeutics in the I-SPY 2 TRIAL

Laura J. van 't Veer, Ph.D., Professor of Laboratory Medicine, University of California San Francisco; Leader, Breast Oncology Program; Associate Director, Applied Genomics, UCSF Helen Diller Family Comprehensive Cancer Center; Principal Investigator, Bay Area Breast Cancer SPORE; Angela and Shu Kai Chan Endowed Chair in Cancer Research

Cancer therapeutics are nowadays targeted to inhibit the activated networks. The multitude of choices is effectively evaluated in the neo-adjuvant therapeutic setting where drugs are given before surgery and direct tumor response can be monitored by imaging. Accompaniment by comprehensive molecular diagnostics allows one to find the right drug for the right patient. The I-SPY 2 breast cancer trial maximizes the neoadjuvant approach by adaptively assigning patients to the treatment arm where their tumors biology is showing the most effective response.

11:15 Optimizing Clinical Trial Designs by PDX Integration

Philip C. Mack, Ph.D., Associate Adjunct Professor, Internal Medicine, Hematology and Oncology, University of California Davis Medical Center

Compared to cell lines and GEMMs, Patient-Derived Xenografts (PDXs) are a superior representation of the molecular complexity and natural evolution of patient tumors. In collaboration with The Jackson Laboratory (JAX), we have developed an extensive, well-characterized resource of over 60 NSCLC PDX models. Models retain the mutational characteristics, heterogeneity and histology of the donor tumor. Integration of PDX modeling into clinical trials provides an opportunity to optimize personalized therapeutic strategies

CLICK HERE TO REGISTER ONLINE!

TriConference.com

TRICON PERKS

COVER

EVENT AT A GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

TECHNOLOGY-DRIVEN ONCOLOGY CLINICAL DEVELOPMENT

continued

that has not been previously available.

11:45 Patient Derived Xenograft Clinical Trial Program

Sponsored by



Neal Goodwin, Ph.D., Vice President, Corporate Research and Development, Champions Oncology

A PDX clinical program to guide patient treatment has engrafted >750 patient specimens with a 70% patient tumor take rate and a >80% correlative treatment accuracy in completed clinical tests. This program has been expanded to support predictive clinical trials for breast, sarcoma, and lung cancer in partnership with clinical trial centers and cooperative trial groups. Ultimately, this program will include matched patient translational studies across numerous patient models for Phase II trial patient stratification.

12:15 pm Session Break**12:25 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own****1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing****TRANSLATIONAL APPROACHES TO CHILDHOOD CANCER****1:40 Chairperson's Remarks****1:50 Translational Genomics of Pediatric Cancers to Identify Novel Biomarkers, Drivers and Therapeutic Targets**

Javed Khan, M.D., Genetics Branch Head, Oncogenomics Section Deputy Branch Chief, Center for Cancer Research, National Cancer Institute

Recently there has been an explosion of information related to the cancer genome. I will describe the use of high-throughput technologies such as next-generation sequencing, siRNA and compound screening to identify novel biomarkers, drivers and therapeutic targets. I will summarize some of the key discoveries made, focusing my comments on neuroblastoma, rhabdomyosarcoma and Ewing's sarcoma. Finally I will describe the use of genomics for precision therapy trials for children with refractory or relapsed cancers

2:20 Preclinical Childhood Cancer Models for Developing Molecularly Targeted Therapies.

Peter Houghton, Ph.D., Director, Greehey Children's Cancer Research Institute, University of Texas Health Science Center, San Antonio

The Pediatric Preclinical Testing Program (PPTP) supported through the National Cancer Institute, has developed in excess

of 150 patient derived tumor xenograft models (PDX). These models have been characterized by expression profiling, SNP analysis and exome sequencing. The primary screen utilizes 49 xenograft models to identify agents that have broad-spectrum or tumor-type selective activity. Examples of the predictive value of expression profiles or sequence data for identification of active agents will be discussed.

2:50 The Institutes for Molecular Medicine at Phoenix Children's Hospital to Address the Unmet Need: Slow Progress in Pediatric Drug Development

Nazneen Aziz, Ph.D., Senior Vice President & Chief Research Officer, Phoenix Children's Hospital

More effective therapies are unavailable in pediatric cancer, in stark contrast to the rapid introduction of targeted therapies in adult cancer that are revolutionizing the treatment of adults with cancer. PCH's Molecular Medicine Program will focus on utilizing genomic methodologies to better understand mechanisms of disease and to stratify patient populations, with the ultimate goal of improving clinical care and outcomes. The program will support a dynamic interplay between the clinic, the laboratory, and pharmaceutical companies focusing on real-time translation of scientific knowledge and patient data to identify the best possible treatment for patients.

3:20 PANEL DISCUSSION: Childhood Cancer Research: Specific Features and Advances

Moderator: Peter Houghton, Ph.D., Director, Greehey Children's Cancer Research Institute, University of Texas Health Science Center, San Antonio

Panelists: Speakers of the Session

3:50 Refreshment Break**ENABLING CANCER RESEARCH AND DEVELOPMENT****4:00 Chairperson's Remarks****4:10 Isolation of DNA/RNA Biomarkers and the Quest for Liquid Biopsy Cancer Diagnostics**

Michael J. Heller, Ph.D., Professor, Nanoengineering & Bioengineering, University of California San Diego

The isolation of circulating cell free (ccf) DNA and ccf-RNA directly from blood and/or plasma remains a complex and time consuming procedure, which is impeding progress toward liquid biopsy and point of care (POC) cancer diagnostics. We have now demonstrated the rapid isolation and detection of ccf-DNA/RNA from a number of different hematological and solid tumor samples.

4:40 Antibody Validation to Prevent Error

David L. Rimm, M.D., Ph.D., Professor, Pathology; Executive Director, Translational Pathology; Director, Yale Pathology Tissue Services, Yale University

Antibodies are an extremely broadly used and valuable tool, both in discovery research, translational research and in the clinic. However, some of the data produced and published in the literature is flawed, or misleading due to non-specificity or cross-reactivity. Here we will look at the use of antibodies, both in the research and clinical setting and show how lack of rigorous validation can produce flawed data. We will also provide guidelines for antibody validation that can be used to avoid flawed, but publishable results.

5:10 Managing Quality in Biorepository Operations to Support Translational Research- Experiences of the OHSU Knight BioLibrary

Devon Kelly, Director, OHSU Knight BioLibrary, Knight Cancer Institute, Oregon Health and Science University

Methods by which human research specimens are consented, collected, stored and distributed varies greatly from repository to repository. This variation is a large contributing factor in the ability of researchers to generate high-quality data from specimens acquired from multiple repositories into a single research project. Therefore, it is important to manage the quality of biobanking activities to maximize the utility of banked specimens collected for future research projects. Experiences in assessing and standardizing practices across a large cancer repository network will be discussed.

5:40 Close of Conference Program

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



CANCER CHANNEL

Recently, the heterogeneity and complexity of malignant tumors has changed the way we think about the initiation, progression, diagnosis, and management of cancer. The Cancer Channel will explore the emerging molecular markers, improved preclinical models, and genomic-based therapies that are increasing the success of personalized medicine.

- Cancer Molecular Markers
- Circulating Tumor Cells
- Translational to Clinical R&D
- Technology-Driven Oncology
Clinical Development - **NEW**
- Predictive Preclinical Models in Oncology

PREDICTIVE PRECLINICAL MODELS IN ONCOLOGY

Modeling for Targeted and Immune-Mediated Therapy Assessment

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

ADVANCES IN TUMOR MODELING=ADVANCES IN CANCER DRUG DISCOVERY AND DEVELOPMENT

11:50 Chairperson's Opening Remarks

Nancy K. Pryer, Ph.D., Executive Director, Translational Research, BioMarin Pharmaceutical, Inc.

12:00 pm Assessing the Predictive Value of Preclinical Cancer Models

Alexander Kamb, Ph.D., Senior Vice President, Discovery Research, Amgen

Cancer drugs work via two general mechanisms: cell-autonomous and non-cell-autonomous. Preclinical experimental models designed to test these mechanisms fall into two basic categories: *in vitro* (cell-based) and *in vivo*. In this presentation I consider the utility of these approaches in their various forms for oncology research.

12:30 Targeting Developmental Pathways in Cancer

Frederic de Sauvage, Ph.D., Vice President, Molecular Oncology, Genentech

Developmental pathways such as Wnt, Notch and Hedgehog play an important role in the development of a number of cancers. I will discuss the use of various mouse models of cancer to study the preclinical activity of pathway inhibitors and characterize potential mechanisms of innate or acquired resistance.

1:00 Session Break

Sponsored by



1:15 Luncheon Presentation I: PDX Models for Improved Translational Research and Preclinical Prediction

Walter Ausser, Ph.D., Business Director, Clinical & In Vivo Services, The Jackson Laboratory

James Keck, Senior Director, Clinical Lab & In Vivo Pharmacology Services, The Jackson Laboratory

Patient-derived xenograft (PDX) models can recapitulate patient tumor histopathology, mutational status, gene expression patterns, and drug response with remarkable fidelity. At The Jackson Laboratory, we have established a repository of more than 350 well-characterized PDX tumor models and are working with leading cancer centers on translational studies at the forefront on personalized medicine. We will discuss recent progress toward the use of PDX models for predictive oncology treatment.

1:45 Luncheon Presentation II (Sponsorship Opportunity Available)

2:15 Session Break

MODELLING AND RESEARCHING BRAIN CANCER

2:30 Chairperson's Remarks

Nancy K. Pryer, Ph.D., Executive Director, Translational Research, BioMarin Pharmaceutical, Inc.

2:40 Preclinical Trials in Mouse Models of Brain Tumors

Eric C. Holland, M.D., Ph.D., Senior Vice President, Director, Human Biology, Solid Tumor Translational Research, Nancy and Buster Alvord Brain Tumor Center, Fred Hutchinson Cancer Research Center, University of Washington

We have been using genetically and histologically accurate models of gliomas for preclinical trials. The models are driven by PDGF that appears to be the initiator for most human GBMs. These models respond to the standard of care for gliomas such as radiation and temozolomide in a similar manner as humans. We have used these models to better understand the biology of therapeutic response as well as optimize and enhance radiation efficacy.

3:10 Intertwined Regulation of Angiogenesis and Immunomodulation in Cancer Progression and Resistance

Kan Lu, Ph.D., Assistant Professional Researcher, Neurological Surgery, Brain Tumor Research Center, University of California, San Francisco

The current evidence suggests that several adaptive mechanisms mediate evasive resistance to anti-angiogenic therapies, of which those facilitating a proangiogenic relapse include upregulation of alternative proangiogenic factors and tumor infiltration of various innate immune cells. All of these cell types display angiogenic and immune suppressive functions in tumors supporting the notion that angiogenesis and immune suppression appear to go hand-in hand. Here, we will discuss how antiangiogenic therapy affects immune modulation and how in turn, immune cells affect antiangiogenic therapy.

3:40 PANEL DISCUSSION: Addressing the Key Challenges in Preclinical Modeling

Moderator: Nancy K. Pryer, Ph.D., Executive Director, Translational Research, BioMarin Pharmaceutical, Inc.

Panelists: Speakers of the Day

- Choosing the appropriate model for our studies
- Modeling the genetic and phenotypic heterogeneity seen in the clinic

- Overcoming drug resistance
- Testing combination strategies
- Identifying translational biomarkers from model data

4:10 Sponsored Presentation

Speaker to be Announced



4:25 Sponsored Presentation (Opportunity Available)

4:40 Break and Transition to Plenary Session

5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by SLONEPARTNERS

TRANSLATIONAL APPROACHES IN CANCER IMMUNOTHERAPY DEVELOPMENT

10:05 Chairperson's Remarks

James F. Smothers, Ph.D., Senior Director & Head, Discovery, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

10:15 Biomarkers in Cancer Immunotherapy

Ira Mellman, M.D., Vice President, Cancer Immunology, Genentech

Recent advances in cancer immunotherapy differ from other developments in oncology therapeutics in several respects. Not only have immunotherapies proved remarkably promising, but also the underlying science promises to be largely driven by findings in the clinic. Thus, both patient selection and the discovery of new therapeutic opportunities will be dependent

PREDICTIVE PRECLINICAL MODELS IN ONCOLOGY

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



TRICON PERKS

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

PREDICTIVE PRECLINICAL MODELS IN ONCOLOGY

continued

on the ability to identify, collect, and understand biomarkers and immunobiology of patient response and lack of response.

10:45 Strategies for Clinical Development of Cancer Immunotherapy

Roy Baynes, M.D., Senior Vice President Global Clinical Development, Merck

The discovery that BRAF is a driver oncogene in cancer, and complementary improvements in our understanding of the immune system have resulted in new targeted and immunotherapies for metastatic melanoma. Targeted therapies achieve impressive clinical results in carefully selected patients but the development of resistance seems inevitable in most cases. Conversely, immune-checkpoint inhibitors can achieve long-term remission and cures, but in a smaller proportion of patients, and biomarkers to predict which patients will respond are not available.

11:15 Translational Approaches for the Development of Intratumoral Immunotherapies

Robert Pierce, M.D., CMO, OncoSec Medical, Inc.

Intratumoral therapies are capable of reversing local immunosuppressive mechanisms and driving systemic anti-tumor immune responses. Given the safety and potential systemic efficacy of this approach, intratumoral therapies will likely play a growing role in future combination immunotherapy regimens. The pros and cons of current syngeneic mouse models will be addressed with particular emphasis on unique aspects of intratumoral therapies.

11:45 Preclinical Validation of Immunotherapies and Combination Strategies for Cancer

James Smothers, Ph.D., Senior Director, Head, Discovery, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

Recent clinical strategies to modulate T cell checkpoint pathways have demonstrated significant patient benefit in melanoma, renal cell carcinoma and non-small cell lung cancer indications. Clinical successes with immuno-oncology medicines greatly depend upon animal disease model studies and other pre-clinical rationale for their development. Translational data coupled with pre-clinical results can further bridge understanding of what patient populations might gain the most benefit from an immuno-oncology experimental medicine alone or in combination with another agent.

12:15 pm Session Break**12:25 Luncheon Presentation: GE Miniature Swine Preclinical Oncology Models**

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

Current model systems of cancer have been informative but present challenges to translating therapies to the clinic. We have developed genetically modified miniature swine models of cancer expressing mutations in the TP53, KRAS, and ATM genes. TP53 mutant pigs have been demonstrated to develop lymphomas and osteogenic tumors. The KRAS mutation is

conditional and can be activated in a tissue specific manner. These pigs provide a novel large animal tumor model that replicates the human condition.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing**UNFOLDING CANCER IMMUNOTHERAPY MECHANISMS****2:00 Chairperson's Remarks**

Alan L. Epstein, M.D., Ph.D., Department of Pathology, USC Keck School of Medicine, Los Angeles

2:10 Inflammation and Cancer: Immune Cells as Targets For Anti-Cancer Therapy

Lisa M. Coussens, Ph.D., Professor and Chair, Director, Basic Research, Department of Cell & Developmental Biology, Knight Cancer Institute, Oregon Health & Sciences University

The concept that leukocytes are components of solid tumors is not new; however, their functional involvement as promoting forces in tumor progression has only recently been appreciated. We are interested in understanding the molecular mechanisms that regulate leukocyte recruitment into neoplastic tissue, subsequent regulation those leukocytes exert on evolving cancer cells, and how malignant cells in turn respond to cytotoxic therapies.

2:40 Criteria for Identifying Responses to Cancer Immunotherapy

Alan L. Epstein, M.D., Ph.D., Department of Pathology, USC Keck School of Medicine, Los Angeles

Immune profiling of tumor biopsies at the time of diagnosis can be used to determine what mechanisms are induced by tumors to defeat host immunity. Specifically, we have determined that evaluation of the immunogenicity of tumors and the identification of immunosuppressive cells and molecules provide critical information. In this way, immune signatures can be used to enhance clinical trial results and reduce the time to approval for new agents.

