CLICK HERE TO REGISTER ONLINE!

TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's 23rd International

Molecular Med TRI-CON 2016

March 6 - 11, 2016

Moscone North Convention Center

San Francisco, CA

PREMIER SPONSORS

bina TECHNOLOGIES

COYOTE

CELLECTA
Discovery is *Yours*.

ELSEVIER

The Jackson Laboratory
Leading the search for tomorrow's cures

nanoString TECHNOLOGIES

PRECISION FOR MEDICINE
THE FUTURE OF MEDICINE IS PRECISION

Seegene

sera care

silicon biosystems
A MENARINI GROUP COMPANY

Surrogen

ThermoFisher SCIENTIFIC

THOMSON REUTERS

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

2016 Event-at-a-Glance

MAIN CONFERENCE AT THE MOSCONE NORTH CONVENTION CENTER

Sunday, March 6

1:00 pm Registration Open
2:00 – 5:00 pm Afternoon Short Courses
5:30 – 8:30 pm Dinner Short Courses
8:30 pm Close of Day

Monday, March 7

7:00 am Registration Open and Morning Coffee
8:00 – 11:00 am Morning Short Courses
11:50 am – 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 Keynote Session
6:00 – 7:30 pm Grand Opening Reception in the Exhibit Hall with Poster Viewing
7:30 pm Close of Day

Tuesday, March 8

7:00 am Registration Open and Morning Coffee
8:00 – 9:00 am Plenary Keynote 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 St. Patrick's Day Celebration in the Exhibit Hall with Poster Viewing
5:00 – 6:00 pm Breakout Discussions in the Exhibit Hall
6:00 pm Close of Day

STAY CONNECTED

#TRICON

Wednesday, March 9

7:00 am Registration Open and Morning Coffee
7:00 am Breakfast Presentations
8:00 – 10:00 am Plenary Keynote Session Panel
10:00 – 10:50 am Refreshment Break & Poster Competition Winner Announced in the Exhibit Hall
10:50 am – 12:30 pm Conference Programs
12:40 – 1:10 pm Luncheon Presentations or Lunch on Your Own
1:10 – 1:50 pm Refreshment Break in the Exhibit Hall with Poster Viewing
1:50 – 5:45 pm Conference Programs
5:45 Close of Conference Programs

SYMPOSIA AT THE HILTON SAN FRANCISCO UNION SQUARE

Thursday, March 10

7:30 am Registration Open and Morning Coffee
8:25 am – 5:00 pm Symposium 2
9:00 am – 5:00 pm Symposia 1,3,4,5,6,7
10:40 – 11:15 am Coffee Break with Exhibit and Poster Viewing
12:40 – 1:15 pm Luncheon Presentations or Lunch on Your Own
3:00 – 3:30 pm Refreshment Break with Exhibit and Poster Viewing
5:00 – 6:00 pm Reception with Exhibit and Poster Viewing
6:30 – 9:00 pm Dinner Short Courses

Friday, March 11

7:00 Registration Open and Morning Coffee
7:00 am Breakfast Presentation Symposium 2
8:00 am Morning Coffee
8:25 am – 12:30 pm Symposia 1-7
10:30 – 11:00 am Coffee Break with Exhibit and Poster Viewing
12:30 pm Close of Molecular Medicine Tri-Conference

Conference Programs

DIAGNOSTICS CHANNEL

Molecular Diagnostics
Personalized Diagnostics
Cancer Molecular Markers
Circulating Tumor Cells
Digital Pathology
Precision Medicine – NEW
PCR for Molecular Medicine
Clinical NGS Diagnostics
Genomic Sample Prep and Biomarker Assay Development
Molecular Diagnostics for Infectious Disease – NEW

GENOMICS CHANNEL

Precision Medicine - NEW
PCR for Molecular Medicine
Clinical NGS Diagnostics
Genomic Sample Prep and Biomarker Assay Development

CANCER CHANNEL

Cancer Molecular Markers
Circulating Tumor Cells
Cancer Immunotherapy – NEW
Predictive Preclinical Models in Oncology

INFORMATICS CHANNEL

Bioinformatics for Big Data
Integrated Informatics Driving Translational Research & Precision Medicine

SYMPOSIA

New Frontiers in Gene Editing
Circulating Cell-Free DNA
Point-of-Care Diagnostics
Biomarkers for Cancer Immunotherapy
Genomics & Sequencing Data Integration, Analysis and Visualization
Companion Diagnostics – NEW
Commercialization of Molecular Diagnostics – NEW

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

PREMIER SPONSORS

bina TECHNOLOGIES

CELLECTA
Discovery is *Yours*.

COYOTE

ELSEVIER

nanoString® TECHNOLOGIES

The Jackson Laboratory
Leading the search for tomorrow's cures

PRECISION FOR MEDICINE℠
THE FUTURE OF MEDICINE IS PRECISION

Seegene

sera care™

silicon biosystems
A MENARINI GROUP COMPANY

Surrogen

ThermoFisher SCIENTIFIC

THOMSON REUTERS

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

CORPORATE SPONSORS

AbGen · ACEA Biosciences, Inc. · ANGLE · aspera an IBM company · Asuragen · agl · applieddnasciences · Beckman Coulter · Biocartis · Biocept Completing the Answer · biodesix · Biological Dynamics Rapid answers for clinical treatment · Bio-Rad · BIOVIA · Boston Healthcare · CareDx Personalized Treatment Surveillance. Better Outcomes. · C.T.L. Cellular Technology Limited · Champions Oncology · discovery from charles river · Celsee Diagnostics · Core Informatics · CREATV MicroTech · Diaceutics Group · envision genomics · Epic Sciences · EXIQON Seek Find Verify · exosomedx · Fibrotx Innovations for Skin · fios Genomics Accelerating the discovery of new biology · GE Healthcare · Glencoe Software · horizon · IBM · illumina · indica labs informed pathology · Lonza · Lucigen Dx Simplifying Diagnostics · m·bio Diagnostics · MSD · METABOLON · MACS Miltenyi Biotec · mdbiosciences · miniFAB Micro-Engineering / Medical / Manufacturing · Molecular Health · MolecularMatch · nodality revealing biology · NORGEN Biotek Corp. · NORTIS · NuGEN imagine more from less · Oncolys BioPharma · Onco design Biotechnology · PerkinElmer For the Better · PGD Personal Genome Diagnostics · PHILIPS · PSYCHE Medical Laboratory Software · Q² Solutions a Quintiles Quest Joint Venture · QIAGEN · Quanterix · RainDance Technologies · sample minded · ScreenCell · SECTRA Knowledge and passion · sequenom Bioscience · serametrix · SIEMENS · SIGMA-ALDRICH · SLONE PARTNERS · SomaLogic · Streck · Systems Imagination · T2Biosystems · TACONIC · Tepnel Pharma Services · Transgenomic Advancing Personalized Medicine · TriMetis · trovagene precision cancer monitoring · xcell biosciences · XIFIN

CORPORATE SUPPORT SPONSORS

COVANCE Solutions Made Real · ENVIGO · Jubilant Biosys · MULTISORB Technologies · MYRIAD RBM · Rarecells · STILLA

ORGANIZED BY: Cambridge HEALTHTECH Institute

PLENARY KEYNOTE PRESENTATIONS

The Tri-Conference has been and will continue to be a platform in recognizing the potential for new technologies and research in molecular medicine, diagnostics, drug discovery, and drug development that have a pivotal role in mitigating disease, improving access to healthcare, and identifying transformative treatments. Our plenary keynote speakers for this meeting will inspire you to continue efforts in developing novel medicines, diagnostics, therapeutics, and approaches to gain a greater understanding of the underpinnings of cancer and advance personalized medicine. Join over 750+ of your colleagues in each of these plenary keynote presentations. They are the only time each day that bring all attendees from the 14 conference tracks together in one room.

MONDAY, MARCH 7 | 5:00 - 6:00 PM

Keynote Introduction to be Announced

Translating Rapid Whole Genome Sequences into Precision Medicine for Babies in Intensive Care Nurseries

Stephen F. Kingsmore, MB, ChB, BAO, D.Sc., FRCPath, President and CEO, Rady Pediatric Genomics & Systems Medicine Institute at Rady Children's Hospital, San Diego

Genetic diseases are the #1 cause of death in newborns in intensive care units. Rapid genome sequencing (STATseq) can diagnose genetic diseases in newborns in 26 hours. However, scaling STATseq to thousands of acutely ill newborns and implementation of precision care plans that improve outcomes are uncharted territory. Problems, potential solutions, and progress to date will be discussed.

Dr. Stephen F. Kingsmore is the President and CEO of Rady Pediatric Genomics & Systems Medicine Institute, San Diego. Dr. Kingsmore comes to Rady Children's from Children's Mercy Kansas City, where he most recently served as Executive Director of Medical Panomics, and from the University of Missouri, Kansas City School of Medicine where he served as Dee Lyons/Missouri Endowed Chair in Genomic Medicine. Previously Dr. Kingsmore was the founding Director of the Center for Pediatric Genomic Medicine at CM-KC, CEO of the National Center for Genome Resources, COO of Molecular Staging Inc., Vice President of Research at CuraGen Corporation, founder of GatorGen, and Assistant Professor at the University of Florida's School of Medicine. Dr. Kingsmore received MB ChB BAO and DSc degrees from the Queen's University of Belfast. He trained in clinical immunology in Northern Ireland and did residency in internal medicine and fellowship at Duke University Medical Center. He is a fellow of the Royal College of Pathologists. He was a MedScape Physician of the year in 2012, and received the 2013 Scripps Genomic Medicine award and 2013 ILCHUN prize of the Korean Society for Biochemistry and Molecular Biology. TIME magazine ranked his rapid genome diagnosis method one of the top 10 medical breakthroughs of 2012.

TUESDAY, MARCH 8 | 8:00 - 9:00 AM

Unlocking the Potential of Next Generation Biomarkers

Jorge Soto, Co-Founder and CTO, Miroculus

This presentation will discuss a simple, noninvasive, affordable point-of-care test that looks for early signs of multiple forms of cancer and infectious diseases based on circulating microRNAs.

Jorge, a graduate of both Tec de Monterrey and Singularity University, is co-founder and CTO of Miroculus, a life science company that aims to push forward a new test for different diseases based on circulating microRNA. Prior to founding Miroculus, he was the deputy general director of civic innovation at the coordination of national digital strategy of Mexico where he designed and launched several projects that uses technology to encourage transparency and improve the communication between citizens and their institutions.

WEDNESDAY, MARCH 9 | 8:00 - 10:00 AM

Plenary Keynote Session Panel: Emerging Technologies and Industry Perspectives

Moderator:
Kristin Ciriello Pothier, Head of Life Sciences/Managing Director, Parthenon-EY (Ernst Young)
Panelists: Bernard Andruss, Ph.D., Vice President, Diagnostic Development, Asuragen
Joseph Beechem, Ph.D., Senior Vice President, Research & Development, NanoString Technologies
Kevin Coker, CEO, Molecular Match
Alexander Chenchik, Ph.D., Founder & CSO, Cellecta Inc.
James Lim, Ph.D., Chief Scientific Officer, Xcell Biosciences
Scott Marshall, Ph.D., Managing Director, Analytics, Precision for Medicine
Russell Garlick, PhD Chief Scientific Officer SeraCare Life Sciences

This panel session will feature a series of presentations on emerging and hot technologies in molecular medicine. Each speaker will have 7 minutes at the podium. After all speakers have presented, there will be a moderated Q&A with attendees. The presentations are not meant to be a corporate or specific product pitch. Each speaker will focus on a technology and solution framed around a motivational clinical problem and how their particular company/organization is solving it.

Sponsored by:

Asuragen®
CELLECTA Discovery is *Yours*.
MolecularMatch
nanoString® TECHNOLOGIES
nodality revealing biology
PRECISION FOR MEDICINE THE FUTURE OF MEDICINE IS PRECISION
seracare™
xcell biosciences

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

SHORT COURSES*

SUNDAY, MARCH 6

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
Allison Welsh, Ph.D., CTC Scientist, Foundation Medicine, Inc.
Benjamin Casavant, Ph.D., Vice President, Tasso

SC2: Microbiome: Sorting Out the Hype from the Hope
Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360
Peter P. Lee, M.D., Executive Chairman, Osel
Peter DiLaura, President and CEO, Second Genome
Collen Cutcliffe, Ph.D., Co-Founder and CEO, Whole Biome
Embriette R. Hyde, Ph.D., Project Manager, American Gut Project and Postdoctoral Scholar, Rob Knight Lab, Department of Pediatrics, University of California, San Diego
Andrew Hryckowian, Ph.D., Postdoctoral Fellow, Sonnenburg Lab, Department of Microbiology and Immunology, Stanford University School of Medicine
Larry Weiss, M.D., CMO, AOBiome, LLC

SC3: NGS Assay Selection, Validation and Compliance
Co-Organized by AMP Association for Molecular Pathology
Eric Duncavage, M.D., Assistant Professor, Pathology & Immunology, Washington University School of Medicine
Colin C. Pritchard, M.D., Ph.D., Assistant Professor & Associate Director, Lab Medicine & Genetics & Solid Tumors, Laboratory Medicine, University of Washington
Avni B. Santani, Ph.D., Assistant Professor, Clinical Pathology and Laboratory Medicine, The Children's Hospital of Philadelphia

SC4: Sequencing 101
Ryan Kim, Ph.D., Director, Korean Bioinformation Center (KOBIC), Korea Research Institute of Bioscience & Biotechnology (KRIBB)

SC6: Reimbursement for Advanced Diagnostics: From Clinical Value Establishment to Coding, Coverage and Pricing
Lon Castle, M.D., CMO, Molecular Genetics and Personalized Medicine, CareCore National
Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)
Lauren Feldman, MHA, Senior Terminology and Strategy Consultant, American Medical Association (AMA)
Sherie Smalley, M.D., Senior Medical Director, Medical Policy, UPMC Health Plan
Additional Instructors to be Announced

DINNER COURSES | 5:30 – 8:30 pm

SC9: Clinical Informatics: Returning Results from Big Data
Co-Organized by AMP Association for Molecular Pathology
Nilesh Dharajiya, M.D., Chief Laboratory Officer and Medical Director, Pathway Genomics
N. Sertac Kip, M.D., Ph.D., Medical Director, Molecular Diagnostics Laboratory, Pathology and Laboratory Medicine, Geisinger Health System
Eric W. Klee, Ph.D., Assistant Professor, Medical Informatics, College of Medicine, Mayo Clinic

SC10: Development of Bioassays for Checkpoint Immunotherapy
Jelveh Lameh, Ph.D., Executive Director & Head, BioPharma Services Laboratory, Genoptix Medical Laboratory, Inc., a Novartis Company
Mei Cong, Ph.D., Director, R&D Custom Assay Services, Promega Corporation
Xiaoyan Du, Ph.D., Senior Scientist, Merck

SC11: Regulatory Compliance in Molecular Diagnostics
Pamela L. Swatkowski, Director, Regulatory Affairs, Abbott Molecular, Inc.
Melina Cimler, Ph.D., Senior Vice President, Quality & Regulatory, Adaptive Biotechnologies

SC12: Digital PCR: Applications and Advances
Jim Huggett, BSc (Hons), Ph.D., Science Leader, Nucleic Acid Metrology, Molecular & Cell Biology, LGC
Additional Instructors to be Announced

SC13: Liquid Biopsy Technologies Overview
Pamela Paris, Ph.D., Professor, Urology, University of California, San Francisco
Kai Wang, Ph.D., Principal Scientist, Institute for Systems Biology
Theresa Zhang, Ph.D., Vice President, Research Services, Personal Genome Diagnostics
Divyaa Ravishankar, MS, Senior Consultant, Life Sciences, Frost & Sullivan

MONDAY, MARCH 7

MORNING COURSES | 8:00 – 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., Professor of Pathology, University of Utah; Medical Director, Genomics and Bioinformatics, ARUP Laboratories
Jamie L Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.
P. Mickey Williams, Ph.D., Director, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research

SC19: Isolation and Characterization of Cancer Stem Cells
Leslie Crews, Ph.D., Assistant Project Scientist, Catriona Jamieson Laboratory, Sanford Consortium for Regenerative Medicine and Moores UCSD Cancer Center
Kristen M. Smith, Ph.D., Senior Scientist, Bionomics, Inc.

SC20: Translating Preclinical Data in the Rational Design of Cancer Combination Therapies
Arijit Chakravarty, Ph.D., Director, Modeling and Simulation (DMPK), Takeda Pharmaceuticals International Co.

SC21: Best Practices in Personalized and Translational Medicine
Julio Fernández, Ph.D., Principal Scientist, Pfizer
Doug Garrett, Research Leader, NGS Pipeline Development Group, Roche Sequencing
Nicholas Iannotti, Manager, R&D Informatics, Pfizer
Rob Futrick, CTO, Cycle Computing
Rachel Rimsky, Associate Director, Research Partnerships, The Michael J. Fox Foundation for Parkinson's Research
Sirimon O'Charoen, Ph.D., Manager, Translational Medicine, Thomson Reuters

SC22: NGS for Infectious Disease Diagnostics
Charles Chiu, M.D., Ph.D., Associate Professor, Lab Medicine and Infectious Diseases; Director, UCSF-Abbott Viral Diagnostics and Discovery Center; Associate Director, University of California, San Francisco Clinical Microbiology Laboratory

SC23: Metabolic Microbiome
Deepak K. Rajpal, D.V.M., Ph.D., Director, Computational Biology, Target Sciences, GlaxoSmithKline
David N. Mayhew, Ph.D., Scientific Investigator, Computational Biology, Target Sciences, GlaxoSmithKline

THURSDAY, MARCH 10

DINNER COURSES | 6:30 – 9:00 pm

SC25: Detection and Characterization of Circulating Biomarkers
Co-Organized by sequenom Bioscience
Nishant Agrawal, M.D., Professor, Surgery; Director, Head and Neck Surgical Oncology, University of Chicago
Chetan Bettegowda, M.D., Ph.D., Assistant Professor, Neurosurgery and Oncology, Johns Hopkins University School of Medicine
Mathias Ehrich, M.D., Senior Vice President, Research & Development, Sequenom
Sonya Parpart-Li, Ph.D., Associate Scientist, Personal Genome Diagnostics

SC26: A Primer to Gene Editing: Tools and Applications
John Doench, Ph.D., Research Scientist, Broad Institute of Harvard and MIT
Michael Bassik, Ph.D., Assistant Professor, Department of Genetics, Stanford University
Charles Joseph, Product Manager, Twist Bioscience
Leigh Brody, Director, Genomic Services, Desktop Genetics Ltd.

*Separate registration required for a la carte pricing

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

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
- Precision Medicine – *New*
- PCR for Molecular Medicine
- Clinical NGS Diagnostics
- Genomic Sample Prep and Biomarker Assay Development
- Molecular Diagnostics for Infectious Disease – *New*

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Thirteenth Annual

MOLECULAR DIAGNOSTICS

Guidelines for Success -The Industry Leader's Networking Event

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

KEYNOTE SESSION: WHY AN ACCURATE DIAGNOSIS IS FUNDAMENTAL TO HEALTH CARE

Co-Organized by AMP Association for Molecular Pathology

11:50 Chairperson's Opening Remarks: The Diagnostic Dilemma in Inherited and *de novo* Disease

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

The era of genomic medicine is advancing rapidly our ability to identify and interpret sequence variation related to human diseases. New technologies allow generation of large amounts of data, yet the utility of such data is being questioned. We propose that an accurate diagnosis has inherent utility. Cases demonstrating the utility of molecular diagnostics will be presented for inherited and for somatic diseases. Modeling genomic testing paradigms to show health economics benefit will also be described.

12:10 pm DNA Intelligence in the War on Cancer: The Utility of Molecular Genetic Analysis

Loren J. Joseph, M.D., Director, Molecular Diagnostics Lab, Pathology, Beth Israel Deaconess Medical Center (Chair, AMP 2014 Clinical Practice Committee)

The ability to sequence any or all the genes in a cancer is like being able to learn the enemy's order of battle. The metaphor can be extended- the information changes over time and is sometimes misleading. Even for such a powerful tool it is appropriate to ask if it has shown the value in practice which is expected in theory. This presentation will survey the evidence for several areas of application, especially for next-generation sequencing.

12:30 An Accurate Diagnosis Impacts the Economics of Health

Linda M. Sabatini, Ph.D., HCLD, CC, Director, Molecular Diagnostics, NorthShore University HealthSystem (Member, AMP Economic Affairs Committee)

With the increasing use of advanced nucleic acid sequencing technologies for clinical diagnostics and therapeutics, it has become important to better understand the costs of performing these procedures and the value they provide to patients, providers and payers. The Association for Molecular Pathology invested in a cost and value analysis of specific genomic sequencing procedures. Modeling genomic testing paradigms in comparison to current testing strategies to assess potential health economic benefits will be discussed.

12:50 PANEL DISCUSSION

1:00 Session Break

Sponsored By nanoString TECHNOLOGIES

1:15 Best Practices for Training and Validation of Gene Expressions Signatures from FFPE Samples

Wesley Buckingham, Manager, Diagnostic Assay Development, NanoString Technologies

Gene expression signatures are emerging as important prognostic and predictive tools for the treatment of cancer. The presentation will discuss best practices for development and validation of gene expression signatures based on NanoString's experience in developing IVD test kits. Two case studies will be presented: 1) Adaptation of the PAM50 signature to the FDA-cleared Prosigna Breast Cancer Prognostic Gene Signature Assay; 2) Training and development of a companion diagnostic gene expression signature for DLBCL based on the Lymph2Cx signature.

Sponsored By Tepnel Pharma Services

1:45 Luncheon Presentation II: How to Turn a Biomarker into a Clinical Test

Bob Holt, Ph.D., Biomarker Services Manager, Hologic Ltd

Overview of the process used by a Dx company to develop a biomarker based Dx product. Focus on the development paths of LDT, CE and FDA IVD products.

The presentation will emphasise the importance of decisions made in the initial stage of development which are critical to the success of a Dx development program.

2:15 Session Break

CPT ARMAGEDDON TWO YEARS LATER: Are Patient Pay Models Working?

2:30 Chairperson's Remarks

Daniel H. Farkas, Ph.D., HCLD, Chief Clinical Laboratory Officer, Celmatix, Inc.

2:35 CPT Armageddon Two Years Later: Are the New Codes Working?

Victoria M. Pratt, Ph.D., FACMG, Director, Pharmacogenomics Laboratory, Medical and Molecular Genetics, Indiana University School of Medicine

With the completion of the Human Genome Project and increased understanding of the genes involved in human disease and cancer biology, clinical molecular testing has grown by leaps and bounds. At the request of payers, the American Medical Association (AMA) developed a new CPT coding system for molecular pathology that was implemented in 2013. This session will review the Molpath CPT coding system and issues around reimbursement.

2:50 Decoding Fertility

Piraye Y. Beim, Ph.D., Founder & CEO, Celmatix, Inc.

It is well established that environmental exposures, starting in utero, and spanning into later life impact an individual's overall reproductive potential. The genetic contributions, however, have been less clear. A growing body of evidence suggests that fertility potential, and how environmental exposures and age impact it, are genetically hard-coded. This information holds the potential to revolutionize reproductive medicine and empower individuals to proactively manage and maximize their fertility potential.

3:05 23andMe: A Decade of Consumer Genomics

Jill Hagenkord, M.D., CMO, 23andMe

Several forces are at play in molecular diagnostics that are seeding a consumer genomics market, including changes in coding, coverage, reimbursement, regulation, and policy. New analyte-specific CPT codes are resulting in more payment denials due to a perceived lack of clinical utility by the payer community. Preventative health, carrier testing, or testing of at risk family members are statutorily excluded from CMS. Consumers and patients still value this information and technology advances enables consumer-priced and accessible genomic information.

3:20 Enabling Patient Access to Breast Cancer Genomic Risk Panels

Elad Gil, Ph.D., CEO, Color Genomics

What are the major obstacles for patients to access genetic testing today? How can these obstacles be removed, while maintaining and ensuring proper care for patients? Learn about the applications of software and web-based services to support providers and enable population-scale access to genomics by patients.

MOLECULAR DIAGNOSTICS
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

3:35 PANEL DISCUSSION

4:10 Beyond SNVs: Comprehensive Variant Detection in Circulating cfDNA
Mark Li, CEO, Resolution Bioscience, Inc.
Cancer is complex. In order to realize the full potential of blood-based genotyping, liquid biopsy assays must move beyond single nucleotide variants and short indels to include fusions and copy number variations. Data will be presented demonstrating the ability of the clinical-grade ctDx™ platform and it's ability to provide a complete, real-time tumor genotype, including gene partner agnostic fusion detection. While analytical and clinical validation are critical, additional commercialization and regulatory challenges remain in bringing NGS-based assays to patients and clinicians.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

Sponsored By
PMC PERSONALIZED MEDICINE COALITION Celebrating 10 Years

BREAKTHROUGHS IN PERSONALIZED MEDICINE OUTSIDE ONCOLOGY

10:05 Chairperson's Remarks
Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

» 10:15 KEYNOTE PRESENTATION: Clinical Deployment of Personalized Medicine - Successes and Challenges
A. Keith Stewart, M.B., Ch.B., Carlson and Nelson Endowed Director, Center for Individualized Medicine; Vasek and Anna Maria Polak Professor, Cancer Research, Mayo Clinic

10:45 15 Years of Personalized Medicine, Can We Move beyond Oncology?
Eric Lai, Ph.D., Senior Vice President and Head, Pharmacogenomics, Companion Diagnostics, Takeda Development Centers of America
Despite the complete sequencing of the Human Genome and the development of new molecular technologies, the clinical application of personalized medicine is still mostly limited to Oncology. This presentation will discuss other potential ways of applying pharmacogenomics to drug development and the use of big research datasets to address unmet medical needs to non-oncology areas. In addition, we will discuss major roadblocks for the next 5 years and beyond.

11:15 Talk Title to be Announced
Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide R&D, Pfizer

11:30 Changing Treatment Paradigms
Greg Keenan, M.D., Vice President, Medical Affairs & US Head Medical Officer, AstraZeneca
Dr. Greg Keenan will explore what constitutes a useful companion diagnostic or biomarker, and the considerations for patients beginning or continuing a therapy over time, and exciting potential opportunities to advance medical science in the treatment of lupus, respiratory disease and other non-oncological disease states.

11:20 PANEL DISCUSSION

12:15 pm Session Break

12:25 Luncheon Presentation I: Expanding Treatment Options with Genomics-Enabled Immuno-Oncology
Sponsored By Q² Solutions a QuintilesQuest Joint Venture
Victor Weigman, Ph.D., Associate Director, Translational Genomics, Q Squared Solutions
Tumor genomic profiling can direct patients to new therapeutic possibilities. Positive responses aside, many patients are left with few treatment options. Genomics can further illuminate the inherently complex tumor microenvironment, with beneficial implications for Immuno-oncology strategies.

12:55 Luncheon Presentation II *(Sponsorship Opportunity Available)*

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

DEVELOPING EVIDENCE TO ESTABLISH CLINICAL VALIDITY OF EMERGING MOLECULAR DIAGNOSTICS

2:00 Chairperson's Remarks
Andrew C. Fish, J.D., Executive Director, AdvaMedDx

2:10 What Clinical Validity Means for Consumers and Clinicians in the New Era of Genomic Medicine
J. Leonard Lichtenfeld, M.D., MACP, Deputy Chief Medical Officer, American Cancer Society, Inc.
The progress in genomic-based medicine highlights challenges and barriers as we implement the science in a rational way. Clinical validity requires that we have confidence that genomic tests are well understood and demonstrate benefit for patients. Getting the balance right will be difficult and will require the input and collaboration of a number of stakeholders. Failure to do so may limit our ability to achieve the benefits offered by this accelerating knowledge.

2:25 Evidence Required by FDA for Establishing Clinical Validity
Alberto Gutierrez, Ph.D., Director, Office of In Vitro Diagnostics & Radiological Health, FDA CDRH

2:40 Understanding Payer Coverage Policies on Emerging Molecular Diagnostics
Kathryn A. Phillips, Ph.D., Professor, Health Economics and Health Services Research, Clinical Pharmacy; Founding Director, UCSF Center for Translational and Policy Research on Personalized Medicine, University of California, San Francisco
Payer coverage policies are a key component of the success of emerging molecular diagnostics. This presentation will discuss a newly developed registry of payer coverage policies and how it can provide greater understanding of coverage policies.

2:55 What Clinical Validity Means to Medicare?
Elaine K. Jeter, M.D., Contractor & Medical Director, Palmetto GBA LLC
Dr. Jeter will provide an overview of what clinical validity means to Medicare coverage and how it is established. She will provide examples of evidence that do and do not meet the minimal standard of clinical validity with regard to diagnostics.

3:10 PANEL DISCUSSION

3:40 Controlling Chaos in Oncology Testing
Sponsored By horizon
Brian Burke, Business Development Director, Horizon Diagnostics
Please join us, contribute to our workshop and enjoy the discussions:

- What is the best approach for setting up assays for cfDNA and cfRNA detection?
- Is NGS the new gold standard for clinical laboratories?
- Developing and implementing assays for fusion gene constructs; NGS or FISH?
- What is the impact of assay failure and how do you monitor for it?

4:10 St. Patrick's Day Celebration in the Exhibit Hall with Poster Viewing

MOLECULAR DIAGNOSTICS
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

DIAGNOSTICS CHANNEL

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

6:00 Close of Day

WEDNESDAY, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

Does your company...

- **Stand to improve patient outcomes and healthcare system cost containment?**
- **Have a value proposition which impresses venture capitalists?**

We are currently recruiting privately backed companies to compete in this year's "Swimming with the Sharks" challenge at the 13th Annual Molecular Diagnostics conference. Selected companies will have the opportunity to pitch their company's clinical value proposition to our expert panel in front of a large targeted audience at this industry flagship event. Click the link below to complete the application form for a chance to compete and have your company reviewed and evaluated.

Top two winners will receive global recognition as the "2016 Tri-Con Most Promising Company", along with detailed feedback including company analysis, feedback and strategy suggestions.

Apply online at www.triconference.com/evaluating-start-ups/

Qualifying Criteria:

- Clinical Utility
- Investor Readiness
- Healthcare Impact

Format:

- 10 companies will give 5 minute presentations in the first round of the competition
- 5 finalists will be chosen to give a 10 minute presentation in the second round of the competition
- Summary and Award for top start-ups (first and second place) will be presented by panel of judges

Panel of Judges:

Harry Glorikian, Healthcare Consultant
Stan Rose, Ph.D., CEO, Transplant Genomics
Enrico Picozza, MS, Venture Partner, HLM Venture Partners
Paul D. Grossman, Ph.D., Venture Partner, Telegraph Hill Partners
Chris Heid, Treasurer and Board Member, Berkeley Angel Network

Selection and Coaching Committee:

Chris Heid, Treasurer and Board Member, Berkeley Angel Network
Peter S. Miller, COO, Genomic Healthcare Strategies; Co-Director, MIT Venture Mentoring Service; and Member, Boston Harbor Angels

10:50 Moderator's Remarks
Alan B. Carter, Consultant, Sales Performance International

11:00 Part 1: First Round of Competition
5 minute presentations by Contestants

12:30 pm Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)*

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

1:50 Part 2: Second Round of Competition
10 minute presentations by Selected Finalists

3:00 Summary and Award for Top Start-Up Presented by the Judges Panel

3:30 Sponsored Presentation *(Opportunity Available)*

4:00 Session Break

ECOSYSTEM PANEL DISCUSSION:
TOWARD A PRECISION MEDICINE ECOSYSTEM: Pooling Data to Save Lives

4:10 Chairperson's Remarks
J. Marty Tenenbaum, Ph.D., Chairman, Cancer Commons

Realizing the potential of precision medicine requires a global ecosystem that can amass data on hundreds of millions of patients in order to identify the best therapies for increasingly rare molecular diseases. Getting there will require bold business models and innovative technology that encourage data sharing across many stakeholders. Representatives of competing cancer networks propose practical steps for sharing data, slashing costs and accelerating learning to save lives.

- Benefits and challenges of a global precision oncology ecosystem
- Review of proprietary ecosystems operated by molecular diagnostic vendors, academics, health systems, entrepreneurs, and nations
- Cross-industry learning: technologies and business models that facilitate data sharing and integrative analysis
- The important roles for national healthcare systems, patient advocacy groups, and pre-competitive consortia in catalyzing data sharing
- What steps can we take today to begin?

Panelists:
Jonathan Hirsch, President & Founder, Syapse
William S. Dalton, Ph.D., M.D., CEO, M2Gen; Director, The DeBartolo Family Personalized Medicine Institute at Moffitt Cancer Center
Piers Mahon, Ph.D., Director, Global Alliances, Cancer Commons
Brady Davis, Senior Director Strategy & Market Development, Illumina
Anil Sethi, Founder and CEO, Gliimpse

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Seventh Annual

PERSONALIZED DIAGNOSTICS

Establishing Clinical Sequencing as a Routine Diagnostic Tool

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

NGS REGULATORY OVERSIGHT AND STANDARDS

11:50 Chairperson's Opening Remarks
Karl V. Voelkerding, M.D., Professor, Pathology, University of Utah; Medical Director, Genomics and Bioinformatics, ARUP Laboratories

12:00 pm "So You've Sequenced My Genome. How Well Did You Do?" - Resources for Validating Clinical Next-Gen Sequencing
Marc Salit, Ph.D., Leader, Genome-Scale Measurements Group, NIST Material Measurement Lab, NIST-JIMB; Consulting Professor, Bioengineering, Stanford University
The NIST-hosted Genome in a Bottle (GIAB) Consortium is one of those working to provide whole human genome reference samples with benchmark variant call sets that are developed in a rigorous, transparent, open, public manner from open, public data sets. The GIAB is also working with others to develop benchmark comparison tools and extend their methods so others can also develop benchmark call sets useful for analytical validation of targeted assays. This presentation will describe these efforts and present a snapshot of current best practices.

12:10 Regulatory Considerations for Next-Generation Sequencing
Xueying Sharon Liang, M.D., Ph.D., Regulatory Scientist, Division of Molecular Genetics and Pathology, OIR/CDRH, FDA
Next-generation sequencing (NGS) is increasingly employed for *in vitro* diagnostic use. As part of the Precision Medicine Initiative (PMI), FDA is actively engaged in discussions with a variety of stakeholders to develop a regulatory pathway to advance innovation in precision medicine and protect public health with sufficiently flexible standards to assess performance of NGS-based tests, including analytical standards, framework on bioinformatics pipeline validation and clinical validity of NGS tests.

12:20 PANEL DISCUSSION

1:00 Session Break

1:15 Luncheon Presentation I: Beyond the Cancer Genome - Computational Enablement of Holistic, Evidence-Driven Patient Care in Clinical Oncology
Sponsored By MOLECULAR HEALTH
Gabriel Bien-Willner, M.D.,Ph.D., Medical Director, Medical, Molecular Health
In oncology,the molecular characterization of tumor genes as part of patient care is now synonymous with the concept of precision medicine. In this talk, I describe a computational platform that enables holistic clinical interpretation of multiple clinico-molecular parameters.

1:45 Spit Matters
Sponsored By AboGen
Stephen Andrews, Ph.D., CSO, AboGen
Manasi Jain, Ph.D., Vice President, AboGen
Saliva is an underappreciated sample material that contains most of the same components found in blood. AboGen's proprietary technology permits the collection, preservation, and isolation of all of these components enabling the noninvasive, home-based collection of blood components from saliva.

2:15 Session Break

WHOLE EXOME SEQUENCING AS A DIAGNOSTIC TOOL

2:30 Chairperson's Remarks

2:40 Clinical Exome Sequencing: Utilities and Obstacles to Implementation in a Clinical Setting
Yaping Yang, Ph.D., Associate Professor, Molecular and Human Genetics, Baylor College of Medicine
Clinical exome sequencing has demonstrated its clinical utility in diagnosing rare genetic disorders. However, obstacles to the implementation of exome testing in a clinical setting exist due to the technical complexity and novelty of NGS, as well as challenges in return of results (ROR) and accessibility/medical insurance acceptances. Continuous efforts are needed to address the challenges to further establish the role of clinical exome sequencing in medical care.

3:10 The Future Use of Exome Sequencing as the Genetic Test of Choice for Clinical Diagnostics
Wendy Chung, M.D., Associate Professor, Clinical Genetics Program, Columbia University
We will review the experience of using whole exome sequencing in clinical diagnostics for a wide range of genetic conditions including technical improvements of the test over time, the clinical yield of testing by indications, and the clinical utility in testing for patient care. We will also look forward to how the test is likely to be used in the future as a first line clinical test for all heritable conditions.

3:40 SNP-Catcher, a Database to Aid Mutation Detection and Discovery in Constitutional Disorders and Cancer
Peter L. Nagy, M.D., Ph.D., Assistant Professor, Pathology and Cell Biology; Director, Clinical Next-Generation Sequencing, Laboratory of Personalized Genomic Medicine
SNP-catcher is a web-based data system for the analysis and reporting of genomic variants for patients with constitutional disorders and cancer. It allows for the automated importing and processing of variant and coverage files and integration with data on frequency and pathogenicity from external databases. The web application allows for easy data mining based on patient and model organism phenotype and the molecular associations of the genes mutated.

4:10 An Integrated System for Targeted NGS that Enables Simultaneous Analysis of DNA Mutations, Fusions and RNA Expression
Sponsored By Asuragen®
Brian Haynes, Ph.D., Senior Scientist, Computational Biology, Manager, Bioinformatics, Asuragen
We present QuantideX™ NGS, a comprehensive system for targeted clinical NGS that enables quantification of DNA and RNA through a streamlined workflow compatible with low-input, low quality total nucleic acid and a bioinformatics solution that incorporates pre-analytical QC data to improve accuracy of variant calling, fusion detection and RNA quantification.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

PERSONALIZED DIAGNOSTICS
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

DIGITAL PATHOLOGY AND IMMUNE CHECKPOINT THERAPY

10:05 Chairperson's Remarks
David L. Rimm, M.D., Ph.D., Professor, Pathology, Yale University

10:15 Tissue-Based Assessment of PD-L1 and Other Tumor Microenvironmental Factors in Melanoma Specimens
Janis M. Taube, M.D., MSc, Director, Dermatopathology; Assistant Professor, Dermatology and Pathology, Johns Hopkins

Immunohistochemical detection of PD-L1 and other checkpoint molecules may serve as biomarkers for selecting immunotherapeutic regimens for patients with advanced melanoma. The evaluation of the utility of PD-L1 as a biomarker has been hampered by the different antibodies and assays used. We will discuss the current issues associated with immune checkpoint companion diagnostics and potential future applications for use of these assays in patients with melanoma.

10:45 Tissue-Based Analyses to Guide Immunotherapy for Lymphoma
Scott Rodig, M.D., Ph.D., Hematopathologist, Pathology, Brigham and Women's Hospital

Targeted immunotherapy has achieved long-lasting clinical responses in a subset of patients with a variety of aggressive malignancies. I will discuss the cellular and molecular characteristics of classical Hodgkin lymphoma that render this tumor-type uniquely susceptible to PD-1 blockade and correlations between tissue-based biomarker analysis and clinical outcome with either conventional chemotherapy or immunotherapy, and extensions of these observations to additional lymphoma subtypes.

11:15 Immune Profiling of Lung Cancer Tissue Specimens
Ignacio I. Wistuba, M.D., Chair, Translational Molecular Pathology, Division of Pathology/Lab Medicine; Anderson Clinical Faculty Chair, Cancer Treatment and Research, The University of Texas MD Anderson Cancer Center

The anti-tumor benefit of blocking immune checkpoints in lung cancer, particularly PD-1 and PD-L1, has revolutionized the therapy of this disease. Because of variable responses to immunotherapy (IMT), there is an urgent need for predictive biomarkers to guide personalization of lung cancer treatment. A comprehensive approach to identify and validate IMT-related biomarkers in lung cancer tissue specimens, including digital pathology and genomic methodologies, will be described.

11:45 Beyond PD-L1: Other Potential Companion Diagnostic Tests for Immune Checkpoint Therapy
David L. Rimm, M.D., Ph.D., Professor, Pathology, Yale University

The current companion diagnostic tests and nearly all publications related to immune checkpoint therapies are based on assessment of PD-L1. Some assess PD-L1 in the epithelial component while others emphasize stromal expression. However, there may be other methods for assessment of response to these therapies based on the presence of subsets of T-cells or assessment of the activation of these T-cells. It is also possible that assessment of other co-stimulators or competitive receptors may influence prediction of response to therapy. These non-Pd-L1 methods will be reviewed in this lecture.

12:15 pm Session Break

12:25 Luncheon Presentation I: Shared Accountability: How Genomics & Informatics Will Engage Consumers, Providers and Payers toward True Personalized Medicine

Sponsored By illumina

Satnam Alag, Ph.D., Vice President, Software Development, Enterprise Informatics

Genomics data is a big deal when context and meaning is attached to it. Smart data - the right data at the right time to the right person - can help Consumers, Providers and Payers enhance and inform care decisions. That's the prize but how do you get your hands on it? We will focus on Genomics & Informatics and how companies like Illumina are working to provide solutions.

12:55 Luncheon Presentation II: Integrated Oncology Diagnostics Enabled by Digital Pathology

Sponsored By PHILIPS

Reinhold Wimberger-Friedl, Ph.D., Principal Scientist, Philips Research Europe, Philips

At Philips we develop an integrated approach of staining-based and molecular characterization of the tumor and its micro-environment. Digital pathology with WSI analytics enables a comprehensive quantification of cellular composition of the tumor. A proprietary model determines the tumor-driving signaling pathways from mRNA expression profiles.

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

CAN EXOMES REPLACE TARGETED PANELS?
Balancing Costs with Results and Regulatory Requirements

2:00 Chairperson's Remarks
Karl V. Voelkerding, M.D., Professor, Pathology, University of Utah; Medical Director, Genomics and Bioinformatics, ARUP Laboratories

2:10 The Utility of Exome Sequencing in Providing Deep Coverage of Disease-Relevant Targets
Avni B. Santani, Ph.D., Assistant Professor, Clinical Pathology and Laboratory Medicine, The Children's Hospital of Philadelphia

To date, disease-targeted gene panels have generated a lot of interest but exome sequencing (ES) is increasingly gaining acceptance for inherited and somatic diseases with locus and allelic heterogeneity. In this talk, we cover our group's effort in creating a technically enhanced ES assay that provides adequate coverage of all currently known disease-relevant genes, thereby facilitating high quality exome interpretation as well as exome "slices" for disease panels. Key considerations for test optimization including cost, specimen pooling, data quality and compliance will be discussed.

2:40 Diagnostic Gene Panels in the Exome Era – Using Exome Sequencing as a Universal Assay to Streamline Assay Development and Laboratory Operations
Birgit H. Funke, Ph.D., FACMG, Associate Professor, Pathology, MGH/Harvard Medical School; Director, Clinical Research and Development, Laboratory for Molecular Medicine, Partners HealthCare

The accelerating pace of disease gene discovery is presenting an increasing challenge for diagnostic laboratories as updating targeted gene panels is costly. Improved exome sequencing assays achieve near equal quality and decreasing costs open the door to replacing gene panel assays with virtual panels. This presentation summarizes our experience moving from targeted gene panels to exome-based virtual panels using inherited renal disorders as an example.

