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2017 EVENT-AT-A-GLANCE

EVENTS AT THE MOSCONE NORTH CONVENTION CENTER

SUNDAY, FEBRUARY 19

1:00 pm Registration Open at Moscone North Convention Center
2:00 – 5:00 pm Afternoon Short Courses
5:30 – 8:30 pm Dinner Short Courses
8:30 pm Close of Day

MONDAY, FEBRUARY 20

7:00 am Registration Open and Morning Coffee
8:00 – 11:00 am Morning Short Courses
11:50 am – 1:00 pm Conference Programs
1:10 – 2:10 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, FEBRUARY 21

7:30 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 Dessert Reception in the Exhibit Hall with Poster Viewing
5:00 – 6:00 pm Breakout Discussions in the Exhibit Hall
6:00 pm Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open and Morning Coffee
7:00 am Breakfast Presentations
8:00 – 10:00 am Plenary Keynote Session
10:00 – 10:50 am Refreshment Break & Poster Competition Winners 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 – 5:15 pm Conference Programs
5:15 Close of Conference Programs
5:15 Registration Open at Moscone South Convention Center for Dinner Short Courses
6:00 – 9:00 pm Dinner Short Courses

EVENTS AT THE MOSCONE SOUTH CONVENTION CENTER

THURSDAY, FEBRUARY 23

7:00 am Registration Open and Morning Coffee
8:25 am – 6:45 pm Symposia Programs
10:30 – 11:15 am Coffee Break with Exhibit and Poster Viewing
12:40 – 1:15 pm Luncheon Presentations or Lunch on Your Own
3:30 – 4:15 pm Refreshment Break & Poster Competition Winner Announced in the Exhibit Hall
5:45 – 6:45 pm Reception with Exhibit and Poster Viewing
6:45 Close of Day

FRIDAY, FEBRUARY 24

8:00 Registration Open
8:00 Breakfast Presentations or Morning Coffee
8:25 am – 12:45 pm Symposia Programs
10:30 – 11:15 am Coffee Break with Exhibit and Poster Viewing
12:45 pm Close of Symposia & Molecular Medicine Tri-Conference

CONFERENCE PROGRAMS

DIAGNOSTICS CHANNEL

Molecular Diagnostics
Personalized Diagnostics
Cancer Molecular Markers
Circulating Tumor Cell and Liquid Biopsy
Digital Pathology
Precision Medicine
PCR & NGS-Based Molecular Diagnostics
Clinical NGS Diagnostics
Genomic Sample Prep, Assay Development and Validation
Molecular Diagnostics for Infectious Disease

CANCER CHANNEL

Cancer Molecular Markers
Circulating Tumor Cells and Liquid Biopsy
Cancer Immunotherapy
Combination Immunotherapy Design Models

GENOMICS CHANNEL

Precision Medicine
PCR & NGS-Based Molecular Diagnostics
Clinical NGS Diagnostics
Genomic Sample Prep, Assay Development and Validation

INFORMATICS CHANNEL

Bioinformatics for Big Data
Integrated Pharma Informatics

SYMPOSIA

New Frontiers in CRISPR-Based Gene Editing
Circulating Cell-Free DNA
Point-of-Care Diagnostics
Biomarkers for Cancer Immunotherapy
NGS Diagnostics: Knowledge Bases, Annotation and Interpretation
Microbiome-Based Precision Medicine - NEW
Commercialization of Molecular Diagnostics

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PLENARY KEYNOTE PRESENTATIONS

MONDAY, FEBRUARY 20 | 5:00 – 6:00 PM

5:05 Chairperson/Moderator Remarks

Allison Proffitt, Editorial Director, Bio-IT World

5:10 Plenary Keynote Presentation:
One in a Billion: The Story of Nic Volker and the Dawn of Genomic Medicine

Amylynne Santiago Volker, Founder, Nicholas Volker One In A Billion Foundation

Liz Worthey, Ph.D., Faculty Investigator and Director, Software Development & Informatics, HudsonAlpha Institute for Biotechnology

Kathleen Gallagher, Reporter, Milwaukee Journal Sentinel; Co-Author, One in a Billion: The Story of Nic Volker and the Dawn of Genomic Medicine

Nic Volker had a never-before-seen disease and a mother who would stop at nothing to ensure his survival. Amylynne Santiago Volker; Kathleen Gallagher, one of two Pulitzer Prize-winning reporters who chronicled the case; and Liz Worthey, the bioinformatician who searched Nic's exome for an answer, discuss the pioneering effort to save Nic by obtaining a diagnosis from exome sequencing. They will also tell the story of how Amylynne's fierce advocacy during her desperately ill son's more than three year diagnostic odyssey helped get him to the doctor who saw that Nic's mysterious disease likely had genetic underpinnings.

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

TUESDAY, FEBRUARY 21 | 8:00 – 9:00 AM

8:00 Organizer Remarks

Cindy Crowninshield, RDN, LDN, Senior Conference Director, Cambridge Healthtech Institute, a division of Cambridge Innovation Institute

8:05 Keynote Introduction: Next-Generation Precision Molecular Diagnostics Powered by XNA

Michael J. Powell, Ph.D., CSO, DiaCarta

DiaCarta's XNA-based platforms are revolutionizing oncology diagnostics and precision medicine. QClamp® is a qPCR method that rapidly and sensitively detect mutations in tumor-derived DNA. OptiSeq(TM) is an innovative NGS application of gene locus specific XNA's to detect tumor 'hotspot' mutations with exquisite precision and sensitivity from liquid biopsy and FNA samples. XNA technology also enhances the screening for CRISPR/Cas9 gene-editing and improves NGS library preparation.

8:15 Plenary Keynote Presentation: Tumor Elicited Inflammation in Colorectal Cancer - the gp130-YAP Connection

Michael Karin, Ph.D., Distinguished Professor of Pharmacology, University of California, San Diego School of Medicine

Dr. Karin received his BSc in Biology in 1975 at Tel Aviv University, Tel Aviv, Israel and his Ph.D. in Molecular Biology in 1979, at the University of California, Los Angeles. Dr. Karin is currently a Distinguished Professor of Pharmacology and Pathology at the School of Medicine, University of California, San Diego, where he has been on the faculty since 1986. Dr. Karin has received numerous awards including the Oppenheimer Award for Excellence in Research from the Endocrine Society in 1990, an American Cancer Society Research Professorship in 1999, the C.E.R.I.E.S. Research Award for Physiology or Biology of the Skin in 2000, the Harvey Prize in Human Health in 2011, the Brupbacher Prize in Cancer Research in 2013 and the William B. Coley Award for Distinguished Research in Basic and Tumor Immunology in 2013. He was a cofounder of Signal Pharmaceuticals (currently Celgene) and served as a member of the National Advisory Council for Environmental Health Sciences. He has been an American Cancer Society Research Professor since 1999. Dr. Karin was elected as a member of the US National Academy of Sciences in 2005, the Institute of Medicine in 2011 and as an associate member of the European Molecular Biology Association in 2007. Much of Dr. Karin's current activity is focused on understanding the link between inflammation, cancer and metabolic disease as well as on understanding the signaling mechanisms used by receptors involved in inflammation and innate immunity. In addition to establishing molecular links between obesity, inflammation and cancer, this work has revealed new targets for cancer prevention and therapy.

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

WEDNESDAY, FEBRUARY 22 | 8:00 – 10:00 AM

Plenary Session Panel: Emerging Technologies and Industry Perspectives

Moderator/Chairperson: Keith F. Batchelder, M.D., CEO and Founder, Genomic Healthcare Strategies

Panelists:

Christopher Mueller, Ph.D., President & CTO, Lab7 Systems

Christopher Ianelli, M.D., Ph.D., Founder & CEO, iSpecimen

Dick Rubin, Vice President, Sales & Marketing, Accel Biotech LLC

Joe Ferrara, President, Boston Healthcare

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

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

Sean Ferree, Ph.D., Vice President, Diagnostic Development, NanoString Technologies

Farideh Bischoff, Ph.D., Chief Clinical Development Officer, North America Menarini Silicon Biosystems

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.

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SHORT COURSES*

THE MOSCONE NORTH N CONVENTION CENTER

SUNDAY, FEBRUARY 19, 2017 | 2:00 - 5:00 PM

SC1: Translating CTCs for Clinical Use

Joshua M. Lang, M.D., MS, Assistant Professor of Medicine, Carbone Cancer Center, University of Wisconsin

Amado Zurita-Saveedra, M.D., Associate Professor, MD Anderson

Benjamin Casavant, Ph.D., Vice President, Tasso

SC2: NGS Assay Selection, Validation and Compliance

Co-organized with AMP

Eric Duncavage, M.D., Assistant Professor, Pathology & Immunology, Washington University School of Medicine (AMP 2016 Training & Education Committee, Member)

Christina Lockwood, Ph.D., DABCC, FACB, Assistant Professor, Department of Laboratory Medicine; Associate Director, Genetics and Solid Tumor Diagnostics Laboratory, University of Washington (AMP Member)

Shashikant Kulkarni, Ph.D., Professor, Molecular and Human Genetics; Co-Vice Chair, Research, Molecular and Human Genetics, Baylor College of Medicine; CSO, Baylor Miraca Genetics Laboratories; Vice President, Operations, Baylor Miraca Genetics Laboratories (AMP Member)

SC3: Sequencing 101

Ryan Kim, Ph.D., Director, Korean Bioinformatics Center (KOBIC), Korea Research Institute of Bioscience & Biotechnology (KRIBB)

SC4: Coverage and Reimbursement for Advanced Diagnostics

Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)

Katherine Tynan, Ph.D., Tynan Consulting LLC

Kurt Matthes, Vice President, RCM Reengineering and Service, Revenue Cycle Management, TELCOR, Inc.

Additional Instructors to be Announced

SC5: Genomics in Drug Discovery and Development: Pharmaceutical Applications of NGS

Oleg Iartchuk, Genomics and NGS, Ph.D., Novartis Institutes for BioMedical Research, Inc.

Additional Instructors to be Announced

SC6: Method Validation According to CLSI Guidelines

Shuguang Huang, Ph.D., CSO, Stat4ward LLC

SC7: Emerging Single Cell Analysis Techniques

Peter Sims, Ph.D., Assistant Professor, Systems Biology, Columbia University Medical Center

Patrizia Paterlini-Brechot, M.D., Ph.D., Professor, Faculty of Medicine, University Paris Descartes

Rajiv Pande, Ph.D., President and CEO, Smpl Bio

THE MOSCONE NORTH N CONVENTION CENTER

SUNDAY, FEBRUARY 19, 2017 (CONT.)
5:30 - 8:30 PM | DINNER SHORT COURSES

SC9: Clinical Informatics: Returning Results from Big Data

Co-organized with AMP

Mark J. Routbort, M.D., Ph.D., Associate Professor, MD Anderson Cancer Center (AMP Informatics Subdivision Representative to the AMP 2017 Clinical Practice Committee)

Somak Roy, M.D., Assistant Professor, Director, Genetic Services and Molecular Informatics; Assistant Director, Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center (AMP Informatics Subdivision Representative to the AMP 2017 Program Committee)

Annette Meredith, Ph.D., Color Genomics, Inc. (AMP Informatics Subdivision Representative to the AMP Global 2017 Organizing Committee)

SC10: Regulatory Compliance in Molecular Diagnostics

Hisani Madison, Ph.D. MPH, Scientific Reviewer, Division of Molecular Genetics and Pathology, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, U.S. Food and Drug Administration

Pamela L. Swatkowski, Director, Regulatory Affairs, Abbott Molecular, Inc.

Melina Cimler, Ph.D., Senior Vice President, Quality & Regulatory, Adaptive Biotechnologies

SC11: Liquid Biopsy Technologies and Applications

Theresa Zhang, Ph.D., Vice President, Research Services, Personal Genome Diagnostics

Hatim Husain, M.D., Physician, Medical Oncology, University of California, San Diego

SC13: Humanized Mouse Models for Pre-Clinical Assessment of Cancer Immunotherapy

Michael Brehm, Ph.D., Associate Professor, The Robert and Sandra Glass Term Chair in Diabetes, Diabetes Center of Excellence, Program in Molecular Medicine, University of Massachusetts Medical School

Barbara Joyce-Shaikh, Associate Principal Scientist, Merck Research Laboratories

SC14: Development of Bioassays for Checkpoint Immunotherapy

Mei Cong, Ph.D., Director, R&D Custom Assay Services, Promega

Additional Instructors to be Announced

SC15: Digital PCR: Applications And Advances

Rebecca Sanders, Ph.D., Researcher, Molecular Biology, LGC

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MONDAY, FEBRUARY 20, 2017 | 8:00 - 11:00 AM

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

Harry Glorikian, Healthcare Consultant

Stan Skrzypczak, Vice President, Corporate Development and Reimbursement, Guardant Health, Inc.

SC18: From Idea to Industry: A History of CAR T-Cells to Where We Are Today, and the Challenges of Commercialization

Ronald P. Dudek, President, Living Pharma, Inc.

Yeong (Christopher) Choi, Ph.D., Assistant Professor, Oncology; Member, Center for Immunotherapy; Director, cGMP Therapeutic Cell Production Facility, Roswell Park Cancer Institute

Cenk Sumen, Ph.D., Senior Manager, Business Development, PCT, a Caladrius company

SC19: Next-Generation Sequencing as a Diagnostics Platform

Karl V. Voelkerding, M.D., Professor of Pathology, University of Utah School of Medicine

Tina Hambuch, Ph.D., FACMG, Medical Director, Pediatric Genetics

Eric Konnick, M.D., MS, FCAP, Acting Assistant Professor, Associate Director, Genetics and Solid Tumor Laboratory Department of Laboratory Medicine University of Washington

SC20: Translating Preclinical Data in the Rational Design of Cancer Combination Therapies

Arijit Chakravarty, Ph.D., CEO, Fractal Therapeutics

SC21: Best Practices in Personalized and Translational Medicine

Andrew J. Mills, Senior Director, Sponsor Solutions, FIRECREST, ICON plc
Mark Evans, Associate Director, Technology Innovation & Bioinformatics, XOMA (US) LLC
Tom Plasterer, Ph.D., US Cross-Science Director, R&D Information, AstraZeneca
Additional Instructors to be Announced

SC22: NGS for Infectious Disease Diagnostics

Charles Chiu, M.D., Ph.D., Associate Professor, Laboratory Medicine and Medicine/ Infectious Diseases, University of California, San Francisco

SC23: NIPT: What's Next in Technology Development

Peter Benn, Ph.D., Professor, Genetics and Genome Sciences, University of Connecticut Health Center

Megan Allyse, Ph.D., Assistant Professor of Biomedical Ethics, The Mayo Clinic

Mark Evans, M.D., President, Fetal Medicine Foundation of America; Professor of Obstetrics and Gynecology, Mt. Sinai School of Medicine; Comprehensive Genetics

Mathias Ehrich, Ph.D., Senior Vice President, Research and Development, Sequenom

SC24: Flow Cytometry and Phenotypic Cell Analysis in Immuno-Oncology

Nathan Standifer, Ph.D., Scientist II, Clinical Pharmacology and DMPK, MedImmune

Mark Edinger, Scientific Advisor, Flow Cytometry, Q Squared

Yoav Peretz, Ph.D., Scientific Director, Caprion Biosciences, Inc. (Formerly ImmuneCarta Services Inc.)

WEDNESDAY, FEBRUARY 22, 2017
6:00 - 9:00 PM | DINNER SHORT COURSES

SC25: Technologies, Applications and Commercialization of Point-of-Care Diagnostics

Holger Becker, Ph.D., Founder & CSO, microfluidic ChipShop GmbH

SC26: Detection and Characterization of Circulating Biomarkers

Catherine Alix-Panabières, Ph.D., Director, Laboratory of Rare Human Circulating Cells (LCCRH), Cellular and Tissular Biopathology of Cancers, University Medical Center of Montpellier

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

SC27: A Primer to Gene Editing: Tools and Applications

Fuguo Jiang, Ph.D., Damon Runyon Research Fellow, Laboratory of Dr. Jennifer Doudna, Department of Molecular and Cell Biology, University of California, Berkeley

Michael Bassik, Ph.D., Assistant Professor, Department of Genetics, Stanford University

Krishanu Saha, Ph.D., Assistant Professor, Department of Biomedical Engineering, & Wisconsin Institute for Discovery, University of Wisconsin-Madison

SC28: Genomics in the Service of Cancer Immunotherapy - Connecting DNA Repair, Mutational Processes and Genotoxic Therapy to Successful Cancer Immunotherapy

Zoltan Szallasi, Ph.D., M.D., Senior Research Scientist, Children's Hospital Informatics Program, Children's Hospital Boston, Harvard Medical School; Assistant Professor, Pediatrics, Harvard Medical School; Assistant Professor, Pediatrics, Boston Children's Hospital

** See registration page for pricing options.*

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DIAGNOSTICS CHANNEL

- Molecular Diagnostics
- Personalized Diagnostics
- Cancer Molecular Markers
- Circulating Tumor Cells and Liquid Biopsy
- Digital Pathology
- Precision Medicine
- PCR & NGS-Based Molecular Diagnostics
- Clinical NGS Diagnostics
- Genomic Sample Prep, Assay Development and Validation
- Molecular Diagnostics for Infectious Disease

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Cambridge Healthtech Institute's Fourteenth Annual

MOLECULAR DIAGNOSTICS

Engaging the Practice of Bespoke Medicine

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

KEYNOTE SESSION: REIMBURSEMENT STORIES

Co-organized with AMP

The roles of clinical validity and clinical utility in determining the medical usefulness of a molecular pathology testing procedure have been the subject of intensifying discussions. Qualitative criteria for clinical validity have historically been the standard for insurance coverage determinations. The variety and increasing complexity of molecular testing methodologies, especially Gene Expression Signatures and Next-Generation Sequencing (NGS) tests, are factors payers cite as reasons for comprehensive scrutiny of validity, outcomes and cost effectiveness. The practice of medicine is determined by the multidisciplinary healthcare team within a hospital/institution and represents the real battle ground where specific and individualized decisions are made involving all aspects of patient care. Often there is a disconnect between the advancing edge of the practice of individualized/personalized medicine and reimbursement policies. Examples highlighting these gaps and challenges will be presented. We will additionally explore solutions that focus on the best possible patient care under such limited reimbursement conditions and make the case for appropriate reimbursement in molecular genetic and oncology testing.

11:50 Chairperson's Opening Remarks

Victoria M. Pratt, Ph.D., FACMG, Director, Pharmacogenomics Laboratory, Department of Medical and Molecular Genetics, Indiana University School of Medicine (AMP Professional Relations Committee, Member)

Dr. Pratt will provide an overview of AMP's published framework for evidence needed for clinical utility. She will compare and contrast the successes and challenges with the lack of or limited coverage decisions from the Medicare Administrative Contractors (MACs) in the case of germline pharmacogenetics, such as CYP2D6.

12:05 pm Garnering Payer Support for Genomic Profiling by Demonstrating Clinical Utility

Pranil K. Chandra, DO, FCAP, FASCP, Vice President, Chief Medical Officer and Medical Director, Genomic and Clinical Pathology Services, PathGroup (AMP Economic Affairs Committee, Member)

Dr. Chandra will review PathGroup's experience with certain payers in garnering appropriate reimbursement. In addition, he will review how to demonstrate clinical utility through illustrative examples highlighting diagnostic, prognostic, and/or therapeutic utility across hematologic and solid tumor malignancies.

12:20 NSCLC and Other Solid Tumors: Genetic Testing and Reimbursement

Rajyasree (Raj) Emmadi, M.D., Associate Professor, Clinical Pathology, Pathology, University of Illinois, Chicago (AMP Professional Relations Committee, Member)

The story of cancer therapy has been gradually evolving with the continuing identification of subpopulations, therapeutic targets and driver and resistance mutations. In this context, Dr. Emmadi will discuss the challenges and successes of forging collaboration between the science of targeted therapy and the practical concerns of reimbursement for non-small cell lung carcinoma (NSCLC) and other solid tumors.