3:10 How to Unleash Anti-Tumor Immunity by Modulating the PI3K Pathway

Khaled Ali, Ph.D., Senior Scientist, Amgen Oncology

The phosphoinositide-3-OH kinase (PI3K) pathway is a key therapeutic target activated in most tumors. Inhibitors against the p110 δ isoform of PI3K have shown remarkable therapeutic efficacy in some human leukemias. As p110 δ is primarily expressed in leukocytes, drugs against p110 δ have not been considered for the treatment of solid tumors. Recently we have demonstrated that p110 δ inactivation in mice protects against a broad range of cancers, including non-hematological solid tumors. p110 δ inactivation in regulatory T cells unleashes CD8 cytotoxic T cells and induces tumor regression.

3:40 Sponsored Presentations (Opportunities Available)**4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing****5:00 Breakout Discussions in the Exhibit Hall (see website for details)****6:00 Close of Day WEDNESDAY, FEBRUARY 18****7:00 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee****8:00 PLENARY SESSION PANEL (see page 5 for details)****9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall****PDX MODELS TO INFORM CLINICAL TRIALS****10:35 Chairperson's Remarks**

Neal Goodwin, Ph.D., Vice President, Corporate Research and Development, Champions Oncology

10:45 Towards Personalized Medicine: Companion Therapeutics in the I-SPY 2 TRIAL

Laura J. van 't Veer, Ph.D., Professor of Laboratory Medicine, University of California San Francisco; Leader, Breast Oncology Program; Associate Director, Applied Genomics, UCSF Helen Diller Family Comprehensive Cancer Center; Principal Investigator, Bay Area Breast Cancer SPORE; Angela and Shu Kai Chan Endowed Chair in Cancer Research

Cancer therapeutics are nowadays targeted to inhibit the activated networks. The multitude of choices is effectively evaluated in the neo-adjuvant therapeutic setting where drugs are given before surgery and direct tumor response can be monitored by imaging. Accompaniment by comprehensive molecular diagnostics allows one to find the right drug for the right patient. The I-SPY 2 breast cancer trial maximizes the neoadjuvant approach by adaptively assigning patients to the treatment arm where their tumors biology is showing the most effective response.

11:15 Optimizing Clinical Trial Designs by PDX Integration

Philip C. Mack, Ph.D., Associate Adjunct Professor, Internal Medicine, Hematology and Oncology, University of California Davis Medical Center

Compared to cell lines and GEMMs, Patient-derived Xenografts (PDXs) are a superior representation of the molecular complexity and natural evolution of patient tumors. In collaboration with The Jackson Laboratory (JAX), we have developed an extensive, well-characterized resource of

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



PREDICTIVE PRECLINICAL MODELS IN ONCOLOGY

continued

over 60 NSCLC PDX models. Models retain the mutational characteristics, heterogeneity and histology of the donor tumor. Integration of PDX modeling into clinical trials provides an opportunity to optimize personalized therapeutic strategies that has not been previously available.

11:45 Patient Derived Xenograft Clinical Trial Program



Neal Goodwin, Ph.D., Vice President, Corporate Research and Development, Champions Oncology

A PDX clinical program to guide patient treatment has engrafted >750 patient specimens with a 70% patient tumor take rate and a >80% correlative treatment accuracy in completed clinical tests. This program has been expanded to support predictive clinical trials for breast, sarcoma, and lung cancers in partnership with clinical trial centers and cooperative trial groups. Ultimately, this program will include matched patient translational studies across numerous patient models for Phase II trial patient stratification.

12:15 pm Session Break

12:25 Luncheon Presentation (*Sponsorship Opportunity Available*) or **Lunch on Your Own**

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

TRANSLATIONAL APPROACHES TO CHILDHOOD CANCER

1:40 Chairperson's Remarks

1:50 Translational Genomics of Pediatric Cancers to Identify Novel Biomarkers, Drivers and Therapeutic Targets

Javed Khan, M.D., Genetics Branch Head, Oncogenomics Section Deputy Branch Chief, Center for Cancer Research, National Cancer Institute

Recently there has been an explosion of information related to the cancer genome. I will describe the use of high throughput technologies such as next-generation sequencing, siRNA and compounds screening to identify novel biomarkers, drivers and therapeutic targets. I will summarize some of the key discoveries made, focusing my comments on neuroblastoma, rhabdomyosarcoma and Ewing's sarcoma. Finally I will describe the use of genomics for precision therapy trials for children with refractory or relapsed cancers.

2:20 Preclinical Childhood Cancer Models for Developing Molecularly Targeted Therapies.

Peter Houghton, Ph.D., Director, Greehey Children's Cancer Research Institute, University of Texas Health Science Center, San Antonio

The Pediatric Preclinical Testing Program (PPTP) supported through the National Cancer Institute, has developed in excess of 150 patient derived tumor xenograft models (PDX). These models have been characterized by expression profiling, SNP

analysis and exome sequencing. The primary screen utilizes 49 xenograft models to identify agents that have broad-spectrum or tumor-type selective activity. Examples of the predictive value of expression profiles or sequence data for identification of active agents will be discussed.

2:50 The Institutes for Molecular Medicine at Phoenix Children's Hospital to Address the Unmet Need: Slow Progress in Pediatric Drug Development,

Nazneen Aziz, Ph.D., Senior Vice President & Chief Research Officer, Phoenix Children's Hospital

More effective therapies are unavailable in pediatric cancer, in stark contrast to the rapid introduction of targeted therapies in adult cancer that are revolutionizing the treatment of adults with cancer. PCH's Molecular Medicine Program will focus on utilizing genomic methodologies to better understand mechanisms of disease and to stratify patient populations, with the ultimate goal of improving clinical care and outcomes. The program will support a dynamic interplay between the clinic, the laboratory, and pharmaceutical companies focusing on real-time translation of scientific knowledge and patient data to identify the best possible treatment of patients.

3:20 PANEL DISCUSSION: Childhood Cancer Research: Specific Features and Advances

Moderator: Peter Houghton, Ph.D., Director, Greehey Children's Cancer Research Institute, University of Texas Health Science Center, San Antonio

Panelists: Speakers of the Session

3:50 Refreshment Break

INNOVATIVE IN VITRO AND IN VIVO MODELING

4:00 Chairperson's Remarks

4:10 Using 3-D Organoid Model to Target Stem Cells in Colorectal Cancer

Felipe de Sousa e Melo, Postdoctoral Research Fellow, Molecular Oncology, Genentech

Cancer stem cells have been reported in various cancers, including in colorectal cancer (CRC). The functional relevance of cancer stemness for tumor growth is still poorly characterized. We have devised a 3-D organoid culture model to define the functional properties of stem cells in CRC. Using this approach, we found that Lgr5 identifies a subpopulation of cancer cells endowed with stem-like properties. Strategies to eradicate this population will be discussed.

4:40 Early Assessment of the Potential Toxicity of Anti-Human Tumor Antigen BiTE® (Bi Specific T Cell Engager) Molecules in Pre-Clinical Cynomolgus Studies"

Olivier P. Nolan-Stevaux, Ph.D., Senior Scientist, Department of Oncology, Amgen, Inc.

5:10 Preclinical Models of Human Cancer at the Center for Advanced Preclinical Research (CAPR): Quantitative Methods for Assaying Drug Efficacy and Resistance

Philip Martin, D.V.M., Veterinary Pathologist, Center for Advanced Preclinical Research (CAPR), Frederick National Laboratory for Cancer Research & Leidos Biomedical Research, Inc.

At CAPR we have developed/optimized several important preclinical cancer models including: pancreatic, lung, melanoma, glioblastoma, and ovarian. This talk will give a brief description of each model including its development as a genetically engineered mouse (GEM) model and its eventual evolution into an immunocompetent transplantation model, and its advantages/disadvantages in modeling the human disease. In addition, the talk will focus on the quantitative methods that we use at CAPR to assay host immune response, drug efficacy, as well as the development of drug resistance.

5:40 Close of Conference Program

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



INFORMATICS CHANNEL

Each year, the Informatics Channel at the Molecular Medicine Tri-Conference brings together leading experts in data science, drug discovery informatics, bioinformatics, and IT. Through lectures, panel discussions, and interactive breakouts, we explore cutting edge ways to manage, analyze, and integrate data to enable drug discovery, biology, and clinical research.

- Genome and Transcriptome Analysis
- Bioinformatics for Big Data
- Integrated Pharma Informatics & Data Science



BIOINFORMATICS FOR BIG DATA

Converting Data into Information and Knowledge

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

MULTISCALE MODELING OF BIOLOGICAL SYSTEMS AND NETWORKS

11:50 Chairperson's Opening Remarks

Michael Liebman, Ph.D., Managing Director, IPQ Analytics, LLC

12:00 pm FEATURED PRESENTATION: Insights into Multiscale Mechanisms of Biological Functions and Polypharmacological Intervention Strategies using Methods of Computational Biology

Ivet Bahar, PhD, Distinguished Professor and John K Vries Chair, Department of Computational & Systems Biology, School of Medicine, University of Pittsburgh

Recent years have seen an explosion in the number of computational studies performed at multiple scales for gaining deeper insights into biomolecular systems dynamics as well as quantitative systems pharmacology. We recently launched a new Center, MMBioS, for multiscale modeling of neurobiological events. The newly developed computational methods open the way to examining complex neurobiological interactions such as excitatory signaling from a systems perspective and identifying new target and polypharmacological intervention methods.

12:30 Multi-Scale Modeling in Breast Cancer: Personalized Medicine in Population-Based Healthcare

*Michael Liebman, Ph.D., Managing Director, IPQ Analytics, LLC
Sabrina Molinaro, Ph.D., Head, Epidemiology, Institute of Clinical Physiology, National Research Council - CNR Italy*

Breast cancer continues to be a focus of big data research to enhance risk assessment, early detection, accurate diagnosis and optimal treatment. Actual clinical practice must deal directly with the patient in addressing these issues but at a personal level and currently, the tools are derived from population-based analyses. This presentation will present the specific instance of moving from population-based risk analysis to personalized risk assessment based on the patient's unique physiologic development and lifestyle.

1:00 Session Break

1:15 Luncheon Presentation I: Text Mining Full Text for Molecular Targets

George Jiang, Ph.D., Product Manager, Text Mining, Biology Products, Corporate Markets, ELSEVIER

Sponsored by



1:45 Luncheon Presentation II (Opportunity Available)

2:15 Session Break

2:30 Chairperson's Remarks

Michael Liebman, Ph.D., Managing Director, IPQ Analytics, LLC

2:40 Predicting Drug Pharmacology Networks and Mechanistic Targets

Michael Keiser, Ph.D., Assistant Professor, Institute for Neurodegenerative Diseases, University of California San Francisco, School of Medicine

Many drugs modulate more than one molecular target. We used the Similarity Ensemble Approach (SEA) to predict "liability target" profiles for hundreds of drugs, asking which account for their adverse reactions. Likewise, one may interrogate phenotypic mechanisms of action, using target profiles to guide chemical-genetic testing. In *C. elegans*, this revealed novel conserved pathways by which compounds up-regulate feeding. Applied at scale, this may automate determination of mechanistic targets underlying drug effects, desired and otherwise.

3:10 Ranking Omics Data to Discover Diagnostic Biomarkers

Professor Corrado Priami, Ph.D., Computer Science, The Microsoft Research, University of Trento Centre for Computational and Systems Biology (COSBI)

An approach based on ranking of measurements is presented to identify patient signatures. The signature can be used to define biomarkers with respect to diseases, stratification of patients with respect to interventions or even toxicology of drugs with respect to doses and number of deliveries. This talk presents the approach and application examples.

3:40 Steroid Resistance in Childhood Nephrotic Syndrome: Transcriptome-Wide Sequence Analysis Identifies SULF2 and Other Marker Genes

Saras Saraswathi, Ph.D., Research Scientist - Data Analyst, Sidra Medical and Research Center

Rashid S. Niaz, M.D., M.P.H., Director of Medical Informatics, DHI, Sidra Medical and Research Center, Qatar Foundation, Doha, Qatar
Glucocorticoids induce remission of nephrotic syndrome (NS) in most children, although 20% present with or develop glucocorticoid resistance. Unfortunately, no biomarkers are available that can reliably distinguish steroid-resistant

(SRNS) vs. steroid sensitive (SSNS) forms of NS. The data sets obtained were processed using statistical methods, a "Binary-Coded Genetic Algorithm", and a neural network-based "Extreme Learning Machine" algorithm, resulting in the identification of twelve candidate genes able to differentiate between SSNS and SRNS patients. Among them is SULF2, which encodes an endoglucosamine-6-sulfatase that is known to be crucial in the physiology of renal podocytes.

4:10 Enabling Patient Centric NGS Workflows through a Hadoop Optimized Compute Platform and Graph Analytics

Sponsored by
CRAY

David Anstey, MBA, Global Head, Life Sciences, Cray, Inc.

The drive to precision medicine is continually taxing compute, storage, archive and analytics capabilities of current NGS pipelines. Using specific use cases, attendees will gain an understanding of how NGS pipelines can be optimized to eliminate data movement and compute bottlenecks. Attendees will also learn how the data generated by the NGS workflows can be rapidly integrated with patient data to support cohort selection and precision medicine initiatives.

4:40 Break and Transition to Plenary Session

» 5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



CLICK HERE TO
REGISTER ONLINE!

TriConference.com



BIOINFORMATICS FOR BIG DATA

continued

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» **8:00 PLENARY SESSION** (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing *Sponsored by* SLONEPARTNERS

BIG DATA AND COMPUTATIONAL DRUG DESIGN: RESCUING AND REPURPOSING OF DRUGS FOR CANCER

10:05 PANEL DISCUSSION: Rescuing and Repurposing of Drugs for Cancer

Drug repurposing is becoming an attractive business strategy. It reduces risks and costs and creates opportunities to fill pipelines with new products that have a higher level of success, an accelerated development timeframe, and a quicker FDA approval process. Repurposing a drug from outside a therapeutic area and combining the drug with a blockbuster offers the potential to add significant and proprietary clinical value beyond that provided by the blockbuster drug alone. This session discusses examples and benefits of synergistic, repurposed-drug combinations; methods for identifying and developing such product candidates; and market trends to discover and develop novel, high-impact drugs for critical unmet clinical needs in the cancer arena.

Chairperson and Moderator:

H. Kim Lyerly, M.D., George Barth Geller Professor of Cancer Research; Professor, Surgery; Associate Professor, Pathology; Assistant Professor, Immunology, Duke University

Panelists:

Devdatt Dubhashi, Ph.D., Professor, Department of Computer Science and Engineering, Chalmers University of Technology

Sandra Gesing, Ph.D., Research Assistant Professor, Center for Research Computing, University of Notre Dame

Prahalad Achutharao, Founder & CEO, InterpretOmics India Pvt. Ltd.

Anil Srivastava, President, Open Health Systems Laboratory

Wenjin Zhou, Ph.D., Assistant Professor, Computer Science and Engineering, Oakland University

12:15 pm Session Break

12:25 Luncheon Presentation: Accelerating Genomics Research using an Integrated High Performance Computing Solution

Yinhe Cheng, Ph.D., Senior Technical Consultant, IBM Life Sciences, Next Generation Sequencing, Software Defined Infrastructure, IBM

Sponsored by
IBM

Jane Yu, Ph.D., Team Lead, Translational Medicine, Software Defined Infrastructure, IBM

Advancements in genomics research pose challenges for IT leaders, researchers and developers to analyze, share and store large scale data. HPC best practices are required to process data efficiently, including workload management software to optimize the genomics pipeline. Infrequently used data must be archived but still be easily accessible. We will discuss your compute and data challenges, the latest architecture for a high performing genomics platform, and real-world strategies adopted by leading genomic research institutions.

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

BIG DATA AND COMPUTATIONAL DRUG REPOSITIONING: FROM DATA TO THERAPEUTICS

2:00 Chairperson's Remarks

2:10 Systematic Drug Repositioning: Analytics for Clinically Viable Novel Indications

Pankaj Agarwal, Ph.D., Director, Systematic Drug Repositioning, Computational Biology, GlaxoSmithKline

2:40pm Talk Title to be Announced

Devdatt Dubhashi, Ph.D., Professor, Department of Computer Science and Engineering, Chalmers University of Technology

3:10 Finding New Uses for Existing Drugs Using Public Drug Data Resources

Atul Butte, M.D., Ph.D., Division Chief and Associate Professor, Stanford University School of Medicine; Director, Center for Pediatric Bioinformatics, Lucile Packard Children's Hospital; Co-Founder, Personalis and NuMedii

Dr. Butte's lab at Stanford builds and applies tools that convert more than a trillion points of molecular, clinical, and epidemiological data into diagnostics, therapeutics, and new insights into disease. Dr. Butte, a bioinformatician and pediatric endocrinologist, will highlight his lab's work on using publicly-available molecular measurements to find new uses for drugs including drug repositioning and discovering new treatable inflammatory mechanisms of disease in Type 2 diabetes.