3:10 Laboratory Accreditation and Proficiency Testing for Next-Generation Sequencing Diagnostics: An Update on College of American Pathologists Programs
Karl V. Voelkerding, M.D., Professor, Pathology, University of Utah; Medical Director for Genomics and Bioinformatics, ARUP Laboratories

By late 2015, nearly 200 laboratories accredited by the College of American Pathologists indicated that they offered next-generation sequencing-based diagnostics. This number is expected to grow. This presentation will provide an update on accreditation requirements

PERSONALIZED DIAGNOSTICS
CONTINUED ON NEXT PAGE

developed by the College specific to laboratories performing NGS based diagnostics. 2015 also marked the launch of the College's first methods-based proficiency testing program for NGS-based detection of germline variants, for which summary results will be discussed.

3:40 Genome-Wide Prenatal Cell Free DNA Testing: Validation and Clinical Experience

Sponsored By sequenom Bioscience

Daniel S. Grosu, M.D., MBA, CMO, Sequenom, Inc.

Sequenom has taken the first step, for specific cases, to have an NIPT option that can deliver a complete assessment of the genetic makeup of the placenta, by enabling genome wide analysis of sub-chromosomal CNV >7Mb. We will outline the technical challenges as well as an overview of analytical and clinical performance for genome wide cfDNA testing.

3:55 Sponsored Presentation *(Opportunity Available)*

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

WHY TARGETED THERAPIES FAIL

10:50 Chairperson's Remarks

Victor Velculescu, M.D., Ph.D., Professor, Oncology; Co-Director, Cancer Biology, Johns Hopkins Sidney Kimmel Cancer Center; Co-Founder, Personal Genome Diagnostics

11:00 Precision Medicine and Cancer Drug Discovery

Atul J. Butte, M.D., Ph.D., Director, Institute for Computational Health Sciences; Professor, Pediatrics, University of California, San Francisco

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, discovering new durable targets in disease, the evaluation of patients and populations presenting with whole genomes sequenced, and new work on integrating and reusing the clinical and genomic data that result from clinical trials. Dr. Butte will especially cover big data in biomedicine as a platform for innovation and entrepreneurship.

11:30 Characterization of Driver Alterations in Tissue and Liquid Biopsies

Victor Velculescu, M.D., Ph.D., Professor, Oncology; Co-Director, Cancer Biology, Johns Hopkins Sidney Kimmel Cancer Center; Co-Founder, Personal Genome Diagnostics

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.

12:00 pm Enterprise-Wide Clinical Sequencing to Match Patients to Personalized Cancer Therapies

Michael F. Berger, Ph.D., Associate Director, Marie-Josée and Henry R. Kravis Center for Molecular Oncology, Memorial Sloan Kettering Cancer Center

Massively parallel sequencing can empower oncologists to make treatment decisions informed by the molecular composition of their patients' cancers. We have developed and implemented a robust molecular profiling platform for use in real-time patient management at a large academic cancer center. I will discuss the large-scale clinical deployment of our platform and its utility in matching patients to clinical trials to provide investigational therapies the greatest chance of success.

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

HOT TOPICS AND CONTROVERSIES IN CANCER SEQUENCING

1:50 Chairperson's Remarks

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

2:00 Novel Clinical Applications of Cancer Genomics

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

Novel technologies to evaluate genomics-based tumor burden in tumor tissue and bodily fluids 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.

2:30 What is a Cancer Mutation? Challenges in Detecting, Interpreting, and Targeting Somatic Variants

Joshua M. Stuart, Ph.D., Baskin Engineering Endowed Chair & Professor, Biomolecular Engineering,; Associate Director, Center for Biomolecular Science and Engineering, University of California, Santa Cruz

DNA sequencing provides an unprecedented potential to catalog all somatic alterations in tumor genomes. Yet the task of assembling raw reads into biologically-interpretable information is still a "Wild West" of algorithms. In the talk, I will discuss an open competition to identify the best mutation calling algorithms. After a year of collecting results from hundreds of methods, we learned some ingenious tricks from some, and pitfalls that tripped up most, competitors.

3:00 Noninvasive Monitoring of Lymphoma by Sequencing of Circulating Tumor DNA

Ash A. Alizadeh, Ph.D., Principal Investigator, Assistant Professor, Medicine, Divisions of Oncology & of Hematology; Attending Physician, Lymphoma Oncology Clinic, Stanford Cancer Center, Stanford University

Recent studies have shown limited utility of routine surveillance imaging for diffuse large B-cell lymphoma (DLBCL) patients achieving remission. Detection of molecular disease in peripheral blood provides an alternate strategy for surveillance. I will describe strategies for noninvasive monitoring of lymphoma by sequencing of circulating tumor DNA, including performance characteristics of various assays, their clinical applications, and their promise for future translations studies.

PERSONALIZED DIAGNOSTICS
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

ORGANIZED BY: Cambridge HEALTHTECH Institute

DIAGNOSTICS CHANNEL

Sponsored By seracare

3:30 NGS-Based Diagnostics: Developing Assays and Monitoring Performance Using Novel Biosynthetic QC Tools
Russell Garlick, Ph.D., CSO, SeraCare Life Sciences
There are currently no widely-accepted NGS QC standards for multi-analyte diagnostic assays which hampers the ability to compare the performance of different assays. Preliminary results will be presented from a study testing the SeraseqTM Solid Tumor Mix-I as a qualitative and quantitative QC indicator for tumor profiling.

4:00 Session Break

4:10 Chairperson's Remarks
German Pihan, M.D., Staff Pathologist and Director, Diagnostic Hematopathology Service, Pathology, Beth Israel Deaconess Medical Center

4:15 Darwinian Cancer Genome Evolution: The Achilles Heel of Precision Cancer Medicine. Can It Be Overcome?
German Pihan, M.D., Staff Pathologist and Director, Diagnostic Hematopathology Service, Pathology, Beth Israel Deaconess Medical Center
The high rate of mutations in cancer is the single most important challenge to the success of precision medicine in cancer. Whole genome sequencing is beginning to elucidate the patterns, pathways and causes of the astonishingly dynamic high rate of somatic mutation in most cancers. Understanding these pathways will prove challenging but fundamentally important to succeed in the fight against cancer. This talk will define the nature of the Darwinian cancer genome evolution challenge and propose possible avenues to surmount it.

4:45 Who Should Regulate Cancer NGS Tests: FDA, CMS/CLIA, or Both?
Roger D. Klein, M.D., J.D., Chair, Professional Relations Committee, Association for Molecular Pathology (AMP); Medical Director, Molecular Oncology, Cleveland Clinic
This presentation will discuss current controversies and potential regulatory approached for the oversight of next generation sequencing testing for oncology applications.

5:15 PANEL DISCUSSION

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Ninth Annual

CANCER MOLECULAR MARKERS

Guiding Cancer Management

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

LIQUID BIOPSY IN INTERVENTIONAL SETTINGS

11:50 Chairperson's Opening Remarks
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf

12:00 pm Liquid Biopsy: Expectations and Required Steps to Bring It into Clinical Practice
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf
Circulating tumor cells (CTCs), nucleic acids (ctDNA, cfmiRNA) and exosomes in the blood of cancer patients have received increasing attention as new diagnostic tool enabling "liquid biopsies". The perspective to avoid invasive tissue biopsies and obtain similar or even more information by a "simple" blood test has enormous implications in cancer diagnostics. Here the expectations and future steps required to bring liquid biopsies into clinical practice will be discussed.

12:30 Circulating Tumor Cells as a Biomarker of Treatment Efficacy and Prediction in Castration-Resistant Prostate Cancer
Howard I. Scher, M.D., Chief, Genitourinary Oncology Service; Member and Attending Physician, Department of Medicine, Memorial Sloan Kettering Cancer Center; Professor, Medicine, Weill Cornell Medical College
Pre and post-therapy circulating tumor number has been shown to be prognostic for survival. Use in clinical practice and in drug development as a measure of treatment efficacy has been more limited. Analyses of the strength of association of the enumeration biomarker with survival will be discussed along with a recent analysis showing that a CTC enumeration biomarker in combination with LDH was shown to meet the Prentice Criteria for individual-patient level surrogacy. Use of a predictive biomarker to guide treatment selection will also be discussed.

1:00 Session Break

1:15 Luncheon Presentation I: Size-Based Isolation of Circulating Tumor Cells Associated to Droplet Digital PCR Allow Prediction of KRAS Mutations in Patients with Colorectal Cancer before Tumor Surgery
Sponsored By ScreenCell
Jérôme A. Denis, M.D., Ph.D., Sorbonne Universités

1:45 Luncheon Presentation II: Comprehensive Ultra-Sensitive CTC Analysis in the Management of Cancer
Sponsored By Biocept Completing the Answer™
Veena Singh, M.D., Senior Vice President & Senior Medical Director, Biocept, Inc.
Circulating tumor cells (CTCs) isolated solely by EPCAM capture and their CK positive, CD45 negative profile miss CK negative non-EPCAM expressing CTCs. These maybe cancer stem cells or those with epithelial mesenchymal transition, and possibly more clinically relevant. Hence we developed a multi-antibody approach for characterization of all CTC phenotypes.

2:15 Session Break

FFPE CONSIDERATIONS FOR NOVEL CANCER BIOMARKER ASSAYS

2:30 Chairperson's Remarks
Robert Daber, Ph.D., Vice President, Genomics Operations and Development, Laboratory Medicine, Bio Reference Laboratories

2:40 Assessment of FFPE Samples for Success in NGS
Helen Fernandes, Ph.D., Director, Molecular Pathology, Pathology & Laboratory Medicine, Weill Cornell Medical College
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, and understanding pre-analytic effects on RNA gene expression.

3:10 Quantitative Comparison of Biomarkers by IHC vs mRNA Using a Nearly Point of Care Cancer Biomarker Platform
David L. Rimm, M.D., Ph.D., Professor, Pathology, Executive Director, Translational Pathology, Director, Yale Pathology Tissue Services, Yale University
The measurement of tissue biomarkers is a challenge in the US, but much more so in less developed countries. Some drugs, like Tamoxifen are inexpensive and effective but need a companion diagnostic test. This work will describe the comparison of a low cost, mRNA based platform for measuring Estrogen Receptor and other tissue biomarkers with immunohistochemistry and quantitative immunofluorescence.

3:40 NGS Applications with FFPE Samples: No Longer a Pipedream
Andrew J. Hollinger, Application Scientist, Broad Genomics Platform, Broad Institute.
The Genomics Platform at the Broad Institute has initiated a number of projects to explore QC of FFPE samples upstream of NGS applications resulting in development of protocols and processes that provide insight into likelihood of success for various NGS processes. This has been enabled in large part by the vast number of samples and large collections of FFPE samples that have been processed to date. Here we discuss our approach to preserving usage of nucleic acid from these limited sample types, high-throughput processing, DNA and RNA QC metrics to estimate likelihood of success, and NGS metrics of interest when working with FFPE.

4:10 Standardizing Molecular Pathology with Fully Automated DNA and RNA Extraction from Formalin-Fixed, Paraffin-Embedded (FFPE) and Fresh Frozen (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 Automating NGS Sample Prep for Challenging Samples and Niche Applications
Sponsored By Beckman Coulter
Brian Idoni, Genomics Sales Specialist, Beckman Coulter Life Sciences
This presentation will discuss Biomek-Automated solutions for NGS sequencing applications including HLA, cfDNA from Plasma, exosomes and working with very low input samples.

4:40 Refreshment Break and Transition to Plenary Session

CANCER MOLECULAR MARKERS
CONTINUED ON NEXT PAGE

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

DIGITAL PATHOLOGY AND IMMUNE CHECKPOINT THERAPY

10:05 Chairperson's Remarks
David L. Rimm, M.D., Ph.D., Professor, Pathology, Yale University

10:15 Tissue-Based Assessment of PD-L1 and Other Tumor Microenvironmental Factors in Melanoma Specimens
Janis M. Taube, M.D., MSc, Director, Dermatopathology; Assistant Professor, Dermatology and Pathology, Johns Hopkins
Immunohistochemical detection of PD-L1 and other checkpoint molecules may serve as biomarkers for selecting immunotherapeutic regimens for patients with advanced melanoma. The evaluation of the utility of PD-L1 as a biomarker has been hampered by the different antibodies and assays used. We will discuss the current issues associated with immune checkpoint companion diagnostics and potential future applications for use of these assays in patients with melanoma.

10:45 Tissue-Based Analyses to Guide Immunotherapy for Lymphoma
Scott Rodig, M.D., Ph.D., Hematopathologist, Pathology, Brigham and Women's Hospital
Targeted immunotherapy has achieved long-lasting clinical responses in a subset of patients with a variety of aggressive malignancies. I will discuss the cellular and molecular characteristics of classical Hodgkin lymphoma that render this tumor-type uniquely susceptible to PD-1 blockade and correlations between tissue-based biomarker analysis and clinical outcome with either conventional chemotherapy or immunotherapy, and extensions of these observations to additional lymphoma subtypes.

11:15 Immune Profiling of Lung Cancer Tissue Specimens
Ignasio I. Wistuba, M.D., Department Chair, Translational Molecular Pathology, Division of Pathology/ Lab Medicine; Anderson Clinical Faculty Chair, Cancer Treatment and Research, The University of Texas MD Anderson Cancer Center
The anti-tumor benefit of blocking immune checkpoints in lung cancer, particularly PD-1 and PD-L1, has revolutionized the therapy of this disease. Because of variable responses to immunotherapy (IMT), there is an urgent need for predictive biomarkers to guide personalization of lung cancer treatment. A comprehensive approach to identify and validate IMT-related biomarkers in lung cancer tissue specimens, including digital pathology and genomic methodologies, will be described.

11:45 Beyond PD-L1: Other Potential Companion Diagnostic Tests for Immune Checkpoint Therapy
David L. Rimm, M.D., Ph.D., Professor, Pathology, Yale University
The current companion diagnostic tests and nearly all publications related to immune checkpoint therapies are based on assessment of PD-L1. Some assess PD-L1 in the epithelial component while others emphasize stromal expression. However, there may be other methods for assessment of response to these therapies based on the presence of subsets of T-cells or assessment of the activation of these T-cells. It is also possible that assessment of other co-stimulators or competitive receptors may influence prediction of response to therapy. These non-Pd-L1 methods will be reviewed in this lecture.

12:15 pm Session Break

12:25 Luncheon Presentation I: Shared Accountability: How Genomics & Informatics Will Engage Consumers, Providers and Payers toward true Personalized Medicine
Sponsored By illumina
Brady Davis, Senior Director Strategy & Market Development, Illumina
Genomics data is a big deal when context and meaning is attached to it. Smart data - the right data at the right time to the right person - can help Consumers, Providers and Payers enhance and inform care decisions. That's the prize but how do you get your hands on it? We will focus on Genomics & Informatics and how companies like Illumina are working to provide solutions.

12:55 Luncheon Presentation II: Satnam Alag, Ph.D., Vice President, Software Development, Enterprise Informatics
Sponsored By PHILIPS
Reinhold Wimberger-Friedl phd principal scientist, Philips Research Europe Philips
At Philips we develop an integrated approach of staining-based and molecular characterization of the tumor and its micro-environment. Digital pathology with WSI analytics enables a comprehensive quantification of cellular composition of the tumor. A proprietary model determines the tumor-driving signaling pathways from mRNA expression profiles.

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

MOUSE MODELS FOR TESTING NEW TECHNOLOGY

2:00 Chairperson's Remarks
Steven A. Soper, Ph.D., Professor, Biomedical Engineering & Chemistry; Associate Editor, Analyst; Director, Center for BioModular Multiscale Systems, University of North Carolina

2:10 Circulating Tumor Cells and Mouse Models of Serous Ovarian Cancer
Victoria Bae-Jump, M.D., Ph.D., Associate Professor, Division of Gynecologic Oncology, University of North Carolina
Ovarian cancer (OC) screening is considered the "holy grail" of gynecologic oncology, given that attempts using CA-125 and other tumor markers as well as ultrasound imaging have largely been unsuccessful in screening for this disease. Our novel circulating tumor cell assay employs a dual selection strategy and is being explored using a genetically engineered mouse model (K18-gT121+/-;p53fl/fl;Brca1fl/fl) of OC, providing access to well-defined early and late stage disease blood samples.

2:40 Orthotopic Mouse Models of Cancer and GFP Labeling for the Study of Circulating Tumor Cells
Robert M. Hoffman, Ph.D., President, AntiCancer, Inc.; Professor, Surgery, University of California, San Diego
We have previously determined that orthotopic mouse models of cancer produce viable circulating tumor cells (CTCs) in contrast to ectopic models. We have also demonstrated that green fluorescent protein (GFP) labels CTCs for further analysis such as metastatic potential or chemosensitivity testing. Patient CTCs can also be selectively labeled with GFP *ex vivo* for analysis.

NEW TECHNOLOGIES

3:10 Early Pancreatic Markers, Biomarkers for Exosome Isolation
Raghu Kalluri, M.D., Ph.D., Professor & Chair, Cancer Biology, University of Texas MD Anderson Cancer Center
Exosomes are lipid-bilayer-enclosed extracellular vesicles that contain proteins and nucleic acids. They are secreted by all cells and circulate in the blood. Specific detection and isolation of cancer-cell-derived exosomes in the circulation is currently lacking. Using mass spectrometry analyses, we identify a cell surface proteoglycan, glypican-1 (GPC1), specifically enriched on cancer-cell-derived exosomes.

CANCER MOLECULAR MARKERS
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

3:40 Exosomal RNA (exoRNA) + ctDNA, the "holy grail" of Liquid Biopsy

Sponsored By exosomedx

Johan Skog, Ph.D., CSO, Research & Development, Exosome Diagnostics

Recently, ctDNA has shown promise for cancer mutation detection. ExoDx platform of exoRNA + ctDNA addresses the limitations of ctDNA alone. ExoRNA is abundant from bio-fluids and yields mutations, splice variants, and fusions.

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

NEW TECHNOLOGIES (Cont'd)

10:50 Chairperson's Remarks

Steven A. Soper, Ph.D., Professor, Biomedical Engineering & Chemistry; Associate Editor, Analyst; Director, Center for BioModular Multiscale Systems, University of North Carolina

» 11:00 KEYNOTE PRESENTATION: New Tools for the Isolation of Circulating Markers: Integrated Microfluidic Systems for the Efficient Isolation of CTCs, Cell-Free DNA and Exosomes

Steven A. Soper, Ph.D., Professor, Biomedical Engineering & Chemistry; Associate Editor, Analyst; Director, Center for BioModular Multiscale Systems, University of North Carolina

Liquid biopsies are generating interest within the biomedical community due to the simplicity for securing important markers to realize precision medicine. These circulating markers consist of whole cells such as CTCs, molecules such as cell-free DNA and nanovesicles such as exosomes. We are developing a microfluidic system that can process whole blood and select all three of these markers from a single blood sample.

11:30 Why Do Cancer Cells Move?

Daniel Irimia, M.D., Ph.D., Assistant Professor, Division of Surgery, Science & Bioengineering, Massachusetts General Hospital and Harvard Medical School; Associate Director, BioMEMS Resource Center

When cancer cells leave the tumor, they set in motion a cascade of events that ends with the formation of distant metastases and the death of 90% of cancer patients. However, despite their importance, our understanding of the conditions that trigger cancer cell migration is very limited. In this presentation, I will discuss the design of novel microfluidic tools which revealed the unexpected ability of cancer cells to navigate microscopic mazes along the shortest path and helped identify novel mechanisms for the cancer cell migration.

12:00 pm Extracellular Vesicles as Couriers of Cancer Information

Hakho Lee, Ph.D., Assistant Professor, Center for Systems Biology, Massachusetts General Hospital, Harvard Medical School

Tumor cells release a variety of extracellular vesicles (EVs) which carry information in the form of protein, DNA and RNA. For example, microRNAs can be transferred via EVs to normal cells, thereby changing their phenotype in support of tumor progression. These vesicles and other extracellular RNA vehicles also carry a representation of the transcriptome of the tumor cells which can be found in biofluids and reports on the genetic drivers and status of the cancer.

12:30 Session Break

12:40 Luncheon Presentation: Telomerase-directed tagging of Circulating Tumor Cells

Jay F. Dorsey, M.D., Ph.D., Assistant Professor, Department of Radiation Oncology, University of Pennsylvania

In this presentation we will discuss the association of "telomerase-dependent CTC findings" with treatment response in a variety of cancer patient populations including malignant glioma and non-small cell lung cancer (NSCLC) along with an analysis of molecular driver characterization in CTCs.

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

CELL-FREE DNA AND RNA ASSAYS

1:50 Chairperson's Remarks

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

2:00 Tethered Lipoplex Nanoparticle (TLN) Biochips For Extracellular Vesicles Based Early Disease Diagnosis and Prognosis

L. James Lee, Ph.D., Helen C. Kurtz Chair, Chemical & Biomolecular Engineering, Ohio State University

Circulating extracellular vesicles (EVs) is currently the major focus of non-invasive early disease detection and prognosis. We show that biochips using tethered lipoplex nanoparticles (TLNs) containing molecular beacons can capture cell-derived EVs from body fluids, and identify encapsulated microRNAs/mRNAs and EV surface membrane protein targets with very small sample size (~20 uL blood for 2 targets) and higher sensitivity than qRT-PCR. We will present TLN applications to cancer and non-cancer diseases.

2:30 The Complexity, Function and Applications of RNA in Circulation.

David Galas, Ph.D., Principal Scientist, The Pacific Northwest Diabetes Research Institute

MicroRNAs (miRNAs) have been implicated to play key roles in normal physiological functions, and altered expression of specific miRNAs has been associated with a number of diseases. It is of great interest to understand their roles and a prerequisite for such study is the ability to comprehensively and accurately assess the levels of the entire repertoire of miRNAs in a given sample. It has been shown that some miRNAs frequently have sequence variations termed isomirs.

3:00 Best Practices for Fusion Detection by Targeted RNA Sequencing: Pre-Analytical Considerations, Assay Validation and More

Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories

This presentation will discuss challenges and benefits of NGS based targeted RNA sequencing in the detection of gene fusion events, including, nucleic acid isolation, sample preparation and downstream data processing. There are a number of specific challenges related to RNA sequencing, standardized quality control metrics both before and after library prep are clearly needed.

3:30 Sponsored Presentation *(Opportunity Available)*

4:00 Session Break

PROPAGATING CELLS: CTCs as Early Guide for Treatment Response Prior to Imaging

4:10 Chairperson's Remarks

Stuart S. Martin, Ph.D., Associate Professor, Physiology, Greenebaum NCI Cancer Center, University of Maryland School of Medicine

CANCER MOLECULAR MARKERS
CONTINUED ON NEXT PAGE

4:15 Small Cell Lung Cancer Circulating Tumour Cell-Derived Explants – A New Preclinical Platform for Examining Drug Response

Kristopher Frese, Ph.D., Associate Scientist, Cancer Research UK, Manchester Institute, The University Of Manchester

Due in part to the paucity of tissue samples available for preclinical studies, the past 30 years of research have not provided any new therapeutic options for small cell lung cancer (SCLC). We have recently demonstrated that SCLC circulating tumour cells (CTCs) are tumorigenic in mice and the resulting patient CTC-derived explants (CDX) mirror patients' disease both *in vivo* and *in vitro*. Studies examining the therapeutic efficacy of novel targeted agents are currently underway.

4:45 Antibody-Free Capture of Tumor Cells from Blood and Novel CTC-Targeting Therapeutics

Michael R. King, Ph.D., Daljit S. and Elaine Sarkaria Professor of Biomedical Engineering, Meinig School of Biomedical Engineering, Cornell University

Our laboratory uses surfactant-nanotube complexes to enhance E-selectin-mediated capture and isolation of tumor cells without the use of capture antibodies. Functionalization with sodium dodecanoate surfactant induces a switch to firm cellular adhesion of tumor cells with a simultaneous de-adhesion of blood leukocytes. This system has proved valuable in testing new liposome-based therapeutics designed to target tumor cells in blood for the prevention of metastasis.

5:15 Microfluidic Isolation of Circulating Tumor Cells from Different Venous Sources in Early Lung Cancer

Vasudha Murlidhar, Ph.D., Candidate, Nagrath Lab, Department of Chemical Engineering, University of Michigan, Ann Arbor

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Sixth Annual

CIRCULATING TUMOR CELLS

Enabling Liquid Biopsy

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

LIQUID BIOPSY IN INTERVENTIONAL SETTINGS

11:50 Chairperson's Opening Remarks
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf

12:00 pm Liquid Biopsy: Expectations and Required Steps to Bring It into Clinical Practice
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf

Circulating tumor cells (CTCs), nucleic acids (ctDNA, cfmiRNA) and exosomes in the blood of cancer patients have received increasing attention as new diagnostic tool enabling "liquid biopsies". The perspective to avoid invasive tissue biopsies and obtain similar or even more information by a "simple" blood test has enormous implications in cancer diagnostics. Here the expectations and future steps required to bring liquid biopsies into clinical practice will be discussed.

12:30 Circulating Tumor Cells as a Biomarker of Treatment Efficacy and Prediction in Castration-Resistant Prostate Cancer
Howard I. Scher, M.D., Chief, Genitourinary Oncology Service; Member and Attending Physician, Department of Medicine, Memorial Sloan Kettering Cancer Center; Professor, Medicine, Weill Cornell Medical College

Pre and post-therapy circulating tumor number has been shown to be prognostic for survival. Use in clinical practice and in drug development as a measure of treatment efficacy has been more limited. Analyses of the strength of association of the enumeration biomarker with survival will be discussed along with a recent analysis showing that a CTC enumeration biomarker in combination with LDH was shown to meet the Prentice Criteria for individual-patient level surrogacy. Use of a predictive biomarker to guide treatment selection will also be discussed.

1:00 Session Break

1:15 Luncheon Presentation I: Size-Based Isolation of Circulating Tumor Cells Associated to Droplet Digital PCR Allow Prediction of KRAS Mutations in Patients with Colorectal Cancer before Tumor Surgery
Jérôme A. Denis, M.D., Ph.D., Sorbonne Universités

Sponsored By ScreenCell

1:45 Luncheon Presentation II: Comprehensive Ultra-Sensitive CTC Analysis in the Management of Cancer
Veena Singh, M.D., Senior Vice President & Senior Medical Director, Biocept, Inc.

Sponsored By Biocept Completing the Answer™

Circulating tumor cells (CTCs) isolated solely by EPCAM capture and their CK positive, CD45 negative profile miss CK negative non-EPCAM expressing CTCs. These maybe cancer stem cells or those with epithelial mesenchymal transition, and possibly more clinically relevant. Hence we developed a multi-antibody approach for characterization of all CTC phenotypes.

2:15 Session Break

THE NEXT THING IN CIRCULATING BIOMARKERS: Beyond Characterization and Enumeration of CTCs

2:30 Chairperson's Remarks
Stefanie Jeffrey, M.D., John and Marva Warnock Professor, Surgery; Chief, Surgical Oncology Research, Stanford University School of Medicine

2:40 FEATURED PRESENTATION: Circulating Epithelial Cells as Biopsies of Subclinical Cancer: Novel Technologies for Molecular Analysis
Andrew D. Rhim, M.D., Assistant Professor, Internal Medicine, Division of Gastroenterology, University of Michigan

Our studies in genetic mouse models have shown that dysplastic epithelial cells are shed into the blood stream long before the formation of clinically detectable tumors. Here, we will summarize our efforts in utilizing circulating epithelial cells as a sampling of clinically undetectable dysplastic lesions that may represent the earliest forms of cancer. This discussion will include recent work in the use of novel microfluidic platforms to achieve ultra-sensitive genomic analysis of captured cells by any platform.

3:10 Disease Associated Immune Cells as Novel Biomarkers for Liquid Biopsy
Lidia C. Sambucetti, Ph.D., Senior Program Director, Cancer Research Technologies, Biosciences Division, SRI International

Liquid biopsies enable the collection of information on a cancer patient's disease from a blood test based on enumeration of circulating tumor cells (CTCs) and characterization of their protein or genetic biomarkers. Using our ultra-high throughput non-enrichment rare cell detection platform, FASTcell™, we now extend the use of liquid biopsies to the detection of rare biomarkers on immune cells for detection of features of the tumor microenvironment and for certain infectious diseases.

3:40 Platelet Cloaking, Cancer Cells and CTCs: Lessons for the Metastatic Cascade
John O'Leary, M.D., Ph.D., Chair, Pathology, Trinity College Dublin; Director, Pathology, Coombe Women and Infants University Hospital; Consultant, Pathologist, St. James's Hospital; Principal Investigator, Biomedical Diagnostics Institute (BDI)

The talk will critically examine the biological pathways involved in these interactions and will describe novel immune surveillance inhibition mechanisms adopted by platelet cloaked cancer cells directly inhibiting natural killer [NK] cell function, including direct receptor-ligand perturbation and immune decoy defense mechanisms.

4:10 Recovery of Single CTCs Using DEPArray™ for Precise Downstream Molecular Profiling and NGS Applications
Farideh Bischoff, Ph.D., Executive Director, Scientific Affairs, Silicon Biosystems

Sponsored By silicon biosystems

DEPArray™ allows recovery of pure and intact target (rare) cells. Given heterogeneity among CTCs , molecular analysis of individual and intact cells is critical to ensure that low level genomic alterations are observed. A workflow for DEPArray-based recovery of individual CTCs is now established.

4:25 Going Beyond Averages and Enumeration – How Epic's 'No Cell Left Behind' Platform is Driving Novel Insights in Cancer
Murali Prahalad, Ph.D., President & CEO, Epic Sciences

Sponsored By EPIC SCIENCES™

Cancer is a disease characterized by incredible cellular heterogeneity often driven by multiple

CIRCULATING TUMOR CELLS
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

clonal species possessing unique proteomic and genomic profiles. This session will highlight how Epic Sciences' unique enrichment-free approach enables new insights into cancer that surpass simple enumeration or the genomic averaging that results from the sequencing of tissue biopsy or cfDNA.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

FUNCTIONAL CTC STUDIES

10:05 Chairperson's Remarks
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf

10:15 Detection, Characterization and *ex vivo* Expansion of Viable Circulating Tumor Cells
Catherine Alix-Panabières, Ph.D., Maître de Conférence - Praticien Hospitalier, Associate Professor, Director, Laboratory of Rare Human Circulating Cells, Institute of University Clinical Research (IURC), University Medical Centre of Montpellier, University of Montpellier
Circulating Tumor Cells (CTCs) in blood are promising new biomarkers potentially useful for prognostic prediction and monitoring of therapies in patients with solid tumors including colon cancer. However, an in-depth investigation of CTCs is hampered by the very low number of these cells, especially in the blood of colorectal cancer patients. Here we describe the establishment of cell cultures and a permanent cell line from CTCs of one colon cancer patient.

10:45 Detection and Molecular Profiling of Single CTCs and a Patient Derived CTC Line
Tobias M. Gorges, Ph.D., Senior Scientist, Department of Tumor Biology, Center of Experimental Medicine, University Medical Center Hamburg-Eppendorf
Detection and molecular characterization of circulating tumor cells (CTCs) is challenging. We compared different approaches for CTC enrichment. A reliable protocol for the molecular characterization of single cells - targeting up to 84 transcripts per single cell - could be established. We also could establish and characterize a patient derived CTC line. Our findings help to understand the complexity of tumor biology.

11:15 A Direct, Chip-Based Approach to Analysis of Cell-Free Nucleic Acids
Shana Kelley, Ph.D., Professor, Biochemistry, University of Toronto
The analysis of cell-free nucleic acids (cfNA) can reveal the mutational spectrum of a tumor without the need for invasive sampling of tissue; however, this requires the differentiation of nucleic acids that originate from healthy cells from the mutated sequences shed by tumor cells. Here we report an electrochemical clamp assay that directly detects mutated sequences in patient serum. This is the first successful detection of cfNA without the need for enzymatic amplification, a step that normally requires extensive sample processing.

11:45 Isolation and *ex vivo* Expansion of CTCs for Molecular Diagnosis and Drug Testing
Sunitha Nagrath, Ph.D., Assistant Professor, Chemical Engineering, University of Michigan
Currently, tumor genotyping is performed from tumor biopsies or re-biopsies. CTCs may provide a non-invasive alternative to traditional biopsy to identify the key genetic signatures and resistance mechanisms. There is currently no way to predict which of the many early phase compounds that target resistance will lead to further response. Here we present a strategy to culture CTCs *ex vivo* reproducibly and allow us to perform *ex vivo* drug testing.

12:15 pm Session Break

Sponsored By ANGLE

12:25 Luncheon Presentation I: Gene Expression Profiling of Circulating Tumor Cells in Breast Cancer
Julie E. Lang, M.D., FACS, Associate Professor, Breast and Soft Tissue Surgery, Norris Comprehensive Cancer Center, University of Southern California
CTCs are prognostic in all stages of breast cancer, yet few studies have examined their role as predictive biomarkers. Affinity based and microfluidic chip-based technologies may be used for sequencing the RNA of CTCs. The current state and what is necessary to move CTCs from a research grade biomarker to a clinical grade biomarker will be discussed.

Sponsored By Celsee Diagnostics

12:55 Luncheon Presentation II: An Automated, Sensitive Microfluidic Device for Capturing and Characterizing CTCs from Whole Blood Samples
Yixin Wang, Ph.D., CSO, Celsee Diagnostics
The Celsee Diagnostics' novel microfluidic technology captures and characterizes CTCs from metastatic cancer patients' whole blood samples based on size and deformability. The design enables downstream characterization of CTCs, including IHC, FISH, PCR and NGS.

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

MOUSE MODELS FOR TESTING NEW TECHNOLOGY

2:00 Chairperson's Remarks
Steven A. Soper, Ph.D., Professor, Biomedical Engineering & Chemistry; Associate Editor, Analyst; Director, Center for BioModular Multiscale Systems, University of North Carolina

2:10 Circulating Tumor Cells and Mouse Models of Serous Ovarian Cancer
Victoria Bae-Jump, M.D., Ph.D., Associate Professor, Division of Gynecologic Oncology, University of North Carolina
Ovarian cancer (OC) screening is considered the "holy grail" of gynecologic oncology, given that attempts using CA-125 and other tumor markers as well as ultrasound imaging have largely been unsuccessful in screening for this disease. Our novel circulating tumor cell assay employs a dual selection strategy and is being explored using a genetically engineered mouse model (K18-gT121+/-;p53fl/fl;Brca1fl/fl) of OC, providing access to well-defined early and late stage disease blood samples.

2:40 Orthotopic Mouse Models of Cancer and GFP Labeling for the Study of Circulating Tumor Cells
Robert M. Hoffman, Ph.D., President, AntiCancer, Inc.; Professor, Surgery, University of California, San Diego
We have previously determined that orthotopic mouse models of cancer produce viable circulating tumor cells (CTCs) in contrast to ectopic models. We have also demonstrated that green fluorescent protein (GFP) labels CTCs for further analysis such as metastatic potential or chemosensitivity testing. Patient CTCs can also be selectively labeled with GFP *ex vivo* for analysis.

NEW TECHNOLOGIES

3:10 Early Pancreatic Markers, Biomarkers for Exosome Isolation
Raghu Kalluri, M.D., Ph.D., Professor & Chair, Cancer Biology, University of Texas MD Anderson Cancer Center
This talk will review our work with exosomes and how we've used mass spectrometry analyses to identify a cell

CIRCULATING TUMOR CELLS
CONTINUED ON NEXT PAGE

surface proteoglycan, glypican-1 (GPC1), specifically enriched on cancer-cell derived exosomes. We'll discuss how we monitored and isolated these by using flow cytometry from the serum of patients and mice with cancer. We will discuss how GPC1(+) crExos may serve as a potential non-invasive diagnostic and screening tool to detect early stages of pancreatic cancer to facilitate possible curative surgical therapy.

3:40 Liquid Biopsy Using Exosome RNA and ctDNA, Realizing the "Holy Grail" of Personalized Medicine

Sponsored By exosomedx

Johan Skog, Ph.D., CSO, Research & Development, Exosome Diagnostics

Recently, ctDNA has shown promise for cancer mutation detection. ExoDx platform of exoRNA + ctDNA addresses the limitations of ctDNA alone. ExoRNA is abundant from bio-fluids and yields mutations, splice variants, and fusions.

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

NEW TECHNOLOGIES (Cont'd)

10:50 Chairperson's Remarks

Steven A. Soper, Ph.D., Professor, Biomedical Engineering & Chemistry; Associate Editor, Analyst; Director, Center for BioModular Multiscale Systems, University of North Carolina

» 11:00 KEYNOTE PRESENTATION: New Tools for the Isolation of Circulating Markers: Integrated Microfluidic Systems for the Efficient Isolation of CTCs, Cell-Free DNA and Exosomes

Steven A. Soper, Ph.D., Professor, Biomedical Engineering & Chemistry; Associate Editor, Analyst; Director, Center for BioModular Multiscale Systems, University of North Carolina

Liquid biopsies are generating interest within the biomedical community due to the simplicity for securing important markers to realize precision medicine. These circulating markers consist of whole cells such as CTCs, molecules such as cell-free DNA and nanovesicles such as exosomes. We are developing a microfluidic system that can process whole blood and select all three of these markers from a single blood sample.

11:30 Why Do Cancer Cells Move?

Daniel Irimia, M.D., Ph.D., Assistant Professor, Division of Surgery, Science & Bioengineering, Massachusetts General Hospital and Harvard Medical School; Associate Director, BioMEMS Resource Center

When cancer cells leave the tumor, they set in motion a cascade of events that ends with the formation of distant metastases and the death of 90% of cancer patients. However, despite their importance, our understanding of the conditions that trigger cancer cell migration is very limited. In this presentation, I will discuss the design of novel microfluidic tools which revealed the unexpected ability of cancer cells to navigate microscopic mazes along the shortest path and helped identify novel mechanisms for the cancer cell migration.

12:00 pm Extracellular Vesicles as Couriers of Cancer Information

Hakho Lee, Ph.D., Assistant Professor, Center for Systems Biology, Massachusetts General Hospital, Harvard Medical School

Tumor cells release a variety of extracellular vesicles (EVs) which carry information in the form of protein, DNA and RNA. For example, microRNAs can be transferred via EVs to normal cells, thereby changing their phenotype in support of tumor progression. These vesicles and other extracellular RNA vehicles also carry a representation of the transcriptome of the tumor cells which can be found in biofluids and reports on the genetic drivers and status of the cancer.

12:30 Session Break

12:40 Luncheon Presentation

Sponsored By Oncolys BioPharma

Jay Dorsey, M.D., Ph.D., Assistant Professor, Department of Radiation Oncology, University of Pennsylvania

In this presentation we will discuss the association of "telomerase-dependent CTC findings" with treatment response in a variety of cancer patient populations including malignant glioma and non-small cell lung cancer (NSCLC) along with an analysis of molecular driver characterization in CTCs.

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

CHALLENGES VS. OPPORTUNITIES - HOW DO WE GET PENETRATION OF NEW CTC TECHNOLOGIES INTO THE MARKETPLACE?

1:50 Chairperson's Remarks

Hsian-Rong Tseng, Ph.D., Professor, Molecular & Medical Pharmacology; Member, JCCC Cancer Molecular Imaging; Faculty, Crump Institute for Molecular Imaging, University of California, Los Angeles

2:00 The NCI SBIR/STTR Program: Accelerating the Commercialization of New CTC Technologies

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

The federal SBIR/STTR program is one of the largest sources of early-stage technology financing in the U.S. Under this program, the National Cancer Institute (NCI) spends $120 million annually to support R&D and commercialization of novel technologies for cancer prevention, diagnostics and treatment, including CTC technologies. In this presentation, Dr. Xing-Jian Lou will discuss efforts to help NCI-funded small businesses overcome regulatory hurdles in the translation of new technologies.

2:15 PANEL DISCUSSION

Steven A. Soper, Ph.D., Professor, Biomedical Engineering & Chemistry; Associate Editor, Analyst; Director, Center for BioModular Multiscale Systems, University of North Carolina
Murali Prahalad, Ph.D., President and CEO, Epic Sciences
Veena Singh, Senior Vice President & Sr. Medical Director, Biocept, Inc.
Farideh Bischoff, Ph.D., Executive Director, Scientific Affairs, Silicon Biosystems, Inc.

3:30 Analyzing Liquid Biopsy Samples with Next-Generation Sequencing in Clinical Research

Sponsored By ThermoFisher SCIENTIFIC

Speaker to be Announced

4:00 Session Break

PROPAGATING CELLS: CTCs as Early Guide for Treatment Response Prior to Imaging

4:10 Chairperson's Remarks

Stuart S. Martin, Ph.D., Associate Professor, Physiology, Greenebaum NCI Cancer Center, University of Maryland School of Medicine

CIRCULATING TUMOR CELLS
CONTINUED ON NEXT PAGE

4:15 Small Cell Lung Cancer Circulating Tumour Cell-Derived Explants – A New Preclinical Platform for Examining Drug Response

Kristopher Frese, Ph.D., Associate Scientist, Cancer Research UK, Manchester Institute, The University Of Manchester

Due in part to the paucity of tissue samples available for preclinical studies, the past 30 years of research have not provided any new therapeutic options for small cell lung cancer (SCLC). We have recently demonstrated that SCLC circulating tumour cells (CTCs) are tumorigenic in mice and the resulting patient CTC-derived explants (CDX) mirror patients' disease both *in vivo* and *in vitro*. Studies examining the therapeutic efficacy of novel targeted agents are currently underway.

4:45 Antibody-Free Capture of Tumor Cells from Blood and Novel CTC-Targeting Therapeutics

Michael R. King, Ph.D., Daljit S. and Elaine Sarkaria Professor of Biomedical Engineering, Meinig School of Biomedical Engineering, Cornell University

Our laboratory uses surfactant-nanotube complexes to enhance E-selectin-mediated capture and isolation of tumor cells without the use of capture antibodies. Functionalization with sodium dodecanoate surfactant induces a switch to firm cellular adhesion of tumor cells with a simultaneous de-adhesion of blood leukocytes. This system has proved valuable in testing new liposome-based therapeutics designed to target tumor cells in blood for the prevention of metastasis.

5:15 Conditional Reprogramming Rapidly and Efficiently Generates Normal and Tumor Cell Cultures

Richard Schlegel, M.D., Ph.D., Professor and Oscar B. Hunter Chair, Pathology; Director, Center for Cell Reprogramming, Georgetown University Medical School

Conditional reprogramming (CR) is a new cell biology technique that allows for the rapid and efficient outgrowth of matched normal and tumor epithelial tissue from patient samples. This approach combines the use of a ROCK inhibitor and irradiated feeder cells to induce and select for stem-like cells from adult tissues. Biobanking using the CR method is now standardly applied in our pathology department in order to generate a renewable resource of patient samples for scientific investigation.