12:35 PANEL DISCUSSION

1:00 Session Break

1:10 Luncheon Presentation I to be Announced

1:40 Luncheon Presentation II: Integrating Computational Pathology and Tissue Analytics for Molecular Pathologyy

Sponsored by PHILIPS

Paul O'Reilly, Ph.D., Head, Research, Image Analytics, Philips Digital Pathology

Computational Pathology will be a powerful driver of change in digital health and has the potential to improve diagnostic, prognostic and predictive pathology. Building powerful and scalable algorithms for tissue analytics allows for a variety of interpretative challenges.

2:10 Session Break

PERSONALIZED/PRECISION MEDICINE: WHERE ARE WE AND WHERE ARE WE GOING?

Sponsored by PMC PERSONALIZED MEDICINE COALITION Celebrating 10 Years

2:30 Chairperson's Remarks

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

2:40 Putting Precision Medicine into Clinical Practice

David B. Roth, M.D., Ph.D., Simon Flexner Professor and Chair, Pathology and Laboratory Medicine Director, Perelman School of Medicine, University of Pennsylvania

Early studies defining the genetic basis for variable drug actions focused on outlier patients or small study groups, and more recent approaches have turned to larger DNA datasets, often coupled to electronic health records (EHRs). These large resources, in turn, have provided the starting point for new discovery in genome science and in pharmacogenomics. This talk will describe some of these advances and recent efforts to use DNA datasets coupled to EHRs to implement pharmacogenomics.

3:00 Challenges in Launching Companies in the Molecular Diagnostics

DIAGNOSTICS CHANNEL

Space
Trevor Hawkins, Ph.D., Entrepreneur in Residence, GE Ventures
More than just a capital partner, GE Ventures provides unrivaled access to a global network of GE expertise and resources. We partner and invest in the best ideas within software, healthcare, energy and advanced manufacturing. We partner with startups to accelerate growth and commercialize innovative ideas in software & analytics, healthcare, energy and advanced manufacturing that will help drive better outcomes for our customers and society. We combine capital, technical and commercial expertise, infrastructure, and access to GE's global network of business units, partners and customers, world-class training, and resources to help companies grow and scale.

3:20 Personalized/Precision Medicine: How Regulatory and Reimbursement Policies Are Influencing Growth and Adoption
Paul Radensky, M.D., Principal, McDermott+Consulting; Partner, McDermott Will & Emery
Personalized/Precision Medicine continues to provide dramatic insights into the molecular basis of disease. The nature and pace of growth in this area raise a number of challenges for regulators and payers who operate under frameworks that were created decades before PM emerged. Recent changes in both regulatory and reimbursement policy are aimed at facilitating growth and adoption of PM. Will these approaches will be effective? What additional changes are needed?

3:40 PANEL DISCUSSION

Sponsored by stratec consumables

4:10 Fully Automated Extraction of Circulating Cell-Free DNA from 4 ml of Plasma Combined with Automated Bisulfite Conversion
Christian Jurinke, Ph.D., Managing Director, STRATEC Molecular GmbH
Circulating cell-free DNA (cfDNA) is of interest in many vlications (e.g. fetal DNA in maternal plasma, or liquid biopsies). We developed an automated cfDNA extraction method for the InviGenius Plus which can be integrated with automated bisulfite conversion.

4:25 Sponsored Presentation *(Opportunity Available)*

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session (please see page 4 for details)

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

IS THE COMPANION DIAGNOSTICS MODEL FOR DRUG DEVELOPMENT WORKING?

10:05 Chairperson's Remarks
Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)
- From the perspective of different stakeholders, what are the strengths and weaknesses of companion diagnostics as an approach for drug and diagnostic development, approval and reimbursement? How can and should these challenges be addressed?
- Why are complementary diagnostics needed? What challenges with the companion diagnostic model do they solve? What new challenges do they create?
- How do different stakeholders envision these two approaches evolving?

10:10 Regulation of Companion and Complementary Diagnostics
Pamela Bradley, Ph.D., Staff Fellow, FDA

10:25 The Diagnostic Continuum of Precision Medicine
Scott D. Patterson, Ph.D., Vice President, Biomarker Sciences, Gilead Sciences, Inc.
The development and implementation of companion diagnostics (CDx) presents multiple challenges at each step. Aside from a few exceptions where the CDx is already part of the patients work-up, some of the challenges that present for a new CDx/drug combination include education across multiple stakeholder groups (physicians, payers, etc.), test availability, the use of Laboratory Developed Tests in place of the CDx, and whether competing CDx/drug combinations exist. These concepts will be introduced for discussion in the panel session.

10:40 Companion Diagnostic Strategies Are Here to Stay in Oncology
Walter H. Koch, Ph.D., Vice President, Global Research, Roche Molecular Systems
The number of targeted therapies with a companion diagnostic (CDx) test in the drug label continues to grow. The biomarker information that the CDx provides is necessary for safe and effective use of a corresponding therapeutic. Numerous examples of kinase inhibitors targeting constitutively activated mutant or overexpressed oncoproteins will be discussed as evidence that this approach will remain important in Oncology for the foreseeable future.

10:55 The Companion and Complementary Diagnostics Business Model
Peter M. Krein, Managing Director, Diaceutics Group
The hope in the clinical Dx world had been that companion Dx tests would finally solve many of the challenges that have plagued the novel molecular testing market. Instead, it has often appeared to accentuate these challenges and shone a light on the difficulties of investing in such tests: namely conflicting interests with biopharma partners, minimal returns on investment, and typically limited barriers to competitive entry. Is there a better approach?

11:10 PANEL DISCUSSION

DIAGNOSTICS CHANNEL

11:45 Reaching the Pinnacle: A Unique Cancer Diagnostic Tool that Harnesses the Power of RNA
Sponsored by COFACTOR genomics
Jon Armstrong, CSO, Cofactor Genomics
Cofactor's Pinnacle assay generates a unique molecular profile for clinical cancer samples. Pinnacle provides quantitative insight for patient stratification and clinical studies by measuring the RNA expression across 318 prominent cancer genes and identifying fusions in 283 critical cancer-associated genes.

12:15 pm Session Break

12:25 Luncheon Presentation I: Lowering the Barriers for the Practical Implementation of High Precision Medicine
Sponsored by BIOCARTIS
Rudi Pauwels, Ph.D., Founder & CEO, Biocartis

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

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

LIQUID BIOPSY - THE PROMISE AND THE PERILS

2:00 Chairperson's Remarks
Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)

- Given the current state of the art, what are appropriate clinical applications for liquid biopsy-based tests and why? How are these different for circulating tumor DNA (ctDNA)-based versus circulating tumor cell-based approaches?
- What will liquid biopsy-based test developers need to prove to various stakeholders for such tests to gain widespread adoption, regulatory approval, and payer coverage and reimbursement for these different clinical applications; for example, for selection of targeted therapies, screening for cancer, minimal residual disease monitoring, etc?

2:05 Optimizing Cancer Treatment with Liquid Biopsies: The Example of Plasma EGFR Mutation Testing in NSCLC
Walter H. Koch, Ph.D., Vice President, Global Research, Roche Molecular Systems
The FDA recently granted the first Liquid Biopsy approval to the Roche cobas® EGFR Mutation Test v2 as a companion diagnostic for the non-small cell lung cancer therapy Tarceva®. Exploratory studies show that beyond therapy selection such tests may become important in monitoring therapy response, disease progression and resistance. There is further promise that liquid biopsy approaches will one day allow minimal residual disease determination, and early detection of cancer.

2:20 Regulation of Liquid Biopsies
Pamela Bradley, Ph.D., Staff Fellow, FDA

2:35 How Payers Are Considering Liquid Biopsy
Bryan Loy, M.D., MBA, Vice President, Oncology, Laboratory, and Personalized Medicine, Health Guidance Organization, Humana
Liquid biopsy based tests have the potential to provide a wide variety of clinical applications such as accurate diagnosis, prognosis, drug selection, or monitoring for disease recurrence. Payer interests include that these tests results are reliable, properly applied and are in fact valuable relative to existing alternatives.

2:50 PANEL DISCUSSION

3:40 Enabling Sequencing Technologies to Reach Their Full Potential
Sponsored by horizon
Brian Burke, Ph.D., Director, Business Development, Horizon Discovery
We're close to something fantastic, the advancement in sequencing technologies (ie. liquid biopsies) is surpassing expectations and the promise of precision medicine is close to being fulfilled. We explore how reference materials help lower barriers so that every lab is able to achieve that gold-standard assay and deliver everything, every time.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

DIAGNOSTICS CHANNEL

10:50 Swimming with the Sharks

Companies seeking venture funding will pitch their company's value proposition to a panel of judges and the top place winner will receive recognition as the "2017 Tri-Con Most Promising Company."

Moderator: Alan B. Carter, CEO, Wobblebase, Inc

Panel of Judges:

Stan Rose, Ph.D., CEO, Transplant Genomics

Mark S. Boguski, M.D., Ph.D., Founder & CMO, Precision Medicine Network, Inc.

Harry Glorikian, Healthcare Consultant

Chris Heid, Treasurer and Board Member, Berkeley Angel Network

Jenny Rooke, Ph.D., Managing Director, 5 Prime Ventures

Selection and Coaching Committee

Alan B. Carter, CEO, Wobblebase, Inc

Chris Heid, Treasurer and Board Member, Berkeley Angel Network

CONGRATULATIONS TO OUR 2016 FINALISTS

- Genomic Expression
- Cube Dx GmbH
- Sandstone Diagnostics
- AboGen Inc.
- Xcell Biosciences
- Nanopore Diagnostics, LLC
- Correlia Biosystems
- Tasso, Inc.
- Luminostics, Inc.
- NIESM Pty Ltd.

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

LOOKING FOR BIOMARKERS IN UNUSUAL PLACES

1:50 Chairperson's Remarks

Karsten Schmidt, Ph.D., CTO, Trovagene

2:00 Cell-Free DNA Investigation in Urine for Cancer Detection

David Berz, M.D., Ph.D., MPH, Assistant Professor, Department of Cellular Therapeutics, City of Hope Beckman Research Institute

2:30 Cell-Free DNA as an Analyte in Transplantation, Autoimmune Disease and Trauma

Dana W. Y. Tsui, Ph.D., Assistant Attending Geneticist; Member, Center for Molecular Oncology, Memorial Sloan Kettering Cancer Center

The analysis of cell-free DNA offers tremendous opportunity for molecular diagnostics. This talk will give a general overview of its applications across different clinical scenarios, focusing on its utility in monitoring organ transplantation, and its characteristics as an analyte in autoimmune disease, such as systemic lupus erythematosus, and its potential as a prognostic marker for trauma patients.

3:00 Central and Peripheral Biomarkers of Neurodegenerative Diseases

Mark Frasier, Senior Vice President, Research Programs, Michael J. Fox Foundation for Parkinson's Research

Clinical trial success of novel disease-modifying drugs in neurodegenerative diseases is dependent upon the existence of reliable objective biomarkers that assist with patient selection, stratification, and data interpretation. Significant investments have been made in developing imaging, biochemical, and digital biomarkers for Parkinson's disease. This talk will survey the current landscape of biomarkers for Parkinson's and Alzheimer's disease and emphasize the challenges and opportunities in neurodegenerative diseases.

3:30 Session Break

MOLECULAR DIAGNOSTICS

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WRESTLING WITH BIG DATA: IMPLICATIONS FOR DISCOVERY, REIMBURSEMENT, REGULATION, AND CLINIC

3:40 Chairperson's Remarks
Andrew C. Fish, J.D., Executive Director, AdvaMedDx

3:45 Big Data – The Devil's in the Details
Elaine K. Jeter, M.D., J1 MolDx Medical Director, Palmetto GBA
Linking effective therapies and expanded trial designations are the expected benefit of the ever-expanding capabilities of genomic biomarker and gene expression identification. More and more data is being generated every day. Keeping that data 'valuable' will require we maintain a critical focus on the quality and comparative values of the data, especially in the area of genomics and more specifically outcomes. Other questions will arise around where the data is collected, how it is curated, and who has access. As a Medicare payer, we support the concept of data collection/aggregation if that data can be effectively mined to create ever improving treatment protocols and more importantly improved outcomes.

4:00 Efficiently Leveraging Commercial and Open Source Bioinformatics Tools for Clinical Interventions and Research Discoveries from Very Large Datasets
Ben Busby, Ph.D., Genomics Outreach Coordinator, NCBI, NLM/NIH
In precision medicine, it is often the case that efficacy does not depend on the appropriate computational intervention, but on the morphology of the data that informs the problem. For example, different strategies should be employed when calling short variants in stable versus unstable regions of the human genome, or when looking for pathogenic effectors in well-characterized versus newly discovered bacterial or viral pathogens. Pragmatic solutions from existing commercial and open source resources will be presented.

4:15 From Bits to Bedside: Developing a Learning Digital Health System to Evaluate Pigmented Skin Lesions
Dexter Hadley, M.D., Ph.D., Assistant Professor, Pediatrics, Institute for Computational Health Sciences, University of California, San Francisco
Melanoma accounts for less than one percent of skin cancer cases but the vast majority of skin cancer deaths. Early screening and diagnosis significantly improves patient outcomes, yet no systematic framework exists for clinical evaluation of common pigmented lesions for risk of melanoma. In this talk, I will describe our approach to develop a learning health system focused on precision screening and diagnosis of skin cancer. We first leverage medical students in the clinics to capture digital samples of pigmented skin lesions at scale with mobile health technology. We then leverage this clinical big data to train state-of-the-art deep learning image classification algorithms to better screen for cancer. Our work translates routinely documented electronic health data into an impactful digital health initiative to directly improve clinical outcomes and advance clinical knowledge.

4:30 PANEL DISCUSSION

5:15 Close of Conference Program

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Cambridge Healthtech Institute's Eighth Annual

PERSONALIZED DIAGNOSTICS

What Can NGS Bring to Medicine?

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

OPENING KEYNOTE SESSION

11:50 Chairperson's Opening Remarks

Trevor W. Brown, MSc, Vice President, Precision Medicine, SeraCare Life Sciences, Inc.

12:00 pm Making Omic Data Clinically Actionable

Elizabeth Worthey, Ph.D., Faculty Investigator, Clinical Informatics Director, and Adjunct Associate Professor, Software Development and Informatics, Pediatrics and Genetics, HudsonAlpha Institute for Biotechnology

The American College of Medical Genetics and Genomics (ACMG), the Association for Molecular Pathology (AMP), and the College of American Pathologists (CAP), recently developed guidelines to standardize interpretation and reporting of genomic test results. Their assessment ultimately ended up producing twenty-eight such weighted criteria as well as suggesting the methods through which they could be combined in order to derive the reporting category.

12:30 Scalable Approach for Continuous Analysis of Exome Sequencing Data

Avni Santani, Ph.D., Director, Division of Genomic Diagnostic, The Children's Hospital of Philadelphia; Assistant Professor, Clinical Pathology and Laboratory Medicine, University of Pennsylvania

With the explosion of genomic information and novel gene discoveries, clinical laboratories are faced with critical challenges in data interpretation. For complex genetic tests such as exome sequencing in pediatric population, the clinical presentation of patient continues to evolve, therefore affecting the phenotype driven analysis of genomic data. Using clinical cases as examples, this presentation will address these challenges and propose strategies that clinical laboratories can utilize for re-analysis of genomic data in exome sequencing.

1:00 Session Break

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

2:10 Session Break

IMMUNOSEQUENCING AND CANCER MEDICINE

2:30 Chairperson's Remarks

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

2:40 Profiling of Exhausted T Cells in Tumors Predicts PD-1 Response

Kelly Mahuron, M.D., Resident, School of Medicine, University of California, San Francisco

Immune checkpoint blockade is revolutionizing therapy for advanced cancer. However, many patients do not respond to treatment. The identification of robust biomarkers that predict clinical response to specific checkpoint inhibitors is critical in order to stratify patients and to rationally select combinations in the context of an expanding array of therapeutic options. We performed multi-parameter flow cytometry on freshly isolated metastatic melanoma samples prior to treatment and correlated subsequent clinical response with tumor immune phenotype.

3:10 Defining Immunoglobulin Somatic Hypermutation in *de novo* Diffuse Large B-Cell Lymphoma Patients: Potential Application for Prognosis and Risk Stratification

Ken H. Young, M.D., Ph.D., Professor, Hematopathology, The University of Texas MD Anderson Cancer Center

Characterization of immunoglobulin gene helps to identify cell-of-origin of mature B cell malignancies such as chronic lymphocytic leukemia, whereas its role in the pathogenesis of DLBCL is poorly understood. In this study, we studied molecular repertoire of both immunoglobulin heavy- and light-chain genes in a large cohort of *de novo* DLBCL patients using high-throughput next generation sequencing (NGS).

3:40 High-Throughput TCR Sequencing Provides Added Value in the Diagnosis of Cutaneous T-Cell Lymphoma

Thomas S. Kupper, M.D., Chair, Dermatology, Brigham and Women's Hospital; Dana Farber Cancer Institute; Thomas B. Fitzpatrick Professor, Harvard Medical School

Cutaneous T Cell Lymphomas (CTCL) are the most common extranodal non-Hodgkins T cell lymphomas. The diagnosis can be difficult and delayed (avg 5-6 years), as the lesions resemble inflammatory skin disorders. Unlike PCR-based clonality assays, high throughput sequencing of the TCR genes yielded a 100% sensitivity for detection of a clonal T cell population in CTCL lesions. HTS can also be used to assess response to therapy.

Sponsored by GENOPTIX

4:10 Automation of NGS-Data Analysis and Interpretation in a High-Throughput Clinical Setting

Matthew McGinniss, Ph.D., FACMG, Executive Director, Clinical Genomics, Genoptix Medical Laboratory

DIAGNOSTICS CHANNEL

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session (please see page 4 for details)

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

BUILD YOUR OWN GENE PANEL- SHARING PRACTICAL INSIGHTS

10:05 Chairperson's Remarks

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

10:15 Validation and Accumulated Experience with Large Gene Panel for the Detection of Somatic and Inherited Cancer Gene Mutations

Colin Pritchard, M.D., Ph.D., Associate Professor, Laboratory Medicine, University of Washington

Genomic sequencing technology is transforming cancer diagnostics by enabling tumor-based mutation profiling for precision cancer therapy. Since 2011, the University of Washington has offered large panel genetic testing for both cancer predisposition and for somatic mutation profiling in tumors. This presentation will review our experience with clinical next-generation sequencing-based panels for cancer including aspects of assay validation, bioinformatics infrastructure, interplay between somatic and germline findings, and interpretation and reporting.

10:45 Enabling a Genetically Informed Approach to Cancer Medicine: Evaluation of the Impact of a Comprehensive Tumor Sequencing Panel

Douglas B. Johnson, Ph.D., Assistant Professor, Medicine, Vanderbilt University Medical Center

Next-generation sequencing profiling is widely used to identify actionable genetic alterations in solid tumors. We reviewed our experience using a sequencing platform of 236-315 genes (FoundationOneTM, Foundation Medicine), and found that most patients (83%) had potentially actionable genetic changes, and 21% of these received genotype-directed treatments. We also observed that total number of mutations identified strongly correlated with response to anti-PD-1 directed therapies in melanoma.

11:15 NGS-Based Panel Testing for Hematologic Malignancies

Frank C. Kuo, M.D., Ph.D., Director, Assay Development, Center for Advanced Molecular Diagnostics, Department of Pathology, Brigham and Women's Hospital

Genomic profiling plays an increasingly important role in the diagnostic workup for patients with hematologic malignancies. Recurrent mutations occur in a few dozen genes involved in signal transduction, splicing, DNA methylation, and transcription regulation with implication in therapeutic decisions and prognosis. An NGS-based panel can provide comprehensive mutational profile in a timely and cost-effective manner and are likely to become an indispensable tool in evaluation of patients with hematologic malignancies.

11:45 PANEL DISCUSSION

12:15 pm Session Break

12:25 Luncheon Presentation I: FibroTx TAP and SELF: Pioneering the Potential of Topical Skin-Biomarkers for Personalized Care

Sponsored by FIBROTX INNOVATIONS FOR SKIN

Pieter Spee, CTO, 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.