3:40 Breaking the Classical Barriers to Collaboration and Scientific Discovery - Distance and Data Size

Michelle Munson, President and Co-founder, Aspera, an IBM company

Life sciences organizations need to dramatically reduce analytics time and speed up clinical interventions, but most still rely on shipping physical disks due to inherent problems with existing networks and transfer protocol inefficiencies.

Sponsored by
aspera
an IBM® company

Spending days to transport data is not a viable option, this session will explore technology infrastructure for file transfer that will catalyze the transition from 1GbE to 10GbE and beyond.

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (see website for details)

6:00 Close of Day

WEDNESDAY, FEBRUARY 18

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

» **8:00 PLENARY SESSION PANEL** (see page 5 for details)

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

MOVING BIG DATA, SCALABLE ANALYSIS

10:35 Chairperson's Remarks

Martin Gollery, CEO, Tahoe Informatics

10:45 Using Amazon Web Services for Large Scale Genomics Analysis

Angel Pizarro, Senior Solutions Architect, Amazon Web Services

In this presentation, we will discuss how customers are utilizing a variety of AWS services to create scalable performance and cost effective solutions for genomics and health big-data workflows. Come learn from technical experts demonstrating best practices for combining S3, Glacier, EC2, EMR, RDS, and RedShift to produce a robust platform for genomics.

11:15 Designing New Algorithms for Emerging Data-Intensive Computing Architectures to Improve the Speed and Accuracy of Shotgun Metagenomic Analysis

Jonathan Allen, Ph.D., Bioinformatics Scientist, Global Security Computing Applications, Lawrence Livermore National Laboratory

Results from analyzing the complete collection of 1000 human genomes data and the complete collection of human microbiome project data using a new data-intensive compute cluster will be used to show how new large memory computing architectures are used for more accurate

BIOINFORMATICS
FOR BIG DATA

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

BIOINFORMATICS FOR BIG DATA

continued

taxonomic analysis of metagenomic samples that scale with increasing sequencer use.

11:45 File Transfer Capabilities with Globus Online
Ian Foster, Ph.D., Director, Computation Institute, Argonne National Lab

12:15 pm Session Break

12:25 Luncheon Presentation (Opportunity Available)

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

TRANSLATING DATA TO PATIENT CARE

1:40 Chairperson's Remarks

Ajay Shah, Ph.D., MBA, PMP, Director, Research Informatics & Systems, City of Hope National Medical Center

1:50 Finding Cohorts for Clinical Trials – An Integrated Informatics Approach

Ajay Shah, Ph.D., MBA, PMP, Director, Research Informatics & Systems, City of Hope National Medical Center

Integrating discovery, clinical and translational research informatics systems and data can help solve one of the key challenges in clinical trials – finding cohorts for clinical trials. SPIRIT – Software Platform for Integrated Research Information and Transformation is utilized to encode computable eligibility criteria, identify cohorts from EMR system via i2b2 and perform cohort analytics and visualization.

2:20 Building the High Performance Genomics Big Data Platform to Support Drug Discovery & Translational Medicine

Monica Wang, Ph.D., Lead Software Engineer, Project and Program Manager, Research Systems, Takeda

With the great advance of sequencing technology, vast amounts of genomics data is being generated every day. The ultimate challenge will be to best utilize the data and extract knowledge out of it to advance science and medicine. We will share our experience building the enterprise Genomics Big Data Platform with a focus on high performance to support our internal research effort for drug discovery and translational medicine.

2:50 Hackathons: Feed Innovation, Creativity, and Promote Thinking Outside of the Box

Kristen Cleveland, PMP, Senior IT Project Manager, R&D IT, Biogen Idec

Explore what a Hackathon is, how to plan it, and how to get the best out of the event for your organization.

3:20 Drug Repositioning in the Era of Precision Medicine

Chris Willis, Ph.D., Manager, Discovery Solution Scientists, IP & Science, Thomson Reuters

Craig Webb, Ph.D., CSO, NuMedii, Inc.

3:50 Refreshment Break

4:00 Chairperson's Remarks

Chris Willis, Ph.D., Manager, Discovery Solution Scientists, IP & Science, Thomson Reuters

» 4:10 KEYNOTE PRESENTATION: GLOBAL EXCHANGE OF HUMAN GENETIC DATA FOR MEDICINE AND RESEARCH

David Haussler, Ph.D., Distinguished Professor and Scientific Director, UC Santa Cruz Genomics Institute, University of California Santa Cruz

Every human disease is a rare disease at the molecular level. No single institute has enough patients to understand any particular molecular subtype. For genomics to benefit medicine and science, we must share data. This presentation outlines the data standards and Application Programming Interfaces developed by the Global Alliance for Genomics and Health that are intended to address this issue, and highlight a few global genomics projects that use them.

4:40 Data Linking and Warehousing to Support Evaluation of Pathogenicity of Genes and Genetic Variants by the Clinical Genome Resource Project

Xin Feng, Ph.D., Assistant Professor, Bioinformatics Research Lab and Department of Molecular and Human Genetics, Baylor College of Medicine

The Clinical Genome Resource (ClinGen) is an NIH-funded program dedicated to creating a database of clinically relevant genomic variants to inform genome interpretation in a variety of clinical contexts. A core component of ClinGen is ClinGenDB, an integration point for data about variants that supports their computational and manual evaluation by experts. In this presentation, we compare the two approaches by going through a number of use cases of data integration in ClinGenDB for the purpose of evaluating pathogenicity of genetic variants.

5:10 XPRIZE: Transforming Science Fiction into Science Reality through Incentivized Competition

Grant Campamy, Senior Director, XPRIZE

Imagine a portable, wireless device in the palm of your hand that monitors and diagnoses your health conditions. That's the technology envisioned by the \$10 million Qualcomm Tricorder XPRIZE competition, and it will allow unprecedented access to personal health metrics. The end result: Radical innovation in healthcare that will give individuals far greater choices in when, where, and how they receive care.

5:40 Close of Conference Program

CLICK HERE TO REGISTER ONLINE!

TriConference.com



INTEGRATED PHARMA INFORMATICS & DATA SCIENCE

From R&D to Real World Data

MONDAY, FEBRUARY 16

10:30 am Conference Program Registration

INTEGRATION, ANALYSIS AND VISUALIZATION OF PHARMA R&D DATA

11:50 Chairperson's Opening Remarks

Michael H. Elliott, CEO, Atrium Research & Consulting LLC

12:00 pm Using Informatics to Enable Precision Medicine in Oncology

Susie Stephens, Senior Director, Oncology & West Coast IT, Pfizer
Successfully enabling precision medicine for oncology requires a robust strategy for working with data, implementing analysis pipelines, and sharing results of analyses with scientists. This presentation highlights capabilities that have been enabled in these areas through a close collaboration between Oncology Research and Research IT.

12:30 Pharmacophore Informatics - Integrate, Analyze, and Visualize Pharma Research Data

Andreas Friese, Head, Research-IT, Bayer HealthCare R&D-IT, Bayer HealthCare AG

Pharmacophore Informatics (Plx) is an IT solution for Bayer HealthCare's Research Organization. The system uses "the power of data" to help the scientists to find the best drug candidates. Pharma research data is integrated, analyzed, and visualized - all in one system for easy usage by the scientist.

1:00 Session Break

1:15 Luncheon Presentation I: Bioinformatic and Information Solutions to Unlock the Power of Omics Data in Precision Medicine

Gavin Coney, Senior Director, Services Strategy, Intellectual Property & Science, Thomson Reuters

As volumes of Omics data and the number of applications in research and clinical care rapidly grows, organisations are faced with the problem of extracting relevant insights from that data to understand disease, identify drug targets and interpret patient genomic profiles. This presentation will talk about Thomson Reuters solutions to manage omics data and extract the relevant insights from this complex data through manual curation of information and sophisticated bioinformatics.

1:45 Luncheon Presentation II: Integrating Data is the Key to Translational Research and the Future of Personalized Medicine

Sponsored by
 THOMSON REUTERS

Sponsored by
 PerkinElmer
For the Better

Daniel Weaver, Ph.D., Senior Product Manager, Translational Medicine Informatics, PerkinElmer, Inc.

Emerging technologies are driving Translational Medicine research and PerkinElmer is developing tools, platforms, and algorithms to generate, analyze, visualize and store those data. This talk will describe how we integrate high-content data with clinical observations to enable our customers to derive and test unique hypotheses.

2:15 Session Break

INFORMATICS IN SUPPORT OF COLLABORATION AND EXTERNALIZATION

2:30 Chairperson's Remarks

Arturo J. Morales, Ph.D., Vice President, Informatics, Beryllium Corp.

2:40 Creating Public & Private Collaborations & Partnerships with Academic, Governmental and Industrial Partners around the Globe to Enable New Innovations to Take Patient Care "Beyond the Pill"

Robert J. Boland, Senior Manager, External Innovation R&D IT, Janssen, Pharmaceutical Companies of Johnson & Johnson

An overview of how translational research can improve the overall results within R&D and the technology architecture provides a new method for working collaboratively across partners. I will discuss how collaborative research can be obtained and remain secure to meet all regulations and show a visual of what a translational research environment would look like and examples of the types of research that can be developed in this type of environment.

3:10 Enabling Discovery Research through Partnerships, Collaboration Tools and Shared Transparency

Arturo J. Morales, Ph.D., Vice President, Informatics, Beryllium Corp.

In the age of externalization and research collaborations, informatics systems play a crucial role and must evolve. Although the exchange of files through portals and email keeps the process going, we must improve the transparency and data flow between systems to lower the physical barriers that we put in place.

3:40 Examining the Landscape of Solutions for Virtualized Research Ecosystems

Michael H. Elliott, CEO, Atrium Research & Consulting LLC

Spending on Virtualized Research Ecosystems

is growing over 20%, creating new data integration and information management challenges. Until recently, point solutions such as provisioning an internal system were the norm. However, this is inadequate for a multi-partner ecosystem. This talk examines trends, tools, and the impact of the cloud.

4:10 Delivering Excellence in R&D Informatics

John Conway, Global Director, R&D Strategy and Solutions, LabAnswer, LLC

Sponsored by
 CERTARA

4:40 Break and Transition to Plenary Session

» 5:00 PLENARY SESSION (see page 5 for details)

6:00 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Day

TUESDAY, FEBRUARY 17

7:00 am Registration and Morning Coffee

» 8:00 PLENARY SESSION (see page 5 for details)

9:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by
SLONEPARTNERS

ASSEMBLY, CREATION AND IMPLEMENTATION OF DATA SCIENCE GROUPS FOR PHARMA

10:05 Chairperson's Remarks

Martin Leach, Ph.D., Vice President, R&D IT, Biogen Idec

10:15 Experience & Challenges of Creating and Implementing a Data Science Function

Juergen Hammer, Ph.D., MBA, Roche Pharmaceutical Research and Early Development; Center Head, Informatics/IT; Global Head, Data Science, Roche Innovation Center New York

The Data Scientist profession has been named "The Sexiest Job of the 21st Century" and is often considered an essential

INTEGRATED PHARMA INFORMATICS & DATA SCIENCE

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



continued

component of Big Data Analytics. However, the Data Scientist Function in Pharma and Biotech is far from being established. I will discuss the organizational positioning of our multi-capability Data Science teams, how we measure performance, and which cultural shifts are required to maximize the impact of Data Science on the drug pipeline.

10:45 Data Sciences at Biogen Idec

Martin Leach, Ph.D., Vice President, R&D IT, Biogen Idec Biogen Idec established an enterprise-wide Data Sciences capability in July of 2013 to enable innovative data-driven approaches at the intersection of science, medicine and economics. We will discuss lessons learned in organizational structure and governance towards this goal. We will also describe our efforts to build out an inventory of inter-related cross-domain data assets across the Company to permit data exploration and analysis.

11:15 Hiring and Growing a Data Science Team – A Broader Industry Perspective

Jake Klamka, Founder, Insight Data Science Fellows Program As the amount of data filling their servers has grown exponentially, Silicon Valley technology companies have aggressively scaled up their data science teams to extract value from this data. This talk will share lessons learned in selecting, hiring and growing a data science team based experience developing an elite data science fellowship program.

11:45 PANEL DISCUSSION: Assembly, Creation and Implementation of Data Science Groups for Pharma

Moderator: Martin Leach, Ph.D., Vice President, R&D IT, Biogen Idec Panelists: Susie Stephens, Senior Director, Oncology & West Coast IT, Pfizer Juergen Hammer, Ph.D., MBA, Roche Pharmaceutical Research and Early Development; Center Head, Informatics/IT; Global Head, Data Science, Roche Innovation Center New York Jake Klamka, Founder, Insight Data Science Fellows Program

12:15 pm Session Break

12:25 Luncheon Presentation I: Text Mining to Support Cancer Immunology Research

Maria Shkrob, Ph.D., Senior Bioinformatics Scientist, Biology Products Research, ELSEVIER

Sponsored by



12:55 Luncheon Presentation II (Opportunity Available)

1:25 Refreshment Break in the Exhibit Hall with Poster Viewing

FROM REAL WORLD DATA TO CLINICAL DATA

2:00 Chairperson's Remarks

Barry Bunin, Ph.D., CEO, Collaborative Drug Discovery (CDD), Inc.

2:10 Enabling Secure Real World Data Exchange and Collaborative Analytics across Healthcare Organizations

Patrick Loerch, Director, Health IT, Information Technology, Merck & Co.

Healthcare reform, the decline in the price of genome sequencing and growing pressures from government and payers to demonstrate the effectiveness of novel therapies are creating a new market centered on access to real world data. We have developed, proven out and executed on a novel approach to enabling the secure sharing and collaborative analysis of real world data across healthcare organizations.

2:40 Modern Drug Research Informatics Applications to CNS, Infectious, Neglected, Rare, and Commercial Diseases

Barry Bunin, Ph.D., CEO, Collaborative Drug Discovery (CDD), Inc.

Layering unique collaborative capabilities upon requisite drug discovery database functionality unlocks and amplifies synergy between biologists and chemists. The application of collaborative technologies to interrogate potency, selectively, and therapeutic windows of small molecule structure activity relationship data will be presented in half a dozen case studies. Novel collaborative technologies in the CDD Vault platform provide an ever-increasing competitive advantage for forward-leaning, open-minded collaborators.

Sponsored by CDD VAULT

3:10 The New FDA Janus Clinical Trial Repository: Data Harmonization Architecture for Accelerated Regulatory Review

Kelly McVearry, Ph.D., Chief Scientist, Ekagra Technologies in collaboration with FDA

FDA Janus Clinical Trials Repository (CTR) system, a standards-based clinical data repository for all future regulatory submissions and FDA medical reviewer analysis, is based on the Biomedical Research Integrated Domain Group model (BRIDG) and is designed to support industry standards and international initiatives for data interoperability.

3:40 ScienceCloud: Collaborative Workflows in Biologics Research and Development

Ton van Daelen, Ph.D., ScienceCloud Product Director, BIOVIA Matt Hahn, Ph.D., CTO, BIOVIA

Sponsored by



The life sciences industry has undergone dramatic changes and effective global collaboration has become a key success factor in this new age. BIOVIA is providing a hosted and comprehensive solution stack for externalized, collaborative research for

pharma/biotech and CROs to address these new challenges. Recently we added support for biologics data management and IP capture. In this talk we will present collaborative and comprehensive capabilities in antibody characterization and development.

3:55 Increasing the Speed and Efficiency of Biomarker Information Analysis and Planning

Sponsored by AMPLION

Adam Carroll, Ph.D., CSO, Amplion Inc.

Information overload is a persistent problem for professionals interested in molecular biomarkers and is exacerbated by "single-use information culture" within organizations. Please join us to hear how Amplion Inc. is solving these problems with BiomarkerBase and biomarker planning products in development.