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Fourth Annual

DIGITAL PATHOLOGY

Transforming Medicine in a Digital World

In Partnership with

API PATHOLOGY INFORMATICS

DIGITAL PATHOLOGY ASSOCIATION DPA

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

HOT TOPICS

11:50 Chairperson's Opening Remarks

» 12:00 PM KEYNOTE PRESENTATION: Implementation of Full Digital Workflow

Paul J. (Paulus Joannes) van Diest, M.D., Ph.D., Professor & Head, Pathology, University Medical Center Utrecht

This presentation will give an impression on how the Department of Pathology at the University Medical Center Utrecht is in the process of implementation of full digital workflow.

12:30 International Telepathology Makes a Difference

Liron Pantanowitz, M.D., Associate Professor, Pathology & Biomedical Informatics; Director, Pathology Informatics and UPMC Shadyside Cytology Divisions; Director, the Pathology Informatics Fellowship Program, University of Pittsburgh Medical Center

This talk about telepathology will focus more on clinical practice than technology, and demonstrate how international teleconsultation can significantly improve patient care by facilitating access to pathology expertise. Several years' worth of experience will be shared involving international teleconsultation between the University of Pittsburgh Medical Center and KingMed Diagnostics in China. This talk will highlight key factors that may hinder or support a successful, sustainable and growing international telepathology partnership.

1:00 Session Break

1:15 Luncheon Presentation I: Manage, Visualize, Analyze, Annotate, Share: The New Digital Pathology Paradigm

Sponsored By Glencoe Software

Rebecca M. Walker, Vice President, Global Sales & Marketing, Glencoe Software

1:45 Luncheon Presentation II *(Sponsorship 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 Potential Roles for *ex vivo* Optical Imaging for Tissue Evaluation in Surgical Pathology Practice

Savitri Krishnamurthy, M.D., Professor, Pathology, The University of Texas MD Anderson Cancer Center

Our work with Confocal microscopy platform using surgically excised tissues and needle core biopsies demonstrate the feasibility of using this technique for rapid evaluation of tissues with a high level of sensitivity and specificity. The role of this technique for tissue evaluation in routine Surgical Pathology practice needs to be evaluated in prospective clinical studies.

3:10 Multiphoton Microscopy: A Valuable Tool to Rapidly Evaluate and Triage *ex vivo* Tissues from a Genito-Urinary Prospective

Manu Jain, M.D., Assistant Attendee Optical Imaging Specialist, Dermatology, Memorial Sloan Kettering Cancer Centre (MSKCC)

Multiphoton microscopy (MPM) generates histology-quality images rapidly from fresh tissue, without tissue processing. Fresh tissue from bladder, kidney, testis and prostate were imaged with MPM. Based on the architectural and cellular details, MPM could characterize normal components of the tissue and differentiate neoplastic from non-neoplastic. We envision MPM as a real-time diagnostic tool for bedside rapid evaluation of tissue and as an adjunct to frozen sectio for intra-operative margin assessment.

3:40 Spectral Biopsy: A Noninvasive Assessment of Tissue Pathology

James W. Tunnell, Ph.D., Associate Professor, Biomedical Engineering, University of Texas, Austin

Optical spectroscopic techniques allow one to noninvasively assess tissue pathology. This so-called "spectral biopsy" requires device and algorithm development to translate these traditional bench-top methods to clinically usable devices. We will highlight our recent work combining several techniques in a multi-modality approach (combined Raman, diffuse optical and laser induced fluoresce), including recent results of its clinical use.

4:10 Demonstrating Clinical Impact: Getting Paid for Next-Generation Sequencing in 2016 and Beyond

Sponsored By XIFIN

Kyle Fetter, Vice President, Advanced Diagnostics, 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.

4:25 Integrated Phenomics and Big Data for Biomarker Discovery and Test Development

Sponsored By DEFINIENS the tissue phenomics company

Ralf Huss, M.D., CSO, Definiens

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

DIGITAL PATHOLOGY AND IMMUNE CHECKPOINT THERAPY

10:05 Chairperson's Remarks

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

DIGITAL PATHOLOGY
CONTINUED ON NEXT PAGE

10:15 Tissue-Based Assessment of PD-L1 and Other Tumor Microenvironmental Factors in Melanoma Specimens

Janis M. Taube, M.D., MSc, Director, Dermatopathology; Assistant Professor, Dermatology and Pathology, Johns Hopkins

Immunohistochemical detection of PD-L1 and other checkpoint molecules may serve as biomarkers for selecting immunotherapeutic regimens for patients with advanced melanoma. The evaluation of the utility of PD-L1 as a biomarker has been hampered by the different antibodies and assays used. We will discuss the current issues associated with immune checkpoint companion diagnostics and potential future applications for use of these assays in patients with melanoma.

10:45 Tissue-Based Analyses to Guide Immunotherapy for Lymphoma

Scott Rodig, M.D., Ph.D., Hematopathologist, Pathology, Brigham and Women's Hospital

Targeted immunotherapy has achieved long-lasting clinical responses in a subset of patients with a variety of aggressive malignancies. I will discuss the cellular and molecular characteristics of classical Hodgkin lymphoma that render this tumor-type uniquely susceptible to PD-1 blockade and correlations between tissue-based biomarker analysis and clinical outcome with either conventional chemotherapy or immunotherapy, and extensions of these observations to additional lymphoma subtypes.

11:15 Immune Profiling of Lung Cancer Tissue Specimens

Ignasio I. Wistuba, M.D., Department Chair, Translational Molecular Pathology, Division of Pathology/ Lab Medicine; Anderson Clinical Faculty Chair, Cancer Treatment and Research, The University of Texas MD Anderson Cancer Center

The anti-tumor benefit of blocking immune checkpoints in lung cancer, particularly PD-1 and PD-L1, has revolutionized the therapy of this disease. Because of variable responses to immunotherapy (IMT), there is an urgent need for predictive biomarkers to guide personalization of lung cancer treatment. A comprehensive approach to identify and validate IMT-related biomarkers in lung cancer tissue specimens, including digital pathology and genomic methodologies, will be described.

11:45 Beyond PD-L1: Other Potential Companion Diagnostic Tests for Immune Checkpoint Therapy

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

The current companion diagnostic tests and nearly all publications related to immune checkpoint therapies are based on assessment of PD-L1. Some assess PD-L1 in the epithelial component while others emphasize stromal expression. However, there may be other methods for assessment of response to these therapies based on the presence of subsets of T-cells or assessment of the activation of these T-cells. It is also possible that assessment of other co-stimulators or competitive receptors may influence prediction of response to therapy. These non-Pd-L1 methods will be reviewed in this lecture.

12:15 pm Session Break

Sponsored By illumina

12:25 :Luncheon Presentation I: Shared Accountability: How Genomics & Informatics Will Engage Consumers, Providers and Payers toward true Personalized Medicine

Satnam Alag, Ph.D., Vice President, Software Development, Enterprise Informatics

Genomics data is a big deal when context and meaning is attached to it. Smart data - the right data at the right time to the right person - can help Consumers, Providers and Payers enhance and inform care decisions. That's the prize but how do you get your hands on it? We will focus on Genomics & Informatics and how companies like Illumina are working to provide solutions.

Sponsored By PHILIPS

12:55 Luncheon Presentation II: Integrated Oncology Diagnostics enabled by Digital Pathology

Reinhold Wimberger-Friedl phd principal scientist, Philips Research Europe Philips

At Philips we develop an integrated approach of staining-based and molecular characterization of the tumor and its micro-environment. Digital pathology with WSI analytics enables a comprehensive quantification of cellular composition of the tumor. A proprietary model determines the tumor-driving signaling pathways from mRNA expression profiles.

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

HOT TOPICS II

2:00 Chairperson's Remarks

Liron Pantanowitz, M.D., Associate Professor, Pathology & Biomedical Informatics; Director, Pathology Informatics and UPMC Shadyside Cytology Divisions; Director, the Pathology Informatics Fellowship Program, University of Pittsburgh Medical Center

2:10 Digital Microbiology – The New Frontier

Susan Novak-Weekley, Ph.D., D(ABMM), Director, Microbiology, Molecular Infectious Disease & Serology Testing, Southern California Permanente Medical Group

Manual workup of bacterial cultures is a process that all clinical microbiologists are familiar with. Newer incubators on the market contain digital cameras that can take an image of growth on a petri dish. These images can then be presented to the technologist for analysis. Digital microbiology allows for culture work up by observing the plates via a computer screen. This lecture will cover the application of Digital Microbiology and important considerations with implementation.

2:40 Comparison of Two PD-L1 Antibodies Using Fluorescence and Brightfield IHC

Michelle Dean, BSc., Functional Tissue Imaging Unit, Translational Labs, Tom Baker Cancer Centre

3:10 WSI – Reduction to Clinical Utility

Stephen M. Hewitt, M.D., Ph.D., Clinical Investigator; Head, Experimental Pathology and Lab of Pathology, Center for Cancer Research, National Cancer Institute, National Institutes of Health, FDA

Whole Slide Imaging has matured greatly over the last decade, however implementation for clinical application is occurring at a much slower pace. Although many challenges have been overcome, the current challenges are the "nuts and bolts" of delivering quality-defined images rapidly to users. This talk will address the challenges of developing and deploying a robust whole slide imaging solution that drives pathologist productivity.

Sponsored By indica labs informed pathology

3:40 Title to be Announced

Katherine Lillard-Wetherell, Ph.D., CSO, Indica Labs
Vlado Ovtcharov, Senior Algorithm Engineer, Indica Labs

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

DIGITAL PATHOLOGY
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

HOW TO MAXIMIZE VALUE OF DIGITAL IMAGING: Improving Quality of Care through Machine Learning Approaches

10:50 Chairperson's Remarks
Kenneth J. Bloom, M.D., CMO, Human Longevity Inc

11:00 Slide-Free Histology via MUSE: UV Surface Excitation Microscopy for Imaging Unsectioned Tissue
Richard Levenson, M.D., Professor and Vice Chair, Strategic Technologies, Pathology & Laboratory Medicine, University of California, Davis Medical Center
Slide-free methods for rapid tissue histological analysis can cut hours off usual pathology slide preparation procedures. One approach to accomplish this is MUSE (Microscopy with UV Surface Excitation), which exploits the shallow penetration of UV light to excite fluorescent signals from only the most superficial tissue elements. The method is non-destructive, and eliminates the need for conventional histology processing, formalin fixation, paraffin embedding, or thin sectioning.

11:30 pm The Impact of Machine Learning on the Practice of Pathology
Kenneth J. Bloom, M.D., CMO, Human Longevity Inc

11:30 Late Breaking Presentation

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Enjoy Lunch on Your Own

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

DIGITIZED CYTOLOGY

1:50 Chairperson's Remarks
David C. Wilbur, M.D., Professor, Pathology, Massachusetts General Hospital

2:00 Cytology Education in the Digital Era
Stanley J. Radio, M.D., Professor and Medical Director, Cytotechnology Program, University of Nebraska Medical Center
The rapidly contracting number of cytotechnology training programs in the U.S. and the advent of digital learning in all aspects of education has provided the impetus for us to establish satellite programs and develop novel methods to deliver instruction to all students. We utilize virtual cytology slides for virtual slide boxes, learning modules that include cytology/histology correlation, slide morphology tests and student presentations, both local and satellite as well as many other applications.

2:30 Digital Pathology Applications in Cytologic Specimens: Unique Aspects and Solutions for Optimization
David C. Wilbur, M.D., Director, Clinical Imaging in Pathology, Massachusetts General Hospital; Professor of Pathology, Harvard Medical School
A number of maneuvers can be accomplished to solve the 3-dimensional problems with cytology specimens, including real time image streaming, multiplane scanning, intercalation of multiple scanned planes, and embedding of focused video clips and high resolution scan areas. Use of these technologies can afford similar accuracy in the interpretation of cytology digital images as is now found to be the case in histologic digital images.

3:00 Cytology Digital Consultation
Liron Pantanowitz, M.D., Associate Professor, Pathology & Biomedical Informatics; Director, Pathology Informatics and UPMC Shadyside Cytology Divisions; Director, the Pathology Informatics Fellowship Program, University of Pittsburgh Medical Center
Experience with the practice of telecytology has greatly increased. Cytology digital teleconsultation has been employed for rapid evaluation of specimens, remote interpretation of Pap tests, and for rendering second opinions on challenging non-gynecologic cases. The aim of this talk is to review the topic of telecytology and highlight the benefits and shortcomings of this digital imaging application.

3:30 PANEL DISCUSSION

4:00 Session Break

REIMAGINING PATHOLOGY IMAGING

4:10 Chairperson's Remarks
Bruce Levy, M.D., CPE, Associate Professor, Pathology, University of Illinois, Chicago; Associate Chief Health Information Officer, University of Illinois at Chicago Hospital and Health Sciences System

4:15 Utilizing High-Resolution Tiled Displays to Enhance Collaboration for Patient Care, Medical Research and Education
Bruce Levy, M.D., CPE, Associate Professor, Pathology, University of Illinois, Chicago; Associate Chief Health Information Officer, University of Illinois at Chicago Hospital and Health Sciences System
Whole-slide images (WSI) can produce disruptive change throughout medicine. We "re-imagined" the microscope in the era of cloud computing by combining WSI with the rich collaborative environment of the Scalable Adaptive Graphics Environment (SAGE). SAGE is well suited to display, manipulate and collaborate using WSI simultaneously with other images and data. We have successfully used SAGE for patient care, multidisciplinary conferences, medical research, and undergraduate and graduate level medical education.

4:45 Digital Imaging Tools for Hematopathology
Mohamed Salama, M.D., Professor, Pathology, University of Utah; Director, Hematopathology Fellowship Program; Director, Immunohistochemistry and Digital Imaging, ARUP Reference Lab
Hematologists and hematopathologists are increasingly using digital imaging tools for a wide spectrum of practice settings. However, digital imaging applications for effective learning and diagnosis rendering are not yet routinely incorporated in practice. We will share our experience in utilizing digital tools for hematopathology. We will demonstrate methods and applications for effectively using digital imaging tools. We will cover the essential elements as well as the pitfalls, advantages and challenges in utilization of digital tools in practice.

5:15 The Need for an Ontology Framework in Computational Histopathology
John E. Tomaszewski, M.D., MASCP, Professor and Chair, Pathology and Anatomical Sciences, School of Medicine and Biomedical Sciences, State University of New York, Buffalo
Quantitative HistoCAD data is of a size which is on par with other modes of big data. HistoCAD data will require highly structured representations in order to support the computational analysis of these data. A quantitative histological image ontology (QHIO) is needed to allow for the structured representation of HistoCAD data. Analogous to the great success of the Gene Ontology (GO), QHIO is anticipated to promote enhanced interoperability of HistoCAD data sets between and amongst investigators in human pathobiology.

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Inaugural

PRECISION MEDICINE

Beyond the Genome for Insights into New Treatments

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

KEYNOTE SESSION: PROSPECTS AHEAD FOR PRECISION MEDICINE

11:50 Chairperson's Opening Remarks
Steven M. Watkins, Ph.D., Chief Technology Officer, Metabolon

12:00 pm Understanding Human Physiology First, then Some Preciseness
John Todd, FRS, FMedSci Ph.D., Professor, Medical Genetics, University of Cambridge; JDRF/ Wellcome Trust Diabetes and Inflammation Laboratory, NIHR Cambridge Biomedical Research Centre, Cambridge Institute for Medical Research, University of Cambridge
This talk will review how detailed longitudinal studies of humans will help us understanding physiology and the effects of potential therapeutics.

12:30 Metabolomis – A Functional Enhancement of Precision Medicine
C. Thomas Caskey, M.D., FACP, FACMG, FRSC, Professor, Molecular & Human Genetics, Baylor College of Medicine
Whole genome and exon sequencing is dependent on relational data bases and mutation character to predict normal and disease risk. We have utilized metabolomics as our first functional measure of gene integrity and predicted disease risk. It has been applied to both, pediatrician and adult cohorts with clarification of sequence changes and their effect on function. Both cohorts will be reported.

1:00 Session Break

Sponsored By
FIBROTX INNOVATIONS FOR SKIN

1:15 FibroTx TAP and SELF: Pioneering the Potential of Topical Skin-Biomarkers for Personalized Care
Pieter Spee, Chief Technology Officer, FibroTx LLC
FibroTx has developed two platform technologies for non-invasive measurements of protein biomarkers directly from skin. TAP allows unique opportunities for product development and biomarker research. SELF is the first practical molecular point-of-care device intended for personalised skin care.

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

2:15 Session Break

2:30 Chairperson's Remarks
Steven M. Watkins, Ph.D., Chief Technology Officer, Metabolon

2:40 The Personalized Medicine Initiative: Implementation of Molecular Medicine into Healthcare
Pieter R. Cullis, Ph.D., FRSC, Chair, Personalized Medicine Initiative, Director, Life Sciences Institute, University of British Columbia
The Personalized Medicine Initiative (PMI) is implementing molecularly-based medicine into the population using British Columbia as a test bed to develop validated approaches. Projects that are underway include introduction of inexpensive genetic tests such as pharmacogenomic analyses to guide drug prescription practices, or genetic analyses to personalize chemotherapy. We are also introducing a preventive medicine "Molecular You" program to develop personal Omic data clouds for early diagnosis of disease.

3:10 BRCA Challenge
David Haussler, Ph.D., Distinguished Professor and Scientific Director, UC Santa Cruz Genomics Institute, University of California, Santa Cruz
The BRCA Challenge of the Global Alliance for Genomics and Health aims to advance understanding of the genetic basis of breast cancer and other cancers by pooling data on BRCA genetic variants from around the world. This is a pilot project of the GA4GH that, if successful, will be extended to other genes and conditions, so that we can break data out of the medical and commercial silos it is getting stuck in. We'll discuss the methodology and current status of the project.

3:40 Revolutionizing Human Health
Brad Perkins, M.D., MBA, CMO, Human Longevity, Inc.
Human Longevity, Inc. (HLI) is building a database of integrated health records including WGS, metabolomics, and microbiome along with extensive clinical data. Machine learning is being applied to translate the language of biology as sequence data into the language of health and disease. HLI is using this database and our informatics capabilities to create new insights for the Life Sciences, Health and Life Insurance, and Health Care industries.

Sponsored By
envision genomics

4:10 Presentation to be Announced
Liz Worthey, Ph.D., Chief Informatics & Product Development Officer, Envision Genomics
Every patient carries information in their genome that is relevant to their care or future care, which is the foundation of Genomic Medicine. Dr. Worthey will discuss the critical role Genomic Medicine diagnostics, tools and resources play in building the knowledge base required to understand (i.e. determine the function of) genomic sequence variants and their impact on disease treatment and overall health.

4:25 Sponsored Presentation *(Opportunity Available)*

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

PRECISION MEDICINE
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

8:00 Plenary Keynote Session *(see page 5 for details)*

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

BREAKTHROUGHS IN PERSONALIZED MEDICINE OUTSIDE ONCOLOGY

Co-Organized with PMC PERSONALIZED MEDICINE COALITION Celebrating 10 Years

10:05 Chairperson's Remarks
Edward Abrahams, Ph.D., President, Personalized Medicine Coalition

» 10:15 KEYNOTE PRESENTATION: Clinical Deployment of Personalized Medicine - Successes and Challenges
A. Keith Stewart, M.B., Ch.B., Carlson and Nelson Endowed Director, Center for Individualized Medicine; Vasek and Anna Maria Polak Professor, Cancer Research, Mayo Clinic

10:45 15 Years of Personalized Medicine, Can We Move Beyond Oncology?
Eric Lai, Ph.D., Senior Vice President and Head, Pharmacogenomics, Companion Diagnostics, Takeda Development Centers of America
Despite the complete sequencing of the Human Genome and the development of new molecular technologies, the clinical application of personalized medicine is still mostly limited to Oncology. This presentation will discuss other potential ways of applying pharmacogenomics to drug development and the use of big research datasets to address unmet medical needs to non-oncology areas. In addition, we will discuss major roadblocks for the next 5 years and beyond.

11:15 Talk Title to be Announced
Hakan Sakul, Ph.D., Executive Director and Head, Diagnostics, Worldwide R&D, Development Operations, Pfizer, Inc.

11:30 Changing Treatment Paradigms
Greg Keenan, M.D., Vice President, Medical Affairs & US Head Medical Officer, AstraZeneca
Dr. Greg Keenan will explore what constitutes a useful companion diagnostic or biomarker, and the considerations for patients beginning or continuing a therapy over time, and exciting potential opportunities to advance medical science in the treatment of lupus, respiratory disease and other non-oncological disease states.

11:20 PANEL DISCUSSION

12:15 pm Session Break

12:25 Luncheon Presentation I: Expanding Treatment Options with Genomics-Enabled Immuno-Oncology
Sponsored By Q² Solutions a Quintiles Quest Joint Venture
Victor Weigman, Ph.D., Associate Director, Translational Genomics, Q Squared Solutions
Tumor genomic profiling can direct patients to new therapeutic possibilities. Positive responses aside, many patients are left with few treatment options. Genomics can further illuminate the inherently complex tumor microenvironment, with beneficial implications for Immuno-oncology strategies.

12:55 Luncheon Presentation II *(Sponsorship Opportunity Available)*

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

PROMOTING PRECISION MEDICINE: WHY IT IS IMPORTANT AND WHAT WE ALL CAN DO

2:00 Introduction and Presentation: Promoting the Value of Pharmacogenomics to the Public
Alan Wu, Ph.D., Director, Pharmacogenomics Laboratory; Professor, Department of Lab Medicine, University of California, San Francisco
The implementation of Precision Medicine into daily medical practice has been slow. There are many barriers to adoption including the cost of testing, limited reimbursement practices, a paucity of randomized clinical trials demonstrating efficacy, the lack of suitable testing platforms and FDA-cleared assays, and the poor knowledge or interest among physicians. We have undergone a program to provide precision medicine to students, patients and the general public.

2:25 Pharmacogenetics Implementation in the Pharmacy and Therapeutics Committee - The First-Year Experience at UCSF
Joshua Galanter, M.D., Assistant Professor, Medicine, University of California, San Francisco
In the talk, I will discuss UCSF's experience forming and implementing a Pharmacogenetics Subcommittee for the P&T committee. I will discuss the challenges that we have faced trying to incorporate evidence-based pharmacogenetics guidelines into the UCSF Medical Center policy and the electronic medical record. Lessons learned from both the successes and failures will be applied towards the committee's plans going forward.

2:50 Trust Everyone, but Cut the Cards—A Patient's Perspective
Jessica Dunne, Painter & Artist, San Francisco Bay Area
I will describe my experience as a breast cancer patient and how non-routine testing helped guide my treatments. This included testing of tamoxifen breakdown products such as endoxifen, showing that, for me, standard 20mg/day tamoxifen dosing yielded low quintile endoxifen levels, and that not until daily doses of 40mg/day were mid-quintile levels reached. I will discuss how different clinicians and laboratory medicine specialists were willing to help me receive precision treatments.

3:15 PANEL DISCUSSION

3:40 The Idylla™ Advantage: High Precision Medicine Made Simple
Sponsored By BIOCARTIS
Rudi Pauwels, CEO, Biocartis
Idylla™, Biocartis' fully integrated, automated, real-time PCR-based molecular diagnostics system, is designed to offer fast and easy access to clinical molecular diagnostic information, anywhere and anytime. IdyllaTM's first tests, the BRAF Mutation Test for metastatic melanoma and KRAS Mutation Test for colorectal cancer have obtained CE-IVD marking.

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

PRECISION MEDICINE
CONTINUED ON NEXT PAGE

WHY TARGETED THERAPIES FAIL

10:50 Chairperson's Remarks
Victor Velculescu, M.D., Ph.D., Professor, Oncology; Co-Director, Cancer Biology, Johns Hopkins Sidney Kimmel Cancer Center; Co-Founder, Personal Genome Diagnostics

11:00 Precision Medicine and Cancer Drug Discovery
Atul J. Butte, M.D., Ph.D., Director, Institute for Computational Health Sciences; Professor, Pediatrics, University of California, San Francisco
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, discovering new durable targets in disease, the evaluation of patients and populations presenting with whole genomes sequenced, and new work on integrating and reusing the clinical and genomic data that result from clinical trials. Dr. Butte will especially cover big data in biomedicine as a platform for innovation and entrepreneurship.

11:30 Characterization of Driver Alterations in Tissue and Liquid Biopsies
Victor Velculescu, M.D., Ph.D., Professor, Oncology; Co-Director, Cancer Biology, Johns Hopkins Sidney Kimmel Cancer Center; Co-Founder, Personal Genome Diagnostics
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.

12:00 pm Enterprise-Wide Clinical Sequencing to Match Patients to Personalized Cancer Therapies
Michael F. Berger, Ph.D., Associate Director, Marie-Josée and Henry R. Kravis Center for Molecular Oncology, Memorial Sloan Kettering Cancer Center
Massively parallel sequencing can empower oncologists to make treatment decisions informed by the molecular composition of their patients' cancers. We have developed and implemented a robust molecular profiling platform for use in real-time patient management at a large academic cancer center. I will discuss the large-scale clinical deployment of our platform and its utility in matching patients to clinical trials to provide investigational therapies the greatest chance of success.

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

WILL POINT-OF-CARE DELIVER PRECISION MEDICINE? Not Just in Oncology

1:50 Chairperson's Remarks
Keith F. Batchelder, M.D., CEO & Founder, Genomic Healthcare Strategies

2:00 Longitudinal Proteomic Monitoring For Early Detection Of Disease
Jun Axup, Ph.D., Chief Operating Officer, MYi Diagnostics and Discovery
We envision a near future where comprehensive in-home biomarker monitoring can promote wellness and detect disease at its earliest signs. To get there, many technological, regulatory, and social challenges must be addressed. MYi is one such technology that can enable longitudinal personalized monitoring. Through our multiplex proteomics technology, we hope to realize point-of-care diagnostics and inform therapeutic intervention.

2:10 Use of the Digital Patient and Point-of-Care Testing to Manage RA
Mark E. Curran, Ph.D., Vice President, Immunology, Systems Pharmacology & Biomarkers, Immunology Therapeutic Area, Janssen Research & Development
At Janssen, as we search for and develop new medicines to better treat disorders, we are also developing and implementing Integrated Patient Solutions incorporating concepts around Companion Diagnostics, The Digital Patient and Point-of-Care testing. In this presentation I will highlight the key features of these disorders and describe our efforts to improve care and provide novel tools to enable patients living with disease to better manage their conditions.

2:20 A Digital Health Solution for Precision Medicine of Epilepsy
David S. Lester, Ph.D., CEO, Management, NIESM Pty Ltd
Because of the complexity of a patient's seizure profile, clinicians are required to manage patients on a personalized level. The process is inaccurate due to the use of the patients recording their seizure activities using written or digital diaries (including apps). The difficulties in obtaining accurate personal profiles will be discussed and NIESM's mobile health platform will be presented as a working solution. The selection of the hardware sensor platform is critical and will be discussed.

2:30 PANEL DISCUSSION

3:30 Quantitative Lipidomics in Precision Medicine
Steven M. Watkins, Ph.D., Chief Technology Officer, Metabolon
We have developed a fully quantitative platform for measuring over 1,000 lipid metabolites from 100uL of plasma or serum. The precision of the platform in measuring lipid classes is equal to that of standard clinical chemistry, enabling a deep and accurate investigation of the lipid molecular pathways linked to phenotype. This talk will show how deep lipid profiling can characterize dramatic individual differences in response to food, exercise and drug treatments, and reveal mechanisms driving risk for disease and response to therapy.

4:00 Session Break

ECOSYSTEM PANEL DISCUSSION: TOWARD A PRECISION MEDICINE ECOSYSTEM: Pooling Data to Save Lives

4:10 Moderator's Remarks
J. Marty Tenenbaum, Ph.D., Chairman, Cancer Commons
Realizing the potential of precision medicine requires a global ecosystem that can amass data on hundreds of millions of patients in order to identify the best therapies for increasingly rare molecular diseases. Getting there will require bold business models and innovative technology that encourage data sharing across many stakeholders. Representatives of competing cancer networks propose practical steps for sharing data, slashing costs and accelerating learning to save lives.

- Benefits and challenges of a global precision oncology ecosystem
- Review of proprietary ecosystems operated by molecular diagnostic vendors, academics, health systems, entrepreneurs, and nations
- Cross-industry learning: technologies and business models that facilitate data sharing and integrative analysis
- The important roles for national healthcare systems, patient advocacy groups, and pre-competitive consortia in catalyzing data sharing
- What steps can we take today to begin?

Panelists:
Jonathan Hirsch, President & Founder, Syapse
William S. Dalton, Ph.D., M.D., CEO, M2Gen; Director, The DeBartolo Family Personalized Medicine Institute at Moffitt Cancer Center
Piers Mahon, Ph.D., Director Global Alliances, Cancer Commons
Brady Davis, Senior Director Strategy & Market Development, Illumina
Anil Sethi, Founder and CEO, Gliimpse

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Third Annual

PCR FOR MOLECULAR MEDICINE

From Assay to FDA: Preparing PCR for Personalized Medicine

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

INCREASING SENSITIVITY AND SPECIFICITY OF ASSAYS

11:50 Chairperson's Opening Remarks
Chen Song, Ph.D., Research Fellow, Dana-Farber Cancer Institute, Harvard Medical School

12:00 pm Novel Approaches for Increasing Sensitivity and Specificity of Molecular Diagnostics Assays, Following Mutation Enrichment
Chen Song, Ph.D., Research Fellow, Dana-Farber Cancer Institute, Harvard Medical School
Detecting rare mutations in clinical samples and liquid biopsies requires methods having highly increased sensitivity while retaining excellent specificity. We present novel methods that provide mutation enrichment either prior to PCR or during PCR and enable established methodologies for detecting mutations at 0.1-0.01% levels or below. We present the advantages of combining a novel approach NaME (Nuclease-assisted Mutation Enrichment) or COLD-PCR with digital PCR, high resolution melting or sequencing.

12:30 Increasing Detection of Rare Cancer Mutation in Exosomes using Digital PCR
Leonora Balaj, Ph.D. Research Fellow, Massachusetts General Hospital, Harvard Medical School
Individual vesicles partially reflect the content of the cells they are released from, but analysis of a large number of vesicles allows full characterization and profiling a primary tumor. Single and rare mutations may not be packaged into every vesicles and analyzing each one individually may increase sensitivity. Also, combined analysis of RNA and DNA may lead to higher sensitivity for several mutations. We used digital PCR to interrogate plasma derived vesicle for tumor mutations from brain tumor patients.

1:00 Session Break

1:15 Diagnostic microRNA Signatures for Prostate Cancer in Exosomes from Urine
Sponsored By EXIQON Seek Find Verify
Peter Mouritzen, Vice President, Research and Development, Exiqon
To develop non-invasive diagnostic tests for prostate cancer (PCa), we have applied our LNA™-based qPCR to identify diagnostic microRNAs in exosomes purified from cell free urine from non-prostate-massaged men. Sensitive and specific PCa signatures have been obtained by different combinations of the identified differentially regulated microRNAs.

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

2:15 Session Break

2:30 Chairperson's Remarks
Jim Huggett, B.Sc. (Hons), Ph.D., Principal Scientist, Nucleic Acid Metrology, Molecular & Cell Biology, LGC

2:40 Resolving Genetic Variation from Biological and Clinical Sample Mixtures at Individual Molecule Resolution
Hanlee P. Ji, M.D., Assistant Professor, Medicine, Oncology, Stanford University
"Digital" molecular assays and sequencing approaches provide high sensitivity to measure genetic variation and the presence of specific genomes. I describe a number of methods, approaches and technologies that our research group has developed that can resolve biological and clonal mixtures. Some of these approaches measure at the level of small number of individual molecules. We have used these methods to detect pathogen genomes, somatic mutations from primary tumors and genetic variation from cell free DNA. The potential of these methods for clinical application will be described.

3:10 End-Specific PCR (ES-PCR) and Helper-Dependent Chain Reaction (HDCR) for Sensitive and Specific Detection of Cancer-Derived DNA
Jason Ross, Ph.D., Research Scientist, Preventative Health Flagship, CSIRO
We have developed two PCR-based techniques particularly useful for the detection of minute quantities of target DNA within a vast excess of non-target DNA, such as in circulating tumor DNA and biopsy sample applications. We have applied these technologies, in particular, to the development of bisulfite-free DNA methylation assays to detect cancer. We have further developed this to provide a platform integrating biomarker discovery and assay development using deep sequencing.

3:40 Developing PCR Assays for Validation and Long-term Life-Cycle Management
Linda Starr-Spires, Ph.D., Director, Nucleic Acid Methods, Global Clinical Immunology, Sanofi Pasteur, Inc.
In the vaccine industry, patients enrolled in clinical trials often undergo long-term follow-up which can last as much as ten or more years. Data generated in the early days of the clinical trials must remain relevant to data generated sometimes many years later. To meet this goal, assays must developed that are very robust, undergo full validation to meet applicable regulatory requirements, and must be monitored for continued performance throughout the life of the trials. Real-life examples of the management of assays developed in-house, including manufacturing of supporting reagents, will be discussed.

4:10 One-Step PCR System as a Genetic BioSensor in Molecular Medicine
Sponsored By COYOTE
Jesus Ching, Ph.D., CTO, Research & Development, Coyote Bioscience
A 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.

4:25 Sponsored Presentation *(Opportunity Available)*

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

PCR FOR MOLECULAR MEDICINE
CONTINUED ON NEXT PAGE

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

COMPARISON AND STANDARDIZATION OF METHODS

10:05 Chairperson's Remarks

Mary Alikian, Ph.D., Senior Research Associate & Registered Principal Clinical Scientist, Imperial Molecular Pathology Laboratory; Haematology, Hammersmith Hospital, Imperial College London

10:15 E.A.C. BCR-ABL1 Assay Performance Validation by dPCR, Including a Cross Platform dPCR Comparison

Mary Alikian, Ph.D., Senior Research Associate & Registered Principal Clinical Scientist, Imperial Molecular Pathology Laboratory; Haematology, Hammersmith Hospital, Imperial College London

The presentation will describe the performance of the routine assay (called the E.A.C. assay) used for monitoring minimal residual disease (MRD) in Chronic Myeloid Leukemia (CML) on several dPCR platforms and provide a head- to-head comparison between these platforms.

10:40 Standardization on Measuring Circulating RNA

Kai Wang, Principal Scientist, Institute for Systems Biology

Circulating RNA has gained significant interest due to their potential diagnostic applications. Despite its potential, there are a number of challenges to accurately measure the levels of specific cell free RNA in circulation. To move this promising field forward, detailed documentation and optimization of laboratory protocols are encouraged which will serve as the foundation of standardization in the future.

11:00 The Role of Digital PCR in Revolutionizing the Standardization of Molecular Medicine

Jim Huggett, B.Sc. (Hons), Ph.D., Principal Scientist, Nucleic Acid Metrology, Molecular & Cell Biology, LGC

dPCR is a unique molecular method as it is able to accurately count DNA molecules and is far more reproducible than contemporary methods. These characteristics make dPCR a candidate to become a reference method that could be used to support inter laboratory performance in diagnostics settings ranging from cancer stratification to infectious disease monitoring. This presentation will discuss the outputs of two European Union funded projects (INFECT-MET and BioSitrace) which have specifically investigated the potential of dPCR to act as a reference method to support other clinical tools.

11:25 Diagnostic RAS Mutation Analysis by PCR

Ian A. Cree, Ph.D., Professor, Pathology, University Hospitals Coventry and Warwickshire; Coventry University

RAS mutation analysis is an important companion diagnostic test. Treatment of colorectal cancer with anti-EGFR therapy requires demonstration of RAS mutation status (both KRAS and NRAS), and it is good practice to include BRAF. In NSCLC and melanoma, assessment of RAS status can be helpful in triaging patient samples for more extensive testing. The presentation will discuss the role of PCR methods in providing rapid diagnostic information.

11:50 Standardization on Measuring BCR-ABL1 Transcripts using Digital PCR based on WHO Primary Reference Material

Hirohito Umemoto, Ph.D., Chief, OMICS Laboratory, Reference Material Institute for Clinical Chemistry Standards

Monitoring fusion transcript level is an important indicator of therapeutic response in a patient with chronic myelogenous leukemia (CML). We have established a high-resolution MRD analysis using Duplex Digital-PCR for monitoring fusion transcript level in CML. From the 3 times serial dilution assays of total RNA in K562, we confirmed that Digital-PCR value can be directly converted to IS% using the WHO primary standard equation.

12:15 pm Session Break

12:25 PCR-Based DNA Manufacture at the Industrial Scale: DNA Diagnostics and Therapy in the 21st Century

Sponsored By appliednasciences

Michael Hogan, Ph.D., Vice President, Life Sciences, Applied DNA Sciences, Inc.

We introduce PCR-based DNA manufacture to enable the gram-scale synthesis of gene-sized reagents directly from synthetic genomics, with chemical modification as needed, and with rigorous, highly-simplified purification: to support DNA diagnostics and therapeutics. Case studies will emphasize the substantial benefits of industrial scale PCR over cloning.

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

INTEGRATING NGS AND PCR WORKFLOWS

2:00 Chairperson's Remarks

Ian A. Cree, Ph.D., Professor, Pathology, University Hospitals Coventry and Warwickshire; Coventry University

2:10 Validating Allele-Specific PCR Somatic Mutations Tests Using NGS: From Basic Research to IVD

Eugene (Gene) Spier, Ph.D., Director, Bioinformatics, Roche Molecular Systems

Roche Molecular developed IVD test to detect somatic mutations in FFPE samples for EGFR, KRAS, BRAF, EZH2 and other oncogenes as companion diagnostics for target cancer therapies. We are adapting these tests to detect and measure somatic mutations in plasma. Allele-specific PCR can detect <0.5% mutated in normal DNA background. I will describe methods and software that enable us detect rare <0.2% somatic mutations in plasma in deep NGS re-sequencing data.

2:40 The Liquid Biopsy Approach - Integrating Both PCR and NGS Solutions for Oncology Biomarker Development

Winston P. Kuo, Ph.D., VP, Business Development Global, Predicine

Extracellular vesicles (EVs) have been shown to carry a variety of biomacromolecules including DNA, mRNA, microRNA and other non-coding RNAs. EVs have emerged as a promising minimally invasive novel source of material for molecular diagnostics with potential clinical utility. This presentation will discuss the flexible and efficient workflow of integrating PCR and NGS of exRNA from serum sample in oncology biomarker development and their applications in therapeutic management and drug development.

3:10 Precision Oncology Applications of Integrative Multiplexed PCR Based Assays

Scott A. Tomlins, M.D., Ph.D., Assistant Professor, Pathology & Urology, University of Michigan

Precision medicine approaches require assays capable of working with small, routine pathology specimens. I will describe multiple approaches we have developed and validated, including a prostate cancer specific combined qRT-PCR and capture based DNAseq approach, as well as a pan-solid tumor multiplexed PCR based DNA and RNAseq assay. Lessons learned from assessing over 1200 specimens will be described.

3:40 "Fit-for-Workflow" Considerations for Designing Multiplex PCR Assays for SNP Detection and Target Enrichment

Sponsored By Seegene

Young Kim, Ph.D., Lead Application Scientist, Seegene Technologies.

Conventional approaches to assay development using PCR are generally limited to very few targets, which is not an ideal companion to NGS. Using examples from BCR-ABL, thrombosis, HPV genotyping, and others, we will discuss novel approaches to develop high-multiplex RT-PCR and qPCR assays that achieve high-throughput, target complexity, specificity and sensitivity.

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

PCR FOR MOLECULAR MEDICINE
CONTINUED ON NEXT PAGE

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

FDA-APPROVAL OF PCR- AND NGS-BASED DIAGNOSTICS

10:50 Chairperson's Remarks
Carl Wittwer, M.D., Ph.D., Professor, Department of Pathology, University of Utah

11:00 Late Breaking Presentation

11:15 One Assay, Two Guvnors: Development of FDA-Approved PCR for the Clinic
Adrian Moody, Ph.D., Director & Head, Design and Development Manchester, MDx Assay Development, QIAGEN
QIAGEN's leadership in companion diagnostics continues to grow, transforming patient care around the world. Our therascreen EGFR test is driving treatment decisions in lung cancer patients across the globe and will be used as a case study to explore the challenges of developing FDA approved PCR in the clinic.

11:30 PANEL DISCUSSION: FDA Approval of PCR- and NGS-Based Diagnostics
Moderator: Carl Wittwer, M.D., Ph.D., Professor, Department of Pathology, University of Utah
Panelists: Jolette Franco, Director, Regulatory Affairs, Myriad Genetic Laboratories, Inc.
Adrian Moody Ph.D., Director, Head, Design and Development Manchester, MDx Assay Development, QIAGEN
This discussion will cover:

- Reimbursement
- Logistical considerations
- Value perception
- Test evidence evaluation

12:30 pm Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

PCR FOR PATIENT STRATIFICATION

1:50 Chairperson's Remarks
Ken C.N. Chang, Ph.D., Senior Principal Scientist, Translational Biomarkers, Merck Research

2:00 Multiplexing DNA/RNA Profiling Assay Development for Patient Stratification—Case Studies: Comparing PCR to Nanostring and NGS-Based Assays
Ken C.N. Chang, Ph.D., Senior Principal Scientist, Translational Biomarkers, Merck Research
Despite of the advancement of next generation genomic profiling technologies common challenges shared by all these technologies exist including the highly fragmented nature of FFPE tissue clinical samples as well as inconsistent detection of mutations with low variant frequency that is close to the detection sensitivity. Unique strategies will be presented to address these issues in PCR-based multiplexing mutation assays, RNA profiling assays, and NGS-based mutation profiling assays.

2:30 Informatics Framework for Deriving Platform Independent Isoform-Level Expression Signatures for Multi-Class Tumor Subtyping
Ramana V. Davuluri, Ph.D., Professor & Director, Advanced Bioinformatics & Biocomputation, Northwestern University Feinberg School of Medicine
We developed novel data-mining method, called PIGExClass (platform-independent isoform-level gene-expression based classification-system), for derivation of multi-gene signature for multi-label molecular stratification of cancer patients, from exon-array or RNA-seq data. The application of this machine learning framework has led to the development of an RT-qPCR based assay for diagnosis of glioblastoma sub-types. I will discuss PIGExClass and its potential application on GBM and other cancers.

3:00 Comprehensive Analyses of Cell-Free DNA in Lung Cancer
Hatim Husain, M.D., Assistant Professor of Medicine, Division of Hematology-Oncology, University of California, San Diego
Many lung cancer patients have genomic aberrations that when targeted may provide clinical benefit to patients. We have performed PCR based analyses of urine from lung cancer patients to identify targetable EGFR mutations. These strategies to evaluate the kinetic changes in circulating tumor DNA are underway to predict who may best benefit from oncogene directed therapies. Larger studies are on-going to evaluate the clinical significance of circulating tumor DNA in urine and blood.

3:30 Sponsored Presentation *(Opportunity Available)*

4:00 Session Break

CLINICAL CASE STUDIES: PCR IN MOLECULAR DIAGNOSTICS

4:10 Chairperson's Remarks
Tara Sigdel, Ph.D., Assistant Professor, Surgery, University of California San Francisco School of Medicine

4:15 The KSORT Assay to Detect Renal Transplant Patients at High Risk for Acute Rejection
Tara Sigdel, Ph.D., Assistant Professor, Surgery, University of California San Francisco School of Medicine
Noninvasive test to improve disease diagnosis and patient monitoring is a critical need. In kidney transplantation, acute rejection (AR) increases the risk for chronic graft injury and failure. We have developed a highly sensitive qPCR based test as a tool to detect high risk of AR of renal transplants. This KSORT test is able to detect AR in blood independent of age, time post-transplantation, and sample source.