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

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

INNOVATION IN CLINICAL SEQUENCING

2:00 Chairperson's Remarks

Avni Santani, Ph.D., Director, Pathology and Laboratory Medicine, The Children's Hospital of Philadelphia

2:10 Tumor Heterogeneity and Mutational Shift: Monitoring Mutations throughout the Course of Their Disease

Jennifer J.D. Morrissette, Ph.D., Clinical Director, Center for Personalized Diagnostics, University of Pennsylvania

Next-generation sequencing has become routine in the diagnosis and subsequent disease monitoring of cancer patients. Hematological malignancies are regularly monitored at diagnosis and at interim follow-ups by NGS using a custom hematological-NGS panel and chromosome analysis to monitor treatment response. This talk will present our experience in tracking the mutational landscape in the context of therapy and disease state.

2:40 PhenoDB and GeneMatcher, Solving the Molecular Basis of Mendelian Phenotypes

Nara Lygia de Macena Sobreira, M.D., Assistant Professor, Genetic Medicine, McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins University

To facilitate data sharing as well as improve the search for patients or model organisms with variants in specific candidate genes, we have added capabilities to PhenoDB (www.phenodb.org) and GeneMatcher (www.genematcher.org). As of September 2016, 5,209 genes were submitted by 2,131 individuals from 57

countries and generated 8,986 matches that have enabled collaborations and the description of novel Mendelian phenotypes and novel Mendelian genes.

3:10 Leveraging Long Read Technologies for Developing Niche Assays with Diagnostic Potential

Robert P. Sebra, Ph.D., Director, Technology Development, Icahn Institute of Genomics & Multiscale Biology; Associate Professor, Genetics & Genomics, Icahn School of Medicine at Mount Sinai

To address technologic limitations and provide a comprehensive assessment of genome variation associated with disease, we employed SMRT sequencing technology to access previously unresolvable genomic regions through unbiased, long read sequences spanning thousands of basepairs. Given these capabilities to comprehensively assess variation using long reads in pathologically relevant regions in support of clinical thinking, the potential exists to characterize health of an individual at a deeper level than previously possible.

3:40 Increasing Diagnostic Yield in Whole Genome Interpretation Using Omicia's Opal Clinical Platform

Sponsored by Omicia

Charlene Son Rigby, MBA, Vice President, Products and Strategy, Omicia

Clinical NGS testing is expanding to exomes and genomes. Omicia's algorithms, VAAST and Phevor, quickly rank disease-causing candidates based on impact and relationship to phenotype, thereby accelerating interpretation and reporting. We highlight our work on Genomics England's 100,000 Genomes Project.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

WHAT THE CHANGING LANDSCAPE OF REGULATION AND REIMBURSEMENT MEANS FOR CLINICAL DIAGNOSTIC

10:50 Chairperson's Remarks

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

11:00 The SPOT/DX Diagnostic Quality Assurance Pilot: An Update

John Pfeifer, M.D., Ph.D., Vice Chair, Clinical Affairs, Pathology, Washington University School of Medicine

The Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) working group has launched a Diagnostic Quality Assurance Pilot designed to develop performance standards, consensus quality control materials, and a transparent pre-market approach to ensure that labs demonstrate their ability to accurately determine the sequence of clinical decision parameters (i.e., genes) regardless of whether they are using an FDA-approved *in vitro* companion diagnostic (IVD) or a laboratory-developed test (LDT).

11:20 Developing Standards for NGS-Based Testing in the Evolving Regulatory Environment

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 complexity and scope of molecular diagnostic testing has dramatically increased and requires not only substantial knowledge and expertise, but also an evolving framework for test design, validation and implementation. This presentation will discuss evolving frameworks for developing standards to meet the increasing demand for enhanced guidance and to enable standardization of molecular testing cross laboratories.

11:40 Regulation and Reimbursement of Genomic Tests: Challenges and Solutions

Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)

The regulatory and reimbursement environment today for genomic tests is in seemingly constant flux. This presentation will review some of the structural challenges with the diagnostics ecosystem and propose some solutions.

12:00 pm PANEL DISCUSSION

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

EMERGING BIOMARKERS PREDICTING RESPONSE TO IMMUNOTHERAPY

1:50 Chairperson's Remarks

Luis A. Diaz, M.D., Head, Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center

2:00 Genomic Features of Resistance to Anti-PD-1 Immunotherapy

Jesse Zaretsky, UCLA-Caltech Medical Scientist Training Program, Department of Molecular and Medical Pharmacology, David Geffen School of Medicine, University of California, Los Angeles

DIAGNOSTICS CHANNEL

Resistance to anti-PD1 immunotherapy can take the form of either innate lack of response, or late acquired resistance after initial tumor regression. For the former, we define a transcriptomic mesenchymal and wound-healing associated expression signature enriched among non-responders in pre-therapy tumors from metastatic melanoma patients. For the latter, exome sequencing of paired pre/post relapse tumors revealed loss of function mutations in the interferon response pathway and antigen presentation machinery.

2:30 Shaping of Immunotherapy Response by Cancer Genomes

Rajarsi Mandal, M.D., Head & Neck Surgical Oncology Fellow; Professor, Surgery, Memorial Sloan Kettering Cancer Institute

Immune checkpoint blockade is a promising approach for the treatment of human malignancies. For example, treatment of patients with advanced lung cancers and melanoma have resulted in improved response rates and durable disease control. However, the extent to which patients derive benefit is diverse and the determinants that drive response to therapy are ill-defined. We have sought to define the genomic determinants of response to immune checkpoint blockade therapies such as anti-CTLA-4 and anti-PD-1. Our work has shown that tumor mutational burden, clonality, and mutational landscape features help dictate clinical response. Mutations in genes that are part of the antigen presentation machinery are rare but can be preferentially downregulated in tumors. Reexpression of genes in the MHC antigen presentation pathway by treatment with epigenetic therapy synergizes with immune checkpoint blockade to boost anti-tumor responses.

3:00 Addressing the Challenges Associated with Immuno-Therapy Biomarker Testing

John Leite, Ph.D., Vice President, Oncology, Market Development & Product Marketing, Illumina, Inc.

Recent developments in immuno-therapy have yielded exciting and promising results, but have also highlighted the need for effective predictive solutions. In this session, we will discuss the inherent testing challenges facing translational researchers, and future challenges facing clinicians seeking to implement these solutions into routine clinical practice.

3:30 Session Break

GENETIC CHARACTERIZATION OF PATIENT TUMORS AND CTCs

3:40 Chairperson's Remarks

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

3:45 Scalable Approach for Whole-Exome Sequencing of Cell-Free DNA from Patients with Metastatic Cancer

Viktor Adalsteinsson, Ph.D., Group Leader, Broad Institute of MIT and Harvard

Whole-exome sequencing of cell-free DNA (cfDNA) may enable comprehensive profiling of tumors from blood. Here, we describe a scalable approach to qualify and sequence whole-exomes of cfDNA. Whole-exome sequencing of cfDNA and biopsies from 23 patients revealed high concordance of clonal somatic mutations (90%), copy number alterations (80%), mutational signatures, and neoantigens. Screening of 879 blood samples from 333 metastatic cancer patients revealed 42% with sufficient tumor content for whole-exome sequencing.

4:15 Simultaneous Detection of Living Circulating Tumor Cells and Cancer Related Extracellular Vesicles in Blood by a Molecular Beacon Based Biochip

L. James Lee, Ph.D., Professor, Chemical and Biomolecular Engineering, The Ohio State University

A novel and facile immune-lipoplex nanoparticle (ILN) biochip is developed to simultaneously capture and characterize living circulating tumor cells (CTCs) and cancer related extracellular vesicles (EVs) in patient blood. Antibodies are used to capture CTCs and EVs in a microfluidic device, while molecular beacons encapsulated in cationic lipoplex nanoparticles and fluorescence labelled antibodies are used to detect coding and non-coding RNA targets and membrane protein targets respectively in both CTCs and EVs. The identified CTCs are alive for further interrogation such as drug resistance.

4:45 Talk Title to be Announced

Amado Zurita-Saveedra, M.D., Associate Professor, MD Anderson

5:15 Close of Conference Program

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Cambridge Healthtech Institute's Tenth Annual

CANCER MOLECULAR MARKERS

Guiding Cancer Management

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

OPENING KEYNOTE SESSION

11:50 Chairperson's Opening Remarks
Stefanie Jeffrey, M.D., John and Marva Warnock Professor, Surgery; Chief, Surgical Oncology Research, Stanford University School of Medicine

12:00 pm VTX-1 Liquid Biopsy System: The Next Step in CTC Isolation
Steve Crouse, M.S., MBA, Chief Commercial Officer, Vortex Biosciences, Inc.
The VTX-1 Liquid Biopsy System isolates and collects intact CTCs directly from whole blood in as little as 1 hour. Clinical data will demonstrate how the proprietary approach results in the capturing of more clinically relevant CTCs with >60% CTC recovery and best in class CTC purity.

12:30 Isolation and Molecular Characterization of Breast Cancer Stem Cells
Max S. Wicha, M.D., Madeline and Sidney Forbes Professor, Oncology; Founding Director Emeritus, University of Michigan Comprehensive Cancer Center
There is substantial evidence that tumors are driven by a subpopulation of cells that display stem cell properties and that these cells mediate tumor metastasis and contribute to treatment resistance. A number of agents designed to target these cancer stem cells are now in early stage clinical trials. The development of robust platforms to isolate and molecularly characterize circulating tumor cells at single cell resolution should greatly facilitate these studies.

1:00 Session Break

Sponsored by ANGLE

1:10 Luncheon Presentation I: CTC Enrichment by Parsortix™- Clinical Applications
Robert Zeillinger, Ph.D., Associate Professor, Molecular Oncology Group, Medical University of Vienna

1:40 Transformational Techniques and Clinical Utilities for Blood Based Biopsies Using CellSieve™ Microfilters

Sponsored by CREATV MicroTech

Cha-Mei Tang, Sc.D., President & CEO, Creatv MicroTech Inc
Daniel Adams, Senior Research Scientist, Creatv MicroTech Inc
CellSieve™ filters capture CTCs and stromal cells from the blood of cancer patients. We describe their prevalence and profiles in the context of early detection and cancer pathogenesis, redefining our understanding of CTCs, stromal cells and blood based diagnostics.

2:10 Session Break

NEW KITS ON THE BLOCK FOR LIQUID BIOPSY: EXOSOMES AND EXTRACELLULAR VESICLES

2:30 Chairperson's Remarks
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University, Medical Center Hamburg-Eppendorf

2:40 Tumor-Educated Platelets as a Blood-Based Liquid Biopsy Platform for Cancer Diagnostics
Myron G. Best, Ph.D. Student, Neurosurgery, Cancer Center Amsterdam, VU University Medical Center Amsterdam, The Netherlands
Blood-based 'liquid biopsies' provide a means for minimally invasive molecular diagnostics. Confrontation of blood platelets with tumor cells via transfer of tumor-associated biomolecules (tumor-educated platelets; TEPs) is an emerging concept. We performed RNA-sequencing of >1000 platelet samples covering multiple tumor types. Our results indicate that platelets provide a valuable platform for cancer diagnostics. The unprecedented ability of TEPs to pinpoint the location of the primary tumor advances the use of liquid biopsies for cancer diagnostics.

3:10 Unveiling the Circulating Tumor Endothelial Cell Cluster
Min-Han Tan, Ph.D., Principal Investigator, Biodevices and Diagnostics, Institute of Bioengineering and Nanotechnology
Circulating cell clusters have been reported for decades in cancer patients as malignant entities with a key role metastasis. Contrary to this consensus, we describe a discrete population of tumor-derived circulating cell clusters with similar cytomorphology and EMT marker expression, but with origins traced instead to the tumor endothelia.

3:40 About Chomsky, DNA Patterns, Non-Coding RNAs and Cancer Patients
George A. Calin, M.D., Ph.D., Professor, Department of Experimental Therapeutics, The University of Texas MD Anderson Cancer Center
The newly discovered differential expression in numerous tissues, key cellular processes and multiple diseases for several families of long and short non-codingRNAs (ncRNAs, RNAs that do not codify for proteins but for RNAs with regulatory functions), including the already famous class of microRNAs (miRNAs) strongly suggest that the scientific and medical communities have significantly underestimated the spectrum of ncRNAs whose altered expression has significant consequences in diseases.

4:10 Recovery & State-of-the-Art Molecular Analysis of Single (Pure) CTCs using DEPArray Based Technology

Sponsored by MENARINI silicon biosystems

Farideh Bischoff, Ph.D., Chief Clinical Development Officer, North America Menarini Silicon Biosystems

DEPArray™ Platform delivers precision in the preparation circulating tumor cells for MDx. Complete workflows have been developed for the recovery of pure single CTCs that are amenable to downstream NGS approaches, including targeted panel and low pass copy number analysis.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session (please see page 4 for details)

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

LIQUID BIOPSY: CURRENT AND FUTURE DIRECTIONS

10:05 Chairperson's Remarks

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

10:15 Single-Cell Phenotypic Analysis of Circulating Tumor Cells

Dino Di Carlo, Ph.D., Professor, Bioengineering, California NanoSystems Institute; Director, Cancer Nanotechnology Program, Jonsson Comprehensive Cancer Center, University of California, Los Angeles

We have developed several workflows for integrating Vortex trapping technology with downstream phenotypic analysis of single circulating tumor cells (CTCs). I will present our results in analyzing single-cell secretions from CTCs in an automated microfluidic workflow and proof of concept clinical studies to evaluate expression levels programmed death ligand 1 (PD-L1) on Vortex-isolated CTCs from non-small cell lung cancer patients on checkpoint inhibitor therapy.

10:45 Circulating Tumor DNA Analysis – Clinical Impact

John Strickler, M.D., Assistant Professor, Medicine, Duke University Medical Center

Interest in ctDNA to diagnose, monitor, and profile solid tumors has surged. The increased use of ctDNA reflects a desire to minimize procedural risk to the patient, while applying therapies tailored to a patient's specific tumor profile. Already, ctDNA is routinely used to guide therapeutic decision-making, and to identify patients for clinical trials. In this presentation, the opportunities and challenges of utilizing ctDNA in the clinic will be discussed.

11:15 Microfluidics for the Efficient Selection of Disease-Associated Extracellular Vesicles from Plasma

Steven A. Soper, Ph.D., Foundation Distinguished Professor, Department of Chemistry, Department of Mechanical Engineering; Director, Center of BioModular Multi-Scale System for Precision Medicine, The University of Kansas

Liquid biopsies are generating interest within the biomedical community due to the simplicity for securing important markers. These circulating markers consist of CTCs, cell free DNA and extracellular vesicles. We are developing a microfluidic that can process plasma and efficiently search for disease-associated extracellular vesicles comprising divergent subpopulations. These subpopulations emanate from different cancer cell types and can supply complimentary clinical information.

11:45 A Novel, High Yield, High Complexity, and Scalable Active-Extraction of Circulating Cell-Free DNA (ccfDNA) from Stabilized Plasma

Sponsored by Covaris

Hamid Khoja, Ph.D., Principal Scientist, Research & Development, Covaris Inc.

In this talk we present data illustrating the effectiveness of the Covaris Adaptive Focused Acoustics™ (AFA) enabled truXTRAC ccfDNA active extraction method. Specifically designed for dissociating and extracting ccfDNA from histone-ccfDNA and other protein-ccfDNA covalently-linked complexes which occur in BCT®-stabilized plasma, the magnetic bead based truXTRAC ccfDNA enables scalable and automatable high throughput sample processing. Furthermore, DNA sequencing confirmed that truXTRAC ccfDNA processed samples resulted in higher library complexity, mapped reads, coverage uniformity, and variant detection sensitivity when compared to passive ccfDNA extraction methods.

Sponsored by Vortex BIOSCIENCES

12:00 pm Presentation to be Announced

12:15 Session Break

12:25 Luncheon Presentation I: Highly Sensitive Isolation and Molecular Characterization of CTC for Early Detection of Tumor Invasion

Sponsored by Rarecells DIAGNOSTICS

Patrizia Paterlini-Brechot, M.D., Ph.D., Professor, Faculty of Medicine, University Paris Descartes

ISET allows to isolate fixed and live tumor cells with sensitivity down to one per 10 mL of blood. We show NGS analyses of single cells enriched by ISET® and of tumor cells before and after isolation and culture.

Sponsored by ARCHER™

12:55 Luncheon Presentation II: Liquid Biopsy Mutation Detection with Anchored Multiplex PCR

Josh Stahl, MSc, MBA, CSO, General Manager, ArcherDX

Liquid biopsies have the potential to be a less invasive method than traditional biopsies to detect advanced solid tumor mutational status. Anchored Multiplex PCR (AMP™) is target enrichment chemistry for NGS that is uniquely suited for highly fragmented material such as liquid biopsy-derived ctDNA. AMP-based ctDNA library preparation uses molecular barcoded adapters to remove PCR duplicates, correcting for both PCR and sequencer-derived sequencing errors while enabling accurate allele frequency quantitation.

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

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TECHNOLOGIES FOR THE ISOLATION OF CIRCULATING MARKERS

2:00 Chairperson's Remarks
Steven A. Soper, Ph.D., Foundation Distinguished Professor, Department of Chemistry, Department of Mechanical Engineering; Director, Center of BioModular Multi-Scale System for Precision Medicine, The University of Kansas

2:10 Comparison of Different CTC Isolation Technologies in the Context of Clinical Utility
Pamela Paris, Ph.D., Professor, Urology, University of California, San Francisco
This presentation will provide an overview of some of the CTC platforms available today. The strengths and limitations of the CTC platforms will be discussed based on first-hand use in the laboratory. Examples will be provided for each platform's potential clinical utility.

2:40 Integrated Extracellular Vesicle Profiling for Minimally Invasive Diagnosis and Early Detection of Cancer
Andrew K. Godwin, Ph.D., Chancellors Distinguished Chair, Biomedical Sciences and Endowed Professor, Professor and Director of Molecular Oncology, Pathology and Laboratory Medicine; Deputy Director, The University of Kansas Cancer Center; Director, Biospecimen Shared Resource Kansas Bioscience Authority; Eminent Scholar, University of Kansas Medical Center
Extracellular vesicle (EV), primarily nano-sized vesicles of endocytic origin referred to as exosomes, are produced and released by most cells types under normal physiologic and in diseased states. Considered little more than garbage cans whose job was to discard unwanted cellular components, recent discoveries have sparked interest as circulating biomarkers. Ways to exploit these circulating EVs and their payloads of proteins and nucleic acids using miniaturized biomedical assays will be discussed.

3:10 Orthogonal Endpoints in Prostate Cancer Circulating Tumor Cell Biomarkers
Joshua M. Lang, M.D., MS, Assistant Professor, Medicine, Carbone Cancer Center, University of Wisconsin
Prostate cancer is a heterogeneous disease with complex, intersecting mechanisms of resistance to targeted therapies. Prospective clinical trials interrogating CTC biomarkers across protein, gene expression and genomic endpoints identify acquired resistance mechanisms and pharmacodynamic biomarkers.

Sponsored by ScreenCell

3:40 Presentation to be Announced

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

TRANSLATIONAL BIOMARKERS IN CANCER IMMUNOTHERAPY DEVELOPMENT

10:50 Chairperson's Remarks
Jianda Yuan, M.D., Ph.D., Director, Translational Immuno-Oncology Research, Early Clinical Oncology Development, Merck & Co., Inc.

11:00 Next Generation Biomarkers for the Era of Combination Cancer Immunotherapy
Sarah Javaid, Ph.D., Senior Scientist, Discovery Pharmacogenomics, Genetics and Pharmacogenomics, Merck & Co., Inc.
Combination approaches are the keys to improving clinical response. From preclinical immune-oncology mouse models to patients enrolled on clinical trials, novel high throughput technologies enable us to understand the mechanisms underlying the complex interactions between the immune system and cancer, identify predictive biomarkers for the patients who will most likely benefit from current immunotherapies, avoid immune-related adverse events and guide the future combination cancer immunotherapy.

11:30 Precision Immunotherapy: The Challenge of Converting Complex Predictive Biomarkers into Practical Companion Diagnostics
Ruslan Novosiadly, Ph.D., Senior Research Advisor, Cancer Immunobiology, Biomarkers, Eli Lilly
Early immunotherapies have produced dramatic results for some patients, but future immunotherapies likely need to be guided by diagnostics to benefit more patients. Properly targeting immunotherapy requires incorporating into clinical practice complex diagnostics which can assess host immune response in addition to cancer biology itself. "Precision Immunotherapy" requires discovery of appropriate predictive biomarkers and incorporating them into practical companion diagnostics which will be adopted by practitioners.