4:10 Mardi Gras Celebration in the Exhibit Hall with Poster Viewing



5:00 Breakout Discussions in the Exhibit Hall (see website for details)

6:00 Close of Day

WEDNESDAY, FEBRUARY 18

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

8:00 PLENARY SESSION PANEL (see page 5 for details)

9:45 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

THE CHALLENGES OF DATA INTEGRATION IN BIOMEDICINE & DRUG DISCOVERY

10:35 Chairperson's Remarks

Mark Schreiber, Ph.D., Director, Information Architecture, Merck Research Laboratories

10:45 Creating a Truly Innovative Holistic System that Captures and Channels Insights out to the Right People

Sebastien Lefebvre, Director, R&D IT Platform, Biogen Idec Combination of technologies to harness data, with 21st Century social media concepts to channel the information to the right people. Gain insight into the recent launches of

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

INTEGRATED PHARMA INFORMATICS & DATA SCIENCE

continued

master data management, an information sharing portal and next generation search techniques.

11:15 Combining Machine & Human Intelligence to Successfully Integrate Biomedical Data

Timothy Danford, CDISC Solution Lead, Tamr

Integrating data sources in order to support unified analysis and insight is made difficult by the huge volume of data to be analyzed, the velocity with which the data is produced, and the wide array of formats and data types in which the data is recorded and stored. To address these challenges, Tamr has been working with researchers from MIT and many leading healthcare companies to develop a hybrid solution which combines both machine learning and human guidance to significantly reduce the time and effort required for data curation, while achieving the level of precision that data scientists expect. The results of these approaches, both social and technical, will be discussed.

11:45 A Global Approach to Genomic Data Using the UCSC Genome Browser

Robert M. Kuhn, Ph.D., Associate Director, Genome Browser, Center for Biomolecular Science & Engineering, University of California Santa Cruz

The UCSC Genome Browser is a public resource that operates under a clearinghouse paradigm, pulling in as many useful databases as possible and allowing a researcher to visualize data from any or all of them at once, along with private data, in a consistent display framework.

12:15 pm Session Break

12:25 LiveDesign - Schrödinger's Next Generation Platform for Collaborative Drug Design

Mark Brewer, Research Leader, Drug Discovery Applications Group, Schrödinger

Medicinal chemists can benefit enormously when collaborating with their computational team members but, in practice, the collaborative process can be challenging and time-consuming. LiveDesign addresses these challenges head-on by providing a platform for enabling real-time collaboration and design by all members of a drug discovery team. In this presentation, we discuss the LiveDesign platform and how it is integrated into existing pharma workflows and infrastructure in order to accelerate small-molecule design processes.

1:00 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

TRANSLATING DATA TO PATIENT CARE

1:40 Chairperson's Remarks

Ajay Shah, Ph.D., MBA, PMP, Director, Research Informatics &

Systems, City of Hope National Medical Center

1:50 Finding Cohorts for Clinical Trials – An Integrated Informatics Approach

Ajay Shah, Ph.D., MBA, PMP, Director, Research Informatics & Systems, City of Hope National Medical Center

Integrating discovery, clinical and translational research informatics systems and data can help solve one of the key challenges in clinical trials – finding cohorts for clinical trials. SPIRIT – Software Platform for Integrated Research Information and Transformation is utilized to encode computable eligibility criteria, identify cohorts from EMR system via i2b2 and perform cohort analytics and visualization.

2:20 Building the High Performance Genomics Big Data Platform to Support Drug Discovery & Translational Medicine

Monica Wang, Ph.D., Lead Software Engineer, Project and Program Manager, Research Systems, Takeda

With the great advance of sequencing technology, vast amounts of genomics data is being generated every day. The ultimate challenge will be to best utilize the data and extract knowledge out of it to advance science and medicine. We will share our experience building the enterprise Genomics Big Data Platform with a focus on high performance to support our internal research effort for drug discovery and translational medicine.

2:50 Hackathons: Feed Innovation, Creativity, and Promote Thinking Outside of the Box

Kristen Cleveland, PMP, Senior IT Project Manager, R&D IT, Biogen Idec

Explore what a Hackathon is, how to plan it, and how to get the best out of the event for your organization.

3:20 Drug Repositioning in the Era of Precision Medicine

Chris Willis, Ph.D., Manager, Discovery Solution Scientists, IP & Science, Thomson Reuters

Craig Webb, Ph.D., CSO, NuMedii, Inc.

3:50 Refreshment Break

4:00 Chairperson's Remarks

Chris Willis, Ph.D., Manager, Discovery Solution Scientists, IP & Science, Thomson Reuters

4:10 KEYNOTE PRESENTATION: GLOBAL EXCHANGE OF HUMAN GENETIC DATA FOR MEDICINE AND RESEARCH

David Haussler, Ph.D., Distinguished Professor and Scientific Director, UC Santa Cruz Genomics Institute, University of California Santa Cruz

Every human disease is a rare disease at the molecular level. No single institute has enough patients to understand any particular molecular subtype. For genomics to benefit medicine and science, we must share data. This presentation outlines the data standards and Application Programming Interfaces developed by the Global Alliance for Genomics and Health that are intended to address this issue, and highlight a few global genomics projects that use them.

4:40 Data Linking and Warehousing to Support Evaluation of Pathogenicity of Genes and Genetic Variants by the Clinical Genome Resource Project

Xin Feng, Ph.D., Assistant Professor, Bioinformatics Research Lab and Department of Molecular and Human Genetics, Baylor College of Medicine

The Clinical Genome Resource (ClinGen) is an NIH-funded program dedicated to creating a database of clinically relevant genomic variants to inform genome interpretation in a variety of clinical contexts. A core component of ClinGen is ClinGenDB, an integration point for data about variants that supports their computational and manual evaluation by experts. In this presentation, we compare the two approaches by going through a number of use cases of data integration in ClinGenDB for the purpose of evaluating pathogenicity of genetic variants.

5:10 XPRIZE: Transforming Science Fiction into Science Reality through Incentivized Competition

Grant Campamy, Senior Director, XPRIZE

Imagine a portable, wireless device in the palm of your hand that monitors and diagnoses your health conditions. That's the technology envisioned by the \$10 million Qualcomm Tricorder XPRIZE competition, and it will allow unprecedented access to personal health metrics. The end result: Radical innovation in healthcare that will give individuals far greater choices in when, where, and how they receive care.

5:40 Close of Conference Program

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENTATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



SYMPOSIA

- New Frontiers in Gene Editing - **NEW**
- Circulating Cell-Free DNA
- Genomics in Medicine
- Point-of-Care Diagnostics
- Clinical Cancer Immunotherapy - **NEW**
- Genomics & Sequencing Data Integration, Analysis and Visualization

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



Cambridge Healthtech Institute
250 First Avenue, Suite 300
Needham, MA 02494
www.healthtech.com

Cambridge Healthtech Institute's Inaugural

NEW FRONTIERS IN GENE EDITING

Transitioning From the Lab to the Clinic

THURSDAY, FEBRUARY 19
7:30 am Registration and Morning Coffee
USING GENE EDITING FOR FUNCTIONAL SCREENS
9:00 Chairperson's Opening Remarks

Joseph C. Wu, M.D., Ph.D., Director, Stanford Cardiovascular Institute and Professor, Department of Medicine/Cardiology & Radiology, Stanford University School of Medicine

» 9:10 KEYNOTE PRESENTATION:
Genome Edited Induced Pluripotent Stem Cells (iPSCs) for Drug Screening

Joseph C. Wu, M.D., Ph.D., Director, Stanford Cardiovascular Institute and Professor, Department of Medicine/Cardiology & Radiology, Stanford University School of Medicine

Dr. Wu's lab is focusing on human iPSCs for cardiac disease modeling, drug discovery, and regenerative medicine. We have been using ZFN, TALEN, and CRISPR to create isogenic iPSC lines that carry various cardiovascular diseases (e.g., LQT, HCM, DCM) as well as reporter genes for *in vitro* and *in vivo* tracking. We are also using this approach for improving the efficiency of high throughput drug screening.

9:40 Exploration of Cellular Stress and Trafficking Pathways Using shRNA and CRISPR/Cas9-Based Systems

Michael Bassik, Ph.D., Assistant Professor, Department of Genetics, Stanford University

We have developed high-complexity shRNA libraries (25 shRNAs/gene) that greatly reduce false negatives/false positives for RNAi screens, and have adapted these libraries to knock down gene pairs to perform systematic genetic interaction maps in mammalian cells. We have used these maps to study ER-trafficking toxins, identify novel protein complexes, and gain insights into retrograde trafficking. We are using this strategy together with the CRISPR/Cas9 system for functional genomics efforts and identification of novel drug targets.

10:10 Gene Editing in Patient-Derived Stem Cells for *in vitro* Modeling of Parkinson's Disease

Birgitt Schuele, M.D., Associate Professor and Director of Gene Discovery and Stem Cell Modeling, The Parkinson's Institute

Recent development of "genome editing" technologies to introduce site-specific genome modifications in disease relevant genes lay the foundation for new approaches to understand direct genotype-phenotype correlations at the molecular level in human disease. With the introduction of next-generation sequencing, many new genetic variants have

been identified in Parkinson's related genes; however, it is currently challenging to interrogate their functional relevance. Human-derived genome edited cell lines will be a way to analyze variants in a high-throughput format.

10:40 Coffee Break with Exhibit and Poster Viewing
INNOVATIVE TOOLS FOR SCREENING & DELIVERY
11:15 Massively Parallel Combinatorial Genetics to Overcome Drug Resistance in Bacterial Infections and Cancer

Timothy K. Lu, M.D., Ph.D., Associate Professor, Synthetic Biology Group, Department of Electrical Engineering and Computer Science and Department of Biological Engineering, Synthetic Biology Center, Massachusetts Institute of Technology

Complex biological phenotypes can result from the interplay of multiple genetic factors but deciphering the multifactorial genotypes that underlie these phenotypes is challenging. We have developed technologies for the scalable and barcoded assembly of high-order combinatorial genetic libraries. These strategies enable multiplexed tracking of individual genetic combinations with next-generation sequencing in pooled screens. We have used these technologies to perform massively parallel combinatorial genetics in bacteria and human cells and to modulate relevant phenotype.

11:45 Nucleic Acid Delivery Systems for RNA Therapy and Gene Editing

Daniel G. Anderson, Ph.D., Professor, Department of Chemical Engineering, Institute for Medical Engineering & Science, Harvard-MIT Division of Health Sciences & Technology and David H. Koch Institute for Integrative Cancer Research, Massachusetts Institute of Technology

High throughput, combinatorial approaches have revolutionized small molecule drug discovery. Here we describe our work on high throughput methods for developing and characterizing RNA delivery and gene editing systems. Libraries of degradable polymers and lipid-like materials have been synthesized, formulated and screened for their ability to deliver RNA, both *in vitro* and *in vivo*. A number of delivery formulations have been developed with *in vivo* efficacy, and show potential therapeutic application for the treatment of genetic disease, viral infection, and cancer.

12:15 pm Advanced Breeding in Plants Using Precision Genome Editing

Greg Gocal, Senior Vice President, Research and Development, Cibus

Precision editing of crop genomes is a central tool in advancing agricultural biotechnology. Cibus, founded in 2001, leads this space with its technology platform called RTDS™. Combining nucleases with GRONs yields rapid and precise spelling changes in native genes.

12:30 Session Break
12:40 Luncheon Presentation: Loss-of-Function Genetic Screening with shRNA and CRISPR Libraries

Paul Diehl, Ph.D., Director, Business Development, Collecta, Inc.

Genome-wide loss-of-function screens provide a direct approach to identify the genes regulating biological responses and find new therapeutic targets. While RNAi screens have proven an effective tool, CRISPR/Cas9 provides an alternative approach. To complement our established shRNA screening platform, we have developed pooled format genome-wide modular sgRNA libraries for cost-effective CRISPR knockout screens. Pooled sgRNA and shRNA libraries were used to identify lethal interactions in isogenic PDX-derived cell line pairs. 1:15 Session Break

TRANSLATING GENE EDITING IN VIVO
1:50 Chairperson's Remarks

Eric N. Olson, Ph.D., Professor and Chairman, Department of Molecular Biology, The University of Texas Southwestern Medical Center

**NEW FRONTIERS IN
GENE EDITING**

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

NEW FRONTIERS IN GENE EDITING

*continued***» 2:00 KEYNOTE PRESENTATION:
Preventing Muscle Disease by Genomic Editing**

Eric N. Olson, Ph.D., Professor and Chairman, Department of Molecular Biology, The University of Texas Southwestern Medical Center

Duchenne muscular dystrophy (DMD) is a fatal muscle disease caused by mutations in the gene encoding dystrophin, a protein required for muscle fiber integrity. We used CRISPR/Cas9-mediated genome editing to correct the dystrophin gene (Dmd) mutation in the germline of mdx mice, a model for DMD. The degree of muscle phenotypic rescue in mosaic mice exceeded the efficiency of gene correction, likely reflecting the progressive contribution of corrected cells to regenerating muscle. Progress toward the correction of DMD in adult myofibers will be discussed.

2:30 CRISPR-Cas: Tools and Applications for Genome Editing

Fei Ann Ran, Ph.D., Post-Doctoral Fellow, Laboratory of Dr. Feng Zhang, Broad Institute and Junior Fellow, Harvard Society of Fellows

Recently, the Cas9 nuclease from the bacterial CRISPR (clustered regularly interspaced short palindromic repeats) adaptive immune system has been adapted for targeted genome editing in a number of plant and animal species. Cas9 can be programmed by short guide RNAs to induce multiplexed gene knockout or homology-directed repair with robust efficiency. We have further identified additional small Cas9 orthologs that can be delivered by adeno-associated virus for effective gene modification of somatic tissues *in vivo*.

3:00 Refreshment Break with Exhibit and Poster Viewing**3:30 Anti-HIV Therapies: Genome Engineering the Virus and the Host**

Paula M. Cannon Ph.D., Associate Professor, Molecular Microbiology & Immunology, Biochemistry, and Pediatrics, Keck School of Medicine, University of Southern California

By taking advantage of cellular repair pathways, targeted nucleases such as, zinc finger nucleases (ZFNs) can be used to achieve precise gene knockout, gene editing, or gene addition. For anti-HIV applications, nucleases can disrupt the CCR5 co-receptor gene, be used to insert anti-HIV genes at a designated site, or inactivate the viral genome that persists in infected cells. We use humanized mouse models to help us evaluate the translational potential of these different applications of targeted nuclease technologies.

4:00 Nuclease-Based Gene Correction for Treating Single Gene Disorders

Gang Bao, Ph.D., Robert A. Milton Chair Professor in Biomedical Engineering, Department of Biomedical Engineering, Georgia Institute of Technology and Emory University

We have developed a clinically applicable gene correction technology to treat sickle cell disease (SCD), which is caused by a single (A-T) mutation in the beta-globin gene. To treat SCD, we constructed TALENs and CRISPR/Cas9 systems that specifically target beta-globin gene and systematically evaluated their on- and off-target cleavage in different cells. We also quantified the nuclease-induced gene modification rates due to homologous recombination and non-homologous end joining. These studies significantly facilitated our pre-clinical investigation using mouse models.

4:30 Genome Editing for Genetic Diseases of the Blood

Matthew Porteus, M.D., Ph.D., Associate Professor, Pediatrics, Stanford University School of Medicine

A potentially ideal approach to the curative treatment of genetic blood diseases is to directly modify the hematopoietic stem cell in a precise fashion using genome editing. With the development of multiple different nuclease platforms, including zinc finger nucleases, TAL effector nucleases, and RNA-guided endonucleases of the CRISPR/Cas9 family this can now be approached in a variety of different ways. We have focused on using this strategy for a number of different diseases and in this presentation will focus on our progress for severe combined immunodeficiency.

5:00 Close of Day**FRIDAY, FEBRUARY 20****8:00 am Morning Coffee****EXPLORING GENE EDITING FOR THERAPEUTIC USES****8:25 Chairperson's Remarks**

Charles A. Gersbach, Ph.D., Assistant Professor, Department of Biomedical Engineering, Center for Genomic and Computational Biology, Duke University

8:30 Genome Engineering Tools for Gene Therapy and Regenerative Medicine

Charles A. Gersbach, Ph.D., Assistant Professor, Department of Biomedical Engineering, Center for Genomic and Computational Biology, Duke University

Genome engineering tools, including zinc finger proteins, TALEs, and the CRISPR/Cas9 system, can be used to both edit gene sequences and control the expression of endogenous genes for applications in medicine and basic science. For example, we have used each of these tools for gene editing to restore the expression of the dystrophin protein that is mutated in cells from Duchenne muscular dystrophy patients. In other studies, we have developed gene regulation tools that can be applied to cell reprogramming for disease modeling and regenerative medicine.