4:45 Monitoring Brain Tumor Mutations from Cerebrospinal Fluids Using Digital PCR
Wenying Pan, Ph.D. Student, Bioengineering, Stanford University
Detecting tumor-derived cell-free DNA (cfDNA) in the blood of brain tumor patients is challenging, presumably owing to the blood-brain barrier. As a counterpart of blood in central nervous system, cerebral spinal fluids (CSF) can serve as an alternative "liquid biopsy" of brain tumors. We developed a method to measure cell-free DNA variants in CSF using digital PCR to characterize brain tumor mutations and monitor patients' response to cancer therapy.

5:15 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Ninth Annual

CLINICAL NGS DIAGNOSTICS

Translating Genomic Data to the Standard of Care

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

ADVANCES IN NGS

11:50 Chairperson's Opening Remarks

Stephen Salipante, M.D., Ph.D., Assistant Professor, Director, Next-Generation Sequencing Analytics Laboratory; Assistant Director, Molecular Diagnosis Section, University of Washington

12:00 pm NGS Assays for Diagnosis of Infectious Diseases

Charles Chiu, M.D., Ph.D., Associate Professor, Lab Medicine and Infectious Diseases; Director, UCSF-Abbott Viral Diagnostics and Discovery Center; Associate Director, UCSF Clinical Microbiology Laboratory

There is great interest and potential in the use of metagenomic next-generation sequencing (NGS) for diagnosis of infectious diseases in clinical settings. We will discuss assay development, clinical validation, bioinformatics analysis, and regulatory considerations involved when developing such NGS-based assays in CLIA-certified laboratories. We will also discuss emerging rapid, point-of-care sequencing technologies and host-based approaches for infectious disease diagnosis.

12:30 Ingredients for a CLIA-Approved Clinical 16S rRNA Gene Assay for Mixed Bacterial Populations by Next-Generation Sequencing

Noah Hoffman, M.D., Ph.D., Associate Professor, University of Washington, Department of Laboratory Medicine, Associate Director, Informatics Division, University of Washington Medical Center

Development of software tools for species-level classification of bacteria using next-generation sequencing, as well as processes for rapid and confident clinical sign out have been particularly challenging in the clinical laboratory setting. In this talk, I will present the development of one of the first NGS 16S gene sequencing assays to be offered by a clinical laboratory, discuss bioinformatic challenges and solutions, and present applications for this assay using case studies.

1:00 Session Break

1:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:15 Session Break

2:30 Chairperson's Remarks

Weian Zhao, Ph.D., Assistant Professor, Department of Pharmaceutical Sciences, Sue and Bill Gross Stem Cell Research Center, Chao Family Comprehensive Cancer Center, Edwards Lifesciences Center for Advanced Cardiovascular Technology, Department of Biomedical Engineering, University of California–Irvine

2:40 Large-Scale Whole Genome Sequencing in Microbiology

Stephen Salipante, M.D., Ph.D., Assistant Professor, Director, Next-Generation Sequencing Analytics Laboratory; Assistant Director, Molecular Diagnosis Section, University of Washington

Next-generation sequencing is making it increasingly feasible to generate whole genome sequence data from large numbers of microorganisms. This session will examine what kinds of information can be obtained from performing large-scale genomic sequencing of bacteria originating directly from the clinical laboratory.

3:10 Assuring the Quality of Next-Generation Sequencing in Clinical Microbiology and Public Health Laboratories

Ira M. Lubin, Ph.D., FACMG, Branch Chief (acting); Team Lead, Genetics, Laboratory Research and Evaluation Branch, Division of Laboratory Systems/CSELS, Office of Public Health Scientific Services, Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention published practice recommendations developed by multidisciplinary workgroups for clinical next-generation sequencing of human genomic DNA. To follow up, CDC began an effort to consider quality issues and guidance for NGS infectious disease testing. The similarities and differences applicable to NGS testing of human and infectious disease samples will be discussed.

3:40 Regulatory Perspective on Infectious Disease NGS Dx Devices

Heike Sichtig, Ph.D., Medical Countermeasures/Multiplex, Microbiology Devices, Center for Devices (CDRH), FDA

The presentation will outline studies to evaluate the use of NGS-based devices as an aid in infectious disease diagnostics, and to gain a better understanding of potential NGS clinical implementation strategies. Focus will be on the possible approaches to validation studies and data for the evaluation of infectious disease NGS-based diagnostics for potential regulatory clearance/approval, and the use of sequence outputs from infectious disease NGS-based devices to evaluate performance.

4:10 Clinical Testing Using an NGS-Based HIV-1 Genotyping Assay (DEEPGENTM HIV): The Importance of Utilizing a Stringent Quality Control

Sponsored By seracare

Miguel E. Quinones-Mateu, Ph.D., Associate Professor & Scientific Director, University Hospitals Case Medical Center/Case Western Reserve University

Robust validation and implementation is essential to the success of NGS-based LDTs in a CLIA-certified environment. I will describe the development and implementation of an ultrasensitive HIV-1 genotyping assay (DEEPGENTM) and the use of novel recombinant RNA technology reference material to monitor HIV drug resistance.

4:25 Utility of Rapid Real-Time PCR using a Novel Random-Access 20-Minute Real-Time PCR System

Sponsored By Streck

Christopher Connelly, Ph.D., Research and Development Scientific Manager, Molecular Technology, Streck

This talk will focus on PCR-based applications for the Philisa® Real-Time PCR System that serve to accelerate workflow for molecular diagnostic analysis. Critical assays for infectious disease testing, such as detection of antibiotic resistant bacteria and RT-PCR-based identification of viruses will benefit from the versatility and performance of the Philisa Real-Time PCR System.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

CLINICAL NGS DIAGNOSTICS
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

NGS-BASED ASSAY DEVELOPMENT

10:05 Chairperson's Remarks

P. Mickey Williams, Ph.D., Director, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research

10:15 Preparing a Multi-Analyte NGS Assay for Use in Clinical Studies for Cancer

P. Mickey Williams, Ph.D., Director, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research

NGS offers a powerful tool for assessment of molecular defects found in cancer. The utilization of NGS is becoming common practice in clinical laboratories. This complex technology requires a new level of analytical performance testing and validation. This discussion will focus on approaches used for analytical validation of the NGS clinical assay used for treatment selection in the NCI-MPACT study. NCI-MPACT study.

10:45 Setting Up a Large Sequencing Center: Assay Development Considerations

William Biggs, Ph.D., Head, Sequencing Operations, Human Longevity, Inc.

The desire to access valuable clinical FFPE samples using advanced molecular techniques such as next-generation sequencing methods in an efficient and productive manner represents an ongoing challenge for most clinical laboratories. At the Clinical Research Sequencing Platform (CRSP) within the Broad Institute methods have been developed, optimized and implemented which allow for the ready and routine access of FFPE samples for such NGS-based analyses as Whole Exome Sequencing and Targeted Re-Sequencing.

11:15 Development of a Clinical Cell-Free Circulating Tumor DNA Assay for Cancer Molecular Profiling

Geoff Otto, Ph.D., Senior Director, Molecular Biology & Sequencing, Foundation Medicine

Profiling circulating tumor DNA (ctDNA) for the genomic alterations (GA) driving oncogenesis promises to provide insight into cancer biology, inform therapy selection when conventional biopsies are unobtainable and enable monitoring of response to therapy. A clinical, NGS-based ctDNA assay was developed; highly accurate detection of GA was analytically validated; and clinical utility investigated from patient-matched FFPE and blood samples across lung, breast and colon cancer at different disease stages.

11:45 Approaches to High Efficiency Nucleic Acid Extraction and Purification from Diverse Sample Types for NGS-Based Pathogen Detection

David R. Hillyard, M.D., Professor, Pathology, University of Utah; Director, Molecular Infectious Disease Testing, Arup Laboratories

Rapid and efficient preparation of well-purified nucleic acids from diverse sample types has increasingly become a critical component of diagnostic testing. Applications such as infectious disease and circulating cell free genetic testing also demand great test sensitivity and may require extraction from larger sample volumes. This presentation will review both currently available and emerging approaches to nucleic acid extraction, and issues relevant to its integration with downstream amplification and analysis technologies for highly multiplexed targeted and NGS-based pathogen detection.

12:15 pm Session Break

12:25 Luncheon Presentation I: Integrated Workflow and Sample Preparation for 3D BiologyTM: Simultaneous, Multiplexed Analysis of DNA, RNA, and Proteins.

Sponsored By nanoString TECHNOLOGIES

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

The field of 3D Biology—the ability to simultaneously quantify DNA (SNVs), mRNA, and proteins (including PTMs)—has been uniquely enabled through the use of NanoString's molecular barcoding technology. Accomplishing this analysis requires integration of sample preparation, analytical instrumentation, and data analysis software. This presentation will describe the development of reagents and workflow designed to prepare specimens for 3D biology analysis on an nCounter® system. This low-sample-input method utilizes magnetic bead capture of cells, followed by automated DNA, RNA, and Protein counting.

12:55 Luncheon Presentation II: DEPArray Digital Sorting of 100% pure tumor cells enables high precision NGS on low input & low cellularity FFPE samples

Sponsored By silicon biosystems

Raimo Tanzi, PhD Chief Commercial Officer Silicon Biosystems

NGS analysis of 100% pure cell populations sorted by DEPArray™ technology from FFPE samples provides unprecedented precision in describing the complete genetic of a tumor, including somatic variants, CNV, LoH, introducing a new way for precise stratification of patients.

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

CAN EXOMES REPLACE TARGETED PANELS?
Balancing Costs with Results and Regulatory Requirements

2:00 Chairperson's Remarks

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

2:10 The Utility of Exome Sequencing in Providing Deep Coverage of Disease-Relevant Targets

Avni B. Santani, Ph.D., Assistant Professor, Clinical Pathology and Laboratory Medicine, The Children's Hospital of Philadelphia

To date, disease-targeted gene panels have generated a lot of interest but exome sequencing (ES) is increasingly gaining acceptance for inherited and somatic diseases with locus and allelic heterogeneity. In this talk, we cover our group's effort in creating a technically enhanced ES assay that provides adequate coverage of all currently known disease-relevant genes, thereby facilitating high quality exome interpretation as well as exome "slices" for disease panels. Key considerations for test optimization including cost, specimen pooling, data quality and compliance will be discussed.

2:40 Diagnostic Gene Panels in the Exome Era – Using Exome Sequencing as a Universal Assay to Streamline Assay Development and Laboratory Operations

Birgit H. Funke, Ph.D., FACMG, Associate Professor, Pathology, MGH/Harvard Medical School; Director, Clinical Research and Development, Laboratory for Molecular Medicine, Partners HealthCare

The accelerating pace of disease gene discovery is presenting an increasing challenge for diagnostic laboratories as updating targeted gene panels is costly. Improved exome sequencing assays achieve near equal quality and decreasing costs open the door to replacing gene panel assays with virtual panels. This presentation summarizes our experience moving from targeted gene panels to exome-based virtual panels using inherited renal disorders as an example.

3:10 Laboratory Accreditation and Proficiency Testing for Next-Generation Sequencing Diagnostics: An Update on College of American Pathologists Programs

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

CLINICAL NGS DIAGNOSTICS
CONTINUED ON NEXT PAGE

Bioinformatics, ARUP Laboratories

By late 2015, nearly 200 laboratories accredited by the College of American Pathologists indicated that they offered next-generation sequencing-based diagnostics. This number is expected to grow. This presentation will provide an update on accreditation requirements developed by the College specific to laboratories performing NGS based diagnostics. 2015 also marked the launch of the College's first methods-based proficiency testing program for NGS-based detection of germline variants, for which summary results will be discussed.

3:40 Genome-Wide Prenatal Cell Free DNA Testing: Validation and Clinical Experience

Sponsored By sequenom Bioscience

Daniel S. Grosu, M.D., MBA, CMO, Sequenom, Inc.

A significant proportion of chromosomal and subchromosomal abnormalities in the prenatal setting are not detectable by conventional cfDNA testing. Sequenom seeks to bridge this informational gap through a genome-wide approach that reports on whole chromosome aneuploidies and CNVs ≥7 Mb in size across the entire genome, in addition to select microdeletions <7 Mb in size. Validation and clinical experience data will be presented for the new approach.

3:55 Sponsored Presentation *(Opportunity Available)*

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

FDA-APPROVAL OF PCR- AND NGS-BASED DIAGNOSTICS

10:50 Chairperson's Remarks

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

11:00 BRACAnalysis CDx: First Laboratory Developed Companion Diagnostic Approval Story

Jolette Franco, Director, Regulatory Affairs, Myriad Genetic Laboratories, Inc.

Short presentation on the PMA approval journey of a laboratory developed companion diagnostic test in conjunction with the approval of AstraZeneca's drug Lynparza.

11:15 One Assay, Two Guvnors: Development of FDA-Approved PCR for the Clinic

Adrian Moody, Ph.D., Director & Head, Design and Development Manchester, MDx Assay Development, QIAGEN

QIAGEN's leadership in companion diagnostics continues to grow, transforming patient care around the world. Our therascreen EGFR test is driving treatment decisions in lung cancer patients across the globe and will be used as a case study to explore the challenges of developing FDA approved PCR in the clinic.

11:30 PANEL DISCUSSION: FDA Approval of PCR- and NGS-Based Diagnostics

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

Panelists: Kirk Ririe, CEO, BioFire Defense

Adrian Moody Ph.D., Director, Head, Design and Development Manchester, MDx Assay Development, QIAGEN

This discussion will cover:

- Reimbursement
- Logistical considerations
- Value perception
- Test evidence evaluation

12:30 pm Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

HOT TOPICS AND CONTROVERSIES IN CANCER SEQUENCING

1:50 Chairperson's Remarks

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

2:00 Novel Clinical Applications of Cancer Genomics

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

Novel technologies to evaluate genomics-based tumor burden in tumor tissue and bodily fluids 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.

2:30 What is a Cancer Mutation? Challenges in Detecting, Interpreting, and Targeting Somatic Variants

Joshua M. Stuart, Ph.D., Baskin Engineering Endowed Chair & Professor, Biomolecular Engineering,; Associate Director, Center for Biomolecular Science and Engineering, University of California, Santa Cruz

DNA sequencing provides an unprecedented potential to catalog all somatic alterations in tumor genomes. Yet the task of assembling raw reads into biologically-interpretable information is still a "Wild West" of algorithms. In the talk, I will discuss an open competition to identify the best mutation calling algorithms. After a year of collecting results from hundreds of methods, we learned some ingenious tricks from some, and pitfalls that tripped up most, competitors.

3:00 Noninvasive Monitoring of Lymphoma by Sequencing of Circulating Tumor DNA

Ash A. Alizadeh, Ph.D., Principal Investigator, Assistant Professor, Medicine, Divisions of Oncology & of Hematology; Attending Physician, Lymphoma Oncology Clinic, Stanford Cancer Center, Stanford University

Recent studies have shown limited utility of routine surveillance imaging for diffuse large B-cell lymphoma (DLBCL) patients achieving remission. Detection of molecular disease in peripheral blood provides an alternate strategy for surveillance. I will describe strategies for noninvasive monitoring of lymphoma by sequencing of circulating tumor DNA, including performance characteristics of various assays, their clinical applications, and their promise for future translations studies.

3:30 NGS-Based Diagnostics: Developing Assays and Monitoring Performance Using Novel Biosynthetic QC Tools

Sponsored By seracare

Russell Garlick, Ph.D., CSO, SeraCare Life Sciences

There are currently no widely-accepted NGS QC standards for multi-analyte diagnostic assays which hampers the ability to compare the performance of different assays. Preliminary results will be presented from a study testing the SeraseqTM Solid Tumor Mix-I as a qualitative and quantitative QC indicator for tumor profiling.

CLINICAL NGS DIAGNOSTICS
CONTINUED ON NEXT PAGE

4:00 Session Break

4:10 Chairperson's Remarks
German Pihan, M.D., Staff Pathologist and Director, Diagnostic Hematopathology Service, Pathology, Beth Israel Deaconess Medical Center

4:15 Darwinian Cancer Genome Evolution: The Achilles Heel of Precision Cancer Medicine. Can It Be Overcome?
German Pihan, M.D., Staff Pathologist and Director, Diagnostic Hematopathology Service, Pathology, Beth Israel Deaconess Medical Center

The high rate of mutations in cancer is the single most important challenge to the success of precision medicine in cancer. Whole genome sequencing is beginning to elucidate the patterns, pathways and causes of the astonishingly dynamic high rate of somatic mutation in most cancers. Understanding these pathways will prove challenging but fundamentally important to succeed in the fight against cancer. This talk will define the nature of the Darwinian cancer genome evolution challenge and propose possible avenues to surmount it.

4:45 Who Should Regulate Cancer NGS Tests: FDA, CMS/CLIA, or Both?
Roger D. Klein, M.D., J.D., Chair, Professional Relations Committee, Association for Molecular Pathology (AMP); Medical Director, Molecular Oncology, Cleveland Clinic

This presentation will discuss current controversies and potential regulatory approached for the oversight of next generation sequencing testing for oncology applications.

5:15 PANEL DISCUSSION

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Third Annual

GENOMIC SAMPLE PREP AND BIOMARKER ASSAY DEVELOPMENT

DNA/RNA Extraction, NGS Assays, Liquid Biopsy, Antibody Validation, & More

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

EMERGING SAMPLE PREP TECHNOLOGIES FOR GENOMICS APPLICATIONS

11:50 Chairperson's Opening Remarks
Robert Daber, Ph.D., Vice President, Genomics Operations and Development, Laboratory Medicine, Bio Reference Laboratories

12:00 pm Eliminating Barriers to Precision Diagnostics: Cost, Content, Turn-Around Time and Sample Size
Robert Daber, Ph.D., Vice President, Genomics Operations and Development, Laboratory Medicine, Bio Reference Laboratories

Next Generation Sequencing has tremendous potential for disrupting routine clinical practice in many areas of medicine. As many health care practices look to build precision medicine programs, access to clinical NGS testing for every patient is currently limited by several challenges. We have set out to build an oncology diagnostics program that reduces or eliminates these barriers by building assays that are cost effective, provide fast turn around time, work with low levels of FFPE DNA input and is focused on content that reduces the incidence of unclear variants.

12:30 Emerging Sample Prep Technologies for Genomics Applications
Jamie L. Platt, Ph.D., Vice President, Genomic Solutions, Molecular Pathology Laboratory Network, Inc.

Non-invasive prenatal testing, solid tumor profiling, liquid biopsy, and other tests all require special consideration not only for specimen characteristics, but also for the detected variant types. In clinical applications, the amount of specimen can be highly limited and the quality can be variable. The challenges of recovering adequate DNA and RNA will be discussed within in the context of these applications and some emerging sample prep technologies that may address these issues will be highlighted.

1:00 Session Break

NOVEL CANCER BIOMARKER FFPE-BASED ASSAYS

2:30 Chairperson's Remarks
Robert Daber, Ph.D., Vice President, Genomics Operations and Development, Laboratory Medicine, Bio Reference Laboratories

2:40 Assessment of FFPE Samples for Success in NGS
Helen Fernandes, Ph.D., Director, Molecular Pathology, Pathology & Laboratory Medicine, Weill Cornell Medical College

This presentation will discuss several important issues, such as: Identification of DNA variants and RNA fusions in FFPE tissue; FFPE DNA quality control and its correlation with NGS data; and understanding pre-analytic variables for obtaining optimal results in NGS assays.

3:10 Quantitative Comparison of Biomarkers by IHC vs mRNA Using a Nearly Point of Care Cancer Biomarker Platform
David L. Rimm, M.D., Ph.D., Professor, Pathology, Executive Director, Translational Pathology, Director, Yale Pathology Tissue Services, Yale University

The measurement of tissue biomarkers is a challenge in the US, but much more so in less developed countries. Some drugs, like Tamoxifen are inexpensive and effective but need a companion diagnostic test. This work will describe the comparison of a low cost, mRNA based platform for measuring Estrogen Receptor and other tissue biomarkers with immunohistochemistry and quantitative immunofluorescence.

3:40 NGS Applications with FFPE Samples: No Longer a Pipedream
Andrew J. Hollinger, Application Scientist, Broad Genomics Platform, Broad Institute.

The Genomics Platform at the Broad Institute has initiated a number of projects to explore QC of FFPE samples upstream of NGS applications resulting in development of protocols and processes that provide insight into likelihood of success for various NGS processes. This has been enabled in large part by the vast number of samples and large collections of FFPE samples that have been processed to date. Here we discuss our approach to preserving usage of nucleic acid from these limited sample types, high-throughput processing, DNA and RNA QC metrics to estimate likelihood of success, and NGS metrics of interest when working with FFPE.

Sponsored By SIEMENS

4:10 Standardizing Molecular Pathology with Fully Automated DNA and RNA Extraction from Formalin-Fixed, Paraffin-Embedded (FFPE) and Fresh Frozen (FF) Tissue
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.

Sponsored By BECKMAN COULTER

4:25 Automating NGS Sample Prep for Challenging Samples and Niche Applications
Brian Idoni, Genomics Sales Specialist, Beckman Coulter Life Sciences

This presentation will discuss Biomek-Automated solutions for NGS sequencing applications including HLA, cfDNA from Plasma, exosomes and working with very low input samples.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

CONTINUED ON NEXT PAGE

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

NGS-BASED ASSAY DEVELOPMENT

10:05 Chairperson's Remarks
P. Mickey Williams, Ph.D., Director, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research

10:15 Preparing a Multi-Analyte NGS Assay for Use in Clinical Studies for Cancer
P. Mickey Williams, Ph.D., Director, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research

NGS offers a powerful tool for assessment of molecular defects found in cancer. The utilization of NGS is becoming common practice in clinical laboratories. This complex technology requires a new level of analytical performance testing and validation. This discussion will focus on approaches used for analytical validation of the NGS clinical assay used for treatment selection in the NCI-MPACT study.

10:45 Setting Up a Large Sequencing Center: Assay Development Considerations
William Biggs, Ph.D., Head, Sequencing Operations, Human Longevity, Inc.

The desire to access valuable clinical FFPE samples using advanced molecular techniques such as next-generation sequencing methods in an efficient and productive manner represents an ongoing challenge for most clinical laboratories. At the Clinical Research Sequencing Platform (CRSP) within the Broad Institute methods have been developed, optimized and implemented which allow for the ready and routine access of FFPE samples for such NGS-based analyses as Whole Exome Sequencing and Targeted Re-Sequencing.

11:15 Development of a Clinical Cell-Free Circulating Tumor DNA Assay for Cancer Molecular Profiling
Geoff Otto, Ph.D., Senior Director, Molecular Biology & Sequencing, Foundation Medicine

Profiling circulating tumor DNA (ctDNA) for the genomic alterations (GA) driving oncogenesis promises to provide insight into cancer biology, inform therapy selection when conventional biopsies are unobtainable and enable monitoring of response to therapy. A clinical, NGS-based ctDNA assay was developed; highly accurate detection of GA was analytically validated; and clinical utility investigated from patient-matched FFPE and blood samples across lung, breast and colon cancer at different disease stages.

11:45 Approaches to High Efficiency Nucleic Acid Extraction and Purification from Diverse Sample Types for NGS-Based Pathogen Detection
David R. Hillyard, M.D., Professor, Pathology, University of Utah; Director, Molecular Infectious Disease Testing, Arup Laboratories

Rapid and efficient preparation of well-purified nucleic acids from diverse sample types has increasingly become a critical component of diagnostic testing. Applications such as infectious disease and circulating cell free genetic testing also demand great test sensitivity and may require extraction from larger sample volumes. This presentation will review both currently available and emerging approaches to nucleic acid extraction, and issues relevant to its integration with downstream amplification and analysis technologies for highly multiplexed targeted and NGS-based pathogen detection.

12:15 pm Session Break

Sponsored By nanoString TECHNOLOGIES

12:25 Integrated Workflow and Sample Preparation for 3D BiologyTM: Simultaneous, Multiplexed Analysis of DNA, RNA, and Proteins
Joseph Beechem, Ph.D., Senior Vice President, Research & Development, NanoString Technologies

The field of 3D Biology—the ability to simultaneously quantify DNA (SNVs), mRNA, and proteins (including PTMs)—has been uniquely enabled through the use of NanoString's molecular barcoding technology. Accomplishing this analysis requires integration of sample preparation, analytical instrumentation, and data analysis software. This presentation will describe the development of reagents and workflow designed to prepare specimens for 3D biology analysis on an nCounter® system. This low-sample-input method utilizes magnetic bead capture of cells, followed by automated DNA, RNA, and Protein counting.

Sponsored By silicon biosystems

12:55 DEPArray Digital Sorting of 100% Pure Tumor Cells Enables High Precision NGS on Low Input & Low Cellularity FFPE Samples
Raimo Tanzi, Ph.D., Chief Commercial Officer, Silicon Biosystems

NGS analysis of 100% pure cell populations sorted by DEPArray™ technology from FFPE samples provides unprecedented precision in describing the complete genetic of a tumor, including somatic variants, CNV, LoH, introducing a new way for precise stratification of patients.

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

DISRUPTIVE INNOVATION IN LABORATORY MEDICINE

2:00 Chairperson's Remarks
David R. Hillyard, M.D., Medical Director, Molecular Infectious Diseases, Arup Laboratories

» 2:10 KEYNOTE PRESENTATION: New Diagnostic Technology with Advances in Electrical Engineering
Ronald W. Davis, Ph.D., Professor of Biochemistry and Genetics, Director, Stanford Genome Technology Center, Stanford University

Recent advances in biosensing technologies present great potential for medical diagnostics, thus improving clinical decisions. However, creating a label-free general sensing platform capable of detecting multiple biotargets in various clinical specimens over a wide dynamic range, without lengthy sample-processing steps, remains a considerable challenge. At Stanford we came up with nanoplasmonic electrical field-enhanced resonating device, which addresses all these impediments on a single platform. Application of this and other new technologies to address unmet needs of clinical diagnostic testing and research will be discussed.

2:40 Mobile Phone-Based Imaging, Sensing and Diagnostics Technologies
Aydogan Ozcan, Ph.D., Electrical Engineering Department, Bioengineering Department, California NanoSystems Institute, University of California, Los Angeles

In this presentation I will discuss some of the emerging applications and the future opportunities/challenges created by the use of mobile phones and other consumer electronics devices as well as their embedded components for the development of next-generation imaging, sensing, diagnostics and measurement tools through computational photonics techniques.

3:10 PANEL DISCUSSION: Advancing Laboratory Medicine through Innovation
Moderator: David R. Hillyard, M.D., Professor, Pathology, University of Utah; Director, Molecular Infectious Disease Testing, Arup Laboratories

Over the last 5 decades, laboratory medicine has witnessed a remarkable wave of innovations that transformed the field from a peripheral to a central player in healthcare delivery. These advances enabled the introduction and performance of new tests on a large scale, some in a decentralized setting, in an accurate and a precise manner, thus leading to better diagnosis, more accurate prediction of disease prognosis, and improved patient management. This discussion features two prominent thought leaders who dedicated their work to adoption of the most innovative and cutting edge technology to advance laboratory medicine.

Sponsored By silicon biosystems

3:40 DEPArray Technology for Single Cell Precision in Oncology: From Research to Clinical Application
Farideh Bischoff, Ph.D., Executive Director, Scientific Affairs, Silicon Biosystems

DEPArray is an innovative technology capable of sorting and isolating 100% pure single or pooled cells through a digitally controlled dielectrophoretic field. The DEPArray system offers the potential for pre-analytical cell-type purification for downstream molecular analysis, which is a major step forward for precision medicine.

GENOMIC SAMPLE PREP AND BIOMARKER ASSAY DEVELOPMENT
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

PORTABLE SEQUENCING AND LAB-ON-CHIP TECHNOLOGY

10:50 Chairperson's Remarks
Kamlesh Patel, Ph.D., Manager, Advance Systems Engineering and Deployment, Sandia National Labs

11:00 Nanopore DNA Strand Sequencing in Basic Biology & Medicine
Mark Akeson, Ph.D., Professor, UC Santa Cruz Genomics Institute & Biomolecular Engineering Department, University of California, Santa Cruz
Nanopore DNA strand sequencing was conceived by Deamer, Branton, and Church over twenty years ago. I will discuss key academic experiments that lead to successful nanopore reads of individual DNA strands, and the subsequent implementation of the commercial Oxford Nanopore 'MinION'. This device is well suited to point of care use due to its portability and direct reads of genomic DNA absent copying. It has been employed in West Africa for Ebola sequencing, and is slated for experiments on the International Space Station.

11:30 Nanopore Sequencing for Real-Time Pathogen Identification
Kamlesh Patel, Ph.D., Manager, Advance Systems Engineering and Deployment, Sandia National Labs
As recent outbreaks have shown, effective global health response to emergent infectious disease requires a rapidly deployable, universal diagnostic capability. We will present our ongoing work to develop a fieldable device for universal bacterial pathogen characterization based on nanopore DNA sequencing. Our approach leverages synthetic biofunctionalized nanopore structures to sense each nucleotide. We aim to create a man-portable platform by combining nanopore sequencing with advance microfluidic-based sample preparation methods.

12:00 pm Q&A with Speakers

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

CELL-FREE DNA AND RNA ASSAYS

1:50 Chairperson's Remarks
Kai Wang, Ph.D., Principal Scientist, Institute for Systems Biology

2:00 Tethered Lipoplex Nanoparticle (TLN) Biochips For Extracellular Vesicles Based Early Disease Diagnosis and Prognosis
L. James Lee, Ph.D., Helen C. Kurtz Chair, Chemical & Biomolecular Engineering, Ohio State University
Circulating extracellular vesicles (EVs) is currently the major focus of non-invasive early disease detection and prognosis. We show that biochips using tethered lipoplex nanoparticles (TLNs) containing molecular beacons can capture cell-derived EVs from body fluids, and identify encapsulated microRNAs/mRNAs and EV surface membrane protein targets with very small sample size (~20 uL blood for 2 targets) and higher sensitivity than qRT-PCR. We will present TLN applications to cancer and non-cancer diseases.

2:30 Measurement of exRNA: Quantitative Studies of Small RNA-seq
David Galas, Ph.D., Principal Scientist, The Pacific Northwest Diabetes Research Institute
A wide range of RNA molecules exist in various body fluids outside of cells and represent potentially important biological information. RNA-seq has is a powerful detection technology, but flawed as a measurement technology. We and others have systematically studied issues like sequence-specific bias, length effects and other phenomena as they are affected by variations in RNA-seq protocols, and will discuss the results.

3:00 Best Practices for Fusion Detection by Targeted RNA Sequencing: Pre-Analytical Considerations, Assay Validation and More
Robert D. Daber, Ph.D., Director, Research and Development and Sequencing Operations, Bio-Reference Laboratories
This presentation will discuss challenges and benefits of NGS based targeted RNA sequencing in the detection of gene fusion events, including, nucleic acid isolation, sample preparation and downstream data processing. There are a number of specific challenges related to RNA sequencing, standardized quality control metrics both before and after library prep are clearly needed.

3:30 Sample Prep Challenges for Bloodstream Infection Assays
Gregory Richmond, Ph.D., Principal Scientist, Ibis Biosciences, Abbott
We describe a sample preparation system that provides for the rapid detection and identification of bacterial and Candidal nucleic acid directly in whole blood specimens from patients with suspected bloodstream infections. A cellular lysis method and DNA purification system were designed for processing 5 ml of whole blood. A novel sample prep approach removed high levels of inhibiting human DNA prior to target detection. The system provides for rapid and sensitive molecular detection of diverse agents of these clinically important infections in approximately 6h.

4:00 Session Break

4:10 Chairperson's Remarks
Gregory Richmond, Ph.D., Principal Scientist, Ibis Biosciences, Abbott

4:15 Validation of Integrated Workflows and Reagents for RNA Sequencing from Blood: A Specific and Sensitive Solution for Research and Clinical Diagnostics Applications
Andrew Brooks, Ph.D., COO and Director, Technology Development, Technology, RUCDR Infinite
Here we report the validation of an end-to-end workflow for RNA-Seq analysis from human whole blood that integrates whole blood sample preservation, automated isolation of total RNA and target specific RNAseq library creation. A three arm study was designed to address several assay performance parameters including intra-assay precision (repeatability), inter-assay precision (reproducibility), and assay sensitivity.

4:45 Sample Prep Challenges for Bloodstream Infection Assays
Gregory Richmond, Ph.D., Principal Scientist, Ibis Biosciences, Abbott
We describe a sample preparation system that provides for the rapid detection and identification of bacterial and Candidal nucleic acid directly in whole blood specimens from patients with suspected bloodstream infections. A cellular lysis method and DNA purification system were designed for processing 5 ml of whole blood. A novel sample prep approach removed high levels of inhibiting human DNA prior to target detection. The system provides for rapid and sensitive molecular detection of diverse agents of these clinically important infections in approximately 6h.

GENOMIC SAMPLE PREP AND BIOMARKER ASSAY DEVELOPMENT
CONTINUED ON NEXT PAGE

5:15 Clinical Development of Gene Expression Signatures

Joel S. Parker, Ph.D., Director, Bioinformatics, Lineberger Comprehensive Cancer Center, Assistant Professor, Department of Genetics, University of North Carolina at Chapel Hill

Gene expression signatures have been used extensively for subtype discovery and classification in cancer research. Subtyping provides a global view of tumor biology, and expression subtypes are typically associated with clinical features. Successful translation of this information requires a clinically actionable hypothesis, model development, validation in a representative cohort, and a reproducible and accurate measurement technology. These challenges and resulting decisions will be reviewed in the context of Prosigna™ assay development, as well as the more recently developed PREDICT-AR™

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Inaugural

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE

Advancing Microbial Diagnostics to Improve Detection and Patient Outcome

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

ADVANCES IN NGS

11:50 Chairperson's Opening Remarks
Stephen Salipante, M.D., Ph.D., Assistant Professor, Director, Next-Generation Sequencing Analytics Laboratory; Assistant Director, Molecular Diagnosis Section, University of Washington

12:00 pm NGS Assays for Diagnosis of Infectious Diseases
Charles Chiu, M.D., Ph.D., Associate Professor, Lab Medicine and Infectious Diseases; Director, UCSF-Abbott Viral Diagnostics and Discovery Center; Associate Director, UCSF Clinical Microbiology Laboratory
There is great interest and potential in the use of metagenomic next-generation sequencing (NGS) for diagnosis of infectious diseases in clinical settings. We will discuss assay development, clinical validation, bioinformatics analysis, and regulatory considerations involved when developing such NGS-based assays in CLIA-certified laboratories. We will also discuss emerging rapid, point-of-care sequencing technologies and host-based approaches for infectious disease diagnosis.

12:30 Ingredients for a CLIA-Approved Clinical 16S rRNA Gene Assay for Mixed Bacterial Populations by Next-Generation Sequencing
Noah Hoffman, M.D., Ph.D., Associate Professor, University of Washington, Department of Laboratory Medicine, Associate Director, Informatics Division, University of Washington Medical Center
Development of software tools for species-level classification of bacteria using next-generation sequencing, as well as processes for rapid and confident clinical sign out have been particularly challenging in the clinical laboratory setting. In this talk, I will present the development of one of the first NGS 16S gene sequencing assays to be offered by a clinical laboratory, discuss bioinformatic challenges and solutions, and present applications for this assay using case studies.

1:00 Session Break

1:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

2:15 Session Break

2:30 Chairperson's Remarks
Weian Zhao, Ph.D., Assistant Professor, Department of Pharmaceutical Sciences, Sue and Bill Gross Stem Cell Research Center, Chao Family Comprehensive Cancer Center, Edwards Lifesciences Center for Advanced Cardiovascular Technology, Department of Biomedical Engineering, University of California–Irvine

2:40 Large-Scale Whole Genome Sequencing in Microbiology
Stephen Salipante, M.D., Ph.D., Assistant Professor, Director, Next-Generation Sequencing Analytics Laboratory; Assistant Director, Molecular Diagnosis Section, University of Washington
Next-generation sequencing is making it increasingly feasible to generate whole genome sequence data from large numbers of microorganisms. This session will examine what kinds of information can be obtained from performing large-scale genomic sequencing of bacteria originating directly from the clinical laboratory.

3:10 Assuring the Quality of Next-Generation Sequencing in Clinical Microbiology and Public Health Laboratories
Amy Gargis, PhD, Laboratory Preparedness and Response Branch, Division of Preparedness and Emerging Infections, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention
The Centers for Disease Control and Prevention published practice recommendations developed by multidisciplinary workgroups for clinical next-generation sequencing of human genomic DNA. To follow up, CDC began an effort to consider quality issues and guidance for NGS infectious disease testing. The similarities and differences applicable to NGS testing of human and infectious disease samples will be discussed.

3:40 Regulatory Perspective on Infectious Disease NGS Dx Devices
Heike Sichtig, Ph.D., Medical Countermeasures/Multiplex, Microbiology Devices, Center for Devices (CDRH), FDA
The presentation will outline studies to evaluate the use of NGS-based devices as an aid in infectious disease diagnostics, and to gain a better understanding of potential NGS clinical implementation strategies. Focus will be on the possible approaches to validation studies and data for the evaluation of infectious disease NGS-based diagnostics for potential regulatory clearance/approval, and the use of sequence outputs from infectious disease NGS-based devices to evaluate performance.

4:10 Clinical Testing Using an NGS-Based HIV-1 Genotyping Assay (DEEPGENTM HIV): The Importance of Utilizing a Stringent Quality Control
Sponsored By seracare
Miguel E. Quinones-Mateu, Ph.D., Associate Professor & Scientific Director, University Hospitals Case Medical Center/Case Western Reserve University
Robust validation and implementation is essential to the success of NGS-based LDTs in a CLIA-certified environment. I will describe the development and implementation of an ultrasensitive HIV-1 genotyping assay (DEEPGENTM) and the use of novel recombinant RNA technology reference material to monitor HIV drug resistance.

4:25 Utility of Rapid Real-Time PCR Using a Novel Random-Access 20-Minute Real-Time PCR System
Sponsored By Streck
Christopher Connelly, Ph.D., Research and Development Scientific Manager, Molecular Technology, Streck
This talk will focus on PCR-based applications for the Philisa® Real-Time PCR System that serve to accelerate workflow for molecular diagnostic analysis. Critical assays for infectious disease testing, such as detection of antibiotic resistant bacteria and RT-PCR-based identification of viruses will benefit from the versatility and performance of the Philisa Real-Time PCR System.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

POINT-OF-CARE TESTING

10:05 Chairperson's Remarks
Nathan A. Ledeboer, Ph.D., D(ABMM), Assistant Professor, Medical Director, Clinical Microbiology, Medical College of Wisconsin

10:15 Syndrome-Specific Infectious Disease Panels: More Answers, More Questions
Elizabeth M. Marlowe, Ph.D., D(ABMM), Technical Director, Microbiology, Kaiser Permanente, The Permanente Medical Group Regional Laboratories
In this talk, we will explore trends in US healthcare in the Era of Consumerism and discuss what is driving the design and implementation of panels. You will understand the role of syndrome-specific panels in the practice of infectious disease testing.

10:45 Nanomaterial Integrated Platforms for Infectious Disease Diagnosis
Siyang Zheng, Ph.D., Associate Professor, Biomedical Engineering, Pennsylvania State University
Infectious diseases can erupt unpredictably, propagate rapidly, affect large population and have potential for explosive global effects. Prompt surveillance on large human or animal population requires high-performance portable tools. Nanomaterial integrated platforms promise to deliver the platform for future infectious disease diagnosis.

11:15 Integrated Comprehensive Droplet Digital Detection Technology (IC 3D) for Rapid and Sensitive Detection of Infectious Diseases
Weian Zhao, Ph.D., Assistant Professor, Department of Pharmaceutical Sciences, Sue and Bill Gross Stem Cell Research Center, Chao Family Comprehensive Cancer Center, Edwards Lifesciences Center for Advanced Cardiovascular Technology, Department of Biomedical Engineering, University of California–Irvine
Rapid and sensitive detection of pathogens for infectious diseases remains a major challenge in medical sciences and healthcare systems. With the capability and versatility, our IC 3D technology has the potential to introduce a new paradigm in rapid detection of low abundance infectious pathogens from complex media. The significant shortened assay time allows timely and effective intervention to reduce mortality and financial costs with patient care.

11:45 Will Point-of-Care Molecular Testing Displace Laboratory-Based Testing?
Nathan A. Ledeboer, Ph.D., D(ABMM), Assistant Professor, Medical Director, Clinical Microbiology, Medical College of Wisconsin
Development of point-of-care molecular assays for the detection of infectious diseases is rapidly expanding. The assays being released have exhibited variable sensitivity and specificity, leaving providers to understand the limitations of point-of-care testing. This session will explore the clinical outcomes of point-of-care testing from an antimicrobial stewardship perspective, particularly focusing on Streptococcal pharyngitis and influenza testing.

12:15 pm Session Break

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

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

INNOVATIVE SOLUTIONS FOR CATEGORY 4 AGENTS

2:00 Chairperson's Remarks
Raymond J. Langley, Ph.D., Assistant Professor, Department of Pharmacology, University of South Alabama

2:10 SPOTLIGHT SESSION: Resolving Molecular Diagnostics Need for Ebola, Advancing Point of Care Testing for the West
Sterghios Moschos, Ph.D., Associate Professor, Biomedical Sciences, University of Westminster
The West African Ebola outbreak galvanized academics and biotech internationally to innovate solutions for mass point of need testing for category 4 biological agents. The international public-private EbolaCheck consortium has addressed this need by developing a 5-step, <30 min, portable system that can quantify Ebola virus in as little as 5 ul of crude biofluids for under US$12 per test. Engineered for West Africa, the technology is now expanding to address differential diagnosis need for future infectious disease outbreaks and beyond.

SEPSIS: NEW APPROACHES

2:40 Novel Approaches to the Laboratory Diagnosis of Sepsis
Jennifer Dien Bard, Director, Clinical Microbiology Laboratory; Assistant Professor of Clinical Pathology, Keck School of Medicine of the University of Southern California
Sepsis is associated with high morbidity and mortality. Prompt microbiological workup that guide appropriate antimicrobial therapy is essential for the optimization of patient outcome. Novel, innovative technologies have revolutionized the detection and identification of bloodstream pathogens in the laboratory. This session will discuss approaches to rapid laboratory diagnosis of sepsis.

3:10 Integrative -Omics Analysis of Sepsis: Biomarkers for Improved Patient Management
Raymond J. Langley, Ph.D., Assistant Professor, Department of Pharmacology, University of South Alabama
Infection-induced severe sepsis patients who do not receive early therapy have a high mortality rate (55%). However, current diagnostics are fairly non-specific. We used an integrative -omics approach to develop a clinico-metabolomic classifier to predict sepsis and the probability of death at the time of presentation.