12:00 pm Utility of Quantifying Circulating Lymphocyte Populations as Pharmacodynamic Biomarkers in Trials of Immune Oncology Therapeutics
Nathan Standifer, Ph.D., Scientist II, Clinical Pharmacology and DMPK, MedImmune
Immune oncology (IO) therapeutics are directed at inducing immune responses against tumor cells. Intrinsic to this mechanism of action is the activation of circulating immune cells, which can be most effectively monitored using flow cytometry-based assays. In this presentation, aspects of assay development, validation, implementation and analysis of clinical flow cytometry datasets will be discussed. Results from clinical trials of IO as single agents or in combination with other IO will be shown and strategies for interpretation and post-hoc analyses will

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be detailed.

12:30 Session Break

Sponsored by CELLECTA Discovery is Yours.

12:40 Luncheon Presentation to be Announced

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

EMERGING BIOMARKERS PREDICTING RESPONSE TO IMMUNOTHERAPY

1:50 Chairperson's Remarks

Luis A. Diaz, M.D., Head, Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center

2:00 Genomic Features of Resistance to Anti-PD-1 Immunotherapy

Jesse Zaretsky, UCLA-Caltech Medical Scientist Training Program, Department of Molecular and Medical Pharmacology, David Geffen School of Medicine, University of California, Los Angeles

Resistance to anti-PD1 immunotherapy can take the form of either innate lack of response, or late acquired resistance after initial tumor regression. For the former, we define a transcriptomic mesenchymal and wound-healing associated expression signature enriched among non-responders in pre-therapy tumors from metastatic melanoma patients. For the latter, exome sequencing of paired pre/post relapse tumors revealed loss of function mutations in the interferon response pathway and antigen presentation machinery.

2:30 Shaping of Immunotherapy Response by Cancer Genomes

Timothy A. Chan, M.D., Ph.D., Radiation Oncologist; Vice Chair, Radiation Oncology; Director, Translational Oncology Division; PaineWebber Chair in Cancer Genetics Memorial Sloan Kettering

Immune checkpoint blockade is a promising approach for the treatment of human malignancies. For example, treatment of patients with advanced lung cancers and melanoma have resulted in improved response rates and durable disease control. However, the extent to which patients derive benefit is diverse and the determinants that drive response to therapy are ill-defined. We have sought to define the genomic determinants of response to immune checkpoint blockade therapies such as anti-CTLA-4 and anti-PD-1. Our work has shown that tumor mutational burden, clonality, and mutational landscape features help dictate clinical response. Mutations in genes that are part of the antigen presentation machinery are rare but can be preferentially downregulated in tumors. Reexpression of genes in the MHC antigen presentation pathway by treatment with epigenetic therapy synergizes with immune checkpoint blockade to boost anti-tumor responses.

3:00 Addressing the Challenges Associated with Immuno-Therapy Biomarker Testing

John Leite, Ph.D., Vice President, Oncology, Market Development & Product Marketing, Illumina, Inc.

Recent developments in immuno-therapy have yielded exciting and promising results, but have also highlighted the need for effective predictive solutions. In this session, we will discuss the inherent testing challenges facing translational researchers, and future challenges facing clinicians seeking to implement these solutions into routine clinical practice.

3:30 Session Break

EMERGING CANCER MOLECULAR MARKERS

3:40 Chairperson's Remarks

Gerald J. Kost, M.D., Ph.D., M.S., FACB, Director, POC Testing Center for Teaching and Research (POCT•CTR), Pathology and Laboratory Medicine, School of Medicine, University of California, Davis

3:45 Deciphering the Code of Single EVs and RNPs Released from Glioblastoma Cells

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

Tumor cells release a variety of content in the extracellular milieu that includes lipid-based vesicles as well as ribonucleoprotein (RNP) complexes. Lipid vesicles are termed extracellular vesicles (EV) and include vesicles ranging from 50nm to 1µm and above. mRNA, miRNA, ncRNA DNA and proteins have all been described to be present in the extracellular environment but it is currently unknown the extent to which each subpopulation is present at any given time. Data will be reported on counting of these molecules from two glioblastoma cells under normal and hypoxic conditions.

4:15 Exosomal MicroRNAs Regulate the Biology of the Tumor Microenvironment

Muller Fabbri, M.D., Ph.D., Assistant Professor, Pediatrics and Molecular Microbiology & Immunology, Pediatric Hematology/Oncology, Children's Hospital Los Angeles - University of Southern California

MicroRNAs can be shuttled between different cell populations of the Tumor Microenvironment. The exchange of microRNAs affects the phenotype of cancer cells and surrounding cells contributing to cancer growth and resistance to therapy. Conversely, immune cells can affect cancer growth by releasing specific exosomic microRNAs. This lecture will focus on the role of exosomal microRNAs as central determinants of the biology of the tumor microenvironment and of cancer resistance.

4:45 Noncoding RNAs as Biomarkers in Gastrointestinal Cancer

Ajay Goel, Ph.D., Professor and Director, Center for Gastrointestinal Research, and Director, Center for Epigenetics, Cancer Prevention and Cancer Genomics, Baylor Research Institute, Baylor University Medical Center

Noncoding RNAs (ncRNAs) are emerging as important regulators of gene expression in cancer. Overexpression of specific noncoding RNAs (including microRNAs, SnoRNAs, piRNAs and circular RNAs) has been linked to the stepwise disease progression in colorectal cancer (CRC). Given their cancer-specific pattern of expression, remarkable stability and presence in blood and other body fluids, ncRNAs are considered to be highly promising cancer biomarkers. Accumulating evidence firmly supports the existence of unique 'ncRNA signatures' that can not only facilitate earlier detection of the tumor, but can also assist in predicting disease recurrence and therapeutic outcome to current treatment regimens.

5:15 Close of Conference Program

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Cambridge Healthtech Institute's Seventh Annual

CIRCULATING TUMOR CELLS AND LIQUID BIOPSY

Enabling Molecular Medicine

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

OPENING KEYNOTE SESSION

11:50 Chairperson's Opening Remarks
Stefanie Jeffrey, M.D., John and Marva Warnock Professor, Surgery; Chief, Surgical Oncology Research, Stanford University School of Medicine

12:00 pm Smart Tumors, CTCs and Liquid Biopsies
George W. Sledge, M.D., Professor, Medicine; Chief, Division of Oncology, Stanford University School of Medicine
Cancers kill because they are resistant to currently available therapies. The promise of CTC and ctDNA technologies is that they will allow either earlier diagnosis of small tumors, or provide crucial evidence regarding drug resistance at a point where that resistance is reversible. What are the prospects for CTC and ctDNA technologies reversing potentially lethal drug resistance, and how will we employ them in the clinic?

12:30 Isolation and Molecular Characterization of Breast Cancer Stem Cells
Max S. Wicha, M.D., Madeline and Sidney Forbes Professor, Oncology; Founding Director Emeritus, University of Michigan Comprehensive Cancer Center
There is substantial evidence that tumors are driven by a subpopulation of cells that display stem cell properties and that these cells mediate tumor metastasis and contribute to treatment resistance. A number of agents designed to target these cancer stem cells are now in early stage clinical trials. The development of robust platforms to isolate and molecularly characterize circulating tumor cells at single cell resolution should greatly facilitate these studies.

1:00 Session Break

Sponsored by ANGLE

1:10 CTC Enrichment by Parsortix™- Clinical Applications
Robert Zeillinger, Ph.D., Associate Professor, Molecular Oncology Group, Medical University of Vienna

Sponsored by CREATV MicroTech

1:40 Transformational Techniques and Clinical Utilities for Blood Based Biopsies Using CellSieve™ Microfilters
Cha-Mei Tang, Sc.D., President & CEO, Creatv MicroTech Inc
Daniel Adams, Senior Research Scientist, Creatv MicroTech Inc
CellSieve™ filters capture CTCs and stromal cells from the blood of cancer patients. We describe their prevalence and profiles in the context of early detection and cancer pathogenesis, redefining our understanding of CTCs, stromal cells and blood based diagnostics

2:10 Session Break

NEW KITS ON THE BLOCK FOR LIQUID BIOPSY: EXOSOMES AND EXTRACELLULAR VESICLES

2:30 Chairperson's Remarks
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University, Medical Center Hamburg-Eppendorf

2:40 Tumor-Educated Platelets as a Blood-Based Liquid Biopsy Platform for Cancer Diagnostics
Myron G. Best, Ph.D. Student, Neurosurgery, Cancer Center Amsterdam, VU University Medical Center Amsterdam, The Netherlands
Blood-based 'liquid biopsies' provide a means for minimally invasive molecular diagnostics. Confrontation of blood platelets with tumor cells via transfer of tumor-associated biomolecules (tumor-educated platelets; TEPs) is an emerging concept. We performed RNA-sequencing of >1000 platelet samples covering multiple tumor types. Our results indicate that platelets provide a valuable platform for cancer diagnostics. The unprecedented ability of TEPs to pinpoint the location of the primary tumor advances the use of liquid biopsies for cancer diagnostics.

3:10 Unveiling the Circulating Tumor Endothelial Cell Cluster
Min-Han Tan, Ph.D., Principal Investigator, Biodevices and Diagnostics, Institute of Bioengineering and Nanotechnology
Circulating cell clusters have been reported for decades in cancer patients as malignant entities with a key role metastasis. Contrary to this consensus, we describe a discrete population of tumor-derived circulating cell clusters with similar cytomorphology and EMT marker expression, but with origins traced instead to the tumor endothelia.

3:40 About Chomsky, DNA Patterns, Non-Coding RNAs and Cancer Patients
George A. Calin, M.D., Ph.D., Professor, Department of Experimental Therapeutics, The University of Texas MD Anderson Cancer Center
The newly discovered differential expression in numerous tissues, key cellular processes and multiple diseases for several families of long and short non-codingRNAs (ncRNAs, RNAs that do not codify for proteins but for RNAs with regulatory functions), including the already famous class of microRNAs (miRNAs) strongly suggest that the scientific and medical communities have significantly underestimated the spectrum of ncRNAs whose altered expression has significant consequences in diseases.

4:10 Recovery & State-of-the-Art Molecular Analysis of Single (Pure) CTCs using DEPArray Based Technology

Sponsored by MENARINI silicon biosystems

Farideh Bischoff, Ph.D., Chief Clinical Development Officer, North America Menarini Silicon Biosystems
DEPArray™ Platform delivers precision in the preparation circulating tumor cells for MDx. Complete workflows have been developed for the recovery of pure single

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CTCs that are amenable to downstream NGS approaches, including targeted panel and low pass copy number analysis.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session (please see page 4 for details)

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

LIQUID BIOPSY: CURRENT AND FUTURE DIRECTIONS

10:05 Chairperson's Remarks

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

10:15 Single-Cell Phenotypic Analysis of Circulating Tumor Cells

Dino Di Carlo, Ph.D., Professor, Bioengineering, California NanoSystems Institute; Director, Cancer Nanotechnology Program, Jonsson Comprehensive Cancer Center, University of California, Los Angeles

We have developed several workflows for integrating Vortex trapping technology with downstream phenotypic analysis of single circulating tumor cells (CTCs). I will present our results in analyzing single-cell secretions from CTCs in an automated microfluidic workflow and proof of concept clinical studies to evaluate expression levels programmed death ligand 1 (PD-L1) on Vortex-isolated CTCs from non-small cell lung cancer patients on checkpoint inhibitor therapy.

10:45 Circulating Tumor DNA Analysis – Clinical Impact

John Strickler, M.D., Assistant Professor, Medicine, Duke University Medical Center

Interest in ctDNA to diagnose, monitor, and profile solid tumors has surged. The increased use of ctDNA reflects a desire to minimize procedural risk to the patient, while applying therapies tailored to a patient's specific tumor profile. Already, ctDNA is routinely used to guide therapeutic decision-making, and to identify patients for clinical trials. In this presentation, the opportunities and challenges of utilizing ctDNA in the clinic will be discussed.

11:15 Microfluidics for the Efficient Selection of Disease-Associated Extracellular Vesicles from Plasma

Steven A. Soper, Ph.D., Foundation Distinguished Professor, Department of Chemistry, Department of Mechanical Engineering; Director, Center of BioModular Multi-Scale System for Precision Medicine, The University of Kansas

Liquid biopsies are generating interest within the biomedical community due to the simplicity for securing important markers. These circulating markers consist of CTCs, cell free DNA and extracellular vesicles. We are developing a microfluidic that can process plasma and efficiently search for disease-associated extracellular vesicles comprising divergent subpopulations. These subpopulations emanate from different cancer cell types and can supply complimentary clinical information.

CIRCULATING TUMOR CELLS AND LIQUID BIOPSY

11:45 A Novel, High Yield, High Complexity, and Scalable Active-Extraction of Circulating Cell-Free DNA (ccfDNA) from Stabilized Plasma

Sponsored by Covaris

Hamid Khoja, Ph.D., Principal Scientist, Research & Development, Covaris Inc.

In this talk we present data illustrating the effectiveness of the Covaris Adaptive Focused Acoustics™ (AFA) enabled truXTRAC ccfDNA active extraction method. Specifically designed for dissociating and extracting ccfDNA from histone-ccfDNA and other protein-ccfDNA covalently-linked complexes which occur in BCT®-stabilized plasma, the magnetic bead based truXTRAC ccfDNA enables scalable and automatable high throughput sample processing. Furthermore, DNA sequencing confirmed that truXTRAC ccfDNA processed samples resulted in higher library complexity, mapped reads, coverage uniformity, and variant detection sensitivity when compared to passive ccfDNA extraction methods.

12:00 pm VTX-1 Liquid Biopsy System: The Next Step in CTC Isolation

Sponsored by Vortex BIOSCIENCES

Steve Crouse, M.S., MBA, Chief Commercial Officer, Vortex Biosciences, Inc.

The VTX-1 Liquid Biopsy System isolates and collects intact CTCs directly from whole blood in as little as 1 hour. Clinical data will demonstrate how the proprietary approach results in the capturing of more clinically relevant CTCs with >60% CTC recovery and best in class CTC purity.

12:15 Session Break

12:25 Luncheon Presentation I: Highly Sensitive Isolation and Molecular Characterization of CTC for Early Detection of Tumor Invasion

Sponsored by Rarecells DIAGNOSTICS

Patrizia Paterlini-Brechot, M.D., Ph.D., Professor, Faculty of Medicine, University Paris Descartes

ISET allows to isolate fixed and live tumor cells with sensitivity down to one per 10 mL of blood. We show NGS analyses of single cells enriched by ISET® and of tumor cells before and after isolation and culture.

12:55 Luncheon Presentation II: Improving NGS-Based Liquid Biopsy Mutation Detection with Anchored Multiplex PCR

Sponsored by ARCHER

Josh Stahl, MSc, MBA, CSO, General Manager, ArcherDX

Liquid biopsies have the potential to be a less invasive method than traditional biopsies to detect advanced solid tumor mutational status. Anchored Multiplex PCR (AMP™) is target enrichment chemistry for NGS that is uniquely suited for highly fragmented material such as liquid biopsy-derived ctDNA. AMP-based ctDNA library preparation uses molecular barcoded adapters to remove PCR duplicates, correcting for both PCR and sequencer-derived sequencing errors while enabling accurate allele frequency quantitation.

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

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TECHNOLOGIES FOR THE ISOLATION OF CIRCULATING MARKERS

2:00 Chairperson's Remarks
Steven A. Soper, Ph.D., Foundation Distinguished Professor, Department of Chemistry, Department of Mechanical Engineering; Director, Center of BioModular Multi-Scale System for Precision Medicine, The University of Kansas

2:10 Comparison of Different CTC Isolation Technologies in the Context of Clinical Utility
Pamela Paris, Ph.D., Professor, Urology, University of California, San Francisco
This presentation will provide an overview of some of the CTC platforms available today. The strengths and limitations of the CTC platforms will be discussed based on first-hand use in the laboratory. Examples will be provided for each platform's potential clinical utility.

2:40 Integrated Extracellular Vesicle Profiling for Minimally Invasive Diagnosis and Early Detection of Cancer
Andrew K. Godwin, Ph.D., Chancellors Distinguished Chair, Biomedical Sciences and Endowed Professor, Professor and Director of Molecular Oncology, Pathology and Laboratory Medicine; Deputy Director, The University of Kansas Cancer Center; Director, Biospecimen Shared Resource Kansas Bioscience Authority; Eminent Scholar, University of Kansas Medical Center
Extracellular vesicle (EV), primarily nano-sized vesicles of endocytic origin referred to as exosomes, are produced and released by most cells types under normal physiologic and in diseased states. Considered little more than garbage cans whose job was to discard unwanted cellular components, recent discoveries have sparked interest as circulating biomarkers. Ways to exploit these circulating EVs and their payloads of proteins and nucleic acids using miniaturized biomedical assays will be discussed.

3:10 Orthogonal Endpoints in Prostate Cancer Circulating Tumor Cell Biomarkers
Joshua M. Lang, M.D., MS, Assistant Professor, Medicine, Carbone Cancer Center, University of Wisconsin
Prostate cancer is a heterogeneous disease with complex, intersecting mechanisms of resistance to targeted therapies. Prospective clinical trials interrogating CTC biomarkers across protein, gene expression and genomic endpoints identify acquired resistance mechanisms and pharmacodynamic biomarkers.

Sponsored by ScreenCell

3:40 3D Telomere Signatures Indicate Prostate Cancer Progression in CTC's Isolated with ScreenCell Technology
Sabine Mai, Ph.D., Professor, University of Manitoba, Director, The Genomic Centre for Cancer research and Diagnosis, Manitoba Institute of Cell Biology/RIOH, University of Manitoba
Using 3D Telomere Technology and circulating tumor cells isolated using the ScreenCell device, we examined intermediate risk prostate cancer patients prior to their radical prostatectomy. 3D nuclear telomeric profiles correctly identified patients with stable vs. progressive disease prior to RP.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

EARLY CANCER DETECTION

10:50 Chairperson's Remarks
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University, Medical Center Hamburg-Eppendorf

11:00 TP53 Mutations for Early Cancer Detection: Challenges Revealed by Duplex Sequencing
Rosana Risques, Ph.D., Assistant Professor, Pathology, University of Washington
The detection of tumor-specific mutations in clinically accessible samples could enable early cancer detection, but it is limited by the high error rate of DNA sequencing. Duplex Sequencing reduces errors by scoring mutations only present in both strands of DNA. Our studies in ovarian cancer demonstrate that TP53 Duplex-Sequencing detects cancer cells with high sensitivity. However, they also reveal prevalent TP53 mutations in non-cancerous tissue, which challenges clinical applications.

11:30 Clonal Hematopoiesis of Indeterminate Potential (CHIP): Common Pre-Malignant State for Blood Cancers
Siddhartha Jaiswal, M.D., Ph.D., Research Fellow and Staff Pathologist, Massachusetts General Hospital and Harvard University; Broad Institute, MIT
We recently identified that clonal hematopoiesis is a common finding in the elderly, with over 10% of individuals over the age of 70 harboring such a mutated clone in their blood. The presence of this condition raises the subsequent risk of developing hematologic malignancy by ~10-fold, making this a bona fide pre-malignant state. Early diagnosis of this condition opens the future possibility of preventing blood cancer in a high-risk population.

12:00 pm Liquid Biopsies and the Early Diagnosis of Cancer
Luis A. Diaz, M.D., Head, Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center

12:30 Session Break

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12:40 Analytical and Clinical Validation of Cell-free DNA Assays in Oncology: Efficient Translation to Clinical Care

Minetta Liu, M.D., Associate Professor, Department of Oncology, Department of Laboratory Medicine and Pathology, Mayo Clinic

Tumor specific molecular alterations increasingly play a part in drug selection and prognosis in cancer. Technologies that allow for the detection of specific mutations in cell free DNA (cfDNA) isolated from the peripheral blood have led to the concept of "liquid biopsies". This has immediate applications in colorectal cancer with potential utility in solid tumor malignancies. This session will discuss efforts to validate molecular biomarkers and develop solutions to promote rapid translation into clinical practice.