9:00 Preventing Transmission of Mitochondrial Diseases by Germline Heteroplasmic Shift Using Transcription Activator-like Effector Nucleases (TALENs)

Juan Carlos Izpisua Belmonte, Ph.D., Roger Guillemin Chair Professor, Gene Expression Laboratory, The Salk Institute for Biological Studies

Mitochondrial diseases include a group of maternally inherited genetic disorders caused by mutations in the mitochondrial DNA (mtDNA). In most of these patients, mutant mtDNA coexists with wild type mtDNA, a situation known as mtDNA heteroplasmy. Pre-implantation genetic diagnosis can only help to reduce, but not fully prevent, the transmission of mitochondrial diseases. We will report a novel strategy towards preventing germline transmission of mitochondrial diseases by induction of mtDNA heteroplasmy shift.

**» 9:30 KEYNOTE PRESENTATION:
Precise Single-base Genome Engineering for Human Diagnostics and Therapy**

Bruce R. Conklin M.D., Investigator, Roddenberry Center for Stem Cell Biology and Medicine, Gladstone Institutes and Professor, Division of Genomic Medicine University of California, San Francisco

Dr. Conklin's research focuses using genome engineering to find therapies for life threatening human genetic diseases. Current projects use human induced pluripotent stem cells (iPSCs) to model cardiac, hepatic and neurological diseases. The Conklin lab has recently developed a method that significantly increases the ability to perform scarless single-base genome editing to induce or revert disease mutations. These studies allow the construction of robust *in vitro* human disease models, and also provide a path to cell therapy with gene corrected cells.

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

NEW FRONTIERS IN GENE EDITING

*continued***10:00 CRISPR Goes Viral***Shawn Shafer, Ph.D., Sigma-Aldrich**Sponsored by***SIGMA-ALDRICH**

While other genome editing reagents exist, the CRISPR system has significant advantages in terms of cost, design, and construction. Most recently, the CRISPR system has been ported into lentiviral particles, allowing researchers to realize the previously unattainable goal of high throughput whole genome knockout screens. Completed screens and their significance will be discussed in this talk, as will the future of this promising new technology and its potential applications.

10:30 Coffee Break with Exhibit and Poster Viewing**THERAPEUTIC LANDSCAPE:
OPPORTUNITIES & CONCERNS****11:00 Gene Editing on the Cusp of Exciting
Opportunities for Human Therapeutics***Rodger Novak, M.D., CEO, CRISPR Therapeutics*

Within less than two years after its inception the CRISPR-Cas system has truly democratized genome editing with many areas of research being transformed due to ease of use and broad applicability of the technology. With such an enormous impact on many areas of life science the translation of the CRISPR-Cas technology into human therapeutics seems to be a logical consequence. However, besides many exciting opportunities a number of challenges will have to be addressed; some of them more obvious than others.

**11:30 Advancing the CRISPR/Cas9 Technology
Platform for Therapeutic Applications***Alexandra Glucksmann., Ph.D., COO, Editas Medicine*

Genome editing technologies, including the CRISPR/Cas9 system, allow for precise and corrective molecular modifications to treat the underlying cause of genetic diseases. Key to the successful translation of CRISPR/Cas9 systems to the clinic is the optimization of the technology within the context of specific therapeutic applications. This presentation will focus on Editas Medicine's approach to improving both activity and specificity of CRISPR/Cas9-mediated gene editing in parallel with the development of delivery solutions for therapeutic applications.

**12:00 pm Small Molecules Modulating
CRISPR Editing***Sheng Ding, Ph.D., William K. Bowes, Jr. Distinguished Investigator, Gladstone Institute of Cardiovascular Disease, and Professor, Department of Pharmaceutical Chemistry, University of California San Francisco*

CRISPR-Cas9 system has emerged as an effective tool for genome editing, but challenges remain. To enhance CRISPR-mediated gene editing, we screened chemical libraries and had identified distinct small molecules that can enhance either HDR-based gene knock-in or NHEJ-based knock-out. The use of small molecules provides a simple and effective strategy that enhances precise genome engineering applications and facilitates the study of DNA repair mechanisms in mammalian cells.

12:30 Close of Symposium**CLICK HERE TO
REGISTER ONLINE!**

TriConference.com



Cambridge Healthtech Institute
250 First Avenue, Suite 300
Needham, MA 02494
www.healthtech.com

CIRCULATING CELL-FREE DNA

Pushing the Limits of Early Detection

THURSDAY, FEBRUARY 19

7:30 am Registration and Morning Coffee

CTDNA DETECTION AND SURVEILLANCE

9:00 Chairperson's Opening Remarks

Dave Hoon, Ph.D., Director & Professor, Molecular Oncology, John Wayne Cancer Institute

**» 9:10 KEYNOTE PRESENTATION:
Detection of Circulating Tumor DNA in Early and Late Stage Human Malignancies**

Chetan Bettgowda, M.D., Ph.D., Assistant Professor, Neurosurgery & Oncology, Johns Hopkins University School of Medicine

Cancer cells shed cell free, tumor specific DNA (ctDNA) into various body fluids. These molecules of DNA harbor genetic alterations that can be harnessed for diagnostic purposes. Using next generation sequencing based approaches, we have been able to detect ctDNA in a large number of advanced and localized malignancies. This suggests that ctDNA has the potential to act as a personalized biomarker for individuals with cancer.

9:40 cfDNA Ultra-Rare Allele Detection and Discovery

Seth D. Crosby, M.D., Director, Partnerships, Genetics, Washington University

We are currently working on methods to both detect known mutations and discover new ones in cell-free plasma DNA.

10:10 Future Clinical and Research Applications of Circulating Tumor DNA

Luis A. Diaz, M.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

10:40 Coffee Break with Exhibit and Poster Viewing

CTDNA IN PATIENT MONITORING

11:15 Evaluation of EGFR Mutations in Plasma from NSCLC Patients: Utility in Managing Patients on TKI Therapy

Mitch Raponi, Ph.D., Senior Director, Molecular Diagnostics, Clovis Oncology

We are utilizing blood-based molecular testing to determine resistance mutation profiles in these patients with the goal of

enabling targeted subsequent therapy without need for repeat lung biopsy. The utility of plasma-based EGFR mutational analysis will be described in the context of CO-1686, a novel third-generation TKI that selectively inhibits the EGFR activating and T790M resistance mutations in NSCLC patients.

11:45 Serial Monitoring of EGFR Mutations in Plasma and Matched Tissue from EGFR Mutant Non-Small Cell Lung Cancer Patients on Erlotinib

Cloud P. Paweletz, Ph.D., Head, Translational Research Laboratory; Biomarker Lead, Belfer Institute for Applied Cancer Science, Dana Farber Cancer Institute

We report on the detection, quantification and monitoring of EGFR mutations by droplet digital PCR in cfDNA on a prospective clinical trial of EGFR-mutant NSCLC patients on erlotinib. Our results strongly suggest that cfDNA genotyping has clinical utility in the molecular assessment of patients at diagnosis, and providing molecular understanding of patient's tumor evolution.

12:15 pm Circulating Cell-Free Necrotic DNA as a Tool for Monitoring Treatment Response in Cancer Patients

Rajaram Krishnan, Ph.D., CEO, Bioengineering, Biological Dynamics, Inc.



12:30 Session Break

12:40 Luncheon Presentation: Detecting Circulating Tumor Cells by Fluid Biopsy and Profiling Somatic Tumors with Next-Gen DNA Sequencing

Darren Link, Ph.D., Co-founder and CTO, Research and Development, RainDance Technologies Inc.

Novel, non-invasive Fluid Biopsy™ research applications are transforming cancer research by enabling more accurate, reliable, and early detection of circulating tumor DNA in plasma. Hear how new Next-Gen DNA Sequencing technology is being deployed to rapidly detect and cost-effectively profile informative driver mutations and how ultra-sensitive Digital PCR technology is being applied to monitor minimal residual disease and for precise follow-up mutation validation, all from a simple blood test. 1:15 Session Break

CLINICAL EVALUATION OF CTDNA

1:50 Chairperson's Remarks

2:00 Tracking Changes in Circulating Tumor

DNA in Patients with Non-Small Cell Lung Cancer

Abhijit A. Patel, M.D., Ph.D., Assistant Professor, Department of Therapeutic Radiology, Yale University School of Medicine

An ultrasensitive, multi-target assay will be presented that can identify and quantify mutant ctDNA using error-suppressed next-generation sequencing. This assay is able to monitor treatment response and disease progression in patients with non-small cell lung cancer, without prior knowledge of the mutation profile of their tumor.

2:30 Clinical Evaluation of cfDNA and Exosomes as Oncology Biomarkers

Shidong Jia, Ph.D., Scientist, Genentech

The enumeration and characterization of circulating tumor cells (CTCs), exosomes and circulating tumor-free DNA (ctDNA) in the peripheral blood may provide important prognostic and diagnostic information and might help to monitor efficacy of therapy. Specific examples will be shown to demonstrate the opportunities and challenges for the development of blood-based clinical diagnostics.

3:00 Refreshment Break with Exhibit and Poster Viewing

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



Cambridge Healthtech Institute
250 First Avenue, Suite 300
Needham, MA 02494
www.healthtech.com

CIRCULATING CELL-FREE DNA

continued

3:30 Enhanced Detection of Low-Level DNA Mutations Using Multiplexed ICE COLD-PCR Coupled to NGS or ddPCR

Katherine Richardson, Ph.D., Vice President, Research & Development, Transgenomic, Inc.

The use of "liquid biopsies", where limited or no tumor tissue is available, is increasingly important for molecular demographics, diagnostics and pharmacodynamic monitoring of patients during therapy. The combination of MX-ICP with NGS and ddPCR platforms means that they can be used efficiently for detection of alterations at $\leq 0.01\%$ in samples with.

4:00 Clinical Utility of a Novel Approach of Digital Sequencing Assessment of Circulating Cell-Free DNA in Melanoma Patients

Dave Hoon, Ph.D., Director & Professor, Molecular Oncology, John Wayne Cancer Institute

4:30 Use of Non-Invasive Tumor Sequencing Assay on Patients with Advanced Cancers and its Clinical Utility

AmirAli Talasaz, Ph.D., President & CTO, Guardant Health, Inc.

5:00 Personalized Cancer Surveillance and Recurrence Detection in Gynecologic Malignancies

John A. Martignetti, M.D., Ph.D., Genetics and Genomic Sciences, Pediatrics, Obstetrics/Gynecology & Reproductive Sciences and Oncological Sciences, Icahn School of Medicine at Mount Sinai

The majority of patients with ovarian cancer who demonstrate a "complete clinical response" by current surveillance methods actually harbor residual disease and almost all will die from their disease. Using ddPCR, we have developed a pipeline for generating highly sensitive and specific ctDNA biomarkers based upon WES and RNASeq of each patient's tumor as part of a personalized cancer program and have begun assessing clinical utility.

5:30 Close of Day

FRIDAY, FEBRUARY 20

8:00 am Morning Coffee

NEW APPLICATIONS IN CIRCULATING RNA

8:25 Chairperson's Remarks

Chris Karlovich, Ph.D., Principal Scientist, Molecular Diagnostics, Clovis Oncology

8:30 Challenges in Measuring Circulating Nucleic Acids

Kai Wang, Ph.D., Principal Scientist, Institute for Systems Biology
Circulating nucleic acids have gained significant interest due to their potential diagnostic applications. The development of NGS platforms provides an opportunity to access a comprehensive profile of circulating nucleic acids. Some circulating DNA species have already been used in clinic;

Sponsored by



however, there are a number of challenges to accurately measuring levels of specific cell free nucleic acids especially for low concentration RNA sequences. However there is a great potential to use the spectrum of circulating nucleic acids to reflect specific physiopathological conditions.

9:00 Isolation of Circulating MicroRNAs from Microvesicles Found in Human Plasma

Pamela B. Cassidy, Ph.D., Research Associate Professor, Dermatology, Oregon Health and Science University

The remarkable stability of circulating miRNAs makes them excellent candidates for biomarkers in diagnostics and therapeutics. We describe a convenient method for the use of ExoQuick, a proprietary resin developed by Systems Biosciences, whereby microvesicles can be purified under gentle conditions using readily available laboratory equipment. This protocol provides a convenient method for identifying potential disease-specific biomarkers in biological fluids including serum and plasma.

9:30 Detecting Hypomethylation and Point Mutations in Circulating Cell-Free DNA

Timothy Harkins, Executive Vice President, Development, Swift Biosciences

Deep sequencing using next generation sequencing (NGS) of circulating cell-free DNA (cfDNA) has shown that tumor specific mutations can be detected, providing an effective means to monitor disease, and treatment efficacy. We have developed a pair of NGS assays that are cost effective, sensitive, and specific to assess the global methylation status of cfDNA with as few as 10 million sequencing reads or detect 1000's of point mutations across oncogenes.

TECHNOLOGY TO CAPTURE AND CHARACTERIZE

10:00 Detection and Quantitative Monitoring of ctDNA Mutation Status in Cancer Patients

Vlada Melnikova, Ph.D., Vice President, Research & Development, Trovagene

An optimized isolation technique for cell-free DNA makes it possible to detect systemically derived cfDNA both in plasma and urine. Using a small footprint capture and enrichment technique, we demonstrate the analytical detection and quantification of these tumor fragments down to sensitivity of less than 0.01%, creating a non-invasive cancer mutation detection platform. Demonstrated correlation with tumor burden, drug response and disease progression supports clinical utility of precision cancer monitoring.

10:30 Coffee Break with Exhibit and Poster Viewing

11:00 Measuring Circulating Tumor DNA in Plasma By Picoliter Droplet-Based PCR For Colorectal Cancer Patient Follow-Up

Geraldine Perkins, GI Oncology, Georges Pompidou European Hospital; Assistance Publique Hopitaux de Paris, INSERM UMR-S1147, Paris Descartes University

Co-Authors: Garlan F, Didelot A., Perkins G., Rice N., Zaanan A.,

Laurent-Puig P and Taly V.

By combining microfluidic systems and clinical advances in molecular diagnostic, picoliter droplet-based digital PCR allows performing millions of single-molecule PCR in parallel to detect and quantify a minority of mutant sequences within a high quantity of non-mutated sequences with a sensitivity unreachable by conventional tools. Our presentation will illustrate the pertinence of this procedure for cancer research with a focus on its application for treatment efficiency follow-up and cancer recurrence by monitoring of circulating tumor DNA.

11:30 Next-Generation Sequencing of Methylated Free Circulating DNA to Develop a Blood-Based Biomarker for Ovarian Cancer

Kristina Warton, Ph.D., Senior Research Officer, Cancer, University of New South Wales and Kinghorn Cancer Centre, Garvan Institute

Free circulating DNA (fcDNA) studies often require analysis of clinical samples with limited or very low DNA concentrations. We have addressed the technical issues this raises by developing modified protocols for the purification of fcDNA from plasma, followed by MethylMiner MBD-2 capture of the methylated fraction and Next-Generation Sequencing. We present the data in the context of developing a blood-based methylation biomarker for ovarian cancer.

12:00 pm Rapid Isolation and Detection of Circulating Cell Free DNA/RNA Biomarkers for Cancer and Other Clinical Diagnostics

Michael J. Heller, Ph.D., Professor, Nanoengineering & Bioengineering, University of California San Diego

We have now demonstrated the rapid isolation and detection of circulating cell free DNA and RNA from a number of different hematological and solid tumor samples. Using AC dielectrophoretic (DEP) microarray devices, ccf-DNA/RNA can be isolated and detected by fluorescence within 10-15 minutes from small volumes (20ul-100ul) of patient blood, plasma and serum samples. Subsequent PCR and DNA sequencing analysis produces analytical results comparable to conventional sample preparation "gold-standard" procedures which require considerably more time, effort, cost, as well as larger sample volumes.