Sponsored By T2Biosystems

3:40 T2 Magnetic Resonance (T2MR) a Revolutionary Breakthrough in Sepsis Diagnostics
Tom Lowery, Ph.D., Chief Scientific Officer, T2 Biosystems
T2MR is the first and only sepsis diagnostic that identifies pathogens directly from whole blood without reliance on insensitive blood cultures. T2MR technology provides faster, easier and more accurate results in 3-5 hours.

Sponsored By QIAGEN

3:55 Isothermal Amplification: an Innovative Tool for Infection Diseases Detection
Roberto Spricigo, Manager, Strategic Alliances & OEM PON, QIAGEN Lake Constance
The presentation gives an overview on isothermal amplification technologies and on the new dedicated solutions provided by QIAGEN Lake Constance GmbH, which could be particularly useful in the detection of Infection Diseases.

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the

CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

Exhibit Hall

ANTIMICROBIAL RESISTANCE AND ANTIMICROBIAL STEWARDSHIP

10:50 Chairperson's Remarks
Romney M. Humphries, Ph.D., D(ABMM), Assistant Professor, UCLA Pathology & Laboratory Medicine, Section Chief of Clinical Microbiology, David Geffen School of Medicine, University of California, Los Angeles

11:00 Identification of CRE Outbreak through Use of Next-Generation Sequencing
Romney M. Humphries, Ph.D., D(ABMM), Assistant Professor, UCLA Pathology & Laboratory Medicine, Section Chief of Clinical Microbiology, David Geffen School of Medicine, University of California, Los Angeles

Antimicrobial resistance among Gram negative bacteria is continually evolving. We identified a novel carbapenem antimicrobial resistance mechanism among *Klebsiella* spp. present in patients at our institution through whole microbial genome sequencing, and tracked this to a large outbreak of carbapenem-resistant *Klebsiella* among patients at our facility, associated with duodenoscopes.

11:30 Rapid Molecular Diagnostics – Role of Antimicrobial Stewardship
Graeme Forrest, M.B.B.S., Associate Professor of Medicine, VA Portland Healthcare System, Division of Infectious Diseases

Rapid molecular testing of blood cultures, respiratory viral and stool specimens has grown rapidly in last few years. How treating providers utilize these results is a great unknown. I will discuss the role of antimicrobial stewardship programs and how they bridge the gap between results and action with these new technologies.

12:00 pm Determination of Antimicrobial Susceptibility by Mass Spectrometry: Where Are We Now and Where Are We Going?
Susan Butler-Wu, Ph.D., D(ABMM), Associate Professor of Clinical Pathology, Keck School of Medicine of the University of Southern California; Director, Clinical Microbiology, LAC+USC Medical Center

MALDI-TOF Mass Spectrometry is increasingly becoming the standard of practice for microorganism identification in clinical microbiology laboratories. There have recently been a variety of efforts to apply this technology to the detection of antimicrobial resistance. In this session, we will discuss the status of the determination of antimicrobial susceptibility testing by MALDI-TOF as well as other forms of mass spectrometry

12:30 Session Break

Sponsored By Seegene

12:40 Luncheon Presentation: TB testing at a diverse inner-city population, an overview of testing platforms from one institute's experience.
Diane Hirigoyen, Lead Molecular Specialist, Mycobacteriology Laboratory, Hennepin County Medical Center

The incidence of active TB has increased amongst certain US populations, resulting in increased detection of multi-drug resistant (MDR) and extreme resistant (XDR) strains of TB as a result. Here we share the experience of The Mycobacteriology Laboratory at HCMC and results on the emergence of TB and TB-like disease in an inner-city and active immigrant community.

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

NOVEL DIAGNOSTIC APPROACHES IN INFECTIOUS DISEASE

1:50 Chairperson's Remarks
Purvesh Khatri, Ph.D., Assistant Professor, Stanford Institute for Immunity, Transplantation and Infection (ITI), Stanford Center for Biomedical Informatics Research (BMIR), Department of Medicine, Stanford University

2:00 Metagenomic Analysis of the Microbiome in Infectious Disease
George M. Weinstock, Ph.D., Professor and Associate Director, Jackson Laboratory for Genomic Medicine, Farmington

Metagenomic analysis of the microbiome can help determine the normal bacteria found in a healthy person versus the bacteria that causes an infectious disease. This talk will discuss the role of next-generation sequencing for metagenomics as well as how examination and metagenomic analysis of the microbiome can lead to new diagnostic approaches.

2:30 Using Heterogeneous Data for Infectious Disease Diagnostic Markers and Therapies
Purvesh Khatri, Ph.D., Assistant Professor, Stanford Institute for Immunity, Transplantation and Infection (ITI), Stanford Center for Biomedical Informatics Research (BMIR), Department of Medicine, Stanford University

Large amounts of publicly available data present novel unprecedented opportunities to carry out integrated, multi-cohort analyses of infectious diseases that are better representatives of heterogeneity observed in the real-world patient population. However, the presence of biological and technical heterogeneity in these data also present significant challenges in their integration. I will discuss a novel computational framework for addressing these challenges while leveraging heterogeneity present in these data. I will demonstrate applications of this framework to various infectious diseases by identifying novel robust and reproducible diagnostic signatures and therapies.

3:00 Decentralized Diagnostics in Low Resource Settings: Innovations in Technology, Linkage to Care, Access, and Impact
Peter J. Dailey, Ph.D., MPH, Senior Technical Officer, FIND (Foundation for Innovative New Diagnostics)

Decentralized diagnostics are playing an increasing role in patient care, disease surveillance, and control in low resource settings with infectious diseases such as Tuberculosis, Malaria, HIV, and Human African Trypanosomiasis. Key gaps remain. Further innovations in decentralized diagnostics are needed to reach the UNAIDS HIV/AIDS 90-90-90 goal, enable the global expansion of Hepatitis C treatment, combat antimicrobial resistance, and support the global elimination of neglected tropical diseases.

3:30 Sponsored Presentation *(Opportunity Available)*

4:00 Session Break

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE
CONTINUED ON NEXT PAGE

OUTCOME STUDIES: EVALUATION AND UTILITY OF DIAGNOSTIC TESTS

4:10 Chairperson's Remarks

Steve Miller, Associate Professor and Director, UCSF Clinical Microbiology Laboratory, University of California, San Francisco

4:15 Critical Role of Clinical and Healthcare Outcome Data in the Evaluation of Molecular Diagnostic Tests for Infectious Diseases

Chris Polage, Director, Clinical Microbiology Laboratory, Department of Pathology and Laboratory Medicine, University of California Davis Medical Center

The clinical significance of positive molecular test results and effect of molecular testing on clinical and healthcare outcomes are rarely evaluated. This presentation will review selected studies that confirm and question the value of molecular diagnostic tests for infectious diseases with two main goals: 1) highlight pitfalls in molecular diagnostic test application and interpretation as pertains to infectious diseases; 2) promote more widespread evaluation of clinical and healthcare outcomes associated with molecular diagnostic test use.

4:45 Respiratory Pathogen Molecular Testing – Inpatient Outcome Study in the Hospital Setting

Susan Novak-Weekley, Ph.D., D(ABMM), Director or Microbiology, Molecular Infectious Disease & Serology Testing, Southern California Permanente Medical Group

Along with the implementation of sophisticated molecular tools in the clinical laboratory, outcome data is needed to substantiate the use and placement of tests. Outcome data will be presented from the pediatric inpatient hospital setting related to quicker result turn-around time for respiratory pathogen testing in patients seen in the hospital or emergency room.

5:15 Utility of Viral Monitoring Tests in Transplant Recipients

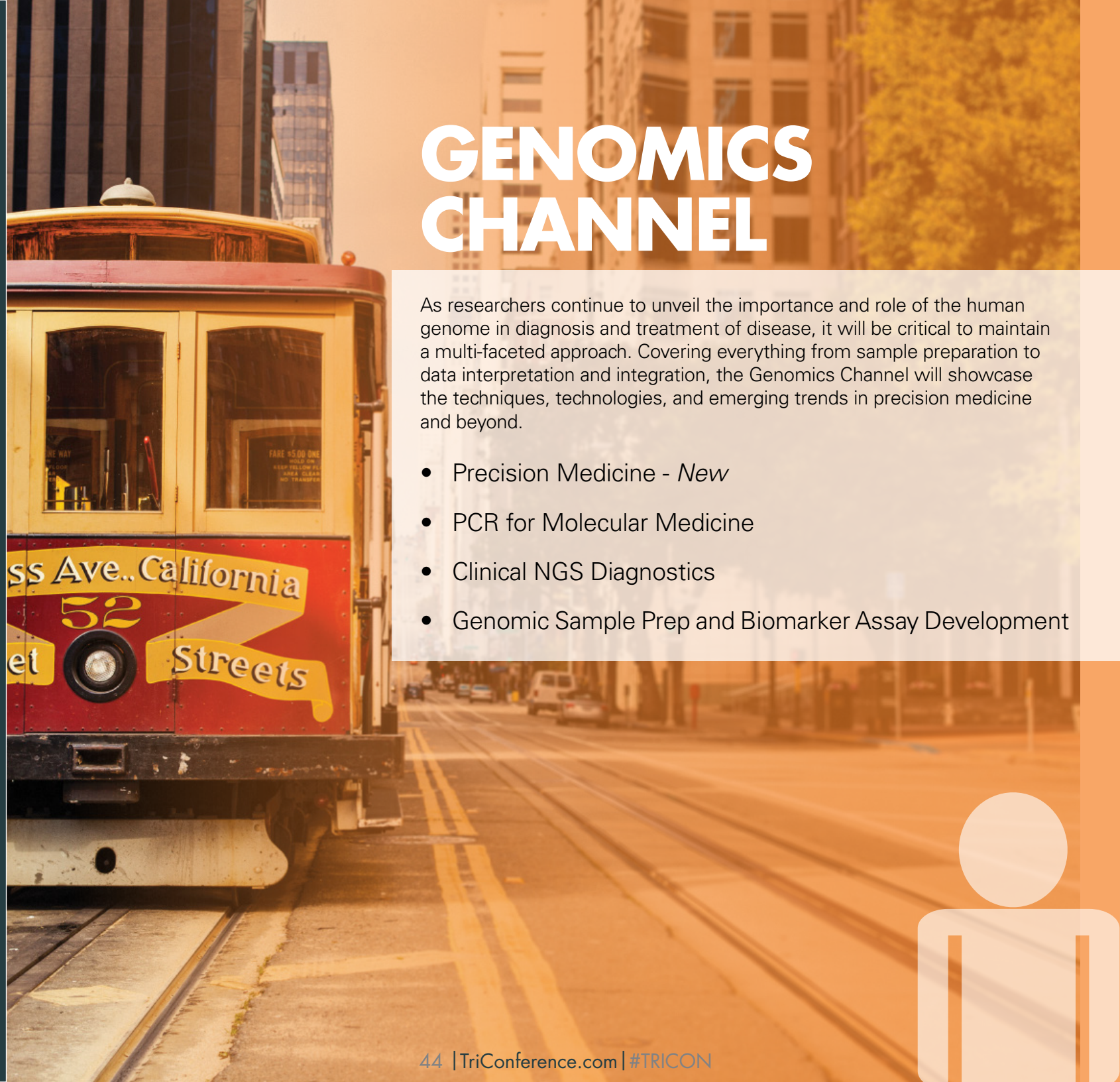
Steve Miller, Associate Professor and Director, UCSF Clinical Microbiology Laboratory, University of California, San Francisco

Transplant recipients are at high risk for viral infection, and a variety of testing strategies are available for monitoring. This talk will discuss the clinical utility and approach to testing these patients for CMV, EBV, BK and adenovirus, and illustrate how these tests can be used to improve patient management and outcomes.

5:45 Close of Conference Program

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute



GENOMICS CHANNEL

As researchers continue to unveil the importance and role of the human genome in diagnosis and treatment of disease, it will be critical to maintain a multi-faceted approach. Covering everything from sample preparation to data interpretation and integration, the Genomics Channel will showcase the techniques, technologies, and emerging trends in precision medicine and beyond.

- Precision Medicine - *New*
- PCR for Molecular Medicine
- Clinical NGS Diagnostics
- Genomic Sample Prep and Biomarker Assay Development

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

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
- Cancer Immunotherapy – *New*
- Predictive Preclinical Models in Oncology

Cambridge Healthtech Institute's Inaugural

CANCER IMMUNOTHERAPY

Emerging Biology, Targets and Strategies

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

HARNESSING NK CELLS FOR NEW ADOPTIVE CELL THERAPIES

11:50 Chairperson's Opening Remarks

James Smothers, Ph.D., Senior Director and Head, Discovery, Immuno-Oncology & Combinations DPU, GlaxoSmithKline

» 12:00 PM KEYNOTE PRESENTATION: Enhancing NK Cell Function for Transplantation and Cancer Therapy

Jeffrey Miller, M.D., Professor, Medicine; Deputy Director; Roger L. and Lynn C. Headrick Chair in Cancer Therapeutics, University of Minnesota Cancer Center

We have performed a number of clinical trials using autologous and allogeneic NK cells. IL-15, a natural cytokine that is critical for NK cell development and homeostasis will be discussed. I will discuss NK cell receptor immunogenetics and their importance in predicting transplantation outcomes. We have discovered a new subset of NK cells termed adaptive with properties of immunologic memory induced by cytomegalovirus. Lastly, I will review how NK cells can be targeted to tumors by bi-specific and tri-specific killer engagers and discuss the future of targeted NK cell therapeutics.

12:30 Immunosurveillance and Immunotherapy of Cancer-Mediated by Natural Killer Cells

David H. Raulet, Ph.D., CH Li Professor of Immunology and Pathogenesis; Co-Chair, Department of Molecular and Cell Biology, University of California, Berkley

We provide evidence that natural killer cells, and receptors they express that recognize cancer cells, provide protection against cancers arising in spontaneous mouse models of cancer. Furthermore, we develop evidence that NK cell activity is often suppressed in tumors by several mechanisms. We successfully tested several approaches to prevent the inactivation of NK cells within tumors, and show evidence for therapeutic benefit in preclinical models.

1:00 Session Break

Sponsored By
discovery from charles river

1:15 Combination Immune Checkpoint Inhibitors for the Treatment of Colon Carcinoma in Humanized NSG Mice

Martin Graf, Director, Charles River Labs

The therapeutic efficacy of combined anti-CTLA4 and anti-PD1 was evaluated in the human RKO colon carcinoma model using HLA-A matched CD34+-NSG humanized mice. Mice with established RKO tumors were treated with ipilimumab and pembrolizumab (100µg each) on days 1, 4, 9, 12 and 15 of the study. Treatment with the combined immune checkpoint inhibitors significantly reduced tumor progression ($p<0.001$) as compared to control CD34+-NSG mice that were treated with non-specific IgG.

1:45 Luncheon Presentation II: Knowledge Based Approaches to New Targets in Cancer Immunotherapy

Sponsored By
THOMSON REUTERS

Richard Harrison, CSO, Product Management, Thomson Reuters

We are applying knowledge based approaches to scout biological pathways for potential new targets for immune based therapies for cancer. This presentation will focus on an overview of the field of cancer immunotherapy, a review of new initiatives, and a look at how these knowledge based approaches are being used to find potential new therapies for cancer treatment.

2:15 Session Break

CLINICAL TRIALS AND COMBINATIONS OF NK CELL THERAPY

2:30 Chairperson's Remarks

James Smothers, Ph.D., Senior Director and Head, Discovery, Immuno-Oncology & Combinations DPU, GlaxoSmithKline

2:40 Cord Blood-Derived Natural Killer Cells for Treatment of Multiple Myeloma

Nina D. Shah, M.D., Medical Director & Assistant Professor, Stem Cell Transplantation Center, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center

NK cells are ideal candidates for allogeneic cellular therapy, as they are safe and do not produce GVHD. We have developed a novel technique for large scale expansion of NK cells from cryopreserved cord blood (CB) units. In this presentation we will discuss the techniques of CB-NK expansion, the activity of these cells and our experience in a first-in-human trial for patients with multiple myeloma. We will also discuss possible mechanisms of action and future applications of this therapy not only for myeloma but a host of hematologic malignancies.

3:10 Utilizing Function-Enabled NK Cells for Cancer Immunotherapy

Todd A. Fehniger, M.D., Ph.D., Associate Professor, Department of Medicine, Oncology Division, Bone Marrow Transplantation & Leukemia Section, Washington University School of Medicine

Recent discoveries have revealed that NK cells remember prior activation, and our work defining and translating cytokine-induced memory-like NK cells from bench to the leukemia patient bedside will be discussed. In addition, we will review the basic science defining the importance of cytokine receptors for NK cell sustenance *in vivo*, and present recent translational results whereby monoclonal antibodies are combined with 'next-generation' function-enhancing cytokines for the immunotherapy of lymphoma.

3:40 Enhancing Antibody-Directed Innate Immunity to Improve Cancer Outcome

Paul M. Sondel, M.D., Ph.D., Reed and Carolee Walker Professor of Pediatrics and Human Oncology; Head, Division of Pediatric Hematology, Oncology and BMT; University of Wisconsin

We have used tumor-reactive mAbs combined with or linked to IL2 (immunocytokines) as an initial platform to induce NK-mediated innate anti-tumor effects in the lab and clinic. Combining this innate approach with radiation therapy and immunomodulatory immunotherapy is enabling engagement of adaptive immunity in tumor-bearing mice, with resultant tumor-specific memory. Our goal is to identify and refine combinations of "off the shelf" immunotherapies that can eliminate cancer.

Sponsored By
CELLECTA
Discovery is Yours.

4:10 Driver-Map: Molecular Deconstruction of the Tumor Microenvironment

Gus Frangou, Director, Clinical Operations, Cellecta

Molecular profiles of the tumor microenvironment (TME) hold considerable promise for biomarker discovery. The talk describes a novel multiplex RNA-Tag-Seq pipeline to quantitatively assess the digital transcription profile of the TME and model tumor purity and infer the presence of infiltrating stromal/immune cells in clinical samples.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

CANCER IMMUNOTHERAPY
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

7:30 Close of Day

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

ADVANCES IN ADOPTIVE T-CELL THERAPY

10:05 Chairperson's Remarks

10:15 CAR T-Cells as Immunotherapy: Where Are We Now?
Marcela Valderrama Maus, M.D., Ph.D., Director, Cellular Immunotherapy, MGH Cancer Center; Assistant Professor of Medicine, Harvard Medical School

Genetically-modified T-cells with chimeric antigen receptors (CARs) have been granted Breakthrough Therapy designation by the FDA at multiple institutions. Despite having been developed in the academic setting, many T-cell therapies are now entering an industry setting to be developed into commercial therapies to treat cancer. We will discuss the components of chimeric antigen receptors, the technologies used in making a T-cell product, some of the factors considered to be important for efficacy, and recent results in hematologic malignancies and solid tumors.

10:45 The ImmTAC Technology: A Cutting Edge Immunotherapy for Cancer Treatment
Martina Canestraro, Ph.D., Scientist, Cell Biology, Immunocore Limited

ImmTACs are bi-specific molecules formed from an affinity enhanced monoclonal T-cell receptor linked to an anti-CD3 specific antibody fragment (CD3-scFv). The mTCR recognises intracellular antigens that have been processed and displayed on class I MHC molecules; the CD3-scFv is a powerful effector function that redirects CD3+ T-cell activity to the tumour cells. Through the targeting of peptides presented by Class I HLA the ImmTAC has access to intracellular antigens that traditional antibody therapeutics are unable to target thus allowing the ImmTACs to recognise a greater variety of targets.

11:15 PANEL DISCUSSION: Current Challenges and Opportunities for CAR T-Cell Therapy
Moderator: James Smothers, Ph.D., Senior Director & Head, Discovery, Immuno-Oncology & Combinations DPU, GlaxoSmithKline

T-cells that have been genetically modified and redirected with a chimeric antigen receptor, or CAR, have shown unprecedented efficacy in B-cell malignancies. This panel discussion will tackle current challenges and emerging opportunities within this rapidly emerging space. Topics will include, but are not limited to:

- Novel and emerging antigens for targeting
- Challenges and opportunities in targeting solid tumors
- Approaches for avoiding or controlling cytokine syndrome
- Enhancing expansion and persistence of T-cells
- Combination strategies to combat tumor microenvironment

Panelists:
David M. Spencer, Ph.D., CSO, Bellicum Pharmaceuticals, Inc.
Richard Morgan, Ph.D., Vice President, Immunotherapy, bluebird bio
Philippe Duchateau, Ph.D., CSO, Cellectis
Marcela Valderrama Maus, M.D., Ph.D., Director, Cellular Immunotherapy, MGH Cancer Center; Assistant Professor of Medicine, Harvard Medical School

12:15 pm Session Break

Sponsored By Oncodesign

12:25 Luncheon Presentation I: From Syngeneic to Humanized Mouse Models: Tools to Address Novel Cancer Immunotherapies
Jean-François Mirjolet, Technology Director, Oncodesign

Therapies such as CTLA-4 or PD-1 targeting antibodies have now received approval and others are under clinical evaluation. However, there is still a huge need in refining preclinical models to address efficacy but also to identify biomarkers. To answer these questions, case studies using syngeneic mouse models and tumor bearing humanized mouse will be described.

Sponsored By C.T.L. Cellular Technology Limited

12:55 Multi Parametric Immune Monitoring Using Fluorescence-based, High Throughput Cell Imaging
Srividya Sundararaman, Ph.D., Staff Scientist, Research & Development, Cellular Technology Limited

CTL has developed a comprehensive Immune Monitoring platform for primary and secondary immune response to antigens; i.e. NK cytotoxicity, measurements of the magnitude and lineage of antigen induced T cells, cytotoxic ability of the cells, and antibody secreting B cells.

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

EMERGING STRATEGIES FOR CHECKPOINT INHIBITOR COMBINATION IMMUNOTHERAPY

2:00 Chairperson's Remarks
Jeff T. Hutchins, Ph.D., Vice President, Preclinical Research, Peregrine Pharmaceuticals

2:10 FEATURED PRESENTATION: The BRAF and MEK Inhibitors Dabrafenib and Trametinib: Effects on Immune Function and in Combination with Immunomodulatory Antibodies Targeting PD-1, PD-L1, and CTLA-4
James Smothers, Ph.D., Senior Director & Head, Discovery, Immuno-Oncology & Combinations DPU, GlaxoSmithKline

PD-L1 expression in tumor cells was upregulated after acquiring resistance to BRAF inhibition *in vitro*. Combinations of trametinib with immunomodulators targeting PD-1, PD-L1, or CTLA-4 in a CT26 model were more efficacious than any single agent. The combination of trametinib with anti-PD-1 increased tumor-infiltrating CD8(+) T cells in CT26 tumors. Concurrent or phased sequential treatment, defined as trametinib lead-in followed by trametinib plus anti-PD-1 antibody, demonstrated superior efficacy compared with anti-PD-1 antibody followed by anti-PD-1 plus trametinib.

Sponsored By CREATV MicroTech

2:40 Blood-Based Biopsies in the Age of Immunotherapy: How Can We Use Circulating Stromal Cells?
Daniel Adams, Senior Research Scientist, Creatv MicroTech, Inc.

CellSieve™ filters isolate circulating stromal cells & circulating tumor cells disseminated from tumor masses allowing for tumor subtyping & stromal targeting. While providing sequential noninvasive sampling, analyzing multiple cell types enables a greater variety of information for immunotherapy treatment selection and monitoring treatment response.

Sponsored By ACEA Biosciences, Inc.

2:55 Label-Free Real-Time Monitoring of Immune Cell-Mediated Killing Using Cellular Impedance
Brandon Lamarche, Ph.D., Scientist, Research & Development, ACEA Biosciences, Inc.

Development of novel cancer immunotherapies requires killing assays capable of predicting long-term killing kinetics of immune cells *in vivo*. To address this unmet need, ACEA developed the label-free real-time xCELLigence assay to quantify immune cell killing kinetics. Case studies on NK/T cell-mediated cytolysis, ADCC, BiTE and CAR-T will be discussed.

CANCER IMMUNOTHERAPY
CONTINUED ON NEXT PAGE

3:10 Potent Anti-Tumor Immunity is Induced by STING Activation in the Tumor Microenvironment Using a Synthetic Human STING-Activating Cyclic Dinucleotide

Sarah McWhirter, Ph.D., Associate Director, STING Program, Aduro Biotech

I will describe how a novel synthetic CDN derivative (ADU-S100), that has improved STING-activating and anti-tumor properties as compared to naturally derived CDNs, was developed for clinical translation. I will show that activation of STING through IT administration of ADU-S100 results in effective anti-tumor efficacy and survival in several mouse syngeneic tumor models. I will discuss some of the mechanisms by which of ADU-S100 induces tumor regression and plans for a Phase 1 clinical study with ADU-S100 to evaluate the safety and tolerability and possible anti-tumor effects in subjects with cutaneously accessible malignancies.

3:40 Combination Immunotherapies – Opening the Gate: Increasing Tumor Infiltrating Activated T-Cells to Optimize and Expand the Benefits of Immune Checkpoint Therapies

Jeff T. Hutchins, Ph.D., Vice President, Preclinical Research, Peregrine Pharmaceuticals

PD-1 and CTLA-4-targeting drugs have significantly improved patient survival in both melanoma and NSCLC, although their efficacy has been limited to a minority of subjects. Phosphatidylserine (PS)-targeting antibodies have demonstrated the ability to override tumor immune suppression and reactivate immune responses when combined with immunotherapies, chemotherapies, radiation, and targeted treatments. Recent translational data demonstrate the potential of PS-targeting antibodies to mediate immune activation and improved anti-tumor responses in low PD-L1 tumor samples.

3:55 Sponsored Presentation *(Opportunity Available)*

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

AGONIST – PD-1 COMBINATION IMMUNOTHERAPY

10:50 Chairperson's Remarks

Andrew D. Weinberg, Ph.D., Chief, Laboratory of Basic Immunology, Providence Cancer Center

11:00 Preclinical Evaluation of an Agonist Antibody Targeting ICOS

Robert Mabry, Ph.D., Director, Protein Sciences and Antibody Technology, Jounce Therapeutics

Jounce is developing an agonistic antibody to the co-stimulatory molecule ICOS. Preclinical studies demonstrate that anti-ICOS agonistic antibodies are efficacious in syngeneic tumor models, with enhanced efficacy observed in combination with PD-1 inhibition.

11:30 Combination of 4-1BB Agonist and PD-1 Antagonist Promotes Antitumor Effector/Memory CD8 T Cells

John C. Lin, Ph.D., Senior Vice President & CSO, Cancer Immunotherapy, Pfizer

Immunotherapies targeting the programmed death 1 (PD-1) coinhibitory receptor have shown great promise for a subset of patients with cancer. However, robust and safe combination therapies are still needed to bring the benefit of cancer immunotherapy to broader patient populations. To search for an optimal strategy of combinatorial immunotherapy, we have compared the antitumor activity of the anti-4-1BB/anti-PD-1 combination with that of the anti-PD-1/anti-LAG-3 combination in the poorly immunogenic B16F10 melanoma model.

12:00 pm OX40 Agonist Combined with PD-1 and TGFb Receptor Blockade

Andrew D. Weinberg, Ph.D., Chief, Laboratory of Basic Immunology, Providence Cancer Center

Human OX40 agonists are currently being tested in the clinic and the rationale for this immunotherapeutic approach was based on their success in preclinical mouse tumor models. Our group has found that when OX40 agonists are delivered when the tumors are large in size the mice become resistant to their therapeutic effects. Therefore we tested two agents in combination with OX40 agonists in mice harboring large tumors: 1) PDL-1 blockade and 2) TGFb-receptor inhibitor. Both agents showed therapeutic synergy when combined with OX40 agonists and enhanced immune infiltration within tumors.

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

NOVEL TARGETS FOR IMMUNOTHERAPY DEVELOPMENT AND SYNERGISTIC COMBINATIONS

1:50 Chairperson's Remarks

Holbrook Kohrt, M.D., Ph.D., Assistant Professor, Medicine (Oncology), Stanford University Medical Center

2:00 Combination Immunotherapy to Enhance Efficacy of Tumor Targeting Antibodies

Holbrook Kohrt, M.D., Ph.D., Assistant Professor, Medicine (Oncology), Stanford University Medical Center

Recent studies indicate that the antitumor efficacy of therapeutic tumor-targeting antibodies can be augmented by the addition of agonistic antibodies targeting CD137. As ligation of CD137 provides a costimulatory signal in multiple immune cell subsets, combination therapy of CD137 antibody with therapeutic antibodies and/or vaccination has the potential to improve cancer treatment. Recently, clinical trials of combination therapies with agonistic anti-CD137 mAbs have been launched.

2:30 Emerging Targets in Cancer Immunotherapy: Beyond CTLA-4 and PD-1

Xingxing Zang, Ph.D., Associate Professor, Microbiology, Immunology and Medicine, Albert Einstein College of Medicine

CTLA-4 and the PD-1/PD-L1 pathway are current focuses in cancer immunotherapy. Dr. Zang will discuss other new immune checkpoints for future human cancer immunotherapy.

3:00 oxMIF as a New Therapeutic Target in Cancer

Michael Thiele, Ph.D., Manager, R&D, Research & Innovation, Baxalta Innovations GmbH

A newly discovered, disease-related isoform of the cytokine macrophage migration inhibitory factor (MIF), designated oxMIF, presents a potential target for novel therapies in cancers with a high unmet medical need. Unlike MIF, OxMIF is specifically expressed in cancerous tissue from patients with different solid tumors, but not in tissue with normal morphology or in healthy subjects. Human monoclonal antibodies (mAbs) directed against oxMIF demonstrated anticancer activity alone, and in combination with chemotherapeutic agents in mouse cancer models.

3:30 Sponsored Presentation *(Opportunity Available)*

4:00 Session Break

ORGANIZED BY: Cambridge HEALTHTECH Institute

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

IMMUNOMONITORING AND MECHANISM OF ACTION OF NEW IMMUNOTHERAPIES

4:10 Chairperson's Remarks
Kip Harry, Director, Conferences, Cambridge Healthtech Institute

4:15 Imnunosequencing and Cancer
Catherine Sanders, Ph.D., Director, Scientific Liason, Adaptive Biotechnologies
Adaptive is at the forefront of immune-based discoveries, combining high-throughput sequencing and expert bioinformatics to profile T-cell and B-cell receptors. We bring the accuracy and sensitivity of our immunosequencing platform into laboratories around the world to drive groundbreaking research in cancer and other immune-mediated diseases. Adaptive also translates immunosequencing discoveries into clinical diagnostics and therapeutic development to improve patient care.

4:45 Biomarkers to Support the Development and Clinical Application of Immunotherapy Combinations
Jelveh Lameh, Ph.D., Executive Director & Head, BioPharma Services Laboratory, Genoptix Medical Laboratory, Inc., a Novartis Company
Biomarkers have successfully been applied to multiple aspects of cancer therapy. Up until now, biomarkers have been applied to various aspects of therapies that were targeted directly at the tumor cells. With the recent advances in immunotherapy, the rationale for combination therapies to circumvent resistance has emerged. Thus, application of biomarkers for such combination therapies is expected to improve patient outcomes.

5:15 Analytical Validation of Multiplex Assays on Simple-Plex Ella Platform for the Measurement of Cytokines
Teresa Davancaze, Principal Research Associate, Genentech
Immune check point inhibitors such as anti-PD-L1 have exhibited durable anti-tumor responses in a variety of cancer indications which break down the tolerogenic state of immune cells and activate T-lymphocytes. These activated lymphocytes release cytokines that directly stimulate immune effector cells at the tumor site and enhance cell recognition by cytotoxic effector cells for elimination of tumors. Measurement of cytokines is actively being pursued to study pharmacodynamic changes which can help understand the mechanism of action of immune checkpoint inhibitors. In this study, we show bioanalytical validation of cytokines assays in plasma on a novel multiplex platform, Simple-Plex Ella. Ella allows multiplexing of four analytes and consumes small sample volume of 25ul. Compared to conventional multiplex immunoassays such as Luminex, Ella offers the specificity of a single-plex ELISA since each sample is run in four channels, each specific to a unique analyte. The assays exhibited excellent sensitivity and specificity. The accuracy and precision were 80-120% and 10% respectively.

5:45 Close of Conference Program

Student Fellowship 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 discounted registration fee of $195. Applications are due by November 20, 2015.

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

Cambridge Healthtech Institute's Third Annual

PREDICTIVE PRECLINICAL MODELS IN ONCOLOGY

Mastering Translational Oncology with Predictive Models and Novel *in silico* Approaches

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

LARGE SCALE *IN VIVO* SCREENING AND BIG DATA VISUALIZATION

11:50 Chairperson's Opening Remarks
Arijit Chakravarty, Ph.D., Director, Modeling and Simulation (DMPK), Takeda Pharmaceuticals International Co.

12:00 pm Utilizing Large Scale *in vivo* Screening with PTX Models Predicts Drug Response in Cancer Patients
Juliet Williams, Ph.D., Head, Oncology Pharmacology Drug Discovery, Novartis Institutes for BioMedical Research

Profiling candidate therapeutics using a limited set of cancer models during preclinical development hinders accurate predictions of clinical efficacy. We established ~1000 patient-derived tumor xenograft models, with comprehensive genomic landscape analyses. Subsequently, we performed population-based *in vivo* compound screens using a 1x1x1 experimental design to assess the response and resistance of 70 treatments across six indications. We demonstrate both the reproducibility and clinical translatability of this approach and additionally demonstrate examples of PTX superiority over cell-based xenografts in predicting clinical response.

12:30 Visualizing and Interacting with Clinical/Molecular Cancer Big Datasets
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 are developing computational tools that allow interactive visualization of large datasets of clinical and molecular cancer patients. These tools are able to analyze any tumor type, but are initially created around the TCGA Glioma data as a demonstration dataset. Using this data, groups of structurally similar tumors can be identified, and the clinical outcomes of these groups can be determined. This tool can be used to identify more homogenous populations of patients for clinical trials.

1:00 Session Break

Sponsored By
The Jackson Laboratory
Leading the search for tomorrow's cures

1:15 Luncheon Presentation I: Patient-Derived Tumor Xenografts in Humanized NSG-SGM3 Mice: A New Immuno-Oncology Platform
James G. Keck, Ph.D., Senior Director, Clinical Lab & in vivo Pharmacology Services, The Jackson Laboratory

Humanized mice engrafted with tumors enable *in vivo* investigation of the interactions between the human immune system and human cancer. We have recently found that humanized NOD-scid IL2Rγnull (NSG) mice bearing patient-derived xenografts (PDX) allow efficacy studies of check-point inhibitors. Next-generation NSG strains include triple transgenic NSG mice expressing human cytokines KITLG, CSF2, and IL3 (NSG-SGM3). Here we provide a direct comparison of check-point inhibitors evaluation in NSG and NSG-SGM3 mice engrafted with CD34+ human hematopoietic progenitor cells (HPCs) from the same donor and implanted with PDX tumors.

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

2:15 Session Break

NOVEL TRANSLATIONAL APPROACHES IN IMMUNO-ONCOLOGY

2:30 Chairperson's Remarks

» 2:40 KEYNOTE PRESENTATION: The Mechanistic Basis of Cancer Immunotherapy
Priti Hegde, Ph.D., Anti-angiogenesis and Cancer Immunotherapy Franchises Biomarker Lead, Oncology Biomarkers, Genentech

3:10 Epigenetic Priming for Immunotherapy in Breast Cancer
Pamela N. Munster, M.D., Professor of Medicine; Program Leader, Development Therapeutics; Director, Early Phase Clinical Trials' Program, Helen Diller Cancer Center, University of California, San Francisco

A break down in immune tumor surveillance plays a crucial role in the development of metastatic cancer. Targeting the programmed death receptor (PD-1) and its ligand (PD-L1) have been major breakthroughs. In breast cancers however, particularly in hormone-driven breast cancer, immune responses are often absent. In reverse-translating clinical findings from the patient to preclinical models we show that epigenetic modulation leads to epigenetic immune priming and enhancement of immune response.

3:40 The Human as the Animal Model: Preclinical and Intra-Clinical Translation in Oncology
Arijit Chakravarty, Ph.D., Director, Modeling and Simulation (DMPK), Takeda Pharmaceuticals International Co.

The challenges of Oncology drug development are legion, and differ subtly from those of other therapeutic areas. On the one hand, disease tissue from patients is readily available for study. On the other hand, the real translational unknown is the toxicity profile. In this presentation, I will make a (contrarian) case for improving the modeling of clinical toxicity data and increasing the reliance on preclinical xenograft efficacy data.

Sponsored By
CHAMPIONS ONCOLOGY

4:10 Advanced PDX Tumor Biology Platforms for Drug Advancement
Neal Goodwin, Vice President, Corporate Research & Development, Champions Oncology

Collections of PDX models have tested investigational compounds for efficacy predictions, and PDX-based platforms can be used with spontaneous mouse models and GEMMs to discover new therapeutic targets, resistance mechanisms, and biomarker signatures of response. There are, however, limits to their use in clinical trial simulation. Coupled-PDX trials are being advanced - clinical trials are combined with companion PDX studies to help guide follow-on trial design. Matched patient-PDX-directed trials will see PDX models used to screen for experimental drug efficacy, with patients enrolled onto trials based on their PDX drug response.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

CONTINUED ON NEXT PAGE

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

MODELS FOR CANCER IMMUNOTHERAPY

10:05 Chairperson's Remarks
Chad May, Ph.D., Director, Oncology Research Unit, Pfizer

10:15 Preclinical Tumor Models for Evaluating Bispecific Redirected T-Cell Therapeutics
Chad May, Ph.D., Director, Oncology Research Unit, Pfizer
Strong evidence exists supporting the important role T-cells play in the immune response against tumors. Still, the ability to initiate tumor specific immune responses remains a challenge. We have developed a bispecific protein engineered with enhanced pharmacokinetic properties to extend *in vivo* half-life, and designed to engage and activate endogenous polyclonal T-cell populations via the CD3 complex in the presence of tumors expressing target antigens.

10:45 Assessing ENPP3 as a Renal Cancer Target for Bi-Specific T-Cell Engager (BiTE®) Therapy
Olivier Nolan-Stevaux, Ph.D., Senior Scientist, Oncology Research, Amgen, Inc.
BiTE® therapeutics are single chain antibody constructs harboring two binding moieties: one directed at a tumor antigen and one directed at the CD3e protein, which triggers T-cell mediated cytotoxicity against targeted cancer cells. Here, we will present the development of BiTE® Antibody Constructs recognizing the ENPP3 protein, a target prominently expressed in clear cell Renal Cell Carcinoma, and the assessment of these molecules *in vitro* and in preclinical models.

11:15 Improved Systemic Responses through the Rational Combination of Immunotherapy with Radiation
James W. Welsh, M.D., Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center
The immune-modulating effects of radiation therapy have recently gained considerable interest and there have been multiple reports of synergy between radiation and immunotherapy. However, additional preclinical studies are needed to demonstrate the antigen-specific nature of radiation induced immune responses and elucidate potential mechanisms of synergy with immunotherapy. Here we demonstrate the ability of stereotactic radiotherapy to induce endogenous antigen-specific immune responses when combined with anti-PD-1 checkpoint blockade immunotherapy.

11:45 Selected Poster Presentation: Preclinical Development of CXCR4 Antagonist Antibody for Cancer Immunotherapy
Dmitry Poteryaev, Ph.D., Acting CSO, Head of Molecular and Cell Biology Department, IBC Generium, LLC

12:15 pm Session Break

12:25 Luncheon Presentation I: Precision Research Models of Human Immune System and Metabolic Function: Applications in Oncology Drug Discovery
Sponsored By TACONIC
Michael Seiler, Ph.D., Associate Director, Product Management, Taconic Biosciences
The development of animal models to mimic human immune responses is crucial to study the pathophysiology of cancer. We will focus on the current state of immune system engraftment models, the next generation huNOG-EXL which extends the functionality of current systems, and recent advances in immuno-oncology.

12:55 Luncheon Presentation II *(Sponsorship Opportunity Available)*

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

CANCER DRUG RESISTANCE MODELING AND RESEARCH

2:00 Chairperson's Remarks
Bruce R. Zetter, Ph.D., Charles Nowiszewski Professor of Cancer Biology, Department of Surgery, Harvard Medical School

2:10 Markers, Mechanisms and Treatment of Resistant Cancer
Bruce R. Zetter, Ph.D., Charles Nowiszewski Professor of Cancer Biology, Department of Surgery, Harvard Medical School
Focusing on resistance to taxanes, we have uncovered novel mechanisms of chemoresistance that depend on upregulation of cell surface Prohibitin 1 (PHB1). XIAP levels are upregulated in several human cancers and correlate with decreased survival in patients with non-small cell lung cancer (NSCLC). Our recent results demonstrate that PHB1 promotes resistance to apoptosis by stabilizing the X-linked inhibitor of apoptosis, XIAP. We further find that systemic delivery of nanoparticles carrying siRNA to PHB1 results in restoration of taxane sensitivity in preclinical models of NSCLC.

2:40 Mouse Models for Oncology Drug Development: Translational Tales
Mallika Singh, Ph.D., Director, Oncology Pharmacology, ORIC Pharmaceuticals

3:10 A Complete Workflow for Isolating Pure Tumor Cell Populations from Primary Tissue for Improved Downstream Analyses
Sponsored By MACS Miltenyi Biotec
Olaf Hardt, Ph.D., Senior Project Manager, Research & Development, Miltenyi Biotec
Both tumor and non-tumor cells exist within the tumor environment. Reliable analyses of tumor cells therefore requires pure cell populations, as contaminating non-tumor cells can affect the results of downstream assays. Depletion of mouse cells from xenograft tumors or stromal cells from human or mouse tumors is simple with our tumor cell isolation workflow.

3:25 A Tissue-Engineered Vascularized Tumor Microenvironment for Preclinical Testing of Anticancer Therapeutics.
Henning Mann, Ph.D., Senior Research Scientist, Research & Development, Nortis, Inc.
Nortis provides microfluidic chips for tissue engineering 3D vascularized tissue microenvironments. Endothelial vessels induced to sprout in response to growth factors create a vascular network that invades tumor tissue. The model will be used to test anticancer therapeutics.

3:40 PANEL DISCUSSION: Modeling and Researching Cancer Drug Resistance
Moderator: Bruce R. Zetter, Ph.D., Charles Nowiszewski Professor of Cancer Biology, Department of Surgery, Harvard Medical School
Panelists:
Chad May, Ph.D., Director, Oncology Research Unit, Pfizer
David L. Rimm, M.D., Ph.D., Yale University School of Medicine
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf
What is the best way to study resistance? What are the challenges in translating promising therapeutic interventions to a clinical setting? These seemingly distinct questions are deeply intertwined. This panel discussion will cover these and other practical topics at the interface of basic science and practical applications in cancer.