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

RECURRENCE MONITORING AND THERAPY SELECTION WITH ctDNA AND CTCs

1:50 Chairperson's Remarks

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

2:00 Circulating Tumor DNA Analysis for Personalized Cancer Detection and Monitoring

Maximilian Diehn, M.D., Ph.D., Assistant Professor, Radiation Oncology, Stanford Cancer Institute, Institute for Stem Cell Biology & Regenerative Medicine, Stanford University

Circulating tumor DNA (ctDNA) represents a promising biomarker for sensitive, specific, and dynamic detection of disease burden in cancer patients. Mutations in tumor-derived DNA represent ideal potential biomarkers since they are highly specific to tumor cells and involved in disease pathogenesis. However, even in advanced cancer patients concentrations of ctDNA are often low and difficult to detect. We have developed a novel, ultra-sensitive and specific method for detection of circulating tumor DNA called Cancer Personalized Profiling by Deep Sequencing (CAPP-Seq). This method was developed specifically for detection of ctDNA in non-small cell lung cancer patients, although it is broadly applicable to other cancer types. In this presentation I will describe our recent work on applications of ctDNA analysis in a variety of clinical settings.

2:30 Circulating Tumor Cell Clusters as Precursors of Breast Cancer Metastasis

Nicola Aceto, Ph.D., Assistant Professor, Oncology, Department of Biomedicine, University of Basel

Using mouse models with color-coded primary tumors, we determine that CTC-clusters are oligoclonal units with up to 50-fold increased metastatic potential compared to single CTCs. In patients with breast and prostate cancer, the presence of CTC-clusters correlates with disease progression. With RNA sequencing followed by loss of function studies, we identify plakoglobin as a major mediator of CTC-clustering and metastasis. Thus, we find that CTC-clusters are a highly efficient, yet targetable mechanism of cancer dissemination.

3:00 Substantial Interindividual and Limited Intraindividual Genomic Diversity among Tumors from Men with Metastatic Prostate Cancer

Peter S. Nelson, M.D., Professor, Medicine, Division of Oncology, Fred Hutchinson Cancer Research Center

The success of precision oncology is dependent on identifying different therapeutic vulnerabilities in tumors between different individuals but the consistent presence of the vulnerability in all or most tumors or tumor cells within an individual patient. In this presentation I will describe the molecular assessments of metastatic prostate cancers and circulating tumor DNA (ctDNA) to assess inter- and intra-individual tumor diversity with implications for treatment selection.

3:30 Session Break

GENETIC CHARACTERIZATION OF PATIENT TUMORS AND CTCs

3:40 Chairperson's Remarks

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

3:45 Scalable Approach for Whole-Exome Sequencing of Cell-Free DNA from Patients with Metastatic Cancer

Viktor Adalsteinsson, Ph.D., Group Leader, Broad Institute of MIT and Harvard

Whole-exome sequencing of cell-free DNA (cfDNA) may enable comprehensive profiling of tumors from blood. Here, we describe a scalable approach to qualify and sequence whole-exomes of cfDNA. Whole-exome sequencing of cfDNA and biopsies from 23 patients revealed high concordance of clonal somatic mutations (90%), copy number alterations (80%), mutational signatures, and neoantigens. Screening of 879 blood samples from 333 metastatic cancer patients revealed 42% with sufficient tumor content for whole-exome sequencing.

4:15 Simultaneous Detection of Living Circulating Tumor Cells and Cancer Related Extracellular Vesicles in Blood by a Molecular Beacon Based Biochip

L. James Lee, Professor, Chemical and Biomolecular Engineering, The Ohio State University

A novel and facile immune-lipoplex nanoparticle (ILN) biochip is developed to simultaneously capture and characterize living circulating tumor cells (CTCs) and cancer related extracellular vesicles (EVs) in patient blood. Antibodies are used to capture CTCs and EVs in a microfluidic device, while molecular beacons encapsulated in cationic lipoplex nanoparticles and fluorescence labelled antibodies are used to detect coding and non-coding RNA targets and membrane protein targets respectively in both CTCs and EVs. The identified CTCs are alive for further interrogation such as drug resistance.

4:45 Talk Title to be Announced

Amado Zurita-Saveedra, M.D., Associate Professor, MD Anderson

5:15 Close of Conference Program

CIRCULATING TUMOR CELLS AND LIQUID BIOPSY

Cambridge Healthtech Institute's Fifth Annual

DIGITAL PATHOLOGY

Transforming Medicine in the Digital Age

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

OPENING KEYNOTE SESSION

11:50 Chairperson's Opening Remarks
Liron Pantanowitz, M.D., Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center, Conference Chairman

12:00 pm IT Standardization in Digital Imaging in Pathology
Marcial García-Rojo, Ph.D., Head, Pathology Department, Hospital de Jerez de la Frontera, Ronda de Circunvalación
The aim of this work is explaining the importance of standards and the process performed on proprietary image formats of histological and cytological slides in pathology to convert them the be compliant with the Digital Imaging and Communication in Medicine (DICOM) standard, according to 145 and 122 supplements, and their subsequent storage in a Picture Archiving and Communication System (PACS).

12:50 Q&A Discussion

1:00 Session Break

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

2:10 Session Break

IN VIVO MICROSCOPY

2:30 Chairperson's Remarks
Richard Levenson, M.D., Professor and Vice Chair, Strategic Technologies, Pathology & Laboratory Medicine, University of California, Davis Medical Center

2:40 Naked Eye to Nucleotide
Babar K. Rao, M.D., FAAD, Clinical Professor, Dermatology, Robert Wood Johnson Medical School, Rutgers University
Histology is an accepted "gold standard" to manage most diseases. Newer non invasive, *in vivo* technologies are gaining popularity and are becoming routine test in many specialities, especially skin. Confocal microscopy is one such tool which has potential to change dermatology practice drastically.

3:10 *Ex vivo* Microscopy: Better, Faster, Cheaper
Maria Shevchuk, M.D., Associate Professor, Pathology & Lab Medicine, Weill Cornell Medical College, Cornell University
Ex vivo microscopy (EVM) is the histologic evaluation of human tissues in real time, without processing, using light of various wave lengths. Uses of EVM include: 1. intraoperative assessments and selection of most significant tissue for frozen section; 2. intraprocedural adequacy assessment of needle biopsies; 3. tissue selection for molecular/genetic studies; and 4. documentation of histology of biobanked tissues. Prompt, definitive diagnosis facilitates patient care, saving the patient and the medical system money.

3:40 Breast Margin Assessment by *ex vivo* Microscopy: The Crucial Role of the Pathologist in Validation
Wendy A. Wells, M.D., MSc, The E. Elizabeth French Professor and Chair, Pathology and Laboratory Medicine, Geisel School of Medicine at Dartmouth; Vice President, Pathology and Laboratory Medicine Service Line, Dartmouth-Hitchcock Medical Center
Clinical uses of real-time, rapid imaging of unprocessed fresh biopsy or excisional tissue by EVM include the intra-operative assessment of tumor margins or sentinel nodes, specimen triaging for tissue bank storage, and biopsy adequacy for molecular genomic studies. The validation of biologically-based image contrast with biomarkers linked to the tissue diagnosis "gold standard" made by pathologists is critical to the successful translation of optical imaging technology to the clinical arena.

Sponsored by XIFIN

4:10 Improving Patient Care through a Diagnostic Collaboration Workflow
Chrystal Adams, Assistant Vice President, Product Marketing, XIFIN, Inc.
David McClintock, M.D., Medical Director, Pathology Informatics, University of Chicago
Due to the disparate nature of current HIT systems, there are notable inefficiencies in care. In order to enable value-based care, these inefficiencies must be overcome. Collaboration and coordinated care involves communication among diagnostics specialists, most notably pathologists and radiologists, in an effort to provide better care at a reduced expense by providing clinicians with practical, actionable results. A key element to achieving collaboration is the ability to access all diagnostic information for a patient at the same time, seamlessly. Interoperable information solutions will address the needs of emerging collaboration centers, which provide services for diagnostics as a whole.

4:25 Sponsored Presentation *(Opportunity Available)*

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session (please see page 4 for details)

DIAGNOSTICS CHANNEL

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

PRACTICAL SKILLS FOR WSI ANALYTICS

10:05 A Hands-On Workshop

This interactive workshop will make use of web-based tools to provide a general survey to participants of contemporary approaches to common image classification and segmentation tasks, as made possible by the increasing availability of digital whole slide imagery. Equal emphasis will be placed on first-principles theory as well as practical considerations such as: workflow optimization, algorithm optimization and pipeline design. Those attendees bringing a laptop will be able to interactively apply the concepts presented by use of content and tools on a specifically-implemented workshop website.

Key aspects of this workshop will include:

- Actual hands-on use of web-based image segmentation and analytics tools (utilizing attendees' laptops)
- Interactive exercises in image segmentation topics
- Interactive exercises in image classification topics
- Interactive exercises in creating streamlined compound image processing pipelines

Instructors:

Ulysses G. J. Balis, M.D., FCAP, FASCP, FAIMBE, Professor, Pathology; Director, Division of Pathology Informatics; Director, Pathology Informatics Fellowship Program, Pathology, University of Michigan Health System

Chris Williams, M.D., Senior Lecturer, Informatics, Department of Pathology, University of Michigan

Sponsored by inspirata

11:45 Unlocking Digital Pathology: Actionable Medical Assays are the Key

Mark Lloyd, Ph.D., MBA, Executive Vice President and Founder, Inspirata, Inc.

Pathology can make the transition from glass to digital but is that a significant enough value proposition? What is the killer app" for pathology? Using morphometric analysis of WSIs to quantify biomarkers, TIL distributions, intratumoral heterogeneity and grading standardization can provide prognostic and predictive indications, leading to better patient outcomes.

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

DIGITIZED CYTOLOGY AND COMPUTATIONAL PATHOLOGY

2:00 Chairperson's Remarks

David C. Wilbur, M.D., Professor, Pathology, Massachusetts General Hospital

2:10 Imaging Fluorescence Flow and Mass Cytometry; New Frontiers in Cellular Analyses

Frederic I. Preffer, Ph.D., Director, Flow Cytometry, Pathology, Massachusetts General Hospital; Associate Professor, Pathology, Harvard Medical School

Flow cytometry (FC) measures the light scatter and fluorescent emissions of conjugated monoclonal antibodies directed to cells in suspension. Imaging flow cytometry extends the utility of FC by adding the ability to simultaneously examine cellular morphology along with the spacial distribution of fluorescence staining. Mass cytometry substitutes metals for fluorescence and dramatically expands the capacity of measurements of cell suspensions and recently has evolved into the analysis of tissue sections.

2:40 Three-Dimensional Imaging of Individual Cells: Use of Cell-CT Has a Variety of Potential Applications in Morphology-Based Assays

David C. Wilbur, M.D., Professor, Pathology, Massachusetts General Hospital

Routine cytologic assays use 2-dimensional analyses either manually or in automated modes. The additional of high resolution 3-dimensional image capture adds fundamentally different information to both conventional morphologic and algorithmic-driven automated analyses, which has the potential to substantially increase the discriminatory power. This talk describes the Cell-CT technology and presents data regarding its potential use in a variety of clinically-relevant applications, most notably lung cancer screening.

3:10 Deep Learning for Computational Pathology

Andrew H. Beck, Ph.D., M.D., CEO, PathAI

Recent advances in computer vision and machine learning offer new opportunities for making the field of pathology more accurate and more predictive. We will present work from these emerging fields, with a focus on the development and application of deep learning technology for pathology.

Sponsored by OptraScan

3:40 Talk Title to be Announced

Clive Taylor, M.D., Ph.D., Consulting CMO, OptraSCAN

3:55 Unparalleled Multiplexing In Situ for Digital Pathology

Stephanie Walter, Ph.D., Research & Development Team Leader, Ultivue

Advances in research and diagnostic tools that combine high multiplexing with spatial information will open the door to discoveries with significant biological and clinical value. Ultivue's InSituPlex uses DNA-mediated sequential imaging to enable unparalleled multiplexing of biomarkers in tissue samples.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

DIGITAL PATHOLOGY

6:00 **Close of Day**

WEDNESDAY, FEBRUARY 22

7:00 am **Registration Open**

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

8:00 **Plenary Keynote Session (please see page 4 for details)**

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

IMAGE ANALYSIS

10:50 **Chairperson's Remarks**

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

11:00 **3D Printing in Anatomy and Surgical Pathology**

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

3D accretive printing is a rapidly evolving technology which offers multiple opportunities for the physical modeling of the complex biological structures. In pathology and anatomical sciences, applications of 3D printing include education, clinical care modeling, rapid prototyping of structurally based experimental systems, and in the not too distant future, tissue engineering. This session will examine some of the techniques, materials and uses of 3D accretive printing.

11:30 **The Role of Micro CT in the Imaging of Surgical Pathology Specimens**

James Michaelson, Ph.D., Director, Laboratory of Quantitative Medicine, Member, Pathology and Surgery, Massachusetts General Hospital; Associate Professor, Harvard University

The absence of rapid, detailed, 3D, information on surgical specimens is a challenge. We have found that a relatively new high resolution X-ray imaging method, Micro CT, can provide useful 3D images for many surgical specimens, including identifying margin positive breast cancer patents in 10 minutes, and locating lymph nodes. Thus, CT can provide rapid, accurate, actionable information on the surgical specimen while the patient is still in the OR.

12:00 pm **Emerging Opportunities for Clinically-Deployed, High-Throughput WSI Analytics: Real World Use Cases Come of Age**

Ulysses G. J. Balis, M.D., FCAP, FASCP, FAIMBE, Professor of Pathology, Director, Division of Pathology Informatics; Director, Pathology Informatics Fellowship Program, Department of Pathology, University of Michigan Health System

Prior to the advent of desktop-based high-throughput computing and immediately scalable cloud-based computing, high performance image analytics were effectively outside the realm of being feasibly deployed in real-world production settings. This presentation will explore and canvas recent developments in high-throughput computational approaches that effectively democratize the availability of real-time solutions in support of anatomic pathology diagnostic workflow, with examples being automated mitotic figure counting and unsupervised laser-capture microdissection image segmentation. Both didactic content and interactive examples will be included in this 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**

REGULATORY AND LEGAL ISSUES AROUND DIGITAL PATHOLOGY

1:50 **Chairperson's Remarks**

Liron Pantanowitz, M.D., Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center, Conference Chairman

2:00 **Digital Pathology: What Will the Regulations Bring**

Esther Abels, Director, Quality and Regulatory and Medical Affairs; Emerging Businesses, Philips Digital Pathology Solutions

Primary diagnosis using digital pathology could become a reality in the United States in the near future. FDA may soon classify Whole Slide Imaging (WSI) systems intended for Primary Diagnosis as Class II devices, simplifying the pre-market process. This would be a big step forward in bringing these systems to market quickly and facilitating their lifecycle management, and could also speed innovation in the field, benefiting specialty of pathology and, most importantly, patients.

2:30 **CAP Quantitative Image Analysis Guideline Update**

Liron Pantanowitz, M.D., Professor, Pathology & Biomedical Informatics, University of Pittsburgh Medical Center, Conference Chairman

Quantitative Image Analysis (QIA) has become increasingly popular in Anatomic Pathology for diagnostic, prognostic and predictive purposes. Drawbacks to employing QIA in clinical practice include lack of standardization. If not implemented, calibrated and used well QIA algorithms can generate misleading results. The College of American Pathologists (CAP) has accordingly assembled a committee to develop guidelines in order to perform consistent QIA. This talk will review these new evidence-based guidelines.

3:00 **WSI Performance Assessment to Inform Digital Pathology Diagnostic Applications**

Mark Simpson, Ph.D., Senior Scientist, Laboratory of Cancer Biology and Genetics, National Cancer Institute

Evaluation of safe replacement of conventional microscopy by whole slide image digital pathology systems, as a suitable method for primary clinical diagnosis, will help with wider adoption of the technology. Elements of instrument approvals for diagnostic tests include validations of hardware and diagnostic performance.

Identification and enumeration of neoplastic mitotic activity serves as an objective and clinically relevant histopathological feature to analyze comparable abilities for diagnostic discrimination using digital pathology in a clinical paradigm. Detailed design, conduct and summary findings of intra- and inter-observer pathologist performance in a multi-center, multi-reader, multi-case clinical study employing a split-plot design to assess performance comparing stains and digital (virtual) and conventional microscopy modalities will be presented.

3:30 Session Break

DIGITAL PATHOLOGY AND IMMUNOTHERAPY MARKERS

3:40 Chairperson's Remarks

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

3:45 Clinical Value of Studying the Tumor Immune Microenvironment Using Multiplex Quantitative Approaches

Kurt A. Schalper, M.D., Ph.D., Assistant Professor, Pathology and Medicine (Medical Oncology), Yale School of Medicine; Director Translational Immuno-oncology Laboratory, Yale Cancer Center

Understanding the tumor immune microenvironment could support the optimal use of novel anti-cancer immunostimulatory therapies. *In situ* detection of immune inhibitory molecules and immune cells in the tumor allows signal measurement with preservation of key contextual (morphological) information. We will discuss the clinical value of objective/quantitative assessment of actionable immune targets, immune cell subpopulations and functional markers in lung cancer specimens using multiparametric imaging and automated analysis.

4:15 Association of PDLs, Cytotoxic T Cells, and Mutational Load to Each Other and to Anti-PD-1

Janis M. Taube, M.D., Associate Professor, Dermatology, Pathology, and Oncology; Director, Dermatopathology Division and Fellowship, Johns Hopkins University School of Medicine

Multiple single immunologic and genetic biomarkers have been identified as both prognostic and predictive of response to PD-1/PD-L1 checkpoint blockade. We use multiplex immunofluorescence and gene expression studies from formalin-fixed paraffin-embedded tissue to explore the relationship between multiple immunoactive features in the tumor microenviornment to each other and to patient outcome. We will discuss prioritizing and combining biomarkers with a focus on patients with melanoma and Merkel cell carcinoma.

4:45 The Role of Digital Pathology in Assessing the Target for PD-L1 Immuno-Therapy

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

The PD-1 axis drugs are making history with dramatic responses in lung cancer and melanoma, but also with the need for, and the confusion around the diagnostic tests that select patients for these therapies. This talk will examine the problems with the existing assays and illustrate the role of digital pathology in finding solutions to these problems.

5:15 Close of Conference Program

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- **PCR & NGS-Based Molecular Diagnostics**
- **Clinical NGS Diagnostics**
- **Genomic Sample Prep, Assay Development and Validation**

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Cambridge Healthtech Institute's Second Annual

PRECISION MEDICINE

Beyond the Genome for Insights into New Treatments

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

OPENING KEYNOTE SESSION

11:50 Chairperson's Opening Remarks
Harry Glorikian, Healthcare Consultant

12:00 pm Accelerating Precision Health for All
Stephanie Devaney, Ph.D., Deputy Director, NIH
The National Institutes of Health seeks to enroll one million people in a national effort to learn more about individual differences that influence health and disease. The Precision Medicine Initiative® Cohort Program will empower participants, health care providers, and researchers to work together, creating a new model of research to accelerate science and improve the health of future generations.

12:30 Cancer Moonshot as a Model for Precision Medicine
Aristides A.N. Patrinos, Ph.D., Senior Adviser, United States Secretary of Energy and Programs and Policy Advisor, Synthetic Genomics Inc.
In his last State of the Union Address, President Obama announced the "Cancer Moonshot" initiative and asked Vice President Biden to lead the effort. Understandably there was much skepticism about yet another "war on cancer" especially one started during the waning period of the Administration. Despite that skepticism, significant progress has been achieved particularly in novel ways to take on the cancer scourge.

1:00 Session Break

Sponsored by inspirata

1:10 Luncheon Presentation I to be Announced

1:40 Luncheon Presentation II *(Sponsorship Opportunity Available)*

2:10 Session Break

PRECISION DIAGNOSIS FOR PRECISION MEDICINE

2:30 Chairperson's Remarks
Mark S. Boguski, M.D., Ph.D., Founder & CMO, Precision Medicine Network, Inc.