12:30 Close of Symposium

GENOMICS IN MEDICINE

Data-Driven Personalized Diagnostics for Improved Outcomes

THURSDAY, FEBRUARY 19
7:30 am Registration and Morning Coffee
IMPACT AND UTILITY OF CLINICAL GENOMICS
9:00 Chairperson's Opening Remarks
Robert Penny, M.D., Ph.D., CEO, Paradigm

» **9:10 KEYNOTE PRESENTATION:**
Update on the MedSeq and BabySeq Projects:
Randomized Trials of Sequencing in Adults and Newborns

Robert C. Green, M.D., MPH, Director, G2P Research Program; Associate Director, Research, Partners Center for Personalized Genetic Medicine, Division of Genetics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School

This talk will present new data from the NIH-funded MedSeq and BabySeq Projects, two of the first randomized trials of genome sequencing versus standard of care, currently being conducted in adults and newborns, respectively. These projects explore the impact of integrating genome sequencing with the practice of medicine in both sick and healthy individuals, measuring medical, behavioral and economic outcomes for patients; and exploring the experience of non-geneticist physicians confronting genomic data in their patients.

9:40 The Vision and the Reality: One Cancer Center's Journey toward Genomic Medicine

Jeff Boyd, Ph.D., Senior Vice President, Molecular Medicine; The Robert C. Young Chair in Cancer Research; Executive Director, Cancer Genome Institute; Chief, Division of Molecular Pathology; Professor, Cancer Biology Program, Fox Chase Cancer Center

10:10 The Impact of Genomic Variation in Clinical Development

Hakon Hakonarson, M.D., Ph.D., Director, Center for Applied Genomics, Children's Hospital of Philadelphia

This presentation will focus on genomic strategies applied in academia to enrich for genetic variants that may inform drug discovery and development for complex medical disorders affecting both children and adults.

10:40 Coffee Break with Exhibit and Poster Viewing
INTEGRATION OF GENOMICS DATA
11:15 Integration of Genomics into Medical Practice: Educational Challenges

Bruce R. Korf, M.D., Ph.D., Wayne H. and Sara Crews Finley Chair in Medical Genetics; Professor and Chair, Genetics; Director, Heflin Center for Genomic Sciences, University of Alabama at Birmingham

Genetics and genomics offers major opportunities to improve health and increase the power of diagnosis and treatment of disease across all areas of medicine. Most physicians in practice today were trained prior to the genomics era, and even students currently in training have limited exposure to this new area of medicine. Taking full advantage of the genetic and genomic approach will require changes in health professional education, including achieving basic competencies in genetics and genomics and having a specialty genetic and genomic workforce to provide assistance.

11:45 Navigating the Genome: Realizing the True Promise of Genomic Medicine in the Clinic

James Evans, M.D., Ph.D., Bryson Distinguished Professor, Genetics and Medicine, Genetics, University of North Carolina School of Medicine

Great advances have been made in our ability to analyze the genome. However, not all basic science advances yield clinical benefit. Where can our new revolutionary sequencing technologies actually benefit human health in the short term?

12:15 pm Paradigm Cancer Diagnostic (PCDx): Development of a Clinical-Grade Next-Generation Sequencing Test for Cancer Patients

Robert Penny, M.D., Ph.D., CEO, Paradigm

Paradigm is an emerging molecular information organization, delivering precision medicine to cancer patients. Incorporating learning's from TCGA and other diagnostic efforts, Paradigm has developed a clinical-grade test to interrogate key alterations in the cancer genome including mRNA, DNA mutations, fusions.

12:30 Session Break

12:40 Luncheon Presentation:
Enabling Translational Diagnostics through Discovery and Development of Signatures with Unified DNA and RNA NGS Panels

Brian Haynes, Ph.D., Senior Scientist, Asuragen

We present a comprehensive solution for NGS-based biomarker discovery and the translation of these markers to our targeted NGS assay, SuraSeq®, using poor quality and low-quantity (FFPE or FNA) tumor biopsies. SuraSeq® enables the simultaneous interrogation of DNA and RNA from total nucleic acid and provides detection and quantification of DNA mutations, expression markers, and RNA fusions to advance diagnostic, prognostic and therapeutic applications, clinical trial assays, and *in vitro* diagnostic products.

Sponsored by


1:15 Session Break
PRACTICAL CONSIDERATIONS FOR INTEGRATION OF GENOMICS DATA INTO MEDICAL PRACTICE
1:50 Chairperson's Remarks

James Evans, M.D., Ph.D., Bryson Distinguished Professor, Genetics and Medicine, Genetics, University of North Carolina School of Medicine

2:00 PANEL DISCUSSION: Practical Considerations for Integration of Genomic Data in Medical Practice

While NGS technologies continue to usher in a new era of genomic medicine, many practical considerations and issues have emerged. These include: the return of patient information; reimbursement of genomic tests; reporting results to physicians, and the sequencing and healthy newborns. This panel will provide an open format for stakeholders to address these issues, while shedding light on best practices.

Moderator: James Evans, M.D., Ph.D., Bryson Distinguished Professor, Genetics and Medicine, Genetics, University of North Carolina School of Medicine

Panelists:

*Bruce R. Korf, M.D., Ph.D., University of Alabama at Birmingham
 Robert C. Green, Brigham and Women's Hospital and Harvard Medical School*

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
 REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

GENOMICS IN MEDICINE

continued

Jeff Boyd, Ph.D., Senior Vice President, Molecular Medicine; The Robert C. Young Chair in Cancer Research; Executive Director, Cancer Genome Institute; Chief, Division of Molecular Pathology; Professor, Cancer Biology Program, Fox Chase Cancer Center Hakon Hakonarson, M.D., Ph.D., Director, Center for Applied Genomics, Children's Hospital of Philadelphia

IDENTIFICATION AND ANNOTATION OF VARIANTS

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Genomic Approaches to Causal Variant Identification

Gregory Cooper, Ph.D., Faculty Investigator, HudsonAlpha Institute for Biotechnology

Analytical challenges slow progress in the precise and robust identification of those genetic variants that are causally relevant to human phenotypes. Variants outside of protein-coding exons are particularly difficult to evaluate. I will discuss ongoing work to develop variant annotations to improve both coding and non-coding causal variant identification, as well as results from use of those annotations in both clinical and research sequencing projects - in particular for the identification of variants that are diagnostically relevant to intellectual disability and developmental delay.

4:00 Decoding the Patient's Genome: Clinical Use of Genome-Wide Sequencing Data

Elizabeth Worthey, Ph.D., Assistant Professor, Pediatrics & Bioinformatics Program, Human & Molecular Genetics Center, Medical College of Wisconsin

Despite significant advances in our understanding of the genetic basis of disease, genome-wide identification and subsequent interpretation of the molecular changes that lead to human disease represent the most significant challenges in modern human genetics. Starting in 2009 at MCW, we have performed clinical WGS and WES to diagnose patients coming from across all clinical specialties. I will discuss findings, pros and cons in approach, challenges remaining and where we go next.

4:30 Clinical Grade Annotations: Public Data Resources for Interpreting Genomic Variants

Gabe Rudy, Vice President, Product Development, Golden Helix
NGS is providing affordable and data-rich assays for rare disease diagnosis, carrier screening, risk prediction, pharmacogenomics and oncology care. But the public sharing

of clinically relevant annotations is not even across these applications. In this talk, I review the fundamental mechanics and challenges of annotating NGS data for clinical grade reporting and interpretations. I compare the accessibility of dbSNP, OMIM, ClinVar, HDMD and COSMIC and how these repositories of clinically relevant annotations are accessed and applied to the interpretation process.

5:00 Close of Day

FRIDAY, FEBRUARY 20

8:00 am Morning Coffee

INTERPRETATION OF CAUSAL VARIANTS

8:25 Chairperson's Remarks

Brian Haynes, Ph.D., Senior Scientist, Asuragen

8:30 Rapid Genome Sequencing, Interpretation and Management in the Neonatal Intensive Care Unit

Euan Ashley, D.Phil., Associate Professor, Medicine and Genetics; Director, Stanford Center for Inherited Cardiovascular Disease, Stanford University School of Medicine

Genetic testing in patients with malignant cardiac arrhythmias can focus personalized management on the underlying cause. In the neonatal setting, the ability to rapidly identify the underlying cause of a malignant arrhythmia can be potentially lifesaving. In this talk, I will outline recent approaches to rapid genome sequencing and interpretation at Stanford hospital and clinics and give examples from patients admitted to the neonatal intensive care unit at Lucile Packard Children's Hospital.

9:00 Reinterpreting Results from Large-Scale Clinical Sequencing or Genetic Testing

Peter Byers, M.D., Director, Center for Precision Diagnostics; Professor, Pathology, Medicine & Genome Sciences, University of Washington School of Medicine

9:30 The Clinical Ramifications of Divergent Oncogenic Pathways in Tumor Evolution

Hanlee Ji, M.D., Assistant Professor, Oncology, Medicine, Stanford University School of Medicine; Senior Associate Director, Stanford Genome Technology Center

Tumor evolution and the resulting clonal diversity is a common process that affects nearly all malignancies and has significant

ramifications for precision cancer medicine. Namely, the use of targeted therapies is significantly complicated by the genetic variance that is a part of tumor evolution. To understand this process requires innovative methods of discriminating the divergent oncogenic pathways that are in play as part of clonal diversity and evolution. New molecular and computational approaches will be described that address this fundamental issue of developing genomic-oriented cancer

10:00 Sponsored Presentations (Opportunities Available)

10:30 Coffee Break with Exhibit and Poster Viewing

SHARING AND MINING PATIENT DATA

11:00 Impact & Utilization of Integrating Genomic Data into EMRs

Dan Roden, M.D., William Stokes Professor, Experimental Therapeutics; Professor, Medicine and Pharmacology; Assistant Vice Chancellor, Personalized Medicine, Vanderbilt University

11:30 Mining Clinical Genomic Data

Joel Dudley, Ph.D., Director, Biomedical Informatics; Assistant Professor, Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai

12:00 pm The ClinGen Resource: Sharing Data. Building Knowledge. Improving Care.

Christa Lese Martin, Ph.D., FACMG, Director & Senior Investigator, Autism & Developmental Medicine Institute (ADMI), Geisinger Health System

Improving genomic interpretation will require a coordinated effort from both clinical and research communities. The Clinical Genome Resource (ClinGen) is a collaborative National Institutes of Health (NIH)-funded program dedicated to harnessing the data from both research efforts and clinical genetic testing, and using it to propel expert and machine-driven curation activities. By facilitating collaboration within the genomics community, we will build our collective knowledge base, moving closer to the promise of personalized genomic medicine.

12:30 Close of Symposium

CLICK HERE TO REGISTER ONLINE!

TriConference.com



POINT-OF-CARE DIAGNOSTICS

Examining Rapid Diagnostics from the Clinic to Consumer

THURSDAY, FEBRUARY 19
7:30 am Registration and Morning Coffee
**POINT-OF-CARE ADOPTION:
DIFFERING PERSPECTIVES**
9:00 Chairperson's Opening Remarks
**» 9:10 KEYNOTE PRESENTATION:
The Evolving Approach to Direct-to-Patient
Care and the Digital Revolution**
*Jeffrey A. Dubois, Ph.D., Vice President, Medical & Scientific
Affairs, Nova Biomedical*

The market for *In Vitro* Diagnostic (IVD) Testing is estimated to be \$54 billion in 2013 with POCT representing 14-15% of the market based on several market research company reports. Since the evolution of blood glucose, blood gas, urinalysis, pregnancy, and coagulation testing in the mid-1990s the menu of POCTs has expanded from <10 tests available in 1995 to approximately 110 tests available today. The presentation overviews the historical, current, and future uses of POCT and poses some interesting questions to clinicians, clinical laboratory scientists, and regulators.

**9:40 Point-of-Care Testing in Patient Care: A Real
World Experience**
*Elizabeth A. Wagar, M.D., Professor and Chair, Laboratory
Medicine, MD Anderson Cancer Center*

All aspects of implementing and managing point-of-care testing from the laboratory director's perspective will be examined, including management features, information transfer, quality programs, and regulatory requirements from the U.S. perspective. Experience from the outpatient and inpatient arenas will be described for two large medical centers, UCLA and the University of Texas MD Anderson Cancer Center. Discussion will be provided to answer pertinent point-of-care technology questions.

**10:10 Point-of-Care Test Device Design: Practical
Tips from the User**
*Valerie Ng, M.D., Ph.D., Chair, Laboratory Medicine & Pathology,
Alameda Health System/Highland General Hospital*

This talk will present common user misuse issues with point of care testing, with suggestions for eliminating misuse through informed device design.

10:40 Coffee Break with Exhibit and Poster Viewing
POC IN HIGH BURDEN DISEASE COUNTRIES
11:15 PANEL DISCUSSION
*Moderator: N. Reginald Beer, Ph.D., Medical Diagnostics Initiative
Leader, Lawrence Livermore National Laboratory*
*Panelists: Philip L. Felgner, Ph.D., Director, Protein Microarray
Laboratory, Infectious Disease; Project Scientist, Epidemiology,
University of California, Irvine School of Medicine*
*Adithya Cattamanchi, M.D., Assistant Professor, University of
California, San Francisco School of Medicine*
Christine Hara, MPH, Consultant
**12:15 pm POCT One-Step Molecular Diagnostic System Bring Complex
Clinical Testing Directly to the Patient**
Sabrina Li, CEO, Coyote Bioscience Company

Coyote Bioscience is dedicated to making break-through innovations in molecular diagnostics that brings complex clinical testing directly to the patient. We would like to introduce both of our lab-in-a-box instrumentation system based one PCR technology and our novel method of one-step gene test without nucleic acids extraction. You will see the first portable system for molecular diagnostics with general 0.2mL PCR tube capacity.



COYOTE

12:30 Session Break
**12:40 Luncheon Presentation:
Developing Innovative, Ultra-
Rapid Diagnostics to Enable a
'Test and Treat' Solution to Infectious Diseases**
Daniel Adlerstein, Ph.D., Director, R&D, Atlas Genetics

Atlas Genetics has developed a diagnostic platform consisting of a small, low cost instrument and test-specific, disposable cartridges. The system provides an accurate, actionable test result in 30 minutes combining and integrating nucleic acid extraction, rapid-PCR and Atlas' proprietary multiplex electrochemical detection. The reduced turn-around time improves patient care by reducing incorrect and empirical treatment and improving antibiotic stewardship.

1:15 Session Break
**CONSUMER HEALTHCARE
AT THE POINT-OF-SERVICE**
1:50 Chairperson's Remarks
*Keith Batchelder, M.D., Founder & CEO, Genomic Healthcare
Strategies*
**2:00 Use of CLIA-Waived POC Tests in Pharmacy-
Based Disease State Management Programs**
*Michael E. Klepser, Pharm.D., FCCP Professor, Pharmacy Practice,
Ferris State University College of Pharmacy*

Dr. Klepser will discuss the opportunities to use CLIA-waived point-of-care tests in community pharmacies.

**2:30 Healthcare, Re-Imagined: Consumer Point-of-
Care**
Eric Saff, Chief Innovation Officer, HealthSpot

Eric Saff will draw on his experience in telehealth software and hardware platform in his presentation on consumer point-of-care. He will include a look at some of the biggest challenges to date, and where disruptive innovation can and should overcome these hurdles to meet new market opportunities and healthcare demands.

**3:00 Refreshment Break with Exhibit and Poster
Viewing**
**3:30 Community Pharmacies: The Face of
Neighborhood Healthcare**
*Alex J. Adams, Pharm.D., IOM, Vice President, Pharmacy
Programs, National Association of Chain Drug Stores (NACDS)*

Community pharmacists are among the most accessible and trusted healthcare professionals; 95% of all Americans live within 5 miles of a pharmacies. Increasingly the public is turning to pharmacies for expanded services such as immunizations and point-of-care tests. This session will describe the community pharmacy landscape and opportunities to bring tests truly to the point of care.

**4:00 Point-of-Care Testing in a Retail Health Clinic
Setting**
*Daniel R. Kerls, MBA, OTR/L, Director, Ambulatory Operations,
CVS MinuteClinic*

With the growth of retail health clinics, more patients are choosing to obtain point of care testing in these settings. In addition, employers are encouraging their employees to obtain biometric screenings in these settings. This presentation will review the types of point of care testing, as well as the challenges and opportunities in this setting.