4:10 St. Patrick's Day 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

CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

WEDNESDAY, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

INFORMING CLINICAL TRIALS

10:50 Chairperson's Remarks
Anderson Clark, Ph.D., Director, in vivo Pharmacology, Oncology, EMD Serono Research & Development

11:00 Integration of PDX Modeling into Clinical Trials: Biological, Clinical and Statistical Perspectives
Joint Presentation: 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)
Philip C. Mack, Ph.D., Associate Adjunct Professor, Internal Medicine, Hematology and Oncology, University of California Davis Medical Center
Mary Redman, Ph.D., Lead Statistician, Lung Cancer Committee Southwest Oncology Group, Lead Statistician, Lung Map Trial, Fred Hutchinson Cancer Research Center

12:00 pm Statistical Analysis of PDX Studies and Preclinical Phase-II-Like Trials (PP2T) at EMD Serono
Anderson Clark, Ph.D., Director, in vivo Pharmacology, Oncology, EMD Serono Research & Development
At EMD Serono, data from PDX (patient-derived xenograft) models of cancer are used to make clinical decisions for Phase II. In increasing the predictive value of these animal models, we have addressed questions about what constitutes a preclinical response in relationship to clinical RECIST criteria and what the proper statistical analyses of these models would be, and these outcomes will be presented.

12:30 Session Break

Sponsored By Surrogen

12:40 Engineered Swine Models of Cancer
David Largaespada, Ph.D., CSO, Surrogen, Inc.
Over the past decade the technology for engineering swine genome has advanced tremendously. Swine models of cancer have great potential for preclinical safety studies, including efficacy & toxicity testing of pharmaceuticals in genetically prone individuals. We are applying precision genetics to provide swine models that mimic human genetic conditions associated with cancer. We will describe our use of TALENs & CRISPR targeted nucleases to develop novel porcine models of cancer with broad preclinical applications.

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

3D MODELS AND GENE EDITING

1:50 Chairperson's Remarks
Byron C. Hann, M.D., Ph.D., Associate Researcher, Manager of Preclinical Therapeutics Core, UCSF Helen Diller Family Comprehensive Cancer Center

2:00 The Critical Role of Extracellular Matrix and Microenvironment in Metastasis and Dormancy
Mina J. Bissell, Ph.D., Distinguished Scientist, Life Sciences Division, Lawrence Berkeley National Laboratory
We have developed a number of versatile assays for human cells to study tissue specificity, breast cancer, dormancy and metastases. These assays have been published and I will briefly describe them to you. I will also discuss some very recent work where we have explored the reason behind the lack of normal and malignant epithelial cell lines for drug discovery and signaling.

2:30 : Cell line genomics in drug discovery
Christian Klijn, Ph.D., Computational Biology, Genentech
Tumor-derived cell lines have served as vital models to advance our understanding of oncogene function and therapeutic responses. Understanding cell line genomics is critical to the effective and accurate use of cell lines in preclinical studies. I will describe our effort to map the transcriptome of more than 600 cell lines and various preclinical applications of this data.

3:00 Genetic Modeling and Screening of Cancer in Mice Using CRISPR
Sidi Chen, Ph.D., Assistant Professor, Department of Genetics and Systems Biology Institute, Yale Cancer Center and Stem Cell Center, Yale University School of Medicine

3:30 Modeling Checkpoint Blockade Using Heterogeneous Chemically-Induced Carcinomas
Rosemary J. Akhurst, Ph.D., Professor and Director, Preclinical Therapeutics Core, UCSF Helen Diller Family Comprehensive Cancer Center
The large majority of patients do not benefit from checkpoint blockade agents when used as monotherapies. It is important to identify agents that accentuate response rates and improve overall survival. We present a novel chemically-induced syngeneic carcinoma model that represents the single nucleotide mutation (SNV) spectra found in environmentally induced human cancers, e.g. melanoma and lung cancer. We tested α-PD-1 and α-pan TGFβ mono- and combination therapies and found responses only in tumors with a high SNV load. This model should be useful to study primary and acquired resistance to α-PD-1.

4:00 Session Break

CO-CLINICAL TRIALS AND PDX MODELS

4:10 Chairperson's Remarks
Byron C. Hann, M.D., Ph.D., Associate Researcher, Manager of Preclinical Therapeutics Core, UCSF Helen Diller Family Comprehensive Cancer Center

4:15 Co-Clinical Trials of Targeted Therapies in Colorectal Cancer Patients and Patient Derived Xenografts
Joint Presentation: Chloe E. Atreya M.D., Ph.D., Assistant Clinical Professor, Gastrointestinal Oncology Program, University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center
Byron Hann, M.D., Ph.D., Research Scientist and Laboratory Director, Preclinical Therapeutics Core, UCSF Helen Diller Family Comprehensive Cancer Center
Patient-derived xenograft (PDX) models share molecular and phenotypic similarity to patient cancer tissue and are presumed to have superior predictive value as a preclinical model. High rates of engraftment, success using needle biopsy starting material, and rapid growth make colorectal cancer (CRC) an ideal model to test this hypothesis. We compare PDX and clinical response to targeted therapeutics, and demonstrate concordance. We conduct co-clinical trials in CRC patients and PDX and aim to use response in PDX to direct selection of experimental agents for CRC patients.

5:15 A Humanized Ossicle-Niche Xenotransplantation Model with Improved Hematopoietic Engraftment
Andreas Reinisch, M.D., Ph.D., Institute for Stem Cell Biology and Regenerative Medicine (ISCBRM), Stanford University
Current xenotransplantation models do not recapitulate human bone marrow (BM) microenvironment components and exhibit limited engraftment of many human hematopoietic malignancies. We developed a xenotransplantation model bearing subcutaneous humanized accessible BM microenvironments formed by *in situ* differentiation of BM-derived mesenchymal stromal cells. In these humanized microenvironments, we detected extensive engraftment of diverse primary acute myeloid leukemia samples at levels much greater than in unmanipulated mice allowing for the identification of leukemia-initiating cells

5:45 Close of Conference Program

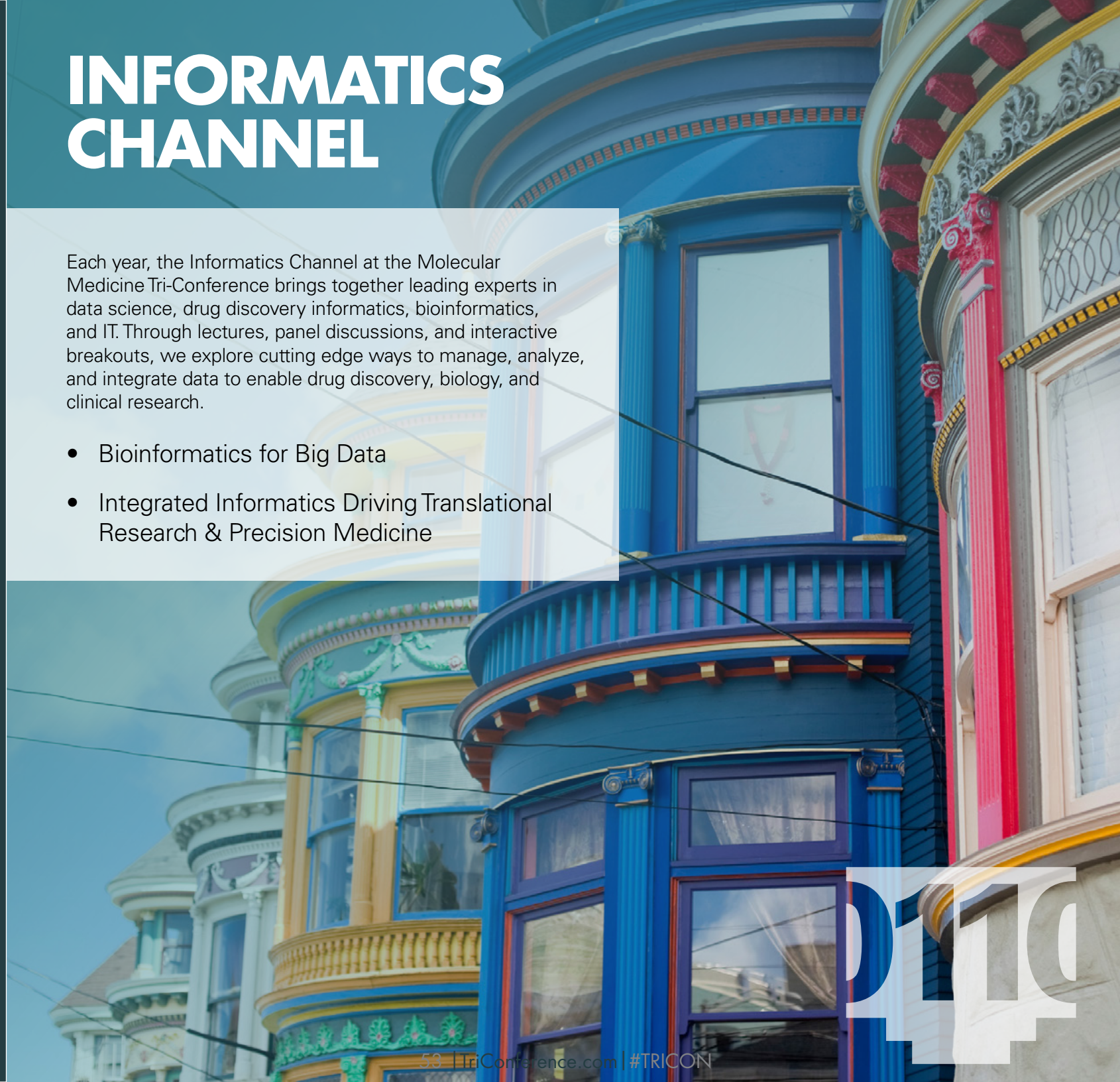
CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

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.

- Bioinformatics for Big Data
- Integrated Informatics Driving Translational Research & Precision Medicine



ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Fifth Annual

BIOINFORMATICS FOR BIG DATA

Converting Data into Actionable Knowledge

MONDAY, MARCH 7

10:30 am Conference Program Registration

GENOMIC AND PRECISION MEDICINE: EVOLVING SCIENCE, MODELS, AND TOOLS

11:50 Chairperson's Opening Remarks
Andreas Kogelnik, M.D., Ph.D., Founder and Director, Open Medicine Institute

12:00 pm Genomics Based Medicines for Masses - Problems and Promises
Andreas Kogelnik, M.D., Ph.D., Founder and Director, Open Medicine Institute
Smart data is big data made actionable in real time. It's about actions that you take in response to data, not just merely collecting the data. Until now, the trend has been to integrate data from multiple sources:instruments, clinical, biochemical, epidemiological, molecular, etc. and then using data mining tools to analyze trends. Turning this data from big to smart can lead to real time assistance in disease prevention, prognosis, diagnostics and therapeutics.

12:30 Big Data in Cancer Research and Precision Oncology
Anthony R. Kerlavage, Ph.D., Chief, Cancer Informatics Branch, Center for Biomedical Informatics & Information Technology, National Cancer Institute
This presentation will focus on the NCI Genomic Data Commons and Cancer Genomics Cloud Pilots as models for democratizing access to data from The Cancer Genome Atlas (TCGA), other cancer research data, and precision medicine clinical trials. The rationale for the pilots will be presented along with an overview of the three different approaches being taken and the context for a future cancer knowledge commons.

1:00 Session Break

Sponsored By ELSEVIER

1:15 Biomarkers, Brain Regions, and Data Reproducibility
Chris Cheadle, Ph.D., Director, Research, Biology Products, Elsevier R&D Solutions
Comprehensive data-mining of the scientific literature has become an increasing challenge, in particular with regards to disease biology and progression. Elsevier uses natural language processing (NLP) to create very large, structured, and constantly expanding literature knowledgebases. With the addition of highly sophisticated visualization tools, users can interactively explore the vast number of connections created to help unravel disease biology. The utility of this approach will be applied to researching neuropsychiatric diseases for: 1. Finding common and unique biomarker elements, 2. Identifying specific enrichment patterns, and 3. Detecting the most reproducible biomarker findings to support biomarker discovery. In addition, an innovative new taxonomy based on brain region identifications will be presented. Together, these innovations can be applied to rapidly increase the knowledge of diseases based on published findings.

Sponsored By bina TECHNOLOGIES

1:45 Luncheon Presentation II to be Announced
Hugo Lam, Senior Director, Bioinformatics, Research & Development, Bina Technologies
Advancements in NGS technologies have produced massive number of short read sequences, making secondary analysis a challenging big data problem. In this seminar, we will talk about the current approaches at Bina in assessing and improving the accuracy of NGS algorithms with research ranging from genomics to cancer genomics and transcriptomics.

2:15 Session Break

2:30 Chairperson's Remarks
Andreas Kogelnik, M.D., Ph.D., Founder and Director, Open Medicine Institute

2:40 Issues Surrounding Genomically-Guided Individualized Cancer Clinical Trials
Nicholas J. Schork, Ph.D., Professor and Director, Human Biology J. Craig Venter Institute

3:10 Big -Omics Data Coupled with Health Coaching to Optimize Wellness and Minimize Disease
Nathan D. Price, Ph.D., Professor & Associate Director, Institute for Systems Biology
We have launched a large-scale 100K person wellness project that integrates genomics, proteomics, transcriptomics, microbiomes, clinical chemistries and wearable devices of the quantified self to monitor wellness and disease. I present results from our proof-of-concept pilot study in a set of 107 individuals (the Pioneer 100 study) over the past year, showing how the interpretation of this data led to actionable findings for individuals to improve health and reduce risk drivers of disease.

3:40 Managing and Analyzing Big Biomedical Data with Globus
Kyle Chard, Ph.D., Senior Researcher and Fellow, Computation Institute, University of Chicago and Argonne National Laboratory
Globus provides software-as-a-service (SaaS) for research data management, including data transfer, synchronization, sharing and publication. Unlike other SaaS providers, Globus provides these capabilities directly from users' computers, without the need to replicate data in the cloud. Here I describe Globus and discuss how it can be used to manage and analyze big biomedical data.

Sponsored By aspera an IBM company

4:10 Solving the File Exchange Problem for Bioinformatics
Jay Migliaccio, Director, Cloud Platforms & Services, Cloud-On-Demand, Aspera, an IBM Company
As new research techniques create gigabytes of data, the need to ingest and exchange digital files quickly, easily, securely, and with the cloud's scale-up capacity is critical. A new SaaS platform allows any organization to establish a branded web-based presence for fast, easy and secure exchange and delivery of any size data between separate organizations.

4:40 Refreshment 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

BIOINFORMATICS FOR BIG DATA
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

TUESDAY, MARCH 8

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

OPTIMIZING HADOOP TO PROCESS BIG DATA

10:05 Chairperson's Remarks
Martin Gollery, CEO, Tahoe Informatics

10:15 Optimizing AWS Hadoop for Bioinformatics: A Case Study
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

In this study we aim to optimize Hadoop parameters to improve the performance of BioPIG on AWS. We chose k-mer analysis as an example as it is an essential part of a large number of NGS data analysis tools. We tuned five Hadoop parameters on a customized Hadoop cluster. We found that each parameter tuning experiment led to various performance improvement, and the overall job execution time was reduced by 50% with an optimized parameter setting.

EXTRACTING KNOWLEDGE FROM GENE EXPRESSION PROFILES

10:45 Prediction of Protein Structure, Dynamics and Function on the Genomic Scale
Andrzej Kloczkowski, Ph.D., Professor, Battelle Center for Mathematical Medicine, The Research Institute at Nationwide Children's Hospital and Department of Pediatrics, The Ohio State University College of Medicine

The theoretical methods of normal mode analysis and elastic network models of biomolecules will be presented. We discuss all these important problems, and propose new methods for genome-wide protein structure and function prediction that have been recently highly successfully blind-tested in Critical Assessment of Protein Structure Prediction (CASP) experiments.

11:15 L1000CDS2: LINCS L1000 Characteristic Direction Signature Search Engine Predicts Kenpaullone as a Potential Therapeutic for Ebola
Avi Ma'ayan, Ph.D., Professor, Department of Pharmacology and Systems Therapeutics, Icahn School of Medicine at Mount Sinai

The library of integrated network-based cellular signatures (LINCS) program aims to systematically profile the molecular and phenotypical outcomes of agent perturbed human cells. We show that processing the L1000 data with the Characteristic Direction method significantly improves signature mappings through several benchmarking pipelines. This processed dataset is served through a state-of-the-art signature search engine called L1000CDS².

11:45 Selected Poster Presentation: Gene Expression Models of BRAF Inhibitor Resistance in Melanoma Predict Drug Repurposing Candidates for Novel Combination Therapies
Kelly Regan, Graduate Student, Department of Biomedical Informatics, Ohio State University

12:15 pm Session Break

12:25 Luncheon Presentation I: Systems Biology Approach to OMICs data Analysis in Application to Patient Stratification
Sponsored By THOMSON REUTERS
Alexander Ivliev, Ph.D., Senior Research Scientist, Thomson Reuters

12:55 A High-Performance Analytics Ecosystem for Translational Research
Sponsored By IBM
Jane Yu, M.D., Worldwide Industry Architect for Healthcare & Life Sciences, IBM

Research scientists are required to access, analyze, share, and store massive volumes of complex, often unstructured, biomedical data. Learn how IBM's high-performance analytics ecosystem for translational research including IBM Watson, IBM Power Systems with OpenPOWER can accelerate discovery of treatments tailored to unique patient molecular profiles.

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

VISUALIZATION AND DATA MAPPING TOOLS REDEFINED

2:00 Chairperson's Remarks
Martin Gollery, CEO, Tahoe Informatics

2:10 NASFinder: Defining a Network Activity Score
Corrado Priami, Ph.D., Computer Science, The Microsoft Research - University of Trento Centre for Computational and Systems Biology (COSBI)

We propose a new approach based on information theory and topological analysis to identify the level of activities of a set of molecules of interest with respect to a transcriptomics or proteomics data set. Relying on curated and extended database obtained by integration of multiple sources, NASFinder will rank the pathways that are more active (distinguishing down and up regulated) according to experimental conditions. The prototype has been tested on biological data from HeLa cells, Macrophages and Adipocytes.

2:40 Genomics for Every Biologist NOW: Introducing the Pantheon of Next-Generation NCBI BLAST Resources
Ben Busby, Ph.D., Genomics Outreach Coordinator, NCBI, NIH

In this overview of next generation BLAST tools, we will discuss 1) SmartBLAST, a tool that allows users to taxonomically define similar proteins with the click of a button; 2) SRA BLAST, which allows access to SRA with no knowledge of genomic mapping or command line interfaces – although there is a command line interface for larger jobs; 3) our BLAST based RNAseq mapper, and 4) moleBLAST, a pushbutton tool that defines operational taxonomic units (OTUs) in metagenomic samples.

3:10 Custom Visualizations to Support Scientific Decision Making
Christian Blumenroehr, Ph.D., Senior Scientist, Roche Innovation Center Basel, F. Hoffmann-La Roche

Data analysis is often a visual process. Especially in times of Big Data, how you visualize your data is very important to be able to draw the right conclusions. Learn new ideas on how to leverage modern HTML5-, JS-, and CSS-based visualizations in combination with a data analysis tool.

3:40 Data Science Driven Pharma R&D Decisions
Timothy Hoctor, Vice President Professional Services, Life Sciences, R&D Solutions, Elsevier

The focus on analysis of large databases, 'big data', continues to increase as the collections of scientific observations accumulate. Elsevier has collected tens of millions of facts from scientific literature in the form of semantic triples. We will present examples of using data frameworks that combine Elsevier and open source pathway and biological activity databases.

4:10 St. Patrick's Day 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

BIOINFORMATICS FOR BIG DATA
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

WEDNESDAY, MARCH 9

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

8:00 Plenary Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

CONVERGENCE OF LARGE POPULATION & PERSONAL DATA FOR PATIENT CARE, CLINICAL TRIALS & R&D

10:50 Chairperson's Remarks
Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360

11:00 PANEL DISCUSSION: The Collaboratory at Work in Multiple Sclerosis and Beyond
Marcia Kean, Chairman, Strategic Initiatives, Feinstein Kean Healthcare
Kenneth Buetow, Ph.D., Director, Computational Sciences and Informatics, Complex Adaptive Systems Initiative (CASI), Arizona State University
Robert McBurney, Ph.D., CEO, Accelerated Cure Project for MS
PCORnet, the national research network, is catalyzing collaborations across academe, government, industry and advocacy organizations to change the research enterprise. iConquerMS™, a Patient-Powered Research Network that recently was awarded Phase II funding, has collected patient-generated health data and a portfolio of emerging collaborations, allowing Big Data analysis by ASU's Next Generation Cyber Capability of high performance hardware, software, and people. Resulting insights will change clinical practice and accelerate research. The audience will gain the learnings from the iConquerMS™ team, including technical and cultural challenges, patient data collection methods, research collaboration strategy, tools for Big Data integration/analysis and transformation into knowledge, and potential use of this initiative as a model.

12:00 pm Innovation from the Clinical Laboratory – The New Role of -Omics-Based Testing & Decision Support
Andreas Matern, Vice President, Commercial Partnerships and Innovation, BioReference Laboratories, Inc.
In this talk we'll discuss how clinical laboratories are changing beyond the simple "send sample, give us results" paradigm to an information-driven ecosystem, working in close partnership with providers, pharmaceutical companies, and hospitals to leverage the knowledge they have accumulated to drive new medical discoveries and improve patient care and outcomes. The emphasis will be on bioinformatics, the combination of large data sets, and building systems that work across multiple end users and groups.

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

1:50 Chairperson's Remarks
Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360

2:00 PANEL DISCUSSION: Big Data and Unmet Clinical Needs: Two Problems Separated by a Common Language
Michael Liebman, Ph.D., Managing Director, IPQ Analytics, LLC
Charles Barr, MD, MPH, Group Medical Director and Head, Evidence Science and Innovation, Genentech
Hal Wolf, Director, National Leader of Information and Digital Health Strategy, The Chartis Group
This panel session explores themes of bio/informatics, business, operational, clinical and real world perspectives and how each area works collaboratively to meet unstated medical needs (not just unmet needs). We will explore different models (or business models that have been inverted) to not only show how technology can work or data collection can work but how to work with data to improve a diagnosis and stratify a disease.

3:00 Integrated Analytics of GBM Tumors from FMI and TCGA Patient Data
Eric Neumann, Ph.D., Vice President, Knowledge Informatics, Foundation Medicine, Inc.
The development of diagnostic and predictive analytics is key for effectively leveraging the potential of complete genomic profiles (CGP) to transform the healthcare model. We show that the classifications of genomic alterations can be applied to multiple tumor types as well as different data sets, such as ours and TCGA. This system can then be used to discover clinical relevant relations across sample sets and even predict outcomes.

3:30 Illuminating Druggable Genome: Knowledge Management Center
Oleg Ursu, Research Asst Professor, Department of Internal Medicine, University of New Mexico
The large part of the human genome's role in biology and human disease remains unknown. The IDG project aims to shed light on four important classes of proteins: GPCR, kinases, ion channels, and nuclear receptors. The knowledge management center's main focus is on integration of knowledge on protein structure, function, tissue expression, and role in human diseases. Data from multiple databases and text mining are standardized and integrated into Target Central Resource Database (TCRD). TCRD is accessible through multifaceted web interface and REST API and aims to provide a versatile tool to navigate and assess druggability of understudied proteins.

4:00 Session Break

4:10 Chairperson's Remarks
Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360

4:15 Leveraging Mobile Devices to Integrate Patient Generated Health Data in the Electronic Health Record
Rajiv B. Kumar, M.D., Medical Director, Clinical Informatics, Stanford Children's Health Clinical Assistant Professor of Pediatric Endocrinology & Diabetes, Stanford University Attending Physician at Stanford Children's Health, California Pacific Medical Center and John Muir Medical Center
The electronic health record (EHR) is the home of patient variables, healthcare provider workflow/analytics, and the method to integrate these data and outcomes across institutional boundaries on our path to effective individualized care plans. Here we will discuss methods of populating said data in the EHR without requiring increased time or effort for patients or providers alike.

4:45 Digital Tools for the Microbiome – An Emerging Field in Genomics and Medicine
Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360
New research shows an association between changes in the microbiome in Lupus and Rheumatoid arthritis. With the convergence of large population data sets and personal data we are beginning to make progress in research, development and clinical trials in autoimmune disease. This talk will highlight new companies using data and digital tools to improve our understanding and treatment of autoimmunity.

5:15 A Full Stack Solution to Pharmacogenomics
Greyson Twist, Software Engineer, Center for Pediatric Genomic Medicine, Children's Mercy Genome Center
Realizing the world personalized medicine requires integrating data from many disparate sources. To accomplish this we are developing a 3 tiered software solution. Astraea to handle locus specific knowledge management through expert curation, Constellation to handle locus allele identification from Next-gen data, and Astronomer to handle drug phenotype prediction. Each of these tools has unique problems, data source integration, standardization, and biologically driven heuristic choice.

5:45 Close of Conference Program

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Eighth Annual

INTEGRATED INFORMATICS DRIVING TRANSLATIONAL RESEARCH & PRECISION MEDICINE

In the Era of Digital Health

MONDAY, MARCH 7

10:30 am Conference Program Registration Open

INTEGRATED INFORMATICS – A PHARMA PERSPECTIVE

11:50 Chairperson's Opening Remarks
Matt Brauer, Senior Scientist, Bioinformatics and Computational Biology, Genentech

12:00 pm Clinical, Genomic, and Real-World Healthcare Data for Pharma R&D
Peter A. Covitz, Ph.D., Senior Director, Research and Translational IT, Biogen
This presentation will describe approaches for bridging historically separate data domains to support biopharmaceutical research. As molecular medicine makes its way into the mainstream, it is important to examine the next horizon: integration of real-world healthcare data to predict and validate the effects of new medical diagnostics and interventions. The audience will gain an appreciation for the way clinical, genomic, and real-world healthcare data can be brought together to address questions of biopharmaceutical safety and efficacy.

12:30 Patient-Centric Integrated Informatics
Ingrid Akerblom, Ph.D., Executive Director Analytics, Collaboration and User Experience, Amgen
Today's competitive R&D landscape demands an integrated view of "patient" to assure drug development is informed by relevant data. Analytics, visualization and search tools matched to user sophistication is critical to driving effective use of information. The presentation will discuss learnings from our journey to deliver value through integrated informatics.

1:00 Session Break

1:15 Computational Epistemology for Pharmaceutical Genomics - New Strategies for Discovering Knowledge Beyond Human Imagination
Sponsored By Systems Imagination
Spyro Mousses, Ph.D., Co-Founder, President & CSO, Systems Imagination Inc.

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

2:15 Session Break

2:30 Chairperson's Remarks
Stu Morton, Ph.D., Research Scientist, LRL, IT Health Informatics, Eli Lilly and Company

2:40 Presentation to be Announced
Speaker to be Announced

ENABLING PRECISION MEDICINE

3:10 Cancer Informatics Strategies to Enable Precision Medicine in Oncology
Sabine Schefzick, Ph.D., Senior Manager, Oncology & West Coast R&D Business Technology, Pfizer
Development of patient enrichment strategies for Oncology clinical trials requires access to human oncogenomics data and *in vitro* and *in vivo* model data. This presentation will highlight several applications that have been developed in-house through a close collaboration between Oncology Research and Research IT to support ongoing efforts. OASIS, for example, was designed to analyze correlations among multiple data types as well as visualize and compare alterations across different cancers.

3:40 Medicinal MatchMaker: Finding Your Virtual Twin
Stu Morton, Ph.D., Research Scientist, LRL IT Health Informatics, Eli Lilly and Company
As EHRs continue to integrate health data from multiple sources such as hospitals, clinics and labs, the ability to mine that data for more effective patient outcomes is becoming a reality. The Medicinal MatchMaker provides analytics to aid physicians to decide what treatment has the best chance of success for the patient in their office by using data collected from health outcomes of patients that most resemble their patient.

4:10 New Informatics for New Science: Big Data from Imaging to Next-Generation Sequencing
Sponsored By PerkinElmer For the Better
Dave John, Product Manager, Translational Product Management, PerkinElmer
PerkinElmer Signals – a cloud-based data management platform that has been designed with flexible and scalable data models to provide the scalability and agility required to support modern life science research. To illustrate the versatility of the platform, we look at examples in areas as varied as Translational Medicine and High Content Screening.

4:25 Strategies for Systems Interoperability Using Modern API's
Sponsored By CORE INFORMATICS
John Stalker, Product Manager, Professional Services, Core
Modern informatics platforms often need to be able to interchange data with legacy systems. Achieving this used to require custom connectors which can be costly and cause system upgrade headaches. With modern API's and a standardized platform, you can avoid the need for customization. This presentation will discuss strategies and examples of how modern software technology can help you achieve your interoperability goals.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session *(see page 5 for details)*

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

7:30 Close of Day

CONTINUED ON NEXT PAGE

TUESDAY, MARCH 8

7:00 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session *(see page 5 for details)*

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

DATA CAPTURE INTEGRATION & ANALYTICS

10:05 Chairperson's Remarks
Daniel H. Robertson, Ph.D., Visiting Science Fellow, Indiana Biosciences Research Institute

10:15 The Center for Expanded Data Annotation and Retrieval: New Technology for Data Discovery and Integration
Mark A. Musen, Ph.D., Professor of Biomedical Informatics, Stanford University
The Center for Expanded Data Annotation and Retrieval (CEDAR) is a new center of excellence founded under the NIH Big Data to Knowledge (BD2K) program. Workers at CEDAR are studying new technologies to develop and manage online templates for describing experimental metadata, and for piecing together those templates to create structures that investigators can use to produce standard metadata descriptions more efficiently and more precisely. CEDAR is working to make the authoring of comprehensive metadata a simple task so that online datasets can be more discoverable, more self-descriptive, and more analyzable by the biomedical community.

10:45 Discovery with Purpose: Understanding Regional Health through Information Capture, Access, Integration and Analytics
Daniel H. Robertson, Ph.D., Visiting Science Fellow, Indiana Biosciences Research Institute
A new industry-lead institute (Indiana Biosciences Research Institute) is attempting to understand and moderate metabolic diseases in the local population. This talk will present efforts to collect, integrate, and analyze information from multiple diverse sources (public, commercial and private) to provide insight into health and disease progression and identify possible discovery, intervention and/or behavioral modification opportunities.

11:15 Rational Data-Driven Development of Novel Poly-Pharmacology Small Molecules
Stephan C. Schürer, Ph.D., Department of Molecular and Cellular Pharmacology, Miller School of Medicine, University of Miami
We developed a scalable computational framework to integrate and query large and diverse systems chemical biology datasets, such as those from the NIH Library of Integrated Network-based Cellular Signaling (LINCS) and Illuminating the Druggable Genome (IDG) projects. Using machine learning and protein structure-based simulations, we leverage this information to prioritize novel compounds with desirable profiles, for example dual kinase and epigenetic reader domain activity to target certain cancers.

11:35 A Platform Strategy for Research
Farida Kopti, Ph.D., Director, Chemistry/Pharmacology/HTS Informatics & IT, Merck & Co., Inc.
Merck is designing an open, cloud-based, integrated research data capture, management, and analytics platform to drive operational efficiency, improved user experience, scientific collaboration (internal and external) and accelerated decision-making. The objective is to enhance reusability of data and scientific informatics capabilities by standardizing data capture and management and creating an application ecosystem that enables rapidly advancing science, while reducing the total cost of operations.

CONTINUED ON NEXT PAGE

11:55 PANEL DISCUSSION: Security Considerations for Virtual Research
Moderator: Michael H. Elliott, CEO, Atrium Research & Consulting LLC
Panelists: Mohit Agnihotri, Associate Director, Informatics, Novartis Institutes for BioMedical Research
Art Morales, Ph.D., Vice President, Technology and Corporate Development, Beryllium
As externalization and virtualization of research has increased, so have concerns over security and data access rights. This panel will discuss their approaches to:

- Managing data access rights through a maze of conflicting partnership agreements
- Security considerations when moving to the cloud
- On-boarding new partners
- Data encryption
- Firewalling internal systems

12:15 pm Session Break

12:25 When Every Piece Matters: Mobilizing Informational Resources for Rare Diseases
Sponsored By ELSEVIER
Marie Shkrob, Ph.D., Project Manger, Elsevier R&D Solutions, Professional Services, Elsevier
Providing comprehensive disease-specific summaries remains a serious challenge as information is scattered across multiple resources. Elsevier is collaborating with a rare disease charity Findacure to create an informational portal for patients, researchers, and doctors to help finding new treatments, increase awareness, streamline information exchange and education. Using an integrative approach of automated and manual curation of literature, we constructed a knowledgebase containing an overview of the disease mechanisms, targets, drugs, key opinion leaders, and institutions. To demonstrate the utility of this approach, congenital hyperinsulinism will be discussed.

12:55 Luncheon Presentation II *(Sponsorship Opportunity Available)*

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

TRANSLATIONAL RESEARCH

2:00 Chairperson's Remarks
Michael H. Elliott, CEO, Atrium Research & Consulting LLC

2:10 Challenges and Opportunities in Data Integration and Analysis in Translational Research
Ajay Shah, Ph.D., MBA, PMP, Division Director, Research Informatics and Systems, City of Hope National Medical Center
Integration of diverse sets of preclinical, clinical research, patient care, pharmacovigilance, etc. data is key to successful translational research. An emerging trend in translational research is inter-institutional collaboration and data sharing which brings even greater challenges and rewards. We describe novel approaches to data collection, coding non-coded data, standardization, integration, analysis and sharing using City of Hope's SPIRIT platform.

2:40 Merck *in vivo* Data Contract: Enabling Translational PK/PD
Farida Kopti, Ph.D., Director, Chemistry/Pharmacology/HTS Informatics & IT, Merck & Co., Inc.
Common data ontology established within Merck harmonizes the attributes of in-life, biomarker and PK analysis data generated internally and externally, to enable successful data mining and aggregation. This has improved our ability to establish links between the PK and PD data at the individual subject level. The quantitative understanding of the relationships between drug dose, exposure, target engagement, and efficacy/safety will improve the translation of compound properties from animal to man.

3:10 PANEL DISCUSSION: Inspiring Others to Innovate with Technology
Moderator: Andreas Matern, Vice President, Commercial Partnerships and Innovation, BioReference Laboratories, Inc.
Panelist: Gamiel Gran, Chief Strategy Officer, SOASTA, Inc.
Tom Arneman, President, Ceiba Solutions
Innovation is not about invention, but inventions can be innovative. Creating opportunities for colleagues to experiment with solutions around a problem is something not well tolerated, as most activities in companies are defined projects, where success is the only option. Getting team members to be innovative is about embracing a culture of risk-taking, where failure is an option, and is welcomed. These topics will be explored by innovative leaders in bio/pharma that will also share their approaches on how to create their cultures of innovation.

3:40 NGS Analysis Reveals Targets and Biomarkers for Treating PNET via Synthetic Lethality
Sponsored By bina TECHNOLOGIES
Chester Chamberlain, Ph.D., Faculty, Asst Researcher, Diabetes Ctr
Pancreatic neuroendocrine tumors (PNETs) are a rare but clinically important form of cancer. Like all cancers, PNETs arise as a result of changes in the DNA sequence of the genome. We will present how we use NGS analysis to identify synthetic lethal interactions in PNET and predict drug efficacy in a patient-derived xenograft model of PNET.

3:55 Sponsored Presentation *(Opportunity Available)*

4:10 St. Patrick's Day 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, MARCH 9

7:00 am Registration Open

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

8:00 Plenary Keynote Session Panel *(see page 5 for details)*

10:00 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

CONVERGENCE OF LARGE POPULATION & PERSONAL DATA FOR PATIENT CARE, CLINICAL TRIALS & R&D

10:50 Chairperson's Remarks
Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360

11:00 PANEL DISCUSSION: The Collaboratory at Work in Multiple Sclerosis and Beyond
Marcia Kean, Chairman, Strategic Initiatives, Feinstein Kean Healthcare
Kenneth Buetow, Ph.D., Director, Computational Sciences and Informatics, Complex Adaptive Systems Initiative (CASI), Arizona State University
Robert McBurney, Ph.D., CEO, Accelerated Cure Project for MS
PCORnet, the national research network, is catalyzing collaborations across academe, government, industry and advocacy organizations to change the research enterprise. iConquerMS™, a Patient-Powered Research Network that recently was awarded Phase II funding, has collected patient-generated health data and a portfolio of emerging collaborations, allowing Big Data analysis by ASU's Next Generation Cyber Capability of high performance hardware, software, and people. Resulting insights will change clinical practice and accelerate

INTEGRATED INFORMATICS DRIVING TRANSLATIONAL RESEARCH & PRECISION MEDICINE
CONTINUED ON NEXT PAGE

research. The audience will gain the learnings from the iConquerMS™ team, including technical and cultural challenges, patient data collection methods, research collaboration strategy, tools for Big Data integration/analysis and transformation into knowledge, and potential use of this initiative as a model.

12:00 pm Innovation from the Clinical Laboratory – The New Role of -Omics-Based Testing & Decision Support

Andreas Matern, Vice President, Commercial Partnerships and Innovation, BioReference Laboratories, Inc.

In this talk we'll discuss how clinical laboratories are changing beyond the simple "send sample, give us results" paradigm to an information-driven ecosystem, working in close partnership with providers, pharmaceutical companies, and hospitals to leverage the knowledge they have accumulated to drive new medical discoveries and improve patient care and outcomes. The emphasis will be on bioinformatics, the combination of large data sets, and building systems that work across multiple end users and groups.

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:10 Refreshment Break in the Exhibit Hall and Last Chance for Poster Viewing

1:50 Chairperson's Remarks

Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360

2:00 PANEL DISCUSSION: Big Data and Unmet Clinical Needs: Two Problems Separated by a Common Language

Michael Liebman, Ph.D., Managing Director, IPQ Analytics, LLC

Charles Barr, MD, MPH, Group Medical Director and Head, Evidence Science and Innovation, Genentech

Hal Wolf, Director, National Leader of Information and Digital Health Strategy, The Chartis Group

This panel session explores themes of bio/informatics, business, operational, clinical and real world perspectives and how each area works collaboratively to meet unstated medical needs (not just unmet needs). We will explore different models (or business models that have been inverted) to not only show how technology can work or data collection can work but how to work with data to improve a diagnosis and stratify a disease.

3:00 Integrated Analytics of GBM Tumors from FMI and TCGA Patient Data

Eric Neumann, Ph.D., Vice President, Knowledge Informatics, Foundation Medicine, Inc.

The development of diagnostic and predictive analytics is key for effectively leveraging the potential of complete genomic profiles (CGP) to transform the healthcare model. We show that the classifications of genomic alterations can be applied to multiple tumor types as well as different data sets, such as ours and TCGA. This system can then be used to discover clinical relevant relations across sample sets and even predict outcomes.

3:30 Illuminating Druggable Genome: Knowledge Management Center

Oleg Ursu, Research Asst Professor, Department of Internal Medicine, University of New Mexico

The large part of the human genome's role in biology and human disease remains unknown. The IDG project aims to shed light on four important classes of proteins: GPCR, kinases, ion channels, and nuclear receptors. The knowledge management center's main focus is on integration of knowledge on protein structure, function, tissue expression, and role in human diseases. Data from multiple databases and text mining are standardized and integrated into Target Central Resource Database (TCRD). TCRD is accessible through multifaceted web interface and REST API and aims to provide a versatile tool to navigate and assess druggability of understudied proteins.

4:00 Session Break

4:10 Chairperson's Remarks

Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360

ORGANIZED BY: Cambridge HEALTHTECH Institute

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

SYMPOSIA

- New Frontiers in Gene Editing
- Circulating Cell-Free DNA
- Point-of-Care Diagnostics
- Biomarkers for Cancer Immunotherapy
- Genomics & Sequencing Data Integration, Analysis and Visualization
- Companion Diagnostics – *New*
- Commercialization of Molecular Diagnostics – *New*

ORGANIZED BY: Cambridge HEALTHTECH Institute

Cambridge Healthtech Institute's Second Annual

NEW FRONTIERS IN GENE EDITING

Striving for Better Design, Precision, and Efficiency

THURSDAY, MARCH 10

7:30 am Registration and Morning Coffee

UNRAVELING CRISPR/Cas9 MEDIATED GENE EDITING

8:30 Chairperson's Opening Remarks
Erik Sontheimer, Ph.D., Professor, RNA Therapeutics Institute and the Program in Molecular Medicine, University of Massachusetts Medical School

8:40 Activities and Applications of *Neisseria meningitidis* Cas9
Erik Sontheimer, Ph.D., Professor, RNA Therapeutics Institute and the Program in Molecular Medicine, University of Massachusetts Medical School

Diverse Cas9 orthologs have the potential to provide novel activities and targeting specificities to the genome engineering toolbox. The Sontheimer lab has established *Neisseria meningitidis* Cas9 (NmeCas9) as a compact genome-editing enzyme. This presentation will describe the NmeCas9 system's features during native bacterial interference, as well as human gene targeting. These features include novel activities that are independent of the tracrRNA, which was previously considered an essential Cas9 co-factor.

9:10 Engineered Nucleases for Targeted Genome Integration
Pablo Perez-Pinera, M.D., Ph.D., Assistant Professor, Department of Bioengineering, University of Illinois at Urbana-Champaign

The CRISPR-Cas9 system can be used to inactivate genes by introducing double-strand breaks in genomic DNA that are preferentially repaired by non-homologous end joining, an error-prone DNA repair pathway that often causes mutations. However, tools for targeted gene insertion in genomes remain elusive. In this talk, I will summarize recent advances in methods for targeted integration of heterologous DNA within complex genomes.

9:40 *In vivo* Genome Engineering Using *S. aureus* Cas9: Development and Applications
Winston Yan, Graduate Student, M.D.-Ph.D. Program, Laboratory of Dr. Feng Zhang, Broad Institute of MIT and Harvard

The small Cas9 ortholog from *Staphylococcus aureus* (SaCas9) has proven to be a versatile and efficient RNA-guided endonuclease ideally suited for *in vivo* applications due to its ability to be packaged into the highly versatile adeno-associated virus (AAV) delivery vehicle. Here, we describe the characterization and structure of SaCas9, and its application in knocking down the cholesterol regulatory gene Pcsk9 in the adult liver as a prototype for efficient *in vivo* genome editing using CRISPR-Cas9.

Sponsored By Surrogen

10:10 Precision Disease Modeling in Swine with TALENS
Scott Fahrenkrug, Ph.D. Founder & CEO Recombinetics, Parent company of Surrogen

Sole reliance on rodent preclinical models has resulted in inflated failure rates due to vast differences in size, anatomy and physiology compared to humans. Pigs are an excellent model of human anatomy and physiology, and we present a new frontier in preclinical models where pigs with precise human disease alleles are produced by gene editing.

10:40 Coffee Break with Exhibit and Poster Viewing

BUILDING THE CRISPR/Cas9 TOOLBOX

11:15 Engineering CRISPR for Visualizing Genome Organization
Wulan Deng, Ph.D., Helen Hay Whitney Fellow, Research Specialist, Transcription Imaging Consortium, Janelia Research Campus, Howard Hughes Medical Institute

We have engineered the nuclease-deficient CRISPR/Cas9 for labeling genomic DNA *in situ* in fixed cells and tissues. Using fluorescently labeled nuclease-deficient Cas9 (dCas9) protein assembled with various single-guide RNA (sgRNA), we demonstrated rapid and multi-color labeling of DNA elements and coding gene loci in mammalian cells. This rapid, less disruptive, and cost-effective technology adds a valuable tool for basic research and genetic diagnosis.