2:40 Computational Pathology: Precision Diagnoses and Beyond
Jeffrey A. Golden, M.D., Ramzi S. Cotran Professor & Head, Pathology, Brigham & Women's Hospital
Computational Pathology leverages the vast, data rich information acquired on patients to inform Precision Medicine. The basic tenets of our approach include: 1. Integrate multiple sources of raw data. 2. Generate algorithms and mathematical models to test hypotheses and statistically validate the data at molecular, individual, and population levels with the goal to provide tools for diagnostic inferences and predictions. 3. Presentation of clinically actionable knowledge to the end user.

3:10 Precision Medicine beyond Oncology
Marielena Mata, Ph.D., Head, Precision Medicine, GlaxoSmithKline
Precision Medicine is often associated with Oncology where the ability to select patients for targeted therapies has resulted in increased efficacy. Yet, the use of biomarkers and companion diagnostics is becoming an important strategy to better identify the patients that will benefit the most from the safe and efficacious use of treatments in other therapeutic areas. We will review the current state of Precision Medicine and identify opportunities and challenges outside of Oncology.

3:40 Precision Microbiota Applications in Clinical Therapy and Diagnosis
Lynn Bry, M.D., Ph.D., Associate Professor, Pathology and Director, Massachusetts Host-Microbiome Center + Crimson Core, Brigham & Women's Hospital
The microbiota, or compending of organisms living on and in us, provide essential functions for normal health and physiology. They also contribute to a variety of diseases. This non-human organ is also increasingly being used to develop and target new therapies for a variety of conditions, from Clostridium difficile colitis, to treatment of IBD, and other autoimmune, allergic and metabolic diseases.

Sponsored by envision genomics

4:10 Presentation to be Announced

Sponsored by biomax informatics ag

4:25 Convergence of Precision Medicine and Real World Evidence
Klaus Heumann, Ph.D., CEO & Founder, Biomax Informatics AG
Real World Evidence Data provides new opportunities for the pharmaceutical industry. We will show how our semantic technologies enable novel concepts of care that implement Precision Medicine based on Real World Evidence Data in clinical practice.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session (please see page 4 for details)

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

IMPLEMENTATION OF PRECISION MEDICINE AT THE PATIENT LEVEL: WHAT DO DOCTORS NEED TO KNOW?

10:05 Chairperson's Remarks
Harry Glorikian, Healthcare Consultant
- What does result mean?
- What do I do with it?
- How do I manage patient?

10:15 Precision Cancer Medicine at the Bedside – The Provider Perspective
Stacy W. Gray, MD, AM, Associate Professor, Population Sciences, Division of Clinical Cancer Genetics, City of Hope Comprehensive Cancer Center
Rapid advances in genomic technologies are revolutionizing oncology. However, genomic data are complex and often highly uncertain in nature. Even after genomic data have been filtered and analyzed, providers may or may not understand how to use genomic data to guide cancer care. This talk will review current research on providers' attitudes about and understanding of large-scale genomic data and discuss possible innovations that aim to address knowledge gaps.

10:45 Precision Oncology Decision Support: Getting the Right Drug(s) to the Right Patient(s) at the Right Time(s)
Kenna R. Mills Shaw, Ph.D., Executive Director, Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personal Cancer Therapy (IPCT)
This talk will review the complexities of implementing a precision oncology decision support system at a major cancer center and why such a system is necessary to ensure optimization of clinical utilization of genomic testing data, particularly for matching to clinical trials.

11:15 Use of Clinical Genome and Exome Sequencing in Patients with Suspected Heritable Disease
Jason Merker, M.D., Ph.D., Co-Director of the Stanford Medicine Clinical Genomics Service, Pathology, Stanford University School of Medicine
Genome and exome sequencing are being increasingly applied in clinical practice for the diagnosis of unexplained heritable disease. I will describe our experience establishing a clinical genomics service at an academic medical center that uses genomic sequencing to identify the molecular etiology in patients with unexplained pediatric syndromes, heritable cardiovascular disease, and heritable cancer predisposition. This will include discussion of the advantages and disadvantages of these methods, clinical workflow, and case examples.

11:45 Sponsored Presentation *(Opportunity Available)*

12:15 pm Session Break

12:25 Luncheon Presentation I: Co-Developing Diagnostics and Therapeutics: Consideration and Case Studies
Sponsored by MolecularMD
Dan Snyder, MBA, President & CEO, MolecularMD

12:55 KEYNOTE PRESENTATION: The Nuts and Bolts of the Precision Pathology Center
Michael H. A. Roehrl, M.D., Ph.D., Director, Precision Pathology Biobanking Center, Memorial Sloan Kettering Cancer Center
We will discuss the central role of Precision Pathology in cutting-edge health care. We have built a new and comprehensive Center around five key pillars: (1) Precision Biobanking; (2) Precision Health Informatics; (3) New and Disruptive Diagnostic Technologies; (4) Pathology Hub for Precision Clinical Trials; and (5) R&D and Commercialization Partnerships with Biotech and Pharma. The talk will highlight the challenges and opportunities of Big Data acquisition, processing, and federation for research and improved patient management.

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

KNOWLEDGE-SHARING IN PRECISION ONCOLOGY

2:00 Chairperson's Remarks
J. Marty Tenenbaum, Ph.D., Founder & Chairman, Cancer Commons
In the era of molecular medicine, knowledge changes very rapidly and is highly dispersed. No single individual knows the optimal way to treat any complex case, nor even how to find out. Current trial designs (including modern "adaptive" designs) can't efficiently search the huge space of (molecular subtypes) x (treatment combinations). In the absence of definitive trials, the best way to help current patients achieve better outcomes, is by mining and validating the insights, intuitions, and experience of our best clinicians. This panel will explore approaches to rapid capture, dissemination, and validation of clinically actionable knowledge.
Benefits and challenges of a precision oncology knowledge sharing network:
- What constitutes knowledge worth sharing?
- How can it be most easily located and captured?
- How can we get it to the right people at the right time?
- How can we validate and refine the knowledge based on clinical experiences?
- What steps can we take today to begin?

2:10 Knowledge Generation and Sharing: An Academic Cancer Center Perspective
Alan Ashworth, Ph.D., FRS, President, UCSF Helen Diller Family Comprehensive Cancer Center; Senior Vice President for Cancer Services, UCSF Health Professor Medicine, Division of Hematology/Oncology, Medicine; E. Dixon Heise Distinguished

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Professor, Oncology, University of California, San Francisco

New technologies are driving the acquisition of large amounts of genomic and other complex data and this is increasingly being used to direct cancer therapy. However interpretation is challenging due to the heterogeneity of cancer. Sharing, aggregation and meta-analysis of this data is essential if the promise of precision medicine for cancer is to be realized. Opportunities and challenges in knowledge generation and sharing will be discussed.

2:20 Can a Professional Society Play a Role in Rapid Cancer Learning

Laurence J. Marton, M.D., Member, Board of Trustees, American Association for Cancer Research Foundation; Member, Board of Directors, Cancer Commons

Professional cancer societies have a membership drawn from students to professors, and from support group members to government and industry participants. A number of these societies are convening groups to collate and share omic and clinical data. Not yet a part of most cooperatives is the ability and imperative to share data, insights, and knowledge that might inform regarding relevant therapeutic interventions for patients who have reached the point of choices beyond the standard of care. The tools to do so are now being crafted and such activity is critical.

2:30 Medbook and Casebook: A Platform and Application for Collaboration between Bioinformatics Researchers and Clinicians

Ted Goldstein, Ph.D., University of California, Santa Cruz

2:40 Capturing, Analyzing, and Publishing Tumor Board Cases and Insights

Jeff Shrager, Ph.D., CTO, Cancer Commons

Advanced tumor boards now regularly consider difficult cases, often considering molecular data. However, it can take years for the unique insights developed in these settings to reach additional patients. The CaseBook platform and process enables tumor boards to aggregate and share clinical insights, especially treatment hypotheses and reasoning, and to search and analyze these data to provide insights that might be relevant to treating new patients.

2:50 PANEL DISCUSSION

3:40 Global Commercialization of Companion Diagnostics: Value Capture in Personalized Medicine

Sponsored by BOSTON HEALTHCARE

Joseph Ferrara, President, Boston Healthcare

Given rapid advances in diagnostic technology and significant changes in the global healthcare funding environment, how can pharmaceutical and diagnostic companies deliver the increased value and access demanded by providers, payers, and patients in personalized medicine? Key commercialization factors for Rx/Dx innovators will be highlighted.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

GENOMIC SEQUENCING AND PRECISION MEDICINE IN NEWBORNS

10:50 Chairperson's Remarks

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

11:00 Genomic Sequencing of Healthy and Sick Newborns in the BabySeq Project

Joel Krier, M.D., MMSc, Clinical Chief, Division of Genetics; Director, Brigham Genomic Medicine, Brigham and Women's Hospital; Instructor, Harvard Medical School

The BabySeq Project is a proof-of-concept randomized control trial examining the implications of genomic newborn sequencing (gNBS) in two populations: a) sick or premature neonates admitted to the Boston Children's Hospital and Brigham and Women's Hospital (BWH) ICUs and b) generally healthy neonates from the BWH well nursery. This presentation will summarize the key progress and findings to date including study design, implementation, and preliminary results.

11:30 Ethical and Social Challenges Associated with Sequencing Newborns

Don Bailey, Ph.D., Distinguished Fellow, RTI International

Next-generation sequencing offers the promise of potentially useful health information but also evokes a number of ethical and social challenges. I describe a few of the major concerns, summarize what is known about each, and suggest strategies by which each could be mitigated.

12:05 pm Exome Sequencing of Newborn Dried Blood Spots: Implications for Newborn Screening and for Exome Diagnostics

Aashish Adhikari, Ph.D., Postdoc, University of California, Berkeley

Public health newborn screening (NBS) identifies newborns with rare treatable conditions, permitting early intervention. The NBSeq project is evaluating the potential of whole exome sequencing in NBS using de-identified, archived dried blood spots (DBS) under an IRB-approved protocol with the California Department

of Public Health. One aim explores feasibility of WES to replace or augment MS/MS for metabolic disorders. DBS of all California newborns from Jul 2005–Dec 2013 with disorders diagnosed by MS/MS and a selection of false positives were made available (1600 samples) and are being studied.

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**

BUILDING THE INFRASTRUCTURE FOR PRECISION MEDICINE: TOOLS AND GUIDELINES

1:50 **Chairperson's Remarks**
Harry Glorikian, Healthcare Consultant

2:00 **Real World Medicine and Real World Patients: Critical Understanding for Translational and Precision Medicine**
Michael N. Liebman, Ph.D., Managing Director, IPQ Analytics, LLC; Professor, Drexel College of Medicine; Professor, Wenzhou First University Medical School

2:30 **Establishing Guidelines for Use in Precision Medicine**
Andrea Ferreira-Gonzalez, Ph.D., Professor and Chair, Division of Molecular Diagnostics; Director, Molecular Diagnostics Laboratory, Pathology, Virginia Commonwealth University
Next-generation DNA sequencing technology is revolutionizing precision medicine in genetics and cancer genomic diagnostics by enabling precision cancer medicine by directing molecularly targeted therapies. Adoption of NGS brings unprecedented challenges in incorporating this technology in the clinical setting. This presentation will provide a comprehensive overview on the key practice guidelines and good laboratory practices for implementation of clinical next-generation sequencing including assay development, validation, data management, analysis and interpretation of data in a CAP/CLIA environment.

3:00 **Is the Idea of a Precision Medicine Information Commons Just a Utopian Dream?**
Maynard V. Olson, Ph.D., Professor Emeritus, Medicine and Genome Sciences, University of Washington
All "Precision Medicine" initiatives will depend on data sets containing clinical and molecular information about enormous numbers of patients. Because current initiatives are building their own data resources with little coordination, future prospects of large-scale data-sharing are poor. The National Research Council's Precision Medicine report makes a strong case for a pre-competitive Information Commons. Now is the time to ask whether this goal remains desirable and, if so, feasible.

3:30 **Session Break**

WRESTLING WITH BIG DATA: IMPLICATIONS FOR DISCOVERY, REIMBURSEMENT, REGULATION, AND CLINIC

3:40 **Chairperson's Remarks**
Andrew C. Fish, J.D., Executive Director, AdvaMedDx

3:45 **Big Data – The Devil's in the Details**
Elaine K. Jeter, M.D., J1 MolDx Medical Director, Palmetto GBA
Linking effective therapies and expanded trial designations are the expected benefit of the ever expanding capabilities of genomic biomarker and gene expression identification. More and more data is being generated every day. Keeping that data 'valuable' will require we maintain a critical focus on the quality and comparative values of the data, especially in the area of genomics and more specifically outcomes. Other questions will arise around where the data is collected, how it is curated, and who has access. As a Medicare payer, we support the concept of data collection/aggregation if that data can be effectively mined to create ever improving treatment protocols and more importantly improved outcomes.

4:00 **Efficiently Leveraging Commercial and Open Source Bioinformatics Tools for Clinical Interventions and Research Discoveries from Very Large Datasets**
Ben Busby, Ph.D., Genomics Outreach Coordinator, NCBI, NLM/NIH
In precision medicine, it is often the case that efficacy does not depend on the appropriate computational intervention, but on the morphology of the data that informs the problem. For example, different strategies should be employed when calling short variants in stable versus unstable regions of the human genome, or when looking for pathogenic effectors in well-characterized versus newly discovered bacterial or viral pathogens. Pragmatic solutions from existing commercial and open source resources will be presented.

4:15 **From Bits to Bedside: Developing a Learning Digital Health System to Evaluate Pigmented Skin Lesions**
Dexter Hadley, M.D., Ph.D., Assistant Professor, Pediatrics, Institute for Computational Health Sciences, University of California, San Francisco
Melanoma accounts for less than one percent of skin cancer cases but the vast majority of skin cancer deaths. Early screening and diagnosis significantly improves patient outcomes, yet no systematic framework exists for clinical evaluation of common pigmented lesions for risk of melanoma. In this talk, I will describe our approach to develop a learning health system focused on precision screening and diagnosis of skin cancer. We first leverage medical students in the clinics to capture digital samples of pigmented skin lesions at scale with mobile health technology. We then leverage this clinical big data to train state-of-the-art deep learning image classification algorithms to better screen for cancer. Our work translates routinely documented electronic health data into an impactful digital health initiative to directly improve clinical outcomes and advance clinical knowledge.

4:30 **PANEL DISCUSSION**

5:15 **Close of Conference Program**

Cambridge Healthtech Institute's Fourth Annual

PCR & NGS-BASED MOLECULAR DIAGNOSTICS

Insight into the Tools that Drive Personalized Medicine

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

VALIDATING NEW TESTS

11:50 Chairperson's Opening Remarks

Tara Sigdel, Ph.D., Assistant Professor, Department of Surgery, University of California, San Francisco

12:00 pm Validation/QC Challenges for Germline Panels, Exomes, and Genomes

Josh Deignan, Ph.D., FACMG, Associate Director, UCLA Molecular Diagnostics Laboratories, Pathology and Laboratory Medicine, University of California, Los Angeles

The validation of next-generation sequencing tests is more complex than the validation of other molecular tests and often requires new approaches to address all of the required validation components. This talk will describe some of those new approaches.

12:30 Rapid Genome Sequencing in Neonatal Intensive Care

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

Within the 4000 known single gene disorders, a significant fraction manifests symptoms during the newborn period. A rapid diagnosis of newborn diseases could make the difference between life and death and reduce length of stay in the neonatal intensive care unit (NICU). A targeted 4200 known disease-causing gene panel has been developed with a short turnaround and a focused interpretation combining genetics etiology with phenotype will provide a comprehensive clinical understanding of disease in NICU.

1:00 Session Break

Sponsored by EXIQON Seek Find Verify

1:10 Luncheon Presentation I: RNA in Liquid Biopsies – Promising New Biomarkers of Diseases

Peter Mouritzen, Vice President, Research & Development, Exiqon

To discover new biomarkers and develop minimal invasive tests, we have developed robust methods for NGS of smallRNA in biofluids. For high-throughput profiling microRNA in biofluids, highly sensitive LNA™-based qPCR is applied. Recent results will be discussed from the prostate cancer program.

1:40 Luncheon Presentation II *(Sponsorship Opportunity Available)*

2:10 Session Break

COMPARISON AND STANDARDIZATION OF METHODS

2:30 Chairperson's Remarks

Tara Sigdel, Ph.D., Assistant Professor, Department of Surgery, University of California, San Francisco

2:40 Validation of Gene Biomarkers: Comparison of Two Gene Expression Assay Platforms Using FFPE Tissues

Tara Sigdel, Ph.D., Assistant Professor, Department of Surgery, University of California, San Francisco

Gene transcript (mRNA) biomarkers are useful as they can be quantified in laboratory setting using methods that are accessible to the researchers in both academic and commercial settings. Because of importance of the quality of generated data, it is in researchers' interest to choose a better system in their research. Here we compared two gene expression quantification methods using probe based vs. conventional QPCR-based detection systems.

3:10 Recent Advances On Circulating MicroRNA Analysis

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

Circulating RNA, especially RNA encapsulated in lipid vesicles, has gained significant interest due to their possible clinical applications. Despite the potential, it is a challenge to accurately profile the circulating RNA. This is due to both sample and technical related issues. We made improvements on sequencing-based small RNA profiling as well as extracellular vesicle purification. These advances provide the foundation of moving this promising field forward.

3:40 Novel Applications of dPCR

Rebecca Sanders, Ph.D., Researcher, Molecular Biology, Science and Innovation, LGC

With the development of ever growing numbers of molecular applications in fields such as diagnostics and synthetic biology, precision in validation and characterisation approaches is increasingly important. Digital (d)PCR has been shown to be accurate and precise, and can be used to interrogate new applications and complement their development. Here will be discussed the use of dPCR with expanding fields such as synthetic biology.

4:10 A Framework for the Quality Assessment of Measurement Procedures (QAMPS) Using *in vitro* Diagnostics
Michael Messenger, Ph.D., Head of Personalised Medicine and Health, University of Leeds; Deputy Director, NIHR Diagnostic Evidence Co-operative Leeds
In Vitro Diagnostic (IVD) medical devices form the basis of ~70% of clinical decision making in the NHS. The accuracy and associated uncertainty surrounding diagnostic testing consequently has a major impact on the overall quality of clinical decisions and subsequent clinical and cost effectiveness. We are not aware of any methods in use for evaluating the quality and appropriateness of measurement procedures within systematic reviews of IVDs. To address this issue, we have identified key parameters for consideration by systematic reviewers and developed a framework for Quality Assessment of Measurements Procedures, using IVDs. Herein we present a case study applying this framework, where several measurement parameters were identified that present a high risk of irreproducibility and inapplicability.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session **(please see page 4 for details)**

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session **(please see page 4 for details)**

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

FDA APPROVAL OF MOLECULAR TESTS

10:05 Chairperson's Remarks
Karen A. Heichman, Ph.D., Vice President, Director, PharmaDx Program, ARUP Laboratories; Pathology, University of Utah

10:15 The FDA Review Process for Companion Diagnostic Devices
Soma Ghosh, Ph.D., Scientific Reviewer, FDA/CDRH/OIR/DMGP
Companion diagnostics have emerged as a powerful tool in personalized medicine allowing treatment decisions to be tailored for each patient. They are essential for the safe and effective use of many emerging and established therapeutic products, and promise a clearer understanding of disease development at the individual level. In the light of their expanding role in clinical decision making, my talk will focus on the critical regulatory review elements that FDA considers when evaluating companion diagnostic devices. I will illustrate key points using recent approvals as examples.

10:45 ARUP Laboratories' Experience with FDA Approval of Companion Diagnostic (CDx) Tests within the Clinical Laboratory Environment
Karen A. Heichman, Ph.D., Vice President, Director, PharmaDx Program, ARUP Laboratories; Pathology, University of Utah
In December 2015, ARUP Laboratories received FDA approval for two CDx tests for Gleevec eligibility: KIT D816V Mutation Detection by PCR and PDGFRB FISH. These two tests are performed exclusively by ARUP as required under HDE regulations. ARUP established an augmented quality system integrated within the CLIA environment, which meets FDA requirements for medical devices, including a design control program. This presentation will address ARUP's successful approach to CDx development.