**4:30 PANEL DISCUSSION: Consumer Healthcare:
Future Perspectives**
Moderator: Keith Batchelder, M.D., Founder & CEO, Genomic

POINT-OF-CARE DIAGNOSTICS

CONTINUED ON NEXT PAGE

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

 CLICK HERE TO
REGISTER ONLINE!

TriConference.com


 TRICON
PERKS

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

POINT-OF-CARE DIAGNOSTICS

*continued**Healthcare Strategies**Panelists:**Donald Klepser, Ph.D., MBA, Associate Professor, Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy**Allison Dering-Anderson, Pharm.D., RP, FAAIM, Clinical Assistant Professor, Pharmacy Practice, University of Nebraska Medical Center College of Pharmacy**Daniel R. Kerls, MBA, OTR/L, Director, Ambulatory Operations, CVS MinuteClinic***5:30 Close of Day****FRIDAY, FEBRUARY 20****8:00 am Morning Coffee****EMERGING POC AND
MOBILE HEALTH TECHNOLOGIES****8:25 Chairperson's Remarks***Jonathan O'Halloran, CSO and Co-Founder, Board, QuantuMDx Group***8:30 Development of a Handheld MDx and Sequencing Device***Jonathan O'Halloran, CSO and Co-Founder, Board, QuantuMDx Group*

QuantuMDx is developing a mobile, handheld DNA sequencing device for PGx, infectious disease and tumour profiling applications. We envision this device preventing pandemics via rapid identification in the field and a cloud-based monitoring system. The Internet of Life will be a real-time map of pathogen mutation and spread created using the data from a network of handheld DNA sequencers across the globe.

9:00 Neurotrack: Transforming the Diagnosis of Alzheimer's*Elli Kaplan, CEO, Neurotrack***9:30 Innovations in Telehealth and Care Delivery***Lena Cheng, M.D., Vice President, Medical Affairs, Doctor on Demand*

Doctor on Demand is the largest provider of video visits in the US. She will discuss how major changes in telehealth are expanding access to providers and facilitating provider interpretation and follow up to point-of-care diagnostics in medicine, genetics and behavioral health. She will discuss how partnerships between clinical providers and diagnostic companies can make point-of-care diagnosis and therapy a reality.

10:00 Reimagining the Future of Point-of-Care Molecular Diagnostics**for Infectious Disease***Hemanth Shenoi, Ph.D., Director, Business Development, Lucigen Corporation*

Point of care testing can lower cost and improve healthcare outcomes; however molecular diagnostic tests are currently not available at POC. Through a case study example, attendees will gain an understanding of the product development and regulatory approval path for a CLIA-waivable molecular diagnostic point of care test platform.

10:15 Sponsored Presentation (Opportunity Available)**10:30 Coffee Break with Exhibit and Poster Viewing****11:00 FEATURED POSTER PRESENTATION:****A Connected Point of Care Solution with Unparalleled Accuracy, Access and Affordability: Novel Platform Delivering Connected Point of Care Solution***Mohan Uttarwar, Cofounder and CEO, iNDx LifeCare Inc.*

iNDx LifeCare offers a Connected Point of Care (cPOC) platform with central lab sensitivity/reliability, multiplexing capability, quick turnaround time and connectivity to "the cloud". As more distributed devices are replacing central locations for labs, connectivity has become a key feature in the success of POC devices. The iNDx LifeCare platform is based on optical waveguide technology, Q-SENS. Using an array of intersecting waveguides and a unique coupling method to avoid complex optics, Q-SENS technology excels where other sensing technologies have failed. The heart of the Q-SENS platform is small Silicon chip. Laser light coupled into a set of waveguides embedded into the Silicon chip, is guided to specially designed sensing areas where it excites fluorescent molecules. Highly efficient excitation through the 'evanescent tail' generates fluorescence which is collected back into a second set of waveguides. Our current design includes 32 different sensing areas on a 3mm X 3mm chip, allowing for testing of 1 to 32 different analytes on each chip from the same sample.

12:00 PM CLOSING KEYNOTE PRESENTATION:**Point of Care Testing (POCT) – Summary of an Evolving Approach to Direct Patient Care***Jeff Dubois, Vice President, Medical & Scientific Affairs, Nova Biomedical***12:30 Close of Symposium****CLICK HERE TO REGISTER ONLINE!**

TriConference.com



CLINICAL CANCER IMMUNOTHERAPY

Translating Cancer Therapy from Promise to Reality

THURSDAY, FEBRUARY 19

7:30 am Registration and Morning Coffee

PROGNOSTIC BIOMARKERS FOR IMMUNOTHERAPY

9:00 Chairperson's Opening Remarks

James R. Mansfield, Director, Quantitative Pathology Applications, PerkinElmer

9:10 Monitoring Immune Competence by Mass Cytometry

Holden T. Maecker, Ph.D., Associate Professor (Research), Microbiology & Immunology, Stanford University

Tumors and traditional cancer therapies are immunosuppressive. Yet immunotherapies require specific immune competence, which is rarely measured, for their success. I will describe the use of highly multiparametric mass cytometry (CyTOF) to monitor baseline immune competence of patients undergoing immunotherapy. We hope to find predictive biomarkers of outcome, and perhaps eventually biomarkers to aid in the choice of immunotherapy.

9:40 Peripheral Blood Immune Profiles and Their Potential to Maximize Response to Immune Therapy

Allan B. Dietz, Ph.D., Co-Director, The Human Cell Therapy Lab, Mayo Clinic Center for Regenerative Medicine

We developed techniques to count more than 100 distinct leukocytes in peripheral blood. More than 200 controls and patients have been analyzed using a bioinformatics approach. We will show the prognostic approach of this technique and its potential to guide immune based therapies.

10:10 Searching for Tumor-Specific Antigens

Qi Zhao, Ph.D., Fellow, Bioinformatics Scientist, Molecular Profiling, Regeneron Pharmaceuticals Inc.

10:40 Coffee Break with Exhibit and Poster Viewing

11:15 Applications of Systems Biology for Characterizing Mechanism of Action and Biomarker Discovery in Cancer

Debraj GuhaThakurta, Director, Computational & Systems Biology, Dendreon Corporation

Better characterization of the immunological mechanism of action against tumors and the identification of predictive and pharmacodynamic biomarkers of clinical outcome are important needs for cancer immunotherapies. We are using various high-content platforms to address such needs for sipuleucel-T, an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic, metastatic castration-resistant prostate cancer. Results from some of these investigations will be presented.

11:45 Type 1 Immunity as a Biomarker for Clinical Response to Immune Therapy of Cancer

William (Bill) Watt, Ph.D., University of Washington Tumor Vaccine Group; CEO & Co-Founder, EpiThany, Inc.

Successful immune therapy of cancer requires tumor-specific Type 1 immunity, whether existing or provided. Evidence of Type 1 immunity such as cross-priming of tumor-proximal T-cells and epitope spreading are amenable to assay in clinical trials, as are the TCR sequences of TILs. We are developing new tumor vaccines to elicit exclusively Type 1 immunity which will capitalize on this approach to clinical biomarkers in cancer.

12:15 pm Sponsored Presentation (Opportunity Available)

12:30 Session Break

12:40 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:15 Session Break

UNDERSTANDING THE MOLECULAR MECHANISMS OF IMMUNOTHERAPIES

1:50 Chairperson's Remarks

William (Bill) Watt, Ph.D., University of Washington Tumor Vaccine Group; CEO & Co-Founder, EpiThany, Inc.

2:00 PANEL DISCUSSION: Moving Forward with Prognostic Biomarkers for Immunotherapy

Moderator: William (Bill) Watt, Ph.D., University of Washington Tumor Vaccine Group; CEO & Co-Founder, EpiThany, Inc.

*Panelists: Holden T. Maecker, Ph.D., Associate Professor (Research), Microbiology & Immunology, Stanford University
Allan B. Dietz, Ph.D., Co-Director, of the Human Cell Therapy Lab, Mayo Clinic Center for Regenerative Medicine*

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Functional Analysis of Disease and Treatment-Associated Changes in Immune Cell and Network Signaling Using Single Cell Network Profiling Targeting of Therapy Resistant Cancers

Rachael E. Hawtin, Ph.D., Vice President & Head, Research, Nodality

4:00 Talk Title to be Announced

Sandip Patel, M.D., Assistant Professor, Cancer Immunotherapy Program, Experimental Therapeutics (Phase 1 Program), Thoracic Oncology, Division of Hematology & Oncology and Center for Personalized Cancer Therapy, UC San Diego Moores Cancer Center

4:30 Phenotyping Immune Cells in Solid Tumors

Bernard A. Fox, Ph.D., Endowed Chair and Chief, Molecular and Tumor Immunology, Robert W. Franz Cancer Research Center; Earle A. Childs Research Institute, Providence Cancer Center; Dept Molecular Microbiology and Immunology, OHSU

Our laboratory's current focus is on understanding the tumor-induced suppressive mechanisms that blunt the efficacy of immunotherapy and developing approaches to overcome these mechanisms. This presentation will showcase some of our recent efforts that are headed into clinical trials.

5:00 Close of Day

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CANCER IMMUNOTHERAPY

*continued***FRIDAY, FEBRUARY 20****8:00 am Morning Coffee****COMBINATION IMMUNOTHERAPIES****8:25 Chairperson's Remarks***Barbara Mittleman, M.D., Vice President, Clinical; Head, Immunology, Nodality***8:30 Activation of iNKT Cells by NKTT320 as an Approach to Cancer Immunotherapy***Robert Mashal, Ph.D., CEO, NKT Therapeutics*

Activation of iNKT cells has been shown to be a promising approach to cancer immunotherapy in both preclinical and clinical studies. NKT Therapeutics has developed NKTT320, a humanized monoclonal antibody that specifically binds and activates iNKT cells. Preclinical data of iNKT cell activating antibodies, both alone and in combination with other immunotherapeutic approaches will be presented.

9:00 Immunotherapy Combinations with Agents Targeting PD-1*Scot W. Ebbinghaus, Executive Director, Clinical Research, Merck*

In this talk, I will discuss the rationale and current clinical data on immunotherapy combinations which include anti-PD1 agents.

9:30 Development of a Novel IL-12 DNA-Based Immunotherapeutic in Combination with Chemotherapy Agents for the Treatment of Advanced Ovarian Cancer*Khursheed Anwer, Ph.D., MBA, Executive Vice President & CSO, Nucleic Acid Therapy, Celsion*

This presentation describes the clinical development of a formulated IL-12 plasmid for local (IP) treatment of peritoneally metastasized ovarian cancer. This treatment approach is designed to increase local concentrations of IL-12, a powerful immune activator, at tumor site without the systemic toxicity associated with rIL-12. The evidence of safety, immune response, and clinical benefits from clinical trials as a single agent and in combination with chemotherapeutic agents will be discussed.

10:00 PANEL: Extended Q&A with Session Speakers*Moderator: Barbara Mittleman, M.D., Vice President, Clinical; Head, Immunology, Nodality***10:30 Coffee Break with Exhibit and Poster Viewing****11:00 Characterizing the Local Tumor Microenvironment to Develop Rational Treatment Combinations***Janis Taube, M.D., MSc, Director, Dermatopathology; Assistant Professor, Dermatology and Pathology, Johns Hopkins*

My laboratory has served as the tissue pathology core for the multi-institutional clinical trials for the first-in-human anti-PD-1 and anti-PD-L1 immunotherapies. This talk will discuss our ongoing efforts to focus on further characterizing the local tumor microenvironment with the aim of developing rational treatment combinations.

11:30 Combinations with CRS-207, a Live-Attenuated Listeria Monocytogenes Expressing Mesothelin*Dirk G. Brockstedt, Ph.D., Senior Vice President, Research & Development, Aduro BioTech, Inc.*

Aduro BioTech recently completed a Phase II trial of the combination of CRS-207 and GVAX Pancreas immunotherapies in patients with advanced-stage metastatic pancreatic cancer. This is the first randomized study to show that immunotherapy is effective in pancreatic cancer, and Aduro has initiated the follow-on Phase IIb ECLIPSE trial. Aduro is also conducting an ongoing Phase I trial of CRS-207 in combination with chemotherapy in patients with malignant pleural mesothelioma.

12:00 pm Promise and Challenges of Immuno-Oncology*Peter P. Lee, City of Hope, Billy Wilder Endowed Professor, Chair, Cancer Immunotherapeutics & Tumor Immunology (CITI), City of Hope Comprehensive Cancer Center*

Immune therapies (Sipuleucel-T and ipilimumab) approved by the FDA in recent years extend patient survival only ~4 months average. Many new treatments are under development and hold great promise. These include PD-1/PDL-1 blocking antibodies and adoptive T cell therapy. Cancer-induced immune dysfunction is a major obstacle to the success of immunotherapy, as the tumor microenvironment prevents optimal function of immune cells. I will discuss our current understanding of these mechanisms and strategies to further enhance the efficacy of cancer immunotherapies.

12:30 Close of Symposium

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



GENOMICS & SEQUENCING DATA INTEGRATION, ANALYSIS AND VISUALIZATION

Impact of Data Quality and Novel Bioinformatics Tools on Life Sciences Research and Clinical

THURSDAY, FEBRUARY 19

7:30 am Registration and Morning Coffee

GENOME AND HEALTHCARE BIG DATA & DIFFERING PERSPECTIVES: TRENDS, CHALLENGES, OPPORTUNITIES

9:00 Chairperson's Opening Remarks

James Lyons-Weiler, Ph.D., Managing Director, Ebola Rapid Assay Development Consortium, Pittsburgh, PA

9:10 Trends in Genomic Data, Big Data Analytics, and Translational Informatics

Scott Kahn, Ph.D., Vice President, Commercial Enterprise Informatics, Illumina

As researchers switch their focus from single genome analysis to cohort-level genomic analysis, and with more comprehensive genomic characterization of each subject (eg, DNA, transcriptome, epigenome, microbiome, etc), the informatics challenges have moved into the realm of Big Data analytics. This presentation will put these trends into context and will provide a perspective on how these challenges are being met for addressing the needs of translational research.

9:40 Downstream Challenges in Whole Genome Sequencing for Clinical Studies

Nicholas J. Schork, Ph.D., Professor and Director, Human Biology, J. Craig Venter Institute

There are a number of challenges in the clinical use of WGS data, many of them occurring in the more 'downstream' interpretation and analysis aspects of sequence data. These challenges include accommodating global human genetic diversity, annotating variants, dealing with phase information, linking therapeutics to genomic alterations and creating reliable 'filters' that can pull out the most relevant variants in a particular patient's genome. This talk describes these challenges, provides real-world examples of them and discusses approaches to overcoming them.

10:10 Accessing Human Genetic Variation in the Rising Era of Individual Genome Sequence

Ben Busby, Ph.D., Genomics Outreach Coordinator, NCBI, NIH

This presentation will describe how NCBI has enhanced several of its genomics resources in the last several months and how some of its public databases can be queried for computational biology and clinical questions. We are in the process of indexing the exons of over 1 million samples from over 800,000 individuals housed in the dbGaP database at every position in the human genome, as well as having expanded access to the raw data in several ways, and made variant data in these and our medical genomics databases widely accessible.

10:40 Coffee Break with Exhibit and Poster Viewing

11:15 Harnessing Clinical Data to Improve Care

Sorena Nadaf, Director, Translational and Biomedical Informatics; CIO, HDFCCC Translational Informatics, University of California San Francisco

11:45 Computational and -omic Stop Gaps in Policies that Thwart Advances in Translational and Individualized Medicine

James Lyons-Weiler, Ph.D., Managing Director, Ebola Rapid Assay Development Consortium, Pittsburgh, PA

The fundamental pieces are in place for an era of massive and rapid strides in biomarker-informed health care, and yet numerous -omic and computational-related policy stopgaps exist that must be, and can be, overcome by coordinated political, didactic actions. Specific examples that demonstrate flawed policies and practices will be shown. The role of government should be to protect people from undue harm from medical procedures, but it also should act to allow others to protect people from the harm of diseases and unnecessary treatments.

12:15 pm Sponsored Presentation (Opportunity Available)

12:30 Session Break

12:40 Luncheon Presentation: Easy Large Scale Clinical and Genomics Dataset Integration, Management and Analysis with MediSapiens Explorer Platform

Ville Parviainen, Ph.D., Manager, Business Development, MediSapiens Ltd.