11:45 Engineered Orthogonal Drug Switchable Precise Control for CRISPR Transcription Regulation
Xin (Cindy) Xiong, Ph.D., Research Scientist, Agenovir Corporation

We have engineered the CRISPRi/a system to precisely control transcription activity and dosage by drug. We identified several drug switchable protein dimerization modules that are highly efficient and specific when combined with CRISPR. By pairing these modules with orthogonal Cas9s, we developed orthogonal drug switches that enable independent transcriptional regulation (activation/repression) of distinct target genes according to the drug inputs.

Sponsored By Lonza

12:15 pm Genomic Editing, Nucleofection, and the Generation of Cell Lines for Cell-Based Assays
Gregory Alberts, Ph.D. Global Subject Matter Expert, Lonza Pharms Bioscience Solutions

Using primary cells in cell-based assays can improve the assays, which should translate more effectively into *in vivo* models. Lonza's Nucleofector™ technology easily transfects primary cells, and with CRISPR, primary cells can be specifically modified at the genomic level, creating isogenic strains of specific cells that differ in only one specific aspect.

12:30 Session Break

Sponsored By CELLECTA Discovery is Yours.

12:45 CRISPR and RNAi: Gene editing and functional genomic screening approaches
Paul Diehl, Ph.D. Director of Business Development, Cellecta, Inc.

While RNAi screens have proven effective genome-wide loss-of-function pooled screens, CRISPR/Cas9 provides a newer attractive alternative. We have developed pooled sgRNA libraries that complement our established shRNA ones, and then compared how each type performs in genetic screens on PDX-derived cell lines.

1:15 Session Break

IDENTIFYING & MODIFYING NOVEL DRUG TARGETS

1:50 Chairperson's Remarks
Nishant Agrawal, M.D., Professor, Surgery; Director, Head and Neck Surgical Oncology, University of Chicago

NEW FRONTIERS IN GENE EDITING
CONTINUED ON NEXT PAGE

2:00 Genome-Edited Reporter Systems to Enable Cell-Based HTS Assays for Chemical Biology and Drug Discovery
James Inglese, Ph.D., Head, Assay Development & Screening Technologies, National Center for Advancing Translational Sciences, NIH
The targeting precision of genome editing was used in combination with advances in reporter gene design to modify the genetic loci of neurologic target genes to create HTS assays for compound library interrogation. Our goal was to identify transcriptionally active pharmacological agents acting by a variety of mechanisms, including through chromatin co-regulators accessible by our assay design. Specific case studies will serve to illustrate progress and findings to date.

2:30 Optimizing CRISPR-Cas9 System to Improve Genome-Wide Knockout Screening Performance
Haoquan Wu, Ph.D., Associate Professor, Department of Biomedical Sciences, Paul L. Foster School of Medicine, Texas Tech University Health Sciences Center
CRISPR-Cas9 system enables genome-wide knockout screening in human cells. One of the limitations is that the knockout efficiency of sgRNAs targeting the same gene can vary significantly, or even dramatically. Here we present data to improve knockout efficiency generally to improve the screening performance of CRISPR-Cas9-mediated knockout screening.

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Parallel shRNA and CRISPR/Cas9 Screens Reveal Biology of Stress Pathways and Identify Novel Drug Targets
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, and have adapted these libraries to knock down gene pairs to perform systematic genetic interaction maps in mammalian cells. Using this strategy in parallel with the CRISPR/Cas9 system, we have uncovered new insights into the biology of stress signaling and identified novel drug targets.

4:00 Strategies and Applications Using shRNA and CRISPR Technology for Identification of New Druggable Targets
Donald Apanovitch, Ph.D., Director, Functional Genomics (Oncology), Pfizer Research
Application of RNAi loss-of-function negative selection screens is a well-documented platform for identification of essential gene function regulating oncogenic pathways and tumorigenesis. In collaboration with the Cold Spring Harbor and the IBB group of Pfizer Oncology we have designed and validated druggable and target-specific lentiviral shRNA libraries. Overview of our mir-based libraries and screening strategy will be presented along with CRISPR applications as an orthogonal tool to characterize differences in shRNA rescue experiments.

4:30 Recent Progress towards Efficient Targeted Gene Modification in Primary Human Hematopoietic Cells
David Rawlings, M.D., Director, Center for Immunity and Immunotherapies Seattle Children's Research Institute; Professor of Pediatrics and Immunology, University of Washington School of Medicine
We have utilized RNA-based nuclease and AAV-mediated donor co-delivery to drive targeted gene modification in primary hematopoietic cells. Using this approach, we achieve ~60% gene targeting in T-cells and we have generated "targeted CAR" T-cells with potent functional activity. We have also applied this method to edit CD34+ stem cells. Overall, primary cells with myriad novel properties can be generated with high-efficiency using this clinically feasible gene editing approach.

5:00 Reception with Exhibit and Poster Viewing

6:00 Close of Day

FRIDAY, MARCH 11

7:30 am Morning Coffee

DEVELOPING PRECISE GENE EDITING

7:55 Chairperson's Remarks
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

8:00 Precise Genome Engineering in Human iPS Cells to Model and Treat Disease
Bruce R. Conklin, M.D., Investigator, Roddenberry Center for Stem Cell Biology and Medicine, Gladstone Institutes; Professor, Division of Genomic Medicine University of California, San Francisco
We have combined droplet digital PCR (ddPCR) technology, TaqMan PCR system, and optimized iPSC culture system to develop Rare Allele Induction and Detection (RAID). This method allows for precise base-by-base genome editing in human iPSCs followed by efficient detection, sub-selection, and isolation of mutant clones. We have made a series of >20 isogenic iPSC-derived cardiomyocytes and observed cardiomyopathy phenotypes with several heterozygous and homozygous single base mutations.

8:30 Engineering Human Stem Cells by CRISPR
Su-Chun Zhang, M.D., Ph.D., Steenbock Professor in Behavioral and Neural Sciences and Professor of Neuroscience and Neurology, Waisman Center, University of Wisconsin
We have adapted the current genome editing technology for human cells. Using the optimized technology, we have engineered human stem cell lines with reporters, inducible gene expression and knockout, as well as functional switches. These genetically modified human cells substantially enable fundamental research, drug discovery, and potentially clinical applications.

9:00 Therapeutic Genome Editing for Blood Diseases
Matthew Porteus, M.D., Ph.D., Associate Professor, Pediatrics, Stanford University School of Medicine
The genome editing toolbox now offers powerful options in designing engineered nucleases and there are multiple different ways to utilize the engineered nucleases to create precise genomic modifications using both non-homologous end-joining and homologous recombination. Harnessing this toolbox so that it can be applied beyond just manipulating cancer cell lines, and instead, utilized to engineer therapeutically relevant cell types is now proceeding. Progress on modifying T-cells and hematopoietic stem and progenitor cells will be presented.

Sponsored By
MilliporeSigma

9:30 Practical Considerations for Genome Engineering of Model Cell Lines
Daniel Teasley, Ph.D., Genome Engineering Specialist, Cell Design Studio, MilliporeSigma
The widespread adoption of CRISPR-based genome editing technology has made cell line engineering more accessible than ever before. Despite these recent advances, engineering the genome of a model cell line remains a challenging task. Common decision points - such as choosing a parental cell line and nuclease - and potential stumbling blocks in the workflow will be discussed. Several case study engineering projects will be reviewed to demonstrate best practices to manage risk and maximize success in model cell line genome engineering.

10:00 Presentation to be Announced
John A. Schiel, Ph,D., Research Scientist, Research & Development, Dharmacon part of GE Healthcare
We describe a CRISPR-Cas9 algorithm that incorporates parameters to predict functional gene knockout of gRNAs and the ability to detect

Sponsored By
GE Healthcare

NEW FRONTIERS IN GENE EDITING
CONTINUED ON NEXT PAGE

potential off-target sites typically missed using existing tools. We also provide guidelines for design of donor templates for optimal HDR and knockins.

10:30 Coffee Break with Exhibit and Poster Viewing

IMPROVING EFFICIENCY AND SPECIFICITY OF CRISPR

11:00 CRISPR Libraries for Functional Genomics: Optimizing On-Target Activity, Avoiding Off-Target Effects

John Doench, Ph.D., Associate Director, Genetic Perturbation Platform, Broad Institute of Harvard and MIT

Pooled screens with CRISPR technology have proven to be a powerful means of understanding gene function. Here I will discuss experiments and computational modeling approaches to optimize sgRNA sequence to both increase on-target activity and decrease off-target effects. The resulting libraries generate deeper, more meaningful hit lists.

11:30 CRISPR-EATING: A Method for Inexpensively Generating Large sgRNA Libraries

Andrew Lane, Ph.D., Postdoctoral Fellow, Laboratory of Dr. Rebecca Heald, Department of Molecular and Cell Biology, University of California, Berkeley

CRISPR-based technologies have emerged as powerful tools to alter genomes and mark chromosomal loci, but an inexpensive method for generating large numbers of RNA guides for genome screening and labeling is lacking. Using a new method, CRISPR-EATING, to construct libraries from any source of DNA, we have labeled a single chromosomal locus in Xenopus egg extracts and show that a complex library can target the *E. coli* genome at high frequency.

12:00 pm Application of Genome Editing Tools to Model Human Genetics Findings in Preclinical Animals

Myung Shin, Ph.D., Senior Principal Scientist, Biology-Discovery, Genetics and Pharmacogenomics, Merck Research Laboratories

Genome editing tools have allowed for rapid generation of genetically engineered models in various preclinical species. We will present how ZFN and CRISPR have been applied to efficiently generate various animal models to recapitulate findings based on human genetics and pathobiology to aid drug discovery process.

12:30 Close of Symposium

Cambridge Healthtech Institute's Third Annual

CIRCULATING CELL-FREE DNA

Clinical Directions and Emerging Avenues for Early Detection

THURSDAY, MARCH 10

7:30 am Registration and Morning Coffee

CLINICAL VALIDATION OF ASSAY SENSITIVITY AND SPECIFICITY

8:25 Chairperson's Opening Remarks

Cloud P. Paweletz, Ph.D., Head, Translational Research Laboratory; Biomarker Lead, Belfer Institute for Applied Cancer Science, Dana Farber Cancer Institute

» 8:30 KEYNOTE PRESENTATION: Deep Sequencing of Circulating Tumor DNA for Personalized Cancer Detection and Monitoring

Maximilian Diehn, M.D., Ph.D., Assistant Professor, Radiation Oncology, Stanford University

I will describe the development and application of CAPP-Seq, a deep sequencing-based method for ultra-sensitive and specific detection of circulating tumor DNA that is broadly applicable to different cancer types and clinical scenarios.

9:10 Clinical Applications of an NGS Assay for Ultrasensitive Measurement of ctDNA

Abhijit Patel, M.D., Ph.D., Assistant Professor, Yale University School of Medicine

Our group has developed an ultrasensitive, multi-target NGS-based assay that can identify and quantify mutant ctDNA using novel error-suppression techniques. Broad coverage of mutation hotspots and warm-spots allows detection of ctDNA without prior knowledge of the tumor's mutation profile. Data will be presented from various ongoing studies to establish the clinical utility of this technology.

9:40 Assay Characterization for Clinical Applications

Rebecca Leary, Ph.D., Lab Head & Research Investigator, Genomics Group, Next Generation Diagnostics, Novartis

Evaluation and characterization of cell-free DNA technologies is a critical step when introducing these assays for the analysis of clinical specimens.

10:10 Multiplexed ICE COLD PCR Enriches Any Low-Level Mutation Present in DNA Isolated from FFPE and Plasma Samples

Sponsored By Transgenomic® Advancing Personalized Medicine

Harjit Kullar, Ph.D., MBA, Vice President, Marketing, Transgenomic

Using Multiplexed ICE COLD-PCR, cancer patients' DNA isolated from FFPE & Plasma was utilized to enrich for any low level mutations present in the samples. The results demonstrated detection of low level mutations in liquid biopsies; thus allowing for disease management with respect to treatment options and/or drug cocktail modifications for cancer patients.

10:40 Coffee Break with Exhibit and Poster Viewing

CLINICAL TRIAL DATA

11:15 Clinical Evidence for the Utility of the cobas® EGFR Mutation Test v2 with Liquid Biopsy Samples from NSCLC Patients

John Palma, Ph.D., Director, Medical Affairs, Roche

Common challenges to ascertaining EGFR mutation status in non-small cell lung cancer are the lack of or inadequacy of biopsy material. The cobas® EGFR Mutation Test v2 was developed to detect the most common mutations in exons 18-21, including T790M, for both tissue and plasma. Using different cutoffs for sample type, the detection of 42 mutations is now possible. While maintaining a high positive predictive value to detect EGFR mutations relative to tissue results, liquid biopsy testing could eventually enable the detection of acquired mutations during treatment.

11:45 Monitoring Cancer through the Blood

Cloud P. Paweletz, Ph.D., Head, Translational Research Laboratory; Biomarker Lead, Belfer Institute for Applied Cancer Science, Dana Farber Cancer Institute

Genomic alterations in genes such as EGFR, ALK, KRAS, and BRAF have been validated as powerful predictive biomarkers in the management of non-small cell lung cancer (NSCLC), colorectal cancer, and melanoma; testing for these mutations is currently standard to personalize treatment decisions. The challenges associated with routine use of NGS include availability of adequate tumor specimens, slow turnaround time, and evolving tumor biology in response to treatment that may necessitate a repeat biopsy to guide subsequent therapy. Here we discuss the use of blood based, non-invasive test to diagnose, monitor and understand lung cancer.

12:15 pm Pharmacodynamic Assessment of Drug Response by Monitoring Mutational Load in Urinary Circulating Tumor DNA

Sponsored By trovagene precision cancer monitoring

Vlada Melnikova, M.D., Ph.D., Vice President, Research & Development, Trovagene

The concept of liquid biopsies is expanding to include urine as a specimen type. Using DNA extraction process that isolates systemic ctDNA and a quantitative PCR-NGS enrichment method for mutation detection at a single copy level, we demonstrate that drug-induced immediate early changes in ctDNA mutational load correlate with tumor burden and treatment response. As a non-invasive specimen, urine enables development of novel algorithms to inform treatment decisions via frequent monitoring of ctDNA.

12:45 Luncheon Presentation: Precision-Based Circulating Tumor DNA Detection and Monitoring in Gynecologic Cancer Samples

Sponsored By RainDance Technologies

John Martignetti, M.D., Ph.D., Icahn School of Medicine at Mount Sinai, Departments of Genetics and Genomic Sciences, Pediatrics, Obstetrics/Gynecology & Reproductive Sciences and Oncological Sciences

Dr. Martignetti and his team are devloping a rapid and efficient approach for variant discovery in gynecologic cancer samples that couples tumor-specific mutation identification and RainDrop® digital PCR-based ctDNA detection. Tumor mutation profiles have been generated for detection and monitoring of tumor status in ovarian and endometrial cancer samples. All results were compared against current FDA-approved biomarkers and the known clinical status of the patients from which the samples were taken, demonstrating the highly sensitive, specific and robust nature of this approach.

CIRCULATING CELL-FREE DNA
CONTINUED ON NEXT PAGE

1:15 Session Break

APPLICABILITY OF CFDNA IN EARLY STAGE DISEASE

1:50 Chairperson's Remarks

Nishant Agrawal, M.D., Associate Professor, Otolaryngology-Head and Neck Surgery, Johns Hopkins University School of Medicine

2:00 Application of Tumor-Derived DNA in the Management of Individuals with Cancer

Chetan Bettegowda, M.D., Ph.D., Assistant Professor, Neurological Surgery, Johns Hopkins University School of Medicine

The development of non-invasive methods to detect and monitor tumors continues to be a major challenge in oncology. The molecules of tumor derived DNA can be distinguished from the background of normal DNA by the presence of somatic mutations. Using sensitive digital PCR based approaches, we have been able to query bio-fluids from a number of human malignancies for levels of tumor derived DNA (ct-DNA). We will present our efforts at detecting ctDNA in a number of different solid tumors and the potential clinical applications of this approach.

2:30 Application of Tumor-Derived DNA in the Management of Individuals with Cancer

Gabriel Otte, President & CEO, Freenome Inc.

Adam Drake, CSO, Computational Research, Freenome Inc.

Current methods of cancer detection perform little better than a coin flip due to inadequate sensitivity and specificity. We have sequenced the cell-free DNA (cfDNA) from blood plasma to a shallow depth and designed classification procedures based on deep learning of genomic data that detect cancer with a 96%+ sensitivity and specificity.

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Maximizing Next-Generation Sequencing Capabilities of Circulating, Cell-Free DNA

Sponsored By Swift Biosciences

Timothy Harkins, President & CEO, Swift Biosciences

Swift Biosciences presents NGS methods that are cost effective, sensitive, and specific to assess cfDNA. Methods discussed for whole genome sequencing from PCR-free libraries, point mutation detection with hyb/capture and multiplex amplicons, and methylation patterns all from single liquid biopsy samples.

4:00 PANEL DISCUSSION: Clinical Implementation of cfDNA

Moderator: Dan Grosu, Sequenom

Panelists: Sabita Sankar, Ph.D., Director, Business Development, Biodesix

Abhijit Patel, M.D., Ph.D., Assistant Professor, Yale University School of Medicine

Cloud P. Paweletz, Ph.D., Head, Translational Research Laboratory; Biomarker Lead, Belfer Institute for Applied Cancer Science, Dana Farber Cancer Institute

- How to implement in a way that benefits patients
- What information are you getting and how will people use it?
- Who pays? Are we ready for plasma-based NGS tests?
- Lessons learned

5:00 Reception with Exhibit and Poster Viewing

6:00 Close of Day

FRIDAY, MARCH 11

7:00 am Breakfast Presentation: Tracking of Circulating Cell-Free DNA from Plasma for Treatment Response Monitoring

Sponsored By Biological Dynamics — Rapid answers for clinical treatment

Raj Krishnan, Ph.D., CEO, Biological Dynamics, Inc.

Interest in the isolation, quantification, and analysis of cell-free biomarkers directly from blood has grown significantly. A proprietary platform has been developed for isolating and quantifying circulating biomarkers from physiological solutions using AC Electrokinetics (ACE). Biomarkers, such as high molecular weight cell-free DNA, have been established as indicators of tumor burden, and our TR(ACE) assay is currently being developed as a rapid, inexpensive method to follow treatment response in cancer patients.

ASSESSMENT OF CFDNA TECHNOLOGIES

7:55 Chairperson's Remarks

Grace Zhao, Ph.D., Co-Founder and Director, Research, AccuraGen

8:00 An Ultra-Accurate System for Cancer Mutation Detection in Circulating Cell-Free DNA from Plasma

Grace Zhao, Ph.D., Co-Founder and Director, Research, AccuraGen

Rare mutation detection using circulating cfDNA presents two major challenges: low input, and relatively high error rate of current NGS technology. At AccuraGen, we have developed an innovative assay platform to amplify cfDNA, and correct sequencing error to enhance mutation detection at a high accuracy. AccuraGen provides flexible liquid biopsy assays that cover from hundreds to handful of genes with a reliable detection rate of 0.05% in 5000 copies of genome.

8:30 High Sensitivity NGS Analysis of ctDNA: Applications to Non-Small Cell Lung Cancer and Beyond

Tim Forshew, Ph.D., Head, Technology Development, Inivata, Ltd.

It is now established that a broad spectrum of cancers release circulating tumor DNA (ctDNA) into the blood. Detection and quantification of this DNA has numerous potential clinical applications but raises challenges that need to be overcome. We published the first NGS method to detect mutations *de novo* through ctDNA sequencing (TAm-Seq) and will present the development of our optimized, highly sensitive multi-gene panel method, with supporting clinical data.

9:00 Multipanel Massive Parallel Sequencing cfDNA in Monitoring Cutaneous Melanoma Progression

Dave S.B. Hoon, Ph.D., Director, Molecular Oncology and Sequencing Center, John Wayne Cancer Institute, Providence Health Care

Analysis of cfDNA gene mutation panel in melanoma patients serial bleeds over several years of follow-up can be very informative on events ongoing during tumor progression. The highly sensitive and approach of multiple gene mutation panel assessment by MPS of cfDNA provides a very comprehensive analysis to allow correlation to real-time clinical events of patients. These retrospective studies demonstrate that cfDNA mutations can arise at different time points during tumor progression. This approach of precision medicine monitoring melanoma progression allows a more accurate real-time assessment of what is transpiring in the patient.

9:30 Measuring Donor-Derived Cell-Free DNA in Organ Transplant Recipients as a Dynamic Biomarker of Rejection

Sponsored By CareDx

John J. Sninsky, Ph.D. CSO, CareDx

A clinical-grade NGS assay was developed to monitor donor-derived cell-free DNA (dd-cfDNA) in plasma from solid organ transplant recipients. Longitudinal samples from heart and kidney transplant patients show elevated dd-cfDNA levels prior to and at the time of acute rejection which are reduced following successful immunosuppressive therapy.

CIRCULATING CELL-FREE DNA
CONTINUED ON NEXT PAGE

Sponsored By BIO-RAD

10:00 Blood Testing for Actionable Variants in NSCLC Patients by ddPCR: A CLIA Lab Experience

Hestia Mellert, Ph.D., Senior Scientist, Biodesix Inc

Clinical validation of cfDNA and cfRNA assays can be challenging due to the low prevalence of some variants. The GeneStrat™ panel is a Lab Developed Test using Droplet Digital PCR performed in a CLIA Laboratory for the detection of EGFR sensitizing and resistance, KRAS and BRAF mutations, and EML4-ALK fusion transcripts using nucleic acids isolated from plasma.

10:30 Coffee Break with Exhibit and Poster Viewing

ESTABLISHING STANDARDS

11:00 Considerations for Establishing Standards for Circulating Cell Free DNA, RNA and Exosome Biomarkers in Cancer Diagnostics

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

Many considerations exist for establishing standards for circulating cell free DNA, RNA and exosome biomarkers in cancer diagnostics. First, these biomarkers will be used for diagnostic assays and tests that range from early cancer detection to patient management and therapy monitoring. Second, clinical decisions will have to be made as to which and how many DNA/RNA mutations and exosomes surface protein biomarkers are most relevant and predictive at different stages of cancer. Third, it is very likely that different diagnostic criteria will used for the many different types of cancer. Fourth, how will solid tumor biopsy information be used with new liquid biopsy information? Finally, standards will not only be dependent upon detection methods (PCR, sequencing, etc.), but also on sample preparation procedures which will ultimately determine viability of the assays in terms of time and cost.

11:30 Plasma Genotyping as a Novel Biomarker in Non-Small Cell Lung Cancer & Tool for Drug Development

Adrian G. Sacher, M.D., Clinical Fellow, Medicine, Dana-Farber Cancer Institute

Plasma genotyping of cell-free DNA (cfDNA) is quickly evolving as a method to select personalized therapy as well as monitor response to therapy in lung cancer. However, prospective data on the optimal platform and utility of plasma genotyping assays is limited. This talk will review the current state-of-the-art and present results from our ongoing prospective studies of plasma genotyping in lung cancer at the Dana-Farber Cancer Institute.

12:00 pm Quality Assessment of Cell-Free DNA to Guide Downstream Molecular Analyses

Muhammed Murtaza, Research Assistant Professor, Co-Leader, Center for Non-Invasive Diagnostics, Translational Genomics Research Institute

Recent proof-of-principle studies have demonstrated potential utility of sequencing cell-free DNA in cancer diagnostics. However, little is understood about the effect of fragment size distributions in plasma DNA on the performance of sequencing-based assays. We developed a multiplexed assay to perform one-step analysis of DNA quantity and integrity from minute amounts of cell-free DNA using picoliter droplet digital PCR. Our results were predictive of diversity and obtainable depth-of-coverage in next-generation sequencing libraries made from cell-free DNA samples.

12:30 Close of Symposium

Cambridge Healthtech Fifth Annual

POINT-OF-CARE DIAGNOSTICS

Examining Rapid Diagnostics from Clinic to Consumer

THURSDAY, MARCH 10

7:30 am Registration and Morning Coffee

POINT-OF-CARE AT THE DOCTOR'S OFFICE

9:00 Chairperson's Opening Remarks
Elsie Yu, Ph.D., DABCC, FACB, System Director, Toxicology and Point-of-Care Testing; Associate Director, Clinical Chemistry, Geisinger Medical Laboratories

9:10 The Inconvenient Truth about Near Patient Testing at the Doctor's Office
Elsie Yu, Ph.D., DABCC, FACB, System Director, Toxicology and Point-of-Care Testing; Associate Director, Clinical Chemistry, Geisinger Medical Laboratories

Performing laboratory testing at the doctor's office allows practitioners to provide immediate consultations. This could improve patient engagement and satisfaction. However, proper laboratory practice and regulatory compliance issues add a layer of complexity to the management of testing. In this presentation, we will look at a few examples to explore the good and the burden of near patient testing at the doctor's office.

9:40 Save a Penny, Lose a Dollar: POC vs. Central Lab Testing in the Hospital Setting
Gyorgy Abel, M.D., Ph.D., Director, Clinical Chemistry and Molecular Diagnostics, Lahey Hospital & Medical Center

Clinical demand, convenience, and innovation are driving POCT worldwide. POCT is resource intensive and generally more expensive than central laboratory testing. As healthcare budgets get tighter and laboratory fee-for-service system is melting away with the emergence of Accountable Care Organizations (ACOs), the potential advantages of POCT must be thoroughly evaluated in the context of clinical benefit and costs. Health economics studies are needed to delineate areas where POCT is cost-effective.

10:10 Microfluidic-Enabled Sample Collection Strategies for PoC Diagnostics
Sponsored By miniFAB
Erol Harvey, Ph.D., CEO, MiniFAB

Microfluidic structures can simplify sample collection and cleanup, making the process more accurate and less prone to user error. Quantitative diagnostics usually require precise sample volumes, from nanolitres to microliters, and this can be achieved without skilled user input.

10:25 Idylla™: Shaping the Future of Point of Impact Testing in Oncology and Infectious Diseases
Sponsored By BIOCARTIS
Rudi Pauwels, CEO, Biocartis

10:40 Coffee Break with Exhibit and Poster Viewing

POINT-OF-CARE IN THE PHARMACY

11:15 Shifting the Paradigm: Bringing Lab Services to the Corner Drugstore
Casey Kozlowski, RPh, MBA, Director, Diagnostic Testing Product Development, Walgreens

Pharmacists and pharmacies play a vital role in patient care. By marrying diagnostic testing with dispensing and adherence-based monitoring, we can improve patient health outcomes and lower overall healthcare costs.

11:45 Implementing Collaborative, Community Pharmacy-Based Disease Management Programs Using CLIA-Waived POC Tests
Michael E. Klepser, Pharm.D., FCCP, Professor, Pharmacy Practice, Ferris State University College of Pharmacy

CLIA-waived POCT can provide useful information to the pharmacist as part of collaborative disease management programs. Data from the successful implementation of such progr ams and the role of POCT in these programs will be discussed.

12:15 pm Reimagining the Future of CLIA-Waivable Point-of-Care Molecular Diagnostics for Infectious Diseases
Sponsored By Lucigen Simplifying Genomics
Dipankar Manna, Ph.D., Principal Scientist, LucigenDx

LucigenDx will describe a new platform designed to bring molecular diagnostics to point-of-care. The platform consists of a test cartridge and a compact instrument designed for CLIA-waiver. Sample prep, amplification and detection are performed by the isothermal amplification platform with no mixing or measuring. A clinical trial for is planned for 2016.

12:30 Session Break

12:40 Luncheon Presentation: POCT One-Step Molecular Diagnostic System Brings Complex Clinical Testing Directly to the Patient
Sponsored By COYOTE
Jesus Ching, Ph.D., CTO, Research & Development, Coyote Bioscience

Coyote Bioscience is dedicated to making break-through innovations in molecular diagnostics that bring complex clinical testing directly to the patient. We would like to introduce both of our lab-in-a-box instrumentation systems based on PCR technology and our novel method of one-step gene test without nucleic acids extraction.

1:15 Session Break

DIRECT-TO-CONSUMER POINT-OF-CARE

1:50 Chairperson's Remarks
Casey Kozlowski, RPh, MBA, Director, Diagnostic Testing Product Development, Walgreens

2:00 The Future of Mobile Health: Closing the Health Loop
Jordan Shlain, M.D., Managing Partner, Private Medical; Chairman, HealthLoop

Doctors are being asked to do more with more but are not being given more time. Information is exploding, patients are getting empowered and doctors are struggling to keep up with all the innovation. Dr. Shlain will talk about how he built Healthloop from a simple idea: follow up. He will also discuss how mobile is on the precipice of transforming the medical experience.

2:30 Implications of Emerging Mobile Health Technologies in Preventative and Point-of-Care Diagnostics
Babette Gresko, Director, Mobile Engagement Technology and Population Health Management, Clinical Operations, HealthSignal Partners

Mobile health technology has the potential to capture a variety of user health data, and help drive early care intervention. The challenges and potential solutions associated with unifying patient data through mobile health applications will be presented, and examples of how mobile health technology provides low cost risk and health management tools, involving patients and

POINT-OF-CARE DIAGNOSTICS
CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

care givers, will be discussed.

3:00 Refreshment Break with Exhibit and Poster Viewing

THE BUSINESS CASE FOR TRUE POINT-OF-CARE

3:30 Bringing Point-of-Care Testing to the "Internet of Things"

Pat Arensdorf, MBA, Principal, Halteres Associates, LLC
Bela T. Matyas, M.D., MPH, Health Officer and Deputy Director, Solano County Health Department
James Killeen, M.D., Clinical Director, Informatics Fellowship; Associate Director Information Services; Director, Beach Program, University of California San Diego Department of Emergency Medicine

Point-of-Care Testing (POCT) is poised to change the practice of medicine in many diverse settings worldwide, providing critical information needed during patient encounters. Enabled by advances in information and communications technologies, POCT results can now also be integrated with both clinical and community data in real time, informing not only individual patient care, but also ongoing population health initiatives, health system responses and resourcing plans. This presentation will focus on initial results from current studies in process to determine the impact of having diagnostic data available in real time for urgent care and public health settings. It will also offer a compelling view of a wider role for POCT in an internet-connected healthcare environment.

4:30 Profound Need to Substantiate Health Economic Claims for POC Testing

Katherine Tynan, Ph.D., Tynan Consulting LLC

One of the major enablers of healthcare changes is the availability of more sophisticated point of care testing and monitoring devices. However POC device developers are under increasing pressure to substantiate claims of cost reduction through increased efficiency (reduction in testing & clinical visits, improvement in work flows etc) through health economic modeling. Examples of how to demonstrate these claims to convince payers to favor POC diagnostics over more traditional approaches will be discussed.

5:00 Reception with Exhibit and Poster Viewing

6:00 Close of Day

FRIDAY, MARCH 11

8:00 am Innovative Plastic Waveguides Enable Fast, Low-Cost Multiplexing at the Point of Care

Sponsored By m·bio™ DIAGNOSTICS

Chris Myatt, Founder & CEO, MBio Diagnostics

Optical waveguide sensors combined with fluorescent detection enable sensitive and highly multiplexed tests for point of care use. We will detail a simple disposable cartridge and portable reader design that permits scalable manufacturing while maintaining laboratory-quality performance. We will provide data from clinical studies run at more than a dozen sites worldwide, including an 88-feature proteomic array for tuberculosis, a blood-borne pathogen panel, and an isothermal molecular influenza test. This approach can open up new decentralized testing applications.

ADVANCES IN POC TECHNOLOGIES

8:25 Chairperson's Remarks

Gyorgy Abel, M.D., Ph.D., Director, Clinical Chemistry and Molecular Diagnostics, Lahey Hospital & Medical Center

8:30 Polystyrene Plastics for Production of On-Demand Antibody Arrays for Point-of-Care Detection

Matthew A. Coleman, Ph.D., Physics and Life Sciences, BBTD, L-452, Lawrence Livermore National Laboratory

Inexpensive plastic biochips are being used as non-traditional alternatives to quantify data rapidly for medical diagnosis, drug development and discovery, and other biological research. We demonstrate that biochips made of polystyrene sheet (PS), commonly known as "Shrinky Dinks" for protein and antibody generation prior to biological detection. These PS devices are able to quantify protein and antibody interactions with 3-4 orders of detection sensitivity. Collectively, these results further expand the utility PS for use in point-of-care settings.

9:00 The Potential for Single Molecule Fluorescence Methods in Point-of-Care Technologies

Ted A. Laurence, Ph.D., Materials Science Division, Physics and Life Sciences, Lawrence Livermore National Laboratory

Single molecule fluorescence measurements at the interface of physics, chemistry and biology provide a new way to understand biological processes. We are developing single molecule-based methods for detection and monitoring of DNA and proteins in un-diluted biological samples. It is not often appreciated that, although technologically advanced, the basic techniques used are relatively simple and amenable to automation. With improved assays and miniaturization, these technologies have great potential to impact point-of-care.

9:30 Next-Generation Point-of-Care Testing: Clinical Needs, Technologies and Opportunities

Ping Wang, Ph.D., Director, Clinical Chemistry, Pathology and Genomic Medicine, Houston Methodist Hospital

Next-generation point-of-care diagnostic technologies are emerging, with potential applications of nanotechnology, microfluidics, sensors compatible with mobile phones and wearable electronics. The challenges lie in how to bridge these novel technologies with current clinical needs. This presentation will review current clinical needs from a clinician perspective, trends and promises of next-generation POCT, and discuss opportunities and strategies needed to realize these promises.

10:00 Rapid Diagnosis of Infectious Diseases at Point-of-Care

Sponsored By agl

Anna Dixon, Ph.D., Research Manager, Research & Development, Atlas Genetics Limited

Atlas has developed an integrated system that can be deployed and used at decentralised settings to identify nucleic acid targets from multiple sample types in under 30 minutes. The io™ system performs all the steps of the assay from DNA extraction through to multiplex detection with no operator intervention following the addition of an unprocessed sample.

10:30 Coffee Break with Exhibit and Poster Viewing

EMERGING POINT-OF-CARE TECHNOLOGIES

11:00 Giving the Patient Power - Opening Pandora's Box or Future Enlightenment?

Francis White, EU General Manager, AliveCor Ltd.

We have developed the AliveCor® Heart Monitor, a clinical-quality low-cost ECG recorder that records, displays, annotates, stores, and transfers single-channel electrocardiogram (ECG) rhythms wirelessly, using the ubiquitous smartphone. The device has US FDA approval, and is CE marked in Europe, available through leading retailers such as Amazon. The device has received an enthusiastic reception by users and has many presented and published clinical trial papers and abstracts that have demonstrated AliveCor's usability, clinical accuracy, and ECG interpretation capabilities.

11:30 Lumify: App-Based Ultrasound on Your Own Compatible Android Smartdevice

Ajay Agarwal, Head, UltraMobile Product Mangement, Philips Healthcare

12:00 pm Biomarker-Based Diagnosis of Alzheimer's Disease Using Acoustic Detection Techniques

Samantha Swarbrick, Ph.D. Student, Mechanical and Manufacturing Engineering, Loughborough University

Here we report feasibility studies for rapid detection of synthetic short single-stranded DNA sequences (ssDNA) in physiological buffer, which are a close model for microRNA, using complementary acoustic techniques. The sensitivity and selectivity of measurements with this entirely electronic technique suggest potential for a rapid and portable diagnostic for Alzheimer's Disease, and in general for any biomarker-mediated clinical diagnostic.

12:30 Close of Symposium

Cambridge Healthtech Institute's Second Annual

BIOMARKERS FOR CANCER IMMUNOTHERAPY

Predictive and Prognostic Biomarkers for Immuno-oncology

THURSDAY, MARCH 10

7:30 am Registration and Morning Coffee

PREDICTIVE AND PROGNOSTIC BIOMARKERS FOR IMMUNO-ONCOLOGY

9:00 Chairperson's Opening Remarks
Scott Rodig, M.D., Ph.D., Hematopathologist, Department of Pathology, Brigham and Women's Hospital

9:10 Combination Therapies with Listeria-Based Immunotherapies: From Chemotherapy to Checkpoint Inhibition
Dirk G. Brockstedt, Ph.D., Senior Vice President, Research & Development, Aduro Biotech, Inc.
This talk will give a detailed description of Listeria-based immunotherapy. It will also review clinical studies in mesothelioma, pancreatic and ovarian cancer. Lastly, it will share results of combination studies with conventional chemotherapy, cell-based therapies and immune modulators.

9:40 Biomarkers for Prediction of Response to Anti-Cancer Immunostimulatory Therapies: Where Are We?
Kurt A. Schalper, M.D., Ph.D., Director, Translational Immuno-oncology Laboratory (T.I.L.)., Yale Cancer Center
Monoclonal antibodies targeting the co-inhibitory immune checkpoint PD-1 or its primary ligand PD-L1 are well tolerated and can induce lasting clinical responses in patients with advanced malignancies. However, the majority of patients treated with such agents do not receive clear benefit, highlighting the need for companion biomarkers to select subjects with the highest potential of response. Current status and recent developments in biomarkers for immunostimulatory therapies will be discussed.

10:10 The Role of Global Immunocompetence in Cancer Immunotherapy
Holden Maecker, Ph.D., Associate Professor, Microbiology and Immunology; Director, Human Immune Monitoring Center, Stanford University
In order to cast a broad net in measuring potential parameters of immunocompetence, we have stimulated patient PBMC with PMA+ionomycin and then analyzed their cell phenotypes and functions using a 40-parameter mass cytometry panel. We combine this with a serum Luminex assay for 63 cytokines. Results from different tumor types and different immunotherapy settings will be presented. We wish to determine whether there are broadly applicable immunocompetence measures as well as those that are unique to a given tumor and/or therapeutic setting.

Sponsored By biodesix

10:25 Blood-Based Cancer Immunotherapy Diagnostics
Heinrich Roder, Ph.D., Chief Technology Officer, Research & Development, Biodesix
Blood-based clinically-actionable, multivariate tests from MALDI ToF data can be designed by modifying ideas from deep learning. Our methodology utilizes time-to-event endpoints in generating training labels. Results for a test stratifying patients for immunotherapy benefit will be shown.

10:40 Coffee Break with Exhibit and Poster Viewing

11:15 Defining the Immune Landscape in Cancer Using Spatially Resolved Approaches
Paul C. Tumeh, M.D., Assistant Professor, Medicine, University of California, Los Angeles
Immunodiagnostics, aimed at comprehensively defining the immune system's response to tumors, must be able to capture two biological hallmarks of immune cell types, i) plasticity and ii) lack of mutations. Spatially resolved approaches that are capable of high molecular content profiling and multiparametric analysis have the ability to define previously unknown spatiotemporal interdependencies that would deepen our understanding of how the immune system responds to tumors before and after immunotherapy.

11:45 Tissue-Based Analyses to Guide Immunotherapy for Lymphoma
Scott Rodig, M.D., Ph.D., Hematopathologist, Department of Pathology, Brigham and Women's Hospital
Targeted immunotherapy has achieved long-lasting clinical responses in a subset of patients with a variety of aggressive malignancies. I will discuss the cellular and molecular characteristics of classical Hodgkin lymphoma that render this tumor-type uniquely susceptible to PD-1 blockade and correlations between tissue-based biomarker analysis and clinical outcome with either conventional chemotherapy or immunotherapy, and extensions of these observations to additional lymphoma subtypes.

12:15 pm Leveraging Ultrasensitive Immunoassay Technology to Drive New Research and Clinical Insights in Immuno-Oncology
Sponsored By Quanterix
Mark Roskey, Vice President and General Manager, Quanterix

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Enjoy Lunch on Your Own

1:15 Session Break

PREDICTORS FOR CHECKPOINT INHIBITORS

1:50 Chairperson's Remarks
Brad Nelson, Ph.D., Director, Deeley Research Centre, BC Cancer Agency

2:00 PD-1 Blockade in Tumors with Mismatch-Repair Deficiency
Luis Diaz, M.D., Associate Professor, Oncology, John Hopkins Kimmel Cancer Center
Somatic mutations have the potential to encode "non-self" immunogenic antigens. Tumors with a large number of somatic mutations due to mismatch-repair defects appear to be highly susceptible to immune checkpoint blockade. This presentation will summarize the clinical and genomic data of using mutations as neoantigens.

BIOMARKERS FOR CANCER IMMUNOTHERAPY
CONTINUED ON NEXT PAGE

2:30 Prognostic and Predictive Markers for Immunotherapy and Combination Therapy

Kathleen M. Mahoney, M.D., Ph.D., Clinical Instructor, Beth Israel Deaconess Medical Center; Research Fellow, Dana Farber Cancer Institute

Tumor expression of PD-L1 has received much attention as a potential biomarker for PD-1/PD-L1 directed therapy. However it is inappropriate as a biomarker for exclusion from treatment, since "PD-L1 negative" tumors may respond to PD-1 pathway blockade. Emerging data suggests multivariate models including PD-L1 expression and the immune infiltrate within the tumor microenvironment may direct immunotherapy decisions. Incorporating the tumor's mutational landscape, in addition to immunohistochemistry and gene expression signatures, may improve these platforms.

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 PANEL: Moving Forward with Prognostic Biomarkers for Immunotherapy

Moderator: Luis Diaz, M.D., Associate Professor, Oncology, John Hopkins Kimmel Cancer Center

Panelists: Bernard A. Fox, Ph.D., Harder Family Chair for Cancer Research, Member & Chief, Laboratory of Molecular & Tumor Immunology, Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute, Providence Cancer Center, Providence Portland Medical Center; CEO, UbiVac

Kurt A. Schalper, M.D., Ph.D., Director, Translational Immuno-oncology Laboratory (T.I.L.)., Yale Cancer Center

Brad Nelson, Ph.D., Director, Deeley Research Centre, BC Cancer Agency

- Status updates on immune biomarkers
- Validation of new biomarkers
- Technologies and high throughput approaches – strengths and weaknesses
- Investigating the tumor microenvironment

4:00 Imprime PGG – An Advanced, Clinical Stage Pathogen Associated Molecular Pattern (PAMP)

Jeremy R. Graff, Ph.D., Senior Vice President, Research, Pharmaceutical Group, Biothera, Inc.

4:30 Genomic Approaches to Deciphering Protective Immune Mechanisms in Cancer

Brad Nelson, Ph.D., Director, Deeley Research Centre, BC Cancer Agency

Tumor-infiltrating lymphocytes are associated with survival in virtually every human cancer studied, but the mechanisms by which they confer protective immunity remain incompletely understood. Focusing on ovarian cancer, our group applies genomic and molecular pathology approaches to define the mechanisms by which the immune system responds to the evolving tumor genome over space and time. We are translating these insights into clinical trials involving adoptive transfer of tumor-reactive T-cells.