11:15 Regulatory Pathways for NGS Applications and Other Advanced Technologies
Pamela Swatkowski, Director, Regulatory Affairs, Abbott Molecular

11:45 Panel with Session Speakers

12:15 pm Session Break

Sponsored by Beckman Coulter Life Sciences

12:25 Luncheon Presentation I: Tackling the Challenge of FFPE DNA Extraction: An Automation Ready Solution Designed with an NGS Focus
JD Harper, Genomics Specialist, Automation & Genomics, Beckman Coulter Life Sciences

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

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

EMERGING TECHNOLOGIES AND TECHNIQUES

2:00 Chairperson's Remarks
Robert J. Meagher, Ph.D., Principal Member, Biotechnology and Bioengineering, Sandia National Laboratories

2:10 Targeted Sequence Capture (ViroCap) to Enhance the Sensitivity of Metagenomic Sequencing for the Detection of Viruses in Clinical Samples
Gregory Storch, M.D., Ruth L. Siteman Professor, Pediatrics, Washington University School of Medicine
Metagenomic sequencing is an emerging method for detecting microbial nucleic acids in clinical samples. We have developed a target-capture method (ViroCap) to enhance the sensitivity of metagenomic sequencing for detecting viruses in complex samples. Our results show dramatic increases in number of viruses detected, and breadth and depth of coverage. With this method, it is often possible to recover the complete viral genome directly from clinical samples.

2:40 FDA Experience with Emerging Genomics Technologies
Weida Tong, Ph.D., Director, Division of Bioinformatics and Biostatistics, NCTR/FDA
Emerging genomics methodologies contribute to our understanding of disease and health. However, its value in regulatory applications requires rigorous assessment

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and consensus between various stakeholders. The presentation overviews the FDA efforts in this field with a specific discussion of the FDA-led community-wide Microarray/Sequencing Quality Control (MAQC/SEQC). The new MAQC project, known as SEQC2, will be introduced which is focused on assessing the power and limitations of whole genome sequencing and target gene sequencing in clinical application.

3:10 Quenching of Unincorporated Amplification Signal Reporters (QUASR) for Robust Monitoring of Isothermal DNA and RNA Amplification Assays

Robert J. Meagher, Ph.D., Principal Member, Biotechnology and Bioengineering, Sandia National Laboratories

Isothermal nucleic acid amplification techniques such as LAMP are promising alternatives to PCR for point-of-need molecular diagnostics, but many of these techniques are hindered by relying upon non-specific detection chemistry. We present a simple, yet powerful modification to LAMP called QUASR that provides bright, multiplexable, target-specific signals with reduced false positives, high sensitivity even with complex sample matrices, and compatibility with simple instrumentation including a smart phone-based fluorescence imager.

Sponsored by METABOLON

3:40 Constructing an Atlas of the Human Metabolome to Enable Phenotyping and Genome Mapping

Mike Milburn, Ph.D., CSO, Metabolon

By producing a comprehensive read-out of an individual, we will describe how metabolomics is creating an "atlas" for understanding human health and disease and elucidating how major drivers like genetics, lifestyle and the microbiome exert their influence.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

ANTIMICROBIAL RESISTANCE AND RAPID SUSCEPTIBILITY TESTING

10:50 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

11:00 Emerging Technologies for Rapid Susceptibility Testing

Jennifer Dien Bard, Director, Clinical Microbiology Laboratory, Assistant Professor, Clinical Pathology, Keck School of Medicine of the University of Southern California

Despite significant advances in the approaches to pathogen identification directly from clinical specimens, antimicrobial susceptibility testing is mainly performed by conventional methods, delaying results by 2-5 days. There is an unmet need for rapid, phenotypic approaches to susceptibility testing directly from clinical specimens. The current multiplexed molecular panels available identify organisms directly from positive blood cultures and detect the presence of resistance markers. This session will summarize the current and emerging technologies for rapid phenotypic susceptibility testing.

11:30 Sizing Up Your Enemy: The Use of Molecular Tests to Predict Antimicrobial Resistance in *Neisseria Gonorrhoeae*

Peera Hemarajata, M.D., Ph.D., D(ABMM), Clinical Instructor, Pathology and Laboratory Medicine, David Geffen School of Medicine, University of California, Los Angeles

Neisseria gonorrhoeae has become a serious threat due to high prevalence of antimicrobial resistance. Prospective susceptibility testing enables physicians to use antimicrobials other than those recommended for empirical treatment, and could potentially delay emergence of resistance to recommended antibiotics. Few laboratories routinely perform culture and susceptibility testing for *N. gonorrhoeae*. We will discuss molecular assays that may be able to predict susceptibility directly from specimens without the need for culture.

12:00 pm Insights into Antimicrobial Resistance Learned from NGS

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

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

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MOLECULAR-BASED POINT-OF-CARE TESTS

1:50 Chairperson's Remarks
Paul Drain, M.D., MPH, FACP, Assistant Professor, Global Health, Medicine, and Epidemiology, University of Washington

2:00 Creating Molecular Point-of-Care Diagnostics for Use in Resource-Limited Settings: Lessons Learned from South Africa
Paul Drain, M.D., MPH, FACP, Assistant Professor, Global Health, Medicine, and Epidemiology, University of Washington
Although point-of-care diagnostics have been widely adopted worldwide, newer molecular tests are facing operational challenges in resource-limited settings. A rapid molecular diagnostic test for tuberculosis was introduced in South Africa, but studies have not demonstrated a significant clinical impact. This presentation will summarize studies on the application of the test in South Africa, as well as the critical lessons learned for the future design and implementation of advanced diagnostics for infectious diseases.

2:30 Nano for Mano: Developing Handheld Molecular Diagnostics with Nanotechnologies
Cesar M. Castro, M.D., Director, Cancer Program, MGH Center for Systems Biology, Massachusetts General Hospital and Harvard Medical School
An inherent tension exists between clinical researchers' molecular diagnostic needs and the practical realities of patient biopsies. Expanded and rapid protein profiling often requires ample specimen. Nanotechnologies create opportunities to extract adequate molecular readouts from less sample amounts. Coupled with advances in miniaturized devices, inroads have been made across disease types. This talk describes such multidisciplinary work in the oncology and infectious disease spaces as means to advance global medicine.

3:00 Point-of-Care Testing for Ebola and Other Highly Infectious Threats: Principles, Practice, and Strategies for Stopping Outbreaks
Gerald J. Kost, M.D., Ph.D., M.S., FACB, Director, POC Testing Center for Teaching and Research (POCT•CTR), Pathology and Laboratory Medicine, School of Medicine, University of California, Davis
We will identify key principles of point-of-care testing (POCT) for Ebola patients and others exposed to highly contagious diseases and assess evidence from recent crises, Ebola in West Africa, MERS in South Korea, and now, Zika. The goals are to stop the spread of disease and to prevent these types of epidemics from happening again. Hospitals that admitted Ebola patients mitigated risk by using POCT for critical care support in isolation units.

3:30 Session Break

EMERGING CANCER MOLECULAR MARKERS

3:40 Chairperson's Remarks
Gerald J. Kost, M.D., Ph.D., M.S., FACB, Director, POC Testing Center for Teaching and Research (POCT•CTR), Pathology and Laboratory Medicine, School of Medicine, University of California, Davis

3:45 Deciphering the Code of Single EVs and RNPs Released from Glioblastoma Cells
Leonora Balaj, Ph.D. Research Fellow, Massachusetts General Hospital, Harvard Medical School
Tumor cells release a variety of content in the extracellular milieu that includes lipid-based vesicles as well as ribonucleoprotein (RNP) complexes. Lipid vesicles are termed extracellular vesicles (EV) and include vesicles ranging from 50nm to 1µm and above. mRNA, miRNA, ncRNA DNA and proteins have all been described to be present in the extracellular environment but it is currently unknown the extent to which each subpopulation is present at any given time. Data will be reported on counting of these molecules from two glioblastoma cells under normal and hypoxic conditions.

4:15 Exosomal MicroRNAs Regulate the Biology of the Tumor Microenvironment
Muller Fabbri, M.D., Ph.D., Assistant Professor, Pediatrics and Molecular Microbiology & Immunology, Pediatric Hematology/Oncology, Children's Hospital Los Angeles - University of Southern California
MicroRNAs can be shuttled between different cell populations of the Tumor Microenvironment. The exchange of microRNAs affects the phenotype of cancer cells and surrounding cells contributing to cancer growth and resistance to therapy. Conversely, immune cells can affect cancer growth by releasing specific exosomic microRNAs. This lecture will focus on the role of exosomal microRNAs as central determinants of the biology of the tumor microenvironment and of cancer resistance.

4:45 Noncoding RNAs as Biomarkers in Gastrointestinal Cancer
Ajay Goel, Ph.D., Professor and Director, Center for Gastrointestinal Research, and Director, Center for Epigenetics, Cancer Prevention and Cancer Genomics, Baylor Research Institute, Baylor University Medical Center
Noncoding RNAs (ncRNAs) are emerging as important regulators of gene expression in cancer. Overexpression of specific noncoding RNAs (including microRNAs, SnoRNAs, piRNAs and circular RNAs) has been linked to the stepwise disease progression in colorectal cancer (CRC). Given their cancer-specific pattern of expression, remarkable stability and presence in blood and other body fluids, ncRNAs are considered to be highly promising cancer biomarkers. Accumulating evidence firmly supports the existence of unique 'ncRNA signatures' that can not only facilitate earlier detection of the tumor, but can also assist in predicting disease recurrence and therapeutic outcome to current treatment regimens.

5:15 Close of Conference Program

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Cambridge Healthtech Institute's Tenth Annual

CLINICAL NGS DIAGNOSTICS

Translating Genomic Data to the Standard of Care

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

NEXT GENERATION SEQUENCING FOR INFECTIOUS DISEASES

11:50 Chairperson's Opening Remarks

Andrew Bryan, M.D., Ph.D., Acting Assistant Professor, Assistant Director, Clinical Microbiology, Department of Laboratory Medicine, University of Washington

12:00 pm Emerging Assays for Infectious Diseases in Diagnosis and Outbreak Surveillance

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

Advances in technology, genomics, and bioinformatics and the vast increases in the size of reference databases have made comprehensive diagnosis of infectious diseases practical. Here we will discuss the promise, challenges, and experience with clinical validation and implementation of a metagenomic next-generation sequencing (mNGS) assay for identification of pathogens in hospitalized patients. We will also discuss the use of new technologies, including nanopore sequencing and transcriptome profiling, for surveillance of epidemics such as the 2015-2016 Zika virus outbreak in the Americas.

12:30 Implementation of Metagenomic Next-Generation Sequencing for Pathogen Detection in the Clinical Laboratory

Samia Naccache, PhD, Clinical Microbiology Fellow, Pathology and Lab Medicine, Children's Hospital Los Angeles

Metagenomic next-generation sequencing (mNGS) for pathogen detection allows for unbiased identification of infectious agent nucleic acid in clinical samples. We have implemented this assay in the UCSF clinical laboratory for diagnosis of meningitis / encephalitis using optimized library preparation and bioinformatics processing steps, with case discussion and decision support through the Microbial Sequencing Board. This talk will outline the mNGS assay performance, clinical utility and effect on patient management decisions.

1:00 Session Break

1:15 Luncheon Presentation: Years On the Bench: Design and Implementation of a Microbial NGS Clinical Diagnostics System

Jeremy Ellis, Ph.D., Research Director, Laboratory Manager, Research & Development, Fry Laboratories, LLC

Translating research-based NGS methods into the clinical diagnostics laboratory poses several unique challenges. Experience with a microbial NGS diagnostics assay will be reviewed in addition to design requirements. Our system, RIDI™, will be used to explore challenges and opportunities.

2:10 Session Break

IMMUNOSEQUENCING AND CANCER MEDICINE

2:30 Chairperson's Remarks

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

2:40 Profiling of Exhausted T Cells in Tumors Predicts PD-1 Response

Kelly Mahuron, M.D., Resident, School of Medicine, University of California, San Francisco

Immune checkpoint blockade is revolutionizing therapy for advanced cancer. However, many patients do not respond to treatment. The identification of robust biomarkers that predict clinical response to specific checkpoint inhibitors is critical in order to stratify patients and to rationally select combinations in the context of an expanding array of therapeutic options. We performed multi-parameter flow cytometry on freshly isolated metastatic melanoma samples prior to treatment and correlated subsequent clinical response with tumor immune phenotype.

3:10 Defining Immunoglobulin Somatic Hypermutation in *de novo* Diffuse Large B-Cell Lymphoma Patients: Potential Application for Prognosis and Risk Stratification

Ken H. Young, M.D., Ph.D., Professor, Hematopathology, The University of Texas MD Anderson Cancer Center

Characterization of immunoglobulin gene helps to identify cell-of-origin of mature B cell malignancies such as chronic lymphocytic leukemia, whereas its role in the pathogenesis of DLBCL is poorly understood. In this study, we studied molecular repertoire of both immunoglobulin heavy- and light-chain genes in a large cohort of *de novo* DLBCL patients using high-throughput next generation sequencing (NGS).

3:40 High-Throughput TCR Sequencing Provides Added Value in the Diagnosis of Cutaneous T-Cell Lymphoma

Thomas S. Kupper, M.D., Chair, Dermatology, Brigham and Women's Hospital; Dana Farber Cancer Institute; Thomas B. Fitzpatrick Professor, Harvard Medical School

Cutaneous T Cell Lymphomas (CTCL) are the most common extranodal non-Hodgkins T cell lymphomas. The diagnosis can be difficult and delayed (avg 5-6 years), as the lesions resemble inflammatory skin disorders. Unlike PCR-based clonality assays, high throughput sequencing of the TCR genes yielded a 100% sensitivity for detection of a clonal T cell population in CTCL lesions. HTS can also be used to assess response to therapy.

Sponsored by GENOPTIX

4:10 Automation of NGS-Data Analysis and Interpretation in a High-Throughput Clinical Setting

Matthew McGinniss, Ph.D., FACMG, Executive Director, Clinical Genomics, Genoptix Medical Laboratory

4:40 Refreshment Break and Transition to Plenary Session

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5:00 Plenary Keynote Session (please see page 4 for details)

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

FDA APPROVAL OF MOLECULAR TESTS

10:05 Chairperson's Remarks
Karen A. Heichman, Ph.D., Vice President, Director, PharmaDx Program, ARUP Laboratories; Pathology, University of Utah

10:15 The FDA Review Process for Companion Diagnostic Devices
Soma Ghosh, Ph.D., Scientific Reviewer, FDA/CDRH/OIR/DMGP
Companion diagnostics have emerged as a powerful tool in personalized medicine allowing treatment decisions to be tailored for each patient. They are essential for the safe and effective use of many emerging and established therapeutic products, and promise a clearer understanding of disease development at the individual level. In the light of their expanding role in clinical decision making, my talk will focus on the critical regulatory review elements that FDA considers when evaluating companion diagnostic devices. I will illustrate key points using recent approvals as examples.

10:45 ARUP Laboratories' Experience with FDA Approval of Companion Diagnostic (CDx) Tests within the Clinical Laboratory Environment
Karen A. Heichman, Ph.D., Vice President, Director, PharmaDx Program, ARUP Laboratories; Pathology, University of Utah
In December 2015, ARUP Laboratories received FDA approval for two CDx tests for Gleevec eligibility: KIT D816V Mutation Detection by PCR and PDGFRB FISH. These two tests are performed exclusively by ARUP as required under HDE regulations. ARUP established an augmented quality system integrated within the CLIA environment, which meets FDA requirements for medical devices, including a design control program. This presentation will address ARUP's successful approach to CDx development.

11:15 Regulatory Pathways for NGS Applications and Other Advanced Technologies
Pamela Swatkowski, Director, Regulatory Affairs, Abbott Molecular

11:45 pm Panel with Session Speakers

12:15 pm Session Break

12:25 Luncheon Presentation I: Tackling the Challenge of FFPE DNA Extraction: An Automation Ready Solution

Sponsored by BECKMAN COULTER Life Sciences

CLINICAL NGS DIAGNOSTICS

Designed with an NGS Focus
Jennifer MacFarland, Field Marketing Manager, Automation and Genomics, Beckman Coulter Life Science
FormaPure DNA provides an automation-ready, SPRI-based extraction reagent kit to support your evolving research needs. Most notably, it provides significant time savings in reduced turnaround times and less than 15 minutes of hands-on time when automated on a Biomek.

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

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

NGS ASSAYS IN ONCOLOGY

2:00 Chairperson's Remarks
Patrick Hurban, Ph.D., Senior Director and Global Head, Translational Genomics, Q Squared Solutions

2:10 Choosing an Effective Validation Plan for NGS Assays in Oncology
Helen Fernandes, Ph.D., Associate Professor, Personalized Genomics Laboratory, Department of Pathology & Cell Biology, Columbia University Medical Center
The analytical validation of an NGS assay for the most part determines the reliability of results and therefore dictates the effectiveness of the assay for management of the cancer. As the number of laboratories offering NGS tests in oncology increases, the need for recommendations and guidelines that address the processes of assay validation are noteworthy. Several organizations and regulatory bodies have been working on developing documents to help and guide laboratories plan and execute the validation of NGS assays for oncology. In this presentation, we will discuss the validation prerequisites that are important and need to be addressed for implementing a reliable and useful NGS assay for oncology.

2:40 Towards Implementation of NGS as Clinical Assay: FFPE Pre-Analytical Optimization and Analytical Consideration in WES Commercial Lab Selection
Ping Qiu, Ph.D., Translational Molecular Biomarkers (TMB), Genomics, Merck Research Laboratories
Higher non-synonymous mutational burden assessed by whole exome sequencing in tumors is associated with durable clinical benefit in immune checkpoint inhibitors treatment. Cancer genome WES poses a unique challenge due to limited tissue, tumor heterogeneity and sequencing artifacts introduced by FFPE tissue. Multiple genomics CROs were assessed on their NGS pre-analytics and the quality of WES data generated. Recommendations are made on FFPE WES pre-analytics and data interpretation.

3:10 Genotyping in an HTP Drug Development Pipeline: Tough Assays, High Sample Numbers, and Ever-Changing Goals
J. Colin Cox, Ph.D., Science Manager, Genentech
Deborah Siler, Ph.D., Senior Research Associate, Mouse Genetics, Genentech
Ultraconserved elements (UCEs) are DNA sequences that have been perfectly (100%) conserved for 300-500 million years. Because neither protein coding, nor enhancer, nor transcription factor binding, nor promoter regions require such

conservation, the mere existence of UCEs has been a long debated conundrum. We propose that UCEs contribute to genome integrity and, hence, may provide a strategy by which otherwise healthy tissues can be culled of cells harboring deleterious rearrangements.

3:40 Real-World Examples of Validating a Cancer Sequencing Assay: Case Example, RNA Fusions

Sponsored by seracare

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

Laboratories have difficulties reconciling vague guidelines against sample scarcity and budget limits. How can labs validate and implement cancer assays? Materials to implement robust and reliable assays and software to track and trend data over time will be presented.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

GENOMIC SEQUENCING AND PRECISION MEDICINE IN NEWBORNS

10:50 Chairperson's Remarks

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

11:00 Genomic Sequencing of Healthy and Sick Newborns in the BabySeq Project

Joel Krier, M.D., MMSc, Clinical Chief, Division of Genetics; Director, Brigham Genomic Medicine, Brigham and Women's Hospital; Instructor, Harvard Medical School

The BabySeq Project is a proof-of-concept randomized control trial examining the implications of genomic newborn sequencing (gNBS) in two populations: a) sick or premature neonates admitted to the Boston Children's Hospital and Brigham and Women's Hospital (BWH) ICUs and b) generally healthy neonates from the BWH well nursery. This presentation will summarize the key progress and findings to date including study design, implementation, and preliminary results.

11:30 Ethical and Social Challenges Associated with Sequencing Newborns

Don Bailey, Ph.D., Distinguished Fellow, RTI International

Next-generation sequencing offers the promise of potentially useful health information but also evokes a number of ethical and social challenges. I describe a few of the major concerns, summarize what is known about each, and suggest strategies by which each could be mitigated.

12:05 pm Exome Sequencing of Newborn Dried Blood Spots: Implications for Newborn Screening and for Exome Diagnostics

Aashish Adhikari, Ph.D., Postdoc, University of California, Berkeley

Public health newborn screening (NBS) identifies newborns with rare treatable conditions, permitting early intervention. The NBSeq project is evaluating the potential of whole exome sequencing in NBS using de-identified, archived dried blood spots (DBS) under an IRB-approved protocol with the California Department of Public Health. One aim explores feasibility of WES to replace or augment MS/MS for metabolic disorders. DBS of all California newborns from Jul 2005–Dec 2013 with disorders diagnosed by MS/MS and a selection of false positives were made available (1600 samples) and are being studied.

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

EMERGING BIOMARKERS PREDICTING RESPONSE TO IMMUNOTHERAPY

1:50 Chairperson's Remarks

Luis A. Diaz, M.D., Head, Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center

2:00 Genomic Features of Resistance to Anti-PD-1 Immunotherapy

Jesse Zaretsky, UCLA-Caltech Medical Scientist Training Program, Department of Molecular and Medical Pharmacology, David Geffen School of Medicine, University of California, Los Angeles

Resistance to anti-PD1 immunotherapy can take the form of either innate lack of response, or late acquired resistance after initial tumor regression. For the former, we define a transcriptomic mesenchymal and wound-healing associated expression signature enriched among non-responders in pre-therapy tumors from metastatic melanoma patients. For the latter, exome sequencing of paired pre/post relapse tumors revealed loss of function mutations in the interferon response pathway and antigen presentation machinery.

2:30 Shaping of Immunotherapy Response by Cancer Genomes

Timothy A. Chan, M.D., Ph.D., Radiation Oncologist; Vice Chair, Radiation Oncology; Director, Translational Oncology Division; PaineWebber Chair in Cancer Genetics Memorial Sloan Kettering

Immune checkpoint blockade is a promising approach for the treatment of human malignancies. For example, treatment of patients with advanced lung cancers and melanoma have resulted in improved response rates and durable disease

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control. However, the extent to which patients derive benefit is diverse and the determinants that drive response to therapy are ill-defined. We have sought to define the genomic determinants of response to immune checkpoint blockade therapies such as anti-CTLA-4 and anti-PD-1. Our work has shown that tumor mutational burden, clonality, and mutational landscape features help dictate clinical response. Mutations in genes that are part of the antigen presentation machinery are rare but can be preferentially downregulated in tumors. Reexpression of genes in the MHC antigen presentation pathway by treatment with epigenetic therapy synergizes with immune checkpoint blockade to boost anti-tumor responses.

3:00 Addressing the Challenges Associated with Immuno-Therapy Biomarker Testing

John Leite, Ph.D., Vice President, Oncology, Market Development & Product Marketing, Illumina, Inc.

Recent developments in immuno-therapy have yielded exciting and promising results, but have also highlighted the need for effective predictive solutions. In this session, we will discuss the inherent testing challenges facing translational researchers, and future challenges facing clinicians seeking to implement these solutions into routine clinical practice.

3:30 Session Break

GENETIC CHARACTERIZATION OF PATIENT TUMORS AND CTCs

3:40 Chairperson's Remarks

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

3:45 Scalable Approach for Whole-Exome Sequencing of Cell-Free DNA from Patients with Metastatic Cancer

Viktor Adalsteinsson, Ph.D., Group Leader, Broad Institute of MIT and Harvard

Whole-exome sequencing of cell-free DNA (cfDNA) may enable comprehensive profiling of tumors from blood. Here, we describe a scalable approach to qualify and sequence whole-exomes of cfDNA. Whole-exome sequencing of cfDNA and biopsies from 23 patients revealed high concordance of clonal somatic mutations (90%), copy number alterations (80%), mutational signatures, and neoantigens. Screening of 879 blood samples from 333 metastatic cancer patients revealed 42% with sufficient tumor content for whole-exome sequencing.

4:15 Simultaneous Detection of Living Circulating Tumor Cells and Cancer Related Extracellular Vesicles in Blood by a Molecular Beacon Based Biochip

L. James Lee, Ph.D., Professor, Chemical and Biomolecular Engineering, The Ohio State University

A novel and facile immune-lipoplex nanoparticle (ILN) biochip is developed to simultaneously capture and characterize living circulating tumor cells (CTCs) and cancer related extracellular vesicles (EVs) in patient blood. Antibodies are used to capture CTCs and EVs in a microfluidic device, while molecular beacons encapsulated in cationic lipoplex nanoparticles and fluorescence labelled antibodies are used to detect coding and non-coding RNA targets and membrane protein targets respectively in both CTCs and EVs. The identified CTCs are alive for further interrogation such as drug resistance.

4:45 Dramatically Reducing the Cost of NGS-Based ctDNA Testing with Robust Wildtype Suppression

Amado Zurita-Saveedra, M.D., Associate Professor, MD Anderson

5:15 Close of Conference Program

Cambridge Healthtech Institute's Fourth Annual

GENOMIC SAMPLE PREP, BIOMARKER ASSAY DEVELOPMENT AND VALIDATION

Technologies to Enable High Sensitivity Molecular Applications

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

ASSAY DEVELOPMENT AND VALIDATION TO ADVANCE GENOMIC MEDICINE

11:50 Chairperson's Opening Remarks
Lin Wu, Ph.D., Vice President, Development, Roche

12:00 pm KEYNOTE PRESENTATION: Analytical Validation of NGS Assays
Lin Wu, Ph.D., Vice President, Development, Roche
Germline DNA mutations that increase the susceptibility of a patient to certain cancers have been identified in various genes, and patients can be screened for mutations in these genes to assess their level of risk for developing cancer.

12:30 Eliminating Barriers to Precision Diagnostics: Cost, Content, Turn-Around Time and Sample Size
Robert Daber, Ph.D., Founder and CEO, Gnosity Consults
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. The key to successful broad adoption is building genomic programs that are cost effective, provide fast turnaround time, work with low levels of FFPE DNA input and are focused on content that reduces the incidence of unclear variants.

1:00 Session Break

Sponsored by Beckman Coulter Life Sciences

1:10 Luncheon Presentation I: Optimization of a Magnetic-Bead Based Extraction Method Compared to a Silica-Based Method to Measure HSV-2 Viral Shedding Rapidly and Efficiently
David Yu, Ph.D., Group Leader, Molecular Core, Translational Medicine, Genocea Biosciences

1:40 Luncheon Presentation II *(Sponsorship Opportunity Available)*

2:10 Session Break

UNCONVENTIONAL SPECIMENS AND NOVEL APPLICATIONS

2:30 Chairperson's Remarks
Robert Daber, Ph.D., Founder and CEO, Gnosity Consultss

2:40 Saliva and Salivaomics
David T.W. Wong, D.M.D., DMSc, University of California Los Angeles, Felix & Mildred Yip Endowed Professor & Associate Dean of Research, School of Dentistry, Director, Center for Oral/Head & Neck Oncology Research
Advances in the science of salivary diagnostics have led to identification of disease signatures of candidate biomarkers and/or confirmation of genetic susceptibility for systemic conditions, particularly in molecular oncology. With the development of the salivary proteome, transcriptome, microRNA, metabolome and microbiome as diagnostics alphabets (salivaomics) fully enable saliva to be translated for personalized individual medicine applications. A recent development is the demonstration of saliva detection of oncogenic mutations in human cancers (e.g. EGFR mutations in NSCLC patients).

3:10 Charting the human transcriptome: the Genotype Tissue Expression (GTEx) project.
François Aguet, Ph.D., Computational Biologist, GTEx LDACC, Broad Institute of Harvard and MIT
The GTEx project is an NIH funded project with an ambitious goal of collecting multiple human tissue samples from post-mortem donors and sequencing both the donor's DNA, and tissue-derived RNA, to characterize the genetic basis of gene expression, gene regulation, and how these relate to health and disease. Over 25,000 histologically-characterized tissues have been collected from 960 donors and RNA-sequenced, creating the largest multi-tissue map of the human transcriptome.

Sponsored by TRANS-HIT BIO

3:40 How to Expedite Access to Large Biospecimen Collections Needed to Validate Liquid Biopsy Based Assays
Pascal Puchois, Ph.D., CEO, Trans-Hit Biomarkers
Access to large biospecimen collection (low-incidence-of-mutations, late-stage-cancers, matched-tissues-and-blood-material, relevant-associated-medical-data,..) is the major bottleneck for rapidly validating liquid biopsy based assays. A worldwide network of biobanks able to collect thousands of specimen (colorectal-cancer, lung-cancer,) under strict procedures is key for Industry,...

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4:10 Total Nucleic Acid Profiling of FFPE Tumors
Jeffrey Conroy, Senior Vice President, Technology Development, OmniSeq Precision Medicine; Director, Genomic Technologies, Roswell Park Cancer Institute
Formalin-fixed, paraffin-embedded (FFPE) tissue samples provide a valuable source of nucleic acids. Extraction of DNA and RNA in tumor samples is a challenge, however, given the limited mass, method of preservation and downstream clinical test requirements. In this talk, we will discuss the aspects of tissue selection, pre-analytical processing, and total nucleic acid extraction from a single tissue specimen for downstream targeted NGS mutation detection and gene expression profiling.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session **(please see page 4 for details)**

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session **(please see page 4 for details)**

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

NGS ASSAY DEVELOPMENT AND VALIDATION

10:05 Chairperson's Remarks
Jamie Platt, Ph.D., Managing Director, BRIDGenomics, LLC

10:15 Whole Exome Sequencing as a Diagnostic Test: From Preanalytical Processing to Assay Validation
Madhuri Hegde, Ph.D., Professor, Executive Director, Emory Genetics Lab
Clinical exome sequencing has been fully integrated into clinical practice with most clinicians successfully ordering this test to end the diagnostic odyssey for many patients. The assay development starts determining the targets which can give a high coverage of >98% for 22,000 genes and a 100% coverage for > 5306 genes associated with disease. The preanalytical phase to complete assay design is a step by step process, which includes development of a bioinformatics pipeline.

10:45 Genomic Assays for Clinical Development: Identifying the Right Solution from a Wealth of Potential Approaches
Patrick Hurban, Ph.D., Senior Director and Global Head, Translational Genomics, Q Squared Solutions
Genomic analysis permeates clinical development, with demonstrated utility at all points along the continuum from discovery to diagnostics. Manifold sample types and testing requirements, as well as evolving needs, pose significant challenges. Developing the right solution requires a detailed understanding of pre-analytical variables and analytical performance across an array of potential technologies. Specific use cases will be presented to demonstrate how these challenges can be overcome, and why a diverse toolkit enhances the likelihood of success.

11:15 Automation of Sample Preparation for Clinical NGS: The Requirements and the Challenges Presented by the Various Clinical Sample Types
Martin Siaw, Ph.D., MB(ASCP), Vice President of Science and Innovation, BRIDGenomics.
Sample preparation is an important component of any molecular testing that is being done in clinical laboratories. With the increasing use of NGS for clinical testing comes the need to process increasingly larger numbers of patient samples. Automation of sample preparation should be considered to be critical to the workflow of diagnostic tests involving the use of NGS. My presentation will focus on the requirements for CLIA certified clinical laboratories, the various patient specimens to be tested (including those for liquid biopsies), the methods currently in use for nucleic acid extraction and the various commercial kits that are available in the market.

11:45 The Insider's Guide to Collecting Quality Human Biosamples and Essential Questions All Researchers Should Be Asking
Sponsored by TriMetis
Jon Wetzel, COO, TriMetis Life Sciences
Asking the right questions can lead to accelerated research. Jon Wetzel, COO of TriMetis Life Sciences, has over 21 years of assessing and auditing multiple biorepositories, biobanks, SOP's and collection procedures. With over 6 of those years as a bench researcher and 15 years acquiring, processing and shipping samples, Jon has experienced first-hand the mistakes companies have made in acquiring these highly-sought after samples. He has taken his experience and is letting researchers in on the essential questions they need to ask to make sure that the samples they are using are going to give them the best experimental results possible.

12:00 pm ThruPLEX® Tag-seq Kit: Unleash the Power of Unique Molecular Tags for Accurate Detection of Low-Frequency Variants
Sponsored by RUBICON GENOMICS
Anthony Popkie, Ph.D., Applications Scientist, Rubicon Genomics
Unique molecular tags differentiate between sequencing artifacts and true variants. Data will be shown that demonstrates libraries prepared with ThruPLEX® Tag-seq kit can detect < 0.5% allele frequency at 99% specificity with as little as 10 ng of cell-free DNA.

12:15 Session Break

12:25 Luncheon Presentation *(Sponsorship Opportunity Available)*

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

NGS ASSAYS IN ONCOLOGY

2:00 Chairperson's Remarks
Patrick Hurban, Ph.D., Senior Director and Global Head, Translational Genomics, Q Squared Solutions

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2:10 Choosing an Effective Validation Plan for NGS Assays in Oncology
Helen Fernandes, Ph.D., Director, Molecular Pathology, Pathology & Laboratory Medicine, Weill Cornell Medical College
The analytical validation of an NGS assay for the most part determines the reliability of results and therefore dictates the effectiveness of the assay for management of the cancer. As the number of laboratories offering NGS tests in oncology increases, the need for recommendations and guidelines that address the processes of assay validation are noteworthy. Several organizations and regulatory bodies have been working on developing documents to help and guide laboratories plan and execute the validation of NGS assays for oncology. In this presentation, we will discuss the validation prerequisites that are important and need to be addressed for implementing a reliable and useful NGS assay for oncology.

2:40 Towards Implementation of NGS as Clinical Assay: FFPE Pre-Analytical Optimization and Analytical Consideration in WES Commercial Lab Selection
Ping Qiu, Ph.D., Translational Molecular Biomarkers (TMB), Genomics, Merck Research Laboratories
Higher non-synonymous mutational burden assessed by whole exome sequencing in tumors is associated with durable clinical benefit in immune checkpoint inhibitors treatment. Cancer genome WES poses a unique challenge due to limited tissue, tumor heterogeneity and sequencing artifacts introduced by FFPE tissue. Multiple genomics CROs were assessed on their NGS pre-analytics and the quality of WES data generated. Recommendations are made on FFPE WES pre-analytics and data interpretation.

3:10 Genotyping in an HTP Drug Development Pipeline: Tough Assays, High Sample Numbers, and Ever-Changing Goals
J. Colin Cox, Ph.D., Science Manager, Genentech
Deborah Siler, Ph.D., Senior Research Associate, Mouse Genetics, Genentech
Ultraconserved elements (UCEs) are DNA sequences that have been perfectly (100%) conserved for 300-500 million years. Because neither protein coding, nor enhancer, nor transcription factor binding, nor promoter regions require such conservation, the mere existence of UCEs has been a long debated conundrum. We propose that UCEs contribute to genome integrity and, hence, may provide a strategy by which otherwise healthy tissues can be culled of cells harboring deleterious rearrangements.

Sponsored by seracare

3:40 Real-World Examples of Validating a Cancer Sequencing Assay: Case Example, RNA Fusions
Russell Garlick, Ph.D., CSO, SeraCare Life Sciences
Laboratories have difficulties reconciling vague guidelines against sample scarcity and budget limits. How can labs validate and implement cancer assays? Materials to implement robust and reliable assays and software to track and trend data over time will be presented.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

LIQUID BIOPSY-BASED ASSAYS

10:50 Chairperson's Remarks
Raja Luthra, Ph.D., Professor, Hematopathology, The University of Texas MD Anderson Cancer Center

11:00 Liquid Biopsy for EGFR, the cobas® EGFR Mutation Test v2: The Long and Winding Road
Sid Scudder, M.D., Senior Director, Clinical Science, Genomics & Oncology, Roche Molecular Systems
Liquid biopsies for the detection of actionable mutations in cancer offer advantages to tissue biopsies in terms of safety, discomfort and sequential testing. Liquid biopsies can obviate the problems of insufficient tissue, tissue exhaustion, or inability to undergo a biopsy. The cobas® EGFR Mutation Test v2 detects 42 mutations in exons 18-21 of the EGFR gene, including T790M and test has been approved by the FDA as a co-diagnostic for Tarceva® and Tagrisso® (tissue). The development of the test as a liquid biopsy highlights the difficulty in developing companion diagnostics along with unexpected pitfalls. It also emphasizes the need for creativity, flexibility and the need for close communication with regulatory agencies to reach the final goal.

11:30 Co-Presentation: Mutation Screening of Liquid Biopsies: Promise, Clinical Utility and Technical Challenges
Raja Luthra, Ph.D., Professor, Hematopathology, The University of Texas MD Anderson Cancer Center
Rajesh Singh, Ph.D., Director, Clinical Next Generation Sequencing Assay Development, MD Anderson Cancer Center
Screening of genomic aberrations in circulating cell free DNA (ccfDNA) holds tremendous promise as a minimally invasive option for early detection, monitoring of disease progression and therapy response in solid tumors. However, its routine implementation in a diagnostic laboratory raises several logistic and technical challenges. This talk will discuss the potential, clinical utility and technical challenges associated with isolation and screening of ccfDNA in a clinical diagnostic laboratory setup.

12:00 pm Correlating Primary and Surrogate Biomarkers Using a Single Sample Processing Approach: Expanding the Utilization of Liquid Biopsies
Andrew Brooks, Ph.D., COO, RUCDR Infinite Biologics
Immune oncology (IO) therapeutics are directed at inducing immune responses against tumor cells. Intrinsic to this mechanism of action is the activation of

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circulating immune cells, which can be most effectively monitored using flow cytometry-based assays. In this presentation, aspects of assay development, validation, implementation and analysis of clinical flow cytometry datasets will be discussed. Results from clinical trials of IO as single agents or in combination with other IO will be shown and strategies for interpretation and post-hoc analyses will be detailed.

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

PORTABLE SEQUENCING AND LAB-ON-CHIP TECHNOLOGY

1:50 Chairperson's Remarks

Joshua T. Smith, Ph.D., Research Staff Member, Translational Systems Biology and Nanobiotechnology, IBM T. J. Watson Research Center

2:00 Co-Presentation: PORTABLE SEQUENCING: Fundamentals in Sequencing Technology with Nanopores, Sample Preparation and Data Analysis

Harikrishnan Jayamohan, Ph.D.,Postdoctoral Appointee, Advance Systems Engineering and Deployment, Sandia National Laboratories

Raga Krishnakumar, Ph.D., Bioinformatics, Sandia National Laboratories

The Oxford Nanopore MinION is a portable real-time sequencing device which operates by sensing the change in current flow through a nanopore as DNA traverses through it. The relative small-size, portability, simple sample preparation, long-read lengths, and real-time informatics makes this commercially available technology a game-changer for DNA sequencing. In this short-course, we will present on the following topics from a users' perspective.

- Overview of the fundamentals in single molecule DNA sequencing technology with nanopores,
- Survey of the latest advancements in nanopore sequencing applications,
- Differentiating strengths compared to traditional sequencing methods,
- Hands-on experience and sample preparation for the nanopore sequencer,
- Emerging bioinformatics and real-time data analysis strategies for long-read sequencing

2:30 Sample Prep for Liquid Biopsies on a Chip: Exosomes, DNA and Beyond

Joshua T. Smith, Ph.D., Research Staff Member, Translational Systems Biology and Nanobiotechnology, IBM T. J. Watson Research Center

We recently used nanoscale deterministic lateral displacement (nanoDLD) technology for on-chip size separation of exosomes and DNA, and showed that its sensitivity is sufficient to interrogate individual exosomes and DNA molecules in samples with low concentrations of analyte. In this talk, we will show that the continuous flow nature of the technology allows us to isolate, enrich and purify analytes at preparative level volumes for downstream genomics analysis.

3:00 Nanopore Sequencing for Real-Time Pathogen Identification

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

Effective global health response to emerging 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. The relative small-size, portability, long-read lengths, and real-time informatics makes this commercially available technology a game-changer for bacterial pathogen identification. We will present our latest results in integrating a microfluidic front-end for rapid sample preparation and a unique bioinformatics strategy for sequencing the entire16S-to-23S ribosomal DNA locus for identification.

3:30 Session Break

NOVEL APPROACHES FOR ASSAY VALIDATION

3:40 Chairperson's Remarks

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

3:45 Finding the Best Fit: Cancer Specimen Predicaments and How to Solve Them

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

With the wave of clinical genomic sequencing performed for cancer diagnosis and prognosis, the decision regarding the correct sample and appropriate breadth of