Next generation sequencing produces large amounts of genomics and descriptive data but causes data underuse and inefficiency due to problems in management and accessing of data. MediSapiens has developed a solution to answer these issues with MediSapiens Explorer Platform. Our flexible and scalable platform allows data management and integration in one system as well as development of customizable user interfaces and analysis tools to utilize that data in the same platform.

1:15 Session Break

DRIVING DATA INTEGRATION AND ANALYTICS: DEALING WITH DATA COMPLEXITIES

1:50 Chairperson's Remarks

Michael Liebman, Ph.D., Managing Director, IPQ Analytics, LLC

2:00 From Drug Discovery to Patient Management: Dealing with the Data Complexities of the Real World

*Michael Liebman, Ph.D., Managing Director, IPQ Analytics, LLC
Sabrina Molinaro, Ph.D., Head, Epidemiology, Institute of Clinical Physiology, National Research Council - CNR Italy*

The real need to drive data integration and analytics resides not in the technologies of data generation and collection but rather in identifying the question that needs to be addressed and what data would be key to enable solving these questions. Two case studies will be presented, one impacting drug discovery through the analysis of co-morbidities and poly-pharmacy issues, the second dealing with patient management in a rare pediatric disease, pARDS.

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

GENOMICS & SEQUENCING DATA INTEGRATION, ANALYSIS AND VISUALIZATION

continued

2:30 Analytics of Functional Single Cell Data to Derive Insights into Drug MOA, Disease Profile, and Patient Stratification

Santosh Putta, Ph.D., Vice President, Computational Sciences, Nodality, Inc.

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Finding a Needle in a Haystack: New Approaches to Identify the Single Disease-Causing Mutation in a Patient's Genome Sequencing Data

Yuval Itan, Ph.D., M.Res., Postdoctoral Associate, Human Genetics of Infectious Diseases, The Rockefeller University

This presentation provides an insight into a new state-of-the-art gene-level metrics, tackling a crucial question in medicine genomics: how to identify the relevance of a mutated gene to a disease? We identified for the first time the accumulated mutational damage for each human gene and the biological distance between all human genes, and showed that both approaches are particularly powerful for the identification of disease genes in patients' high-throughput data.

4:00 Pharmacogenomics Strategies in Precision Medicine

Dongliang Ge, Ph.D., Director, Bioinformatics, Gilead Sciences

4:30 Hardware and Software Infrastructure for Mining Big Metagenomic Datasets

Zhong Wang, Ph.D., Computational Biologist & Genome Analysis Group Lead, Lawrence Berkeley National Lab & DOE Joint Genome Institute; Adjunct Associate Professor, University of California at Merced

High throughput metagenome shotgun sequencing has evolved into a powerful tool for studying microbial communities consist of thousands of species that are difficult to culture. Analyzing metagenome data sets, however, poses great challenges computationally, both in hardware infrastructure and in software algorithms, as the datasets are large in volume (typically in terabase range) and complex in nature. This talk provides my personal experience in metagenome dataset analysis and our recent statistical framework to automatically predict single genomes from complex metagenomic datasets.

5:00 Close of Day

FRIDAY, FEBRUARY 20

8:00 am Morning Coffee

LARGE-SCALE DATA ANALYSIS

8:25 Chairperson's Remarks

Ben Busby, Ph.D., Genomics Outreach Coordinator, NCBI, NIH

8:30 Large-Scale NGS data Analysis on Amazon Web Services Using Globus Genomic

Ravi Madduri, Fellow, Computation Institute, University of Chicago and Argonne National Lab

9:00 Genome Browser in a Box: Viewing Private Annotations and Custom Sequences Made Easy

Pauline Fujita, Ph.D., Training and Outreach Coordinator, UCSC Genome Browser

9:30 iReport: An Integrative "omics" Reporting and Visualisation Platform

Andrew Stubbs, Ph.D., Assistant Professor, Bioinformatics, Erasmus University Medical Center

Current tools in Galaxy lack the ability to summarise the results of an experiment on an individual sample basis, or across the whole experiment, from multi-platform "omics" results. We developed iReport, an integrative "omics" reporting and visualisation platform in Galaxy, used to deliver Genetic Test Reports, Fusion gene selection and immunodeficiency repertoire screening.

10:00 Talk Title to be Announced

Carlos D. Bustamante, Ph.D., Professor, Department of Genetics, Stanford University; Co-Founding Director, Stanford Center for Computational, Human, and Evolutionary Genomics; Director of Informatics, Stanford Center for Genomics and Personalized Medicine

10:30 Coffee Break with Exhibit and Poster Viewing

DATA PRIVACY AND SECURITY STRATEGIES

11:00 Privacy Technologies and Big Data Approaches

Rakesh Radhakrishnan, Principal (Chief) IS Security Architect, Amgen

11:30 An Expert's Guide through the Identity Landscape

Mollie Shields-Uehling, President and CEO, SAFE-BioPharma Association

Identity trust is essential for secure Internet communications subject to regulatory requirements. The presentation overviews US and EU government and industry-driven identity management initiatives resulting in trusted industry/government and industry/industry communities of trust. Learn about types and levels of identity credentials (one serves as a single identity passport to the Internet), government and industry organizations involved in establishing identity trust infrastructures, applicable standards, governance models and approaches to cloud based identity management.

12:00 pm Using 1000 Human Genomes Project Data to Improve the Accuracy of Metagenomic Microbial Profiling

Jonathan Allen, Ph.D., Bioinformatics Scientist, Global Security Computing Applications, Lawrence Livermore National Laboratory

This presentation discusses the finding of microbial contaminants in the 1000 human genomes project and our assessment of the privacy implications for the human DNA inadvertently left in the human microbiome project data.

12:30 Close of Symposium

CLICK HERE TO REGISTER ONLINE!

TriConference.com



COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



SPONSOR & EXHIBIT OPPORTUNITIES

Sponsor

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding and networking with specific prospects. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on early will allow you to maximize exposure to qualified decision-makers.

Podium Presentations – Available Within the Main Agenda!

Showcase your solutions to a guaranteed, targeted audience. Package includes a 15- or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding, access to cooperative marketing efforts by CHI, and more.

Breakfast & Luncheon Podium Presentations

Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner/Hospitality Suite

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor's objectives i.e.: purely social, focus group, reception style, plated dinner with specific conversation focus.

Exhibit

Exhibitors will enjoy facilitated networking opportunities with qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

Additional branding and sponsorship opportunities available, including:

- Mobile App
- Hotel Room Keys
- Footprint Trails
- Staircase Ads
- Conference Tote Bags
- Literature Distribution (Tote Bag Insert or Chair Drop)
- Badge Lanyards
- Padfolios
- Program Guide Advertisement

Looking for additional ways to drive leads to your sales team? Discover the difference by utilizing CHI's database of over 800,000 life sciences & drug discovery professionals!

CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Whitepapers
- Web Symposia
- Custom Market Research Surveys
- Podcasts

Advertising opportunities such as marketing and promotional emails are also available.



Exhibitors and Sponsors have the opportunity to showcase their new product. Contact us for more information!

Contact:

Companies A-K

Jon Stroup
Business Development Manager
jstroup@healthtech.com
781-972-5483

Companies L-Z

Joseph Vacca
Business Development Manager
jvacca@healthtech.com
781-972-5431

Current Sponsors & Exhibitors As of September 18th, 2014

Abbott Informatics	Translational Research	Illumina	NuGEN Technologies Inc	ScreenCell
Accelrys Inc	Certara	Indica Labs	Oasis Diagnostics® Corporation	Siemens Healthcare Diagnostics, Inc.
Advanced Cell Diagnostics Inc	Champions Oncology	iRepertoire, Inc.	Omega Bio Tek	Simulations Plus, Inc.
Almac Group	ChemAxon	The Jackson Laboratory	Oncolys BioPharma Inc	Singulex
ALS Automated Lab Solutions GmbH	Collaborative Drug Discovery	Janssen Diagnostics, LLC.	Oncotest GmbH	Slone Partners
Analytical Biological Services, Inc. (ABS)	Core Informatics	JSR Life Sciences	OpenEye Scientific Software	SomaLogic, Inc.
Analytik Jena/ UVP LLC	Covaris, Inc.	Kellison & Company	Paradigm	Source BioScience
ApoCell, Inc.	Coyote Bioscience Company	KMC Systems, Inc.	Parthys Reverse Informatics	SurModics IVD
Asuragen	Creatv MicroTech, Inc.	Leica Biosystems Imaging Inc	PerkinElmer	Swift Biosciences Inc
Axxin	Cureline, Inc.	Lucigen Corp	Personal Genome Diagnostics Inc	SVBio, Inc.
BIO OPTIONS, INC.	Cycle Computing LLC	Luminex Corporation	Precision for Medicine	Thomson Reuters
Biocartis	Definiens, Inc.	Maverix Biomics Inc	Promega Corp	Titian Software
Biological Dynamics Inc	DiaCarta	MCLAB (Molecular Cloning Laboratories)	ProteoGenex Inc	Transgenomic, Inc.
BioLine USA	Diagenode, Inc.	Meso Scale Discovery	QIAGEN Informatics	Trovagene Inc
Biomatrix, Inc.	Dotmatics	Metanomics Health GmbH	Quansys Biosciences	UNICConnect
Biomatters	EKF Diagnostics	MiniFAB (AUST) Pty Ltd	Quanterix	ViraCor-IBT Laboratories
Bioneer Corporation	ELSEVIER LIFE SCIENCE SOLUTIONS	Molecular Response	RainDance Technologies Inc	Wi Inc
Biosearch, Technologies Inc.	Fluxion Biosciences	MolecularHealth Inc	Randox Labs Laboratories	World Courier, Inc.
BioStorage Technologies, Inc.	Folio Biosciences	Myriad RBM, Inc.	ResearchDx, LLC.	XIFIN Inc.
BioView USA, Inc.	Golden Helix Inc	NanoString Technologies	Scienion, US.	YarcData
Catholic Health Initiatives Center for	Horizon Discovery Ltd.	Norgen Biotek Corp	Scottish Development International	

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO REGISTER ONLINE!

TriConference.com



HOTEL & TRAVEL

Top Reasons To Stay At The InterContinental Hotel

1. Take advantage of the great discounted room rate!
2. Save \$100 OFF your conference registration (when reserving in the Tri-Conference room block)
3. Complimentary internet to Tri-Conference attendees in their guest room
4. Easy access to the Moscone Convention Center
5. Enjoy San Francisco and surround yourself with world-class shopping, restaurants and theaters - all the city has to offer

Conference Venue:

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

Host Hotel and Symposia

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

Discounted Group Rate: \$242 s/d

Room Rate Cut Off Date: January 16, 2015

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

SAVE \$100 OFF YOUR CONFERENCE REGISTRATION

- Reserve at the InterContinental, Westin Market Street, or Marriott Marquis
**You must book your reservation under the Tri-Conference room block for a minimum of 4 nights at the InterContinental, Westin Market Street or Marriott Marquis. One discount per hotel room.

Please visit **TriConference.com**
for additional hotels and
travel information

COVER

EVENT-ATA-GLANCE

PLENARY SESSION

SHORT COURSES

DIAGNOSTICS CHANNEL

CLINICAL CHANNEL

CANCER CHANNEL

INFORMATICS CHANNEL

SYMPOSIA

SPONSOR & EXHIBIT OPPORTUNITIES

HOTEL & TRAVEL INFORMATION

REGISTRATION INFORMATION

CLICK HERE TO
REGISTER ONLINE!

TriConference.com



How to Register: TriConference.com

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **MMTC F** when registering

TRI-CON ALL ACCESS PACKAGE - BEST VALUE! (FEBRUARY 15-20)

Includes: 2 Short Courses, 1 Conference Program, and 1 Symposia

Advanced Registration Discount until January 16

Registrations after January 16 and onsite

Commercial

\$3,195

\$3,295

Academic, Government,
Hospital-affiliated

\$2,099

\$2,199

REGULAR PRICING - A LA CARTE OPTIONS

SHORT COURSES (FEBRUARY 15-16)

1 Short Course

\$750

\$450

2 Short Courses

\$1,025

\$795

Sunday, February 15 - 2:00-5:00pm

SC1: Translating CTCs to Clinical Use

SC2: Latest Advances in Molecular Pathology

SC3: Validation and Compliance Considerations for an NGS Lab

SC4: Sequencing 101

SC5: PCR Part I: Primer Design for PCR Experiments

SC6: Reimbursement for Advanced Diagnostics

Sunday, February 15 - 5:30 - 8:30pm

SC9: Clinical Informatics Needs of an NGS Lab

SC10: Knowing Your NGS Analysis Upstream

SC11: Regulatory Compliance in Molecular Diagnostics

SC12: Introduction to Hadoop for Bioinformatics

SC13: PCR Part II: Digital PCR Applications and Advances

Monday, February 16 - 8:00 - 11:00am

SC17: Commercialization Boot Camp

SC18: Next-Generation Sequencing as a Diagnostics Platform

SC19: Isolation and Characterization of Cancer Stem Cells

SC20: Using Preclinical Models in Oncology

SC21: Best Practices in Personalized and Translational Medicine

SC22: NGS for Infectious Disease Diagnostics

CONFERENCE PROGRAMS (FEBRUARY 16-18)

Advanced Registration Discount until January 9

\$2,250

\$1,299

Registrations after January 9 and onsite

\$2,450

\$1,399

DIAGNOSTICS CHANNEL

(P1) Molecular Diagnostics

(P2) Personalized Diagnostics

(P3) Cancer Molecular Markers

(P4) Circulating Tumor Cells

(P5) Digital Pathology

(P6) Companion Diagnostics

(P7) PCR for Molecular Medicine

(P8) Genomic Sample Prep & Biospecimen Science

(P9) Epigenomics in Disease

(P10) Genome and Transcriptome Analysis

(P11) Technologies for Patient Stratification

CLINICAL CHANNEL

(P9) Epigenomics in Disease

(P11) Genomic Technologies for Patient Stratification

(P12) Translational to Clinical R&D

(P13) Clinical Sequencing

(P14) Technology-Driven Oncology Clinical Development

CANCER CHANNEL

(P3) Cancer Molecular Markers

(P4) Circulating Tumor Cells

(P12) Translational to Clinical R&D

(P14) Technology-Driven Oncology Clinical Development

(P15) Predictive Preclinical Models in Oncology

INFORMATICS CHANNEL

(P10) Genome and Transcriptome Analysis

(P16) Bioinformatics for Big Data

(P17) Integrated Pharma Informatics & Data Science

SYMPOSIA (FEBRUARY 19-20)

Symposia Pricing

\$1,495

\$1,095

(S1) New Frontiers in Gene Editing

(S3) Genomics in Medicine

(S5) Cancer Immunotherapy

(S2) Circulating Cell-Free DNA

(S4) Point-of-Care Diagnostics

(S6) Genomics & Sequencing Data Integration Analysis and Visualization

CONFERENCE DISCOUNTS

BayBio Member Discount 20%

ISCB Member Discount 20%

Alumni* Discount SAVE 20%:

We appreciate your past participation at the Molecular Med TRI-CON. Through loyalty like yours, this event has become a must-attend for senior level decision makers. As a result of your great loyalty, we are pleased to extend this exclusive opportunity to save an additional 20% off the registration rate.

Hotel Discount (\$100 Off):

Reserve your hotel and save \$100 OFF your conference registration *you must book your reservation under the Tri-Conference room block for a minimum of 4 nights. One discount per hotel room

POSTER SUBMISSION (\$50 OFF):

Dedicated poster sessions for Symposia and Conference Programs. Special poster deadlines apply.

To secure a poster board and inclusion in specific conference materials, your abstract must be submitted, approved and your registration paid in full by the following deadlines:

December 12, 2014

Printed Program Guide and Electronic Program Materials

January 16, 2015

Electronic Program Materials only

[Please click here for details.](#)

All poster abstracts are due no later than January 16, 2015.

REGISTER 3 - 4th IS FREE:

Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply. Additional discounts are available for multiple attendees from the same organization. For more information on group rates contact David Cunningham at +1-781-972-5472

Alumni, Twitter, LinkedIn, Facebook, Society Discounts, or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.

ADDITIONAL REGISTRATION DETAILS

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

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

To view our Substitutions/Cancellations Policy, go to www.healthtech.com/regdetails. Video and/or audio recording of any kind is prohibited onsite at all CHI events.