5:00 Reception with Exhibit and Poster Viewing

6:00 Close of Day

FRIDAY, MARCH 11

8:00 am Morning Coffee

IMMUNOTHERAPY CLINICAL TRIALS

8:25 Chairperson's Remarks

Bernard A. Fox, Ph.D., Harder Family Chair for Cancer Research, Member & Chief, Laboratory of Molecular & Tumor Immunology, Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute, Providence Cancer Center, Providence Portland Medical Center; CEO, UbiVac

8:30 Immunotherapy at a Tipping Point: DPV-001 – A DC-Targeted Strategy with More than 100 Cancer Antigens, Multiple TLR Agonists and Damps Induces Broad-Spectrum Anti-Cancer Immunity in Patients with Cancer

Bernard A. Fox, Ph.D., Harder Family Chair for Cancer Research, Member & Chief, Laboratory of Molecular & Tumor Immunology, Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute, Providence Cancer Center, Providence Portland Medical Center; CEO, UbiVac

Cancer immunotherapy is providing objective responses in patients with many cancers. Unfortunately, response rates are low and most regressions are not complete. One hypothesis to explain these results is that only patients with immunity against a spectrum of antigens, expressed on highly heterogeneous metastases, obtain a complete, and potentially curable, response. A Phase II trial is testing the ability of DPV-001, a DC-targeted micro-vesicle, to induce broad anti-cancer immunity.

9:00 Cancer Immunotherapy Biomarkers: Lessons from Clinical Trials

Lisa H. Butterfield, Ph.D., Professor, Medicine, Surgery and Immunology; Director, UPCI Immunologic Monitoring and Cellular Products Laboratory, University of Pittsburgh

There is a critical need for the identification, standardization and validation of biomarkers for cancer immunotherapy. Predictive and prognostic biomarkers are needed to focus therapies on those able to benefit. While many candidates have been identified in clinical trials, there are technical issues with measurements and biomarkers correlate in some settings and diseases and not others. This presentation will discuss recent trials, candidate biomarkers and the SITC Biomarkers Taskforce initiative.

9:30 Product Characteristics and Pharmacodynamic Biomarker Profile of Patients Receiving Anti-CD19 CAR T Cell Therapy: Correlates of Clinical Response

Adrian Bot, Ph.D., Vice President, Translational Medicine, Kite Pharma, Inc.

Anti-CD19 chimeric antigen receptor (CAR) engineered autologous T-cell therapy has shown promising efficacy in an ongoing Phase I study in the setting of B–cell malignancies conducted at the NCI. In a Kite Pharma-sponsored Phase I - II multi-center study, ZUMA-1, subjects received KTE-C19: autologous T-cells engineered with the same anti-CD19 CAR construct as the NCI utilizing an optimized 6 - 8 day process. Potential correlates of clinical response to KTE-C19 will be presented, including KTE-C19 product composition, anti-CAR T-cell expansion profile and serum pharmacodynamic markers.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break with Exhibit and Poster Viewing

ESTABLISHING COMPANION DIAGNOSTICS ACROSS TARGETED IMMUNOTHERAPIES

11:00 Moderator's Remarks

James R. Mansfield, Global Head, Imaging, Quantitative Pathology Solutions, PerkinElmer

11:05 Establishing a PD-L1 Companion Diagnostic for Opdivo, a Novel Immune Checkpoint Inhibitor for the Treatment of Cancer

Steven D. Averbuch, M.D., Vice President, Development, Oncology & Pharmacodiagnostics, Bristol-Myers Squibb

PD-L1 expression on the membrane surface of solid tumors may correlate with the efficacy of PD-1 pathway inhibitors. Nivolumab is a fully human IgG4 PD-1 immune checkpoint inhibitor antibody that selectively prevents interaction with PD-L1 and PD-L2 to inhibit the suppression of antitumor T-cell function. A comprehensive analytical and clinical evaluation of PD-L1 expression by IHC to determine the association between expression and clinical outcome for Nivolumab will be described.

BIOMARKERS FOR CANCER IMMUNOTHERAPY
CONTINUED ON NEXT PAGE

11:15 A Critical Appraisal of Biomarkers for Immune Therapy: The Pathologist's Perspective

Robert A. Anders, M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins School of Medicine; Director, Liver Pathology, Division of Gastrointestinal and Liver Pathology, Johns Hopkins Hospital

Dr. Anders will summarize the current understanding of immune checkpoint inhibitors. The mechanism of action of check point inhibitors targeting PD-1/PD-L1 and CTLA will be the focus of the discussion. Particular emphasis will be on gastrointestinal malignancies. He will discuss the challenges in developing prognostic and predictive biomarkers in patient derived tissues.

11:35 Developing an Immunohistochemistry Test for "Programmed Cell Death 1 Ligand" (PD-L1) as a Companion Diagnostic for Pembrolizumab

Kenneth Emancipator, M.D., Executive Medical Director, Molecular Biomarkers and Diagnostics, Merck Research Laboratories

Tumors express PD-L1 to contribute to escape from immunosurveillance. Pembrolizumab blocks this escape mechanism and thus effectively treats a number of cancers. The rapid clinical development of pembrolizumab required rapid development of an immunohistochemistry assay for PD-L1. Merck developed the assay initially to determine whether or not PD-L1 is a predictive biomarker, then to enrich clinical trials, and ultimately partnered with a diagnostics company to develop the assay as a companion diagnostic.

11:45 PANEL DISCUSSION

12:30 pm Close of Symposium

Cambridge Healthtech Institute's Third Annual

GENOMICS & SEQUENCING DATA INTEGRATION, ANALYSIS AND VISUALIZATION

Deriving Insights and Relationships from Big Data Sets to Advance Research and Patient Health

THURSDAY, MARCH 10

7:30 am Registration and Morning Coffee

DRIVING DATA ANALYTICS AND VISUALIZATION

9:00 Chairperson's Opening Remarks
Deepak Sheoran, Principal Engineer, Orion Integrated Biosciences, Inc.

9:10 Power to the People: Annotation, Analysis and Visualization for Systems Biology and Precision Medicine Using Crosstalker™
Mark Chance, Ph.D., Vice Dean for Research; Director, Center for Proteomics and Bioinformatics; Charles W. and Iona A. Mathias Professor of Cancer Research, School of Medicine, Case Western Reserve University and Neo Proteomics, Inc.
Integration and visualization of diverse sets of molecular targets is one of the most challenging yet important approaches in order to identify dysregulated molecular targets in complex disease. To overcome this challenge, we have developed an integrated set of commercial tools that includes Crosstalker™, a user-friendly and transparent (e.g. white-box) analytical engine for molecular data analysis and integration, including but not limited to individual or simultaneous integration of mutations, SNPs, CNVs, array, RNAseq, and proteomics data.

9:40 Benchtop Sequence Analysis: Empowering Bench Scientists to Analyze Big Data through Web Interfaces
Dave Barkan, Ph.D., Investigator, Infectious Diseases, Novartis Institutes for BioMedical Research
For some basic sequence analysis tasks, a bioinformaticist's role may be simply to launch an established software pipeline on the command line with default parameters and send the generated results back to the bench scientists. In NIBR, the Bioinformatics and IT groups are working together to eliminate this intermediate step by building web front-ends that launch in-house bioinformatics pipelines and return the results and visualizations directly to the end-users in their browser.

LEVERAGING SEQUENCING APPROACHES TO IDENTIFY DISEASE AND THERAPEUTIC INTERVENTIONS

10:10 Metabolomics, the Microbiome and Understanding Complex Diseases
Andreas Kogelnik, M.D., Ph.D., Founder and Director, Open Medicine Institute
This talk will discuss two projects focused on integrating blood metabolomic and gut microbiomic data with direct clinical application. We will discuss how these technologies are being used to improve diagnostic rigor and pointing the way to therapeutic targets, in particular, for complex diseases and chronic disease management. Current integrative -omics appears on course to re-shape precision diagnostics and therapies.

10:40 Coffee Break with Exhibit and Poster Viewing

11:15 Next-Generation Sequence Analysis System: Discovering the Unknown in Complex Genomic and Metagenomic Datasets
Deepak Sheoran, Principal Engineer, Orion Integrated Biosciences, Inc.
NGS sequencing offers the possibility to sequence the DNA of known and unknown organisms. Despite the exponential accumulation of microbial genomic information, there is not a reference database where researchers can retrieve curated sequences specific to a give taxonomic group. This situation continues to hinder the rapid development of standardized diagnostic reagents, prophylactics and therapeutics. This talk discusses methods and technology to exploit genomic and metagenomics information to discover and prioritize targets to counter the impact of infectious agents.

11:45 Identification and Relevance of Fusion Transcripts in a Novel *in vitro* Progression Model of High-Grade Serous Ovarian Cancer
Sharmila Bapat, Ph.D., FNASc, FASc, Independent Project Investigator and Group Head, National Centre for Cell Science (NCCS), Pune India
High-grade serous ovarian adenocarcinoma (HGSC) is recognized to rapidly progress from asympomatic, silent onset to aggressive metatstatic disease that leads to the most dismal prognosis. Lack of early diagnosis has led to an opinion that better disease management through detailed molecular and biological understanding of tumors could pave the way for development of targeted 'personalized' therapeutic strategies and improve patient prognosis.

12:15 pm Sponsored Presentation *(Opportunity Available)*

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

LEVERAGING SEQUENCING APPROACHES TO IDENTIFY DISEASE AND THERAPEUTIC INTERVENTIONS

1:50 Chairperson's Remarks
Deepak Sheoran, Principal Engineer, Orion Integrated Biosciences, Inc.

2:00 Software and Computational Platforms to Integrate Diverse Genomics and Epigenomic Datasets
Duygu Ucar, Ph.D., Assistant Professor, Genomic Medicine, Jackson Laboratory
We are building software and computational algorithms to integrate epigenetic datasets with other data sources including chromatin interaction maps, public data repositories (SNPs, gene sets, immune modules), and transcriptome. Attendees will learn about the methods and software we are developing in my lab, as well as the research directions that Jackson Laboratory for Genomic Medicine is taking, which is a brand-new genomics institute dedicated to understand human diseases, including cancer, immune diseases, and diabetes.

CONTINUED ON NEXT PAGE

ORGANIZED BY: Cambridge HEALTHTECH Institute

2:30 Mitochondrial Function, Mutation, and Diseases
Zhenglong Gu, Ph.D., Associate Professor, Division of Nutritional Sciences, Cornell Center for Comparative and Population Genomics, Cornell University
A majority of mitochondrial DNA (mtDNA) mutations reported to be implicated in diseases are heteroplasmic, a status with co-existing mtDNA variants in a single cell. Quantifying the prevalence of mitochondrial heteroplasmy and its pathogenic effect in healthy individuals could further our understanding of its possible roles in various diseases. In this talk I will discuss our results regarding this issue.

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 New Gene-Level Approaches to Identify Disease-Causing Mutations in Next-Generation Sequencing Data of Patients
Yuval Itan, Ph.D., MRes, Postdoctoral Associate, Human Genetics of Infectious Diseases, The Rockefeller University
We developed two novel gene-level approaches to estimate the relevance of a specific gene to a disease. We describe the gene damage index (GDI), a genome-wide, gene-level estimate of accumulated mutational damage for human protein-coding genes. We then present the mutation significance cutoff (MSC), a gene-specific threshold to differentiate between benign and damaging variants. We demonstrate the combination of the GDI and MSC approaches significantly increase the discovery rate of new disease-causing mutations in NGS data of patients.

4:00 Clinical Transcriptomic Profiles – Providing Clues for Novel Therapeutic Development Strategies: A Case Study on Psoriasis
Deepak K. Rajpal, D.V.M., Ph.D., Director, Computational Biology, Target Sciences, GlaxoSmithKline
Psoriasis is a chronic inflammatory skin disease with complex pathological features. By mining the publicly available clinical transcriptomic profile data, we present a framework for developing new therapeutic intervention strategies. We propose a psoriasis disease signature, and the reversal of such signature on therapeutic intervention, presents approaches to drug repurposing and novel target selection strategies. These approaches would potentially support biomarker and drug discovery strategies for psoriasis.

4:30 Ten Things You Probably Don't Know About GenBank
Ben Busby, Ph.D., Genomics Outreach Coordinator, NCBI, NIH

5:00 Reception with Exhibit and Poster Viewing

6:00 Close of Day

FRIDAY, MARCH 11

8:00 am Morning Coffee

PRECISION MEDICINE WORKFLOW AND ENTERPRISE INTEROPERABILITY REQUIREMENTS

8:25 Chairperson's Remarks
Martin Gollery, CEO, Tahoe Informatics

8:30 Role of Hadoop and Data Analysis to Move Genomics from Research to Personalized Medicine
Martin Gollery, CEO, Tahoe Informatics

9:00 Evolution of a Genomics Data Ecosystem: Efficient NGS Data Tracking, Processing, Integration and Results Sharing
Lihua Yu, Ph.D., Vice President, Data Science and Information Technology, H3 Biomedicine, Inc.
We have built a genomic data ecosystem with components including data storage, NGS data analysis with pipelines and workflow management tools, genomic data management/ warehouse using AWS Redshift, genomic data integration system that allow data exploration for both computational biologists and other scientists, to results and knowledge sharing in a company-wide collaboration platform. This presentation discusses the importance of having such an eco-system that also provides tractability and visibility and reusability of both the data and the scientific insights from genomics studies.

9:30 Speeding Up Drug Research with MongoDB: Introducing MongoDB into an RDBMS Environment
Doug Garrett, Research Leader, NGS Pipeline Development Group, Roche Sequencing
Genetic testing of animal models has been critical to Genentech Research in understanding the underlying cause of many diseases and in developing drugs to address those diseases. This importance has driven an increase in both the number and complexity of genetic testing requirements for the transgenic Genetic Analysis Lab. To address our requirements from a financial, resource, and workflow perspective, we embarked on a major redesign, which included the use of MongoDB, a noSQL document database with a flexible schema.

10:00 Selected Poster Presentation: Limitations and Problems of Genomic Data Sharing: Enabling Data Discovery and Accessibility
Amanda A McMurray, Ph.D., MBA, MIoD, Chief Financial Officer, Repositive Limited
The success of next generation sequencing technologies potentially opens up new horizons in clinical research and practice. But before one can really benefit from genomic clinics of the future, multiple issues must be addressed. Human genomics research relies on the availability of genomic datasets that are needed to test a hypothesis. Although a large amount of data is generated around the world, individual researchers still often lack access to it. Exemplary collaborative practices demonstrated during the realisation of the Human Genome Project do not reflect the state of data sharing in the community today: data sharing is not the default, but the exception. Data sharing has continually been recognised as important, not only for the advancement of scientific knowledge, but also for the preservation of information: verification of conclusions and safeguarding against misconduct. But data sharing in human genomics is a multifaceted challenge. Ethical considerations combined with the uniqueness of the genome of an individual require special precautions to enable sharing whilst protecting data privacy. Here, we investigate the current extent of human genomic data sharing by examining the data handling processes and needs of human genomics researchers in different settings. We explore how researchers are including data access and data sharing in their current workflows and whether any bottlenecks need to be addressed to enable more efficient data collaborations.

10:30 Coffee Break with Exhibit and Poster Viewing

SECURITY AND SCALING CAPACITIES IN THE CLOUD

11:00 Securing Sensitive Workloads in the Cloud: Best Practices and Procedures for Securing Your Data on Amazon Web Services
Brad Dispensa, Senior Solutions Architect, Amazon Web Services
Data security, access controls and monitoring are common areas of confusion for researchers interested in moving to the cloud. In this presentation I will cover how to configure your research to run securely using Amazon Web Services. We will review Amazon's shared security model, encryption techniques, automation of security controls and resource provisioning and HIPAA workload design patterns on AWS

11:30 Storms and Silver Linings: Developing Cloud-based Genomic Tools for a University Community
Stephan Sanders, Ph.D., Assistant Professor, Department of Psychiatry, University of California, San Francisco

12:00 pm Lessons Learned Scaling Up Analysis for Thousands of Samples Using Amazon Web Services
Ravi Madduri, Fellow, Computation Institute, University of Chicago; Project Manager, Math and Computer Science Division, Argonne National Lab
Globus Genomics is a cloud-based, large scale genomics analysis service that is used by research consortiums, healthcare providers for analyzing 1000s of raw genomics datasets. In order to deliver results of the analyses on the tight deadlines, we created cost-aware resource scheduling on AWS resources that leverages the computational profiles that we created for various tools to schedule cost/performance optimized execution. In this talk, we will present some of the use cases and success stories from our work.

12:30 Close of Symposium

Cambridge Healthtech Institute's Fourth Annual

COMPANION DIAGNOSTICS

Strategies for Guiding Treatment and Improving Health

THURSDAY, MARCH 10

7:30 am Registration and Morning Coffee

NEW MODELS FOR MANAGING RISK IN COMPANION DIAGNOSTICS

9:00 Chairperson's Opening Remarks
Glenn A. Miller, Ph.D., President, CDx Vision, LLC

9:10 Personalized Medicine Risk-Sharing Business Models: What Does It Really Mean?
Cecilia Schott, MBA, Head, Personalized Healthcare, Corporate Development & Ventures, AstraZeneca
The term risk-sharing business models in personalized healthcare (PHC) has been approached in different ways. One simple way of understanding the risk associated with the development of new drugs that incorporate a PHC is by breaking it down in three parts: (1) development, (2) regulatory approval, and (3) commercialization of the companion diagnostic and the drug. This presentation will take a critical look at what it really means to risk share the co-development of a drug and a diagnostic.

9:20 Preventive Diagnostics: The Future of Personalized Healthcare
Adrian Moody, Ph.D., Director & Head, Design and Development Manchester, MDx Assay Development, QIAGEN
I will review the emerging trends in Personalized Healthcare, which includes companion diagnostics and NGS with lead multi-biomarkers and multiplex testing. Pharma and Diagnostics companies are advancing through formation of consortia to foster the emergence of liquid biopsy and monitoring testing in cancer and chronic diseases. I will discuss how combinatorial & targeted therapy and immunooncology will be established and how diagnostic testing will be a key component. Furthermore, bioinformatics will become an integral part for the analysis, interpretation and reporting of biological and clinical data.

9:30 Seeking the Evidence Base: How Will Personalized Medicine Save Medical Cost?
Mark E. Nunes, M.D., Associate Professor, Pediatrics, Division Chief, Medical Genetics, Kaiser Permanente
By its own definition, the target population for personalized medicine diagnostics and therapeutics is small and highly selected, resulting in greater costs. Would a focus on prevention, rather than therapy, improve the equation? Challenges in establishing the model and evidence from the payor's perspective will be examined.

9:40 PANEL DISCUSSION

10:40 Coffee Break with Exhibit and Poster Viewing

SOFTWARE AS A MEDICINE: Integrating Information for Better Outcomes

11:15 Chairperson's Remarks
Christopher Larkin, CTO, GE Software

11:30 Building a Rapid Learning System to Improve Cancer Care
Richard L. Schilsky, M.D., FASCO, CMO, American Society of Clinical Oncology
ASCO is developing CancerLinQ to capture the complete, longitudinal electronic health record of every patient along with practice management data from all participating practices to "learn" from every patient. Over time, the value of the CancerLinQ data will be enhanced by incorporating genomic data, imaging data and patient-reported outcomes. This information will provide the ability to rapidly generate the evidence needed to deliver the best care for each cancer patient.

11:45 Creating an Integrated Multi-Site Cancer Care Program – Electronic Measurement of Impact of Value vs. Volume Algorithms
Derek Raghavan, M.D., Ph.D., FACP, FRACP, FASCO, President, Levine Cancer Institute, Carolinas HealthCare System; Professor of Medicine, University of North Carolina School of Medicine
This brief review of Carolina HealthCare System's novel, integrated multi-site system of cancer care, incorporating an academic pattern of practice and the use of pathways, apps, video conferencing and telemedicine, illustrates novel approaches to cost reduction, improvement of access to care and scientific progress via clinical trials, and reflects the move from volume-driven to value-driven/high volume adjusted health care practice and tight fiscal planning without loss of patient-driven satisfaction scores.

12:00 pm Technology Providers and Solution Integrators
Christopher Larkin, CTO, GE Software
In this talk, I will describe how we are generating copious amount of data and it will be necessary to ensure real-time data acquisition as well as analytics to begin mining the optimal pathways associated with outcomes. I will review how cloud infrastructure and EMR technologies are paving the way. The current limitation is understanding the analytics and how to optimize those in a fast and expedient way to ensure HCPs and patients go through the right journey.

Sponsored By
MSD

12:15 Driving to a New Paradigm in Personalized Medicine through Multiplex Protein Biomarkers
Pankaj Oberoi, Vice President, Commercial Assays, Meso Scale Discovery
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.

12:30 Session Break

12:40 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

1:50 PANEL DISCUSSION: Integrating Information for Better Outcomes
Moderator: Christopher Larkin, CTO, GE Software
Panelists:
Richard L. Schilsky, M.D., FASCO, CMO, American Society of Clinical Oncology
Derek Raghavan, M.D., Ph.D., FACP, FRACP, FASCO, President, Levine Cancer Institute, Carolinas

COMPANION DIAGNOSTICS
CONTINUED ON NEXT PAGE

HealthCare System; Professor of Medicine, University of North Carolina School of Medicine
Christopher Larkin, CTO, GE Software
Pankaj Oberoi, Scientific Director, Meso Scale Discovery

3:00 Refreshment Break with Exhibit and Poster Viewing

PREDICTIVE ANALYTICS FOR BIG DATA AND PRECISION MEDICINE

3:30 Fusing Systems Biology and Predictive Analytics for Integration of Multi `Omic Data: Demonstration of the PATHTM Platform for Knowledge Generation

Scott Marshall, Ph.D., Managing Director, Analytics, Precision for Medicine

The future of healthcare will be transformed by flexible frameworks designed to discover complex signals in rich datasets through the merger of predictive genomic analytics and systems biology that are designed to incorporate information about molecular and cellular systems across multi `omic data. PATH™ a secure, scalable, cloud-based solution for predictive genomic analytics serves as a knowledge generation platform for translational and clinical research.

4:00 Application of Pharmacogenomic in Non-Oncology Areas: Why Is It So Hard?

Eric Lai, Ph.D., Senior Vice President and Head, Pharmacogenomics, Companion Diagnostics, Takeda Development Centers of America

Pharmacogenomics has been applied successfully in mainly oncology but not in other therapeutic areas. This presentation will examine some of the factors that are limiting the use of pharmacogenomics in non-oncology areas.

4:30 PANEL DISCUSSION

5:00 Reception with Exhibit and Poster Viewing

6:00 Close of Day

FRIDAY, MARCH 11

8:00 am Morning Coffee

STANDARDS FOR NGS-BASED TESTING

8:25 Chairperson's Remarks

John D. Pfeifer, M.D., Ph.D., Vice Chair & Professor, Pathology & Immunology, Washington University

8:45 The Payer's Need for Standards

Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)

Palmetto's MolDX is a pilot program launched in 2011 that attempts to make more transparent, consistent and robust the mechanisms by which molecular tests are coded, covered, and reimbursed. During this presentation, we will briefly review the technical assessment process at MolDX

9:05 Using Plasmid-Based Materials as Multiplex Quality Controls and Calibrators for Clinical Next-Generation Sequencing Assays

Jason Lih, Ph.D., Principal Scientist, Molecular Characterization & Clinical Assay Development Laboratory (MoCha), Frederick National Laboratory for Cancer Research

Though the next-generation sequencing technologies have been widely adapted for clinical diagnostic applications, an urgent need exists for multiple-analyte control materials to evaluate and monitor the assays' performance. Control materials play a major role in the assessment and improvement for developing assays and serve as standards for cross lab/platform comparison study. A plasmid-based control materials approach will be reported to provide effective multi-analyte controls for clinical NGS assays.

9:25 *In silico* Datasets as Multiplex Quality Controls and Calibrators for Clinical Next-Generation Sequencing Assays

John D. Pfeifer, M.D., Ph.D., Vice Chair & Professor, Department of Pathology, Washington University

Biologic control specimens challenge both the "wet lab" and "bioinformatic" aspects of NGS tests. However, it is difficult to use biologic specimens to comprehensively evaluate the full spectrum of mutations, range of variant allele frequencies, and multiple genetic loci characteristic of NGS assays. *In silico* datasets (i.e., NGS sequence files manipulated by computerized algorithms to introduce a spectrum of sequence variants) are ideal standards for the "bioinformatic" aspects of clinical NGS assays from alignment through variant detection, annotation, and interpretation, and thus are complimentary to biologic specimens as multianalyte controls.

9:45 PANEL DISCUSSION

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break with Exhibit and Poster Viewing

ESTABLISHING COMPANION DIAGNOSTICS ACROSS TARGETED IMMUNOTHERAPIES

11:00 Moderator's Remarks

James R. Mansfield, Global Head, Imaging, Quantitative Pathology Solutions, PerkinElmer

11:05 Establishing a PD-L1 Companion Diagnostic for Opdivo, a Novel Immune Checkpoint Inhibitor for the Treatment of Cancer

Steven D. Averbuch, M.D., Vice President, Development, Oncology & Pharmacodiagnostics, Bristol-Myers Squibb

PD-L1 expression on the membrane surface of solid tumors may correlate with the efficacy of PD-1 pathway inhibitors. Nivolumab is a fully human IgG4 PD-1 immune checkpoint inhibitor antibody that selectively prevents interaction with PD-L1 and PD-L2 to inhibit the suppression of antitumor T-cell function. A comprehensive analytical and clinical evaluation of PD-L1 expression by IHC to determine the association between expression and clinical outcome for Nivolumab will be described.

11:20 A Critical Appraisal of Biomarkers for Immune Therapy: The Pathologist's Perspective

Robert A. Anders, M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins School of Medicine; Director, Liver Pathology, Division of Gastrointestinal and Liver Pathology, Johns Hopkins Hospital

Dr. Anders will summarize the current understanding of immune checkpoint inhibitors. The mechanism of action of check point inhibitors targeting PD-1/PD-L1 and CTLA will be the focus of the discussion. Particular emphasis will be on gastrointestinal malignancies. He will discuss the challenges in developing prognostic and predictive biomarkers in patient derived tissues.

11:35 Developing an Immunohistochemistry Test for "Programmed Cell Death 1 Ligand" (PD-L1) as a Companion Diagnostic for Pembrolizumab

Kenneth Emancipator, M.D., Executive Medical Director, Molecular Biomarkers and Diagnostics, Merck Research Laboratories

Tumors express PD-L1 to contribute to escape from immunosurveillance. Pembrolizumab blocks this escape mechanism and thus effectively treats a number of cancers. The rapid clinical development of pembrolizumab required rapid development of an immunohistochemistry assay for PD-L1. Merck developed the assay initially to determine whether or not PD-L1 is a predictive biomarker, then to enrich clinical trials, and ultimately partnered with a diagnostics company to develop the assay as a companion diagnostic.

11:50 PANEL DISCUSSION

12:30 pm Close of Symposium

Cambridge Healthtech Institute's Inaugural

COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS

Strategies and Case Studies for Successful Product Development

THURSDAY, MARCH 10

7:30 am Registration and Morning Coffee

THE ECONOMICS OF PRODUCT DEVELOPMENT

9:00 Chairperson's Opening Remarks
Lyssa Friedman, Consultant, Lyssa Friedman Consulting

9:10 The Economics of Molecular Diagnostics: Addressing the Challenges to Commercial Success
John Beeler, Ph.D., Vice President, Business Development, Inivata
This presentation will discuss the unique challenges of bringing molecular tests to market and review the current landscape and proposed initiatives to foster continued investment of innovative molecular diagnostic products.

9:40 Developing the Reimbursement Story: It's Never Too Early
Lyssa Friedman, Consultant, Lyssa Friedman Consulting
A novel diagnostic is developed from a previously unimagined discovery. The market is untapped, the unmet medical need is vast. Yet, without a clear reimbursement story and the published studies needed to tell it, the business opportunity will likely fizzle. This session will explore study design to support the reimbursement case and strategies for addressing reimbursement early in the development process.

10:10 The Role of Cost Effectiveness in Health Technology Assessments - Overcoming Parti Pris in Payer Policy Determinations
John W. Hanna, MBA, Vice President, Endocrinology, Veracyte, Inc.
As pressure on healthcare costs increases laboratories must demonstrate that the addition of molecular diagnostics do more than add costs, that they change patient management and health outcomes. Molecular tests are perceived by payers to be expensive relative to traditional lab services. This talk will review how to overcome perceptions related to cost effectiveness when undergoing a health technology assessment with a healthcare payer.

10:40 Coffee Break with Exhibit and Poster Viewing

11:15 Leveraging Coordinated Care Technologies to Achieve Healthcare Economics
Sponsored By XIFIN
Chrystal Adams, Assistant Vice President, Product Line Management, Marketing, XIFIN, Inc.
Recent studies reveal that physicians are not able to access the expertise and collaboration they require to ensure accurate diagnostics. As reimbursement patterns shift from fee-for-service to value-based care, achieving improved outcomes will require a continued digital transformation.

11:30 Sponsored Presentation *(Opportunity Available)*

11:45 PANEL DISCUSSION: Business Models to Optimize Commercial Success
Moderator: John W. Hanna, MBA, Vice President, Endocrinology, Veracyte, Inc.
Panelists: Bill Cook, Principal, Diagnostics Commercialization, WECA
Topics for discussion include:
- Partnerships
- Economics of product development
- Reimbursement and regulatory hurdles

12:30 pm Session Break

12:40 Luncheon Presentation: CDx Commercialization - What You Need to Understand Before You Develop Strategy and What to Monitor When You Launch
Sponsored By Diaceutics GROUP
Peter Keeling, Chief Executive Officer, Diaceutics Group
Pharma teams need to understand what analytics, insights and data are needed to inform strategy and ensure a successful target therapy launch. Diaceutics will share the company's experience and learnings from more than 10 years of targeted therapy commercialization projects.

1:15 Session Break

PERSONALIZED MEDICINE TECHNOLOGIES

1:50 Chairperson's Remarks
Mara G. Aspinall, Executive Chairman, GenePeeks

2:00 Delivering on the Promise of Personalized Medicine Technologies
Josephine N. Harada, Ph.D., MBA, Senior Director, Strategic Alliances, 10X Genomics
While the diagnostic requirements of personalized medicine are increasingly well understood, significant limitations remain in the ability of conventional molecular diagnostic technologies to serve the clinical and commercial requirements of the field. This presentation will review how key challenges may be addressed by new technologies that disrupt the status quo and improve genome analysis in comparison to current diagnostic systems.

COMMERCIALIZING COMPANION DIAGNOSTICS

2:30 Companion Diagnostics – The Breakthrough that We Have Been Waiting For?
Mara G. Aspinall, Executive Chairman, GenePeeks
Diagnostics and Companion Diagnostics have finally emerged – or have they? Pharma is paying for them, scientists are improving them and venture capitalists are funding them. Yet, physicians are not using them regularly, medical schools are not teaching them, regulators are perplexed by them, and payors are looking for ways to pay less for them. What is happening? Will Companion Diagnostics bridge this real and perceived gap in respect and recognition?

ORGANIZED BY: Cambridge HEALTHTECH Institute

COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS
CONTINUED ON NEXT PAGE

3:00 Refreshment Break with Exhibit and Poster Viewing

STRATEGIES FOR BRINGING DIAGNOSTICS TO MARKET

Sponsored By
BOSTON HEALTHCARE

3:30 Global Commercialization of Companion Diagnostics: Value Capture in Personalized Medicine

Joseph Ferrara, President, Boston Healthcare Associates

How can a global drug launch best embed companion test commercial considerations? Key commercialization factors for pharmaceutical and diagnostics innovators will be highlighted, including balancing test access and quality, effective commercial partnerships, and navigating evolving test funding models.

4:00 Business Strategies to Bring Diagnostics to Market

Keith F. Batchelder, M.D., CEO & Founder, Genomic Healthcare Strategies

Peter Miller, COO, Genomic Healthcare Strategies

Traditional business models for bringing diagnostics to market still work, but market changes make success difficult for developers, marketers, and investors. The traditional model is flawed: academic discovery of a biomarker, followed by licensing to a large firm or founding of a company to productize the biomarker, with the goal of finding bench space in a large reference lab. There are many more opportunities and paths today; routes to market access will be very different than in the past.

This talk focuses on business considerations and on strategy, not tactics.

We will discuss:

- Common approaches which often are not successful, with examples
- The difference between tactics and strategy
- A strategic process, with examples
- Necessary candidate characteristics
- Inertia and traditional practice
- Some discussion of the changes in roles of patients, payors, and providers will influence diagnostics

5:00 Reception with Exhibit and Poster Viewing

6:00 Close of Day

FRIDAY, MARCH 11

8:00 am Morning Coffee

IMPLEMENTING NGS: COMMERCIAL AND CLINICAL LABORATORY CHALLENGES

8:25 Chairperson's Remarks

Scott C. Palmer, Vice President, Life Sciences, Parthenon-EY, Ernst & Young LLP

8:30 Global Innovation and Advancement of NGS

Scott C. Palmer, Vice President, Life Sciences, Parthenon-EY, Ernst & Young LLP

As NGS transitions from the research bench to the clinic, NGS companies will need to develop new strategies while pharmaceutical companies will need to proactively develop partnerships in order to fully maximize the potential of personalized medicine. Lastly, established and emerging companies will need to innovate rapidly as next-next generation sequencing comes to fruition.

9:00 PANEL DISCUSSION: Implementing NGS: Commercial and Clinical Laboratory Challenges

Moderator: Scott C. Palmer, Vice President, Life Sciences, Parthenon-EY, Ernst & Young LLP

Panelists:

Josephine N. Harada, Associate Director, Alliances, Illumina

The NGS space is evolving rapidly, with new tests and new technologies coming online at an ever-accelerating pace. According to Richard Klausner, Chief Medical Officer of Illumina, we are moving out of the era of companion diagnostics and into the era of companion therapeutics. This panel will address:

- Getting started with NGS: From cost to assays
- Technological limitations
- Integration into routine workflow
- Developing the infrastructure needed to sustain an NGS program
- Partnerships

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break with Exhibit and Poster Viewing

STRATEGIES FOR SUCCESSFUL COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS

11:00 Accelerating Molecular Diagnostic Programs

Bill Cook, Principal, Diagnostics Commercialization, WECA

The commercialization of molecular diagnostics from initial proof of clinical utility through commercial product launch and market development poses many hidden obstacles. We will explore the use of a Commercialization Roadmap to identify and address these critical issues.

11:30 pm Late Breaking Presentation

12:00 Close of Symposium

ORGANIZED BY: Cambridge HEALTHTECH Institute

CLICK HERE TO REGISTER ONLINE!
TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

SPONSOR, EXHIBIT & LEAD GENERATION OPPORTUNITIES

Sponsorship, Exhibit, and Lead Generation Opportunities

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 promotional opportunities are available, including:

- 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?

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

For sponsorship and exhibit information, please contact:

Companies A-K

Jon Stroup
Senior Manager, Business Development
781-972-5483
jstroup@healthtech.com

Companies L-Z

Joseph Vacca
Associate Director, Business Development
781-972-5431
jvacca@healthtech.com

Current Sponsors & Exhibitors As of October 7th, 2015

Abcam
Almac Group
ALS Automated Lab Solutions GmbH
Analytical Biological Services, Inc. (ABS)
Analytik Jena/UVP LLC
ANGLE plc
Aspera, an IBM Company
Asterand BioScience, Inc.
Asuragen
Atlas Genetics Ltd.
Axxin
Bina Technologies, part of Roche Sequencing
BIO | OPTIONS, INC.
BioCartis
Biocept
BioLine USA
Biological Dynamics, Inc.
Biomatters
Bioneer, Inc.
Bio-Rad
BioView USA inc.
Boston Healthcare Associates
Canon Biomedical
CareDx, Inc.
CHI Center for Translational Research
Cell Signaling Technology, Inc.
Cellecta
Champions Oncology
Charles River
Conversant Biologics
Copan Diagnostics
Core Informatics
Covaris, Inc.
Coyote Bioscience
Creatv MicroTech, Inc.
Cureline, Inc.
CureSeq, Inc.
Defi niens, Inc.
DeNovo Sciences
DiaCarta, Inc.
Diagenode, Inc.
Diversigen, Inc.
DNA Genotek Inc.
Dotmatics
Elsevier, Inc.
Enigma Diagnostics Ltd
Envision Genomics
Epic Sciences
Epistem Ltd.
Exosome Diagnostics
Fluxion Biosciences
Folio Biosciences
Geneticist Inc.
Glencoe Software, Inc.
GPB Scientific, LLC
Hemosure
Hochuen International Corp.
Horizon Discovery
iCubate®
Illumina
Indica Labs
Isohelix
The Jackson Laboratory
Janssen Diagnostics, LLC
JSR Life Sciences
Kellison & Company
KMC Systems, Inc.
LGC Biosearch Technologies
Lifecode, Inc.
Link Technologies Ltd
LucigenDx
LRE Medical
Macrogen Clinical Laboratory
Maverix Biomics, Inc.
Mawi DNA Technologies
Meso Scale Discovery
Metabolon, Inc.
Metanomics Health
Miltenyi Biotec
MiniFAB
Molecular Health
Molecular Match
Multisorb Technologies
Myriad RBM
Nanostring Technologies
NeoGenomics Laboratories
Nodality, Inc.
Norgen Biotek Corp.
Novodiax
NuGEN Technologies, Inc.
Oasis Diagnostics® Corporation
Oncodesign
PerkinElmer, Inc.
Personal Genome Diagnostics
Precision *for* Medicine
ProteoGenex, Inc.
Quansys Biosciences
Quanterix
RainDance Technologies
Rarecells Diagnostics SAS
ResearchDx, LLC
Sampleminded - Laboratory Mission Control
Scienion
ScreenCell
Sequenom Laboratories
SeraCare
Seven Bridges Genomics
Siemens Healthcare Diagnostics, Inc.
Silicon Biosystems
Simulations Plus, Inc.
Singulex, Inc.
Smart Lab Diagnostics
SomaLogic
Sony DADC
STRATEC Molecular GmbH
Streck
SurModics IVD
Swift Biosciences
Symbient Product Development
T2 Biosystems
Taconic Biosciences
Tepnel Pharma Services
thinXXS Microtechnology AG
Thomson Reuters
Transgenomic
tranSMART Foundation
TriMetis Life Sciences
Trovagene
UNIConnect
Wi
Xcell Biosciences Inc.
XIFIN, Inc.

CLICK HERE TO REGISTER ONLINE!

TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

HOTEL & TRAVEL INFORMATION

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

Conference Hotel:
Hilton San Francisco Union Square
333 O'Farrell Street
San Francisco, CA 94102
Phone: 1-800-HILTONS

RESERVATIONS:
Click here to make your reservations

Discounted Room Rate: $279/ $299/ $329 s/d
Discounted Cut-off Date: February 8, 2016

Click here for additional information

Media Partners

Official Media Sponsors:

Bio·IT World | Clinical Informatics News – Clinical Trials to the Clinic | Diagnostics World

Lead Sponsoring Publications:

Drug Discovery Today | Insight Pharma Reports – Expert Intelligence for Better Decisions | Science – AAAS

Sponsoring Publications:

bioquick news | DDNews | drug target review | PharmaVOICE

Web Partners:

AllSeq | Big3Bio | BioSpace.com – Global Infosite for the life sciences | CanBiotech – Biotechnology Portal & B2B Marketplace | DNAvaccine.com | EIN News – a digital news provider | genomeweb | Global BioDefense | mendelspod.com | NGS Leaders – A Community for Next Generation Sequencing Pioneers

Sponsoring Organizations and Associations:

AMP – Association for Molecular Pathology | api Pathology Informatics | CLSA – California Life Sciences Association | Digital Pathology DPA Association | ISCB – International Society for Computational Biology – Affiliated Conference

CLICK HERE TO REGISTER ONLINE!

TriConference.com

ORGANIZED BY: Cambridge HEALTHTECH Institute

TRI-CON ALL ACCESS PACKAGE - BEST VALUE! (MARCH 6-11)

Includes: 2 Short Courses, 1 Conference Program, and 1 Symposia	Commercial	Academic, Government, Hospital-affiliated
Registrations after February 5th and onsite	$3,295	$2,199

REGULAR PRICING - A LA CARTE OPTIONS

SHORT COURSES (MARCH 6, 7, 10)

1 Short Course	$750	$475
2 Short Courses	$1,025	$825

Sunday, March 6

SC1: Translating CTCs to Clinical Use
SC2: Microbiomics
SC3: NGS Assay Selection, Validation and Compliance
SC4: Sequencing 101
SC6: Reimbursement for Advanced Diagnostics: From Clinical Value Establishment to Coding, Coverage And Pricing
SC9: Clinical Informatics: Returning Results from Big Data
SC10: Development of Cell-Based Bioassays for Checkpoint Inhibitor Targeting
SC11: Regulatory Compliance in Molecular Diagnostics - Detailed Agenda
SC12: Digital PCR: Applications and Advances
SC13: Liquid Biopsy Technologies Overview

Monday, March 7

SC17: Commercialization Boot Camp: Manual for Success in Molecular Diagnostics
SC18: Next-Generation Sequencing as a Diagnostics Platform
SC19: Isolation and Characterization of Cancer Stem Cells
SC20: Translating Preclinical Data in the Rational Design of Cancer Combination Therapies
SC21: Best Practices in Personalized and Translational Medicine
SC22: NGS for Infectious Disease Diagnostics
SC23: Metabolic Microbiome

Thursday, March 10

SC25: Detection and Characterization of Circulating Biomarkers
SC26: A Primer to Gene Editing: Tools and Applications

CONFERENCE PROGRAMS (MARCH 7 - 9)

Registrations after February 5th and onsite	$2,495	$1,399

DIAGNOSTICS CHANNEL

P1: Molecular Diagnostics
P2: Personalized Diagnostics
P3: Cancer Molecular Markers
P4: Circulating Tumor Cells
P5: Digital Pathology
P6: Precision Medicine – NEW
P7: PCR for Molecular Medicine
P8: Clinical NGS Diagnostics
P9: Genomic Sample Prep and Biomarker Assay Development
P10: Molecular Diagnostics for Infectious Disease – NEW

GENOMICS CHANNEL

P6: Precision Medicine - NEW
P7: PCR for Molecular Medicine
P8: Clinical NGS Diagnostics
P9: Genomic Sample Prep and Biomarker Assay Development

CANCER CHANNEL

P3: Cancer Molecular Markers
P4: Circulating Tumor Cells
P11: Cancer Immunotherapy – NEW
P12: Predictive Preclinical Models in Oncology

INFORMATICS CHANNEL

P13: Bioinformatics for Big Data
P14: Integrated Informatics Driving Translational Research & Precision Medicine

SYMPOSIA (MARCH 10-11)

Symposia Pricing	$1,495	$1,095

S1: New Frontiers in Gene Editing
S2: Circulating Cell-Free DNA
S3: Point-of-Care Diagnostics
S4: Biomarkers for Cancer Immunotherapy
S5: Genomics & Sequencing Data Integration, Analysis and Visualization
S6: Companion Diagnostics – NEW
S7: Commercialization of Molecular Diagnostics – NEW

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

CONFERENCE DISCOUNTS

CLSA 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:

January 8, 2016
Printed Program Guide and Electronic Program Materials

February 5, 2016
Electronic Program Materials only

Please click here for details.

All poster abstracts are due no later than February 5, 2016.

REGISTER 3 - 4TH IS FREE:
Individuals must register for the same conference or conference combination and submit completed registrationform 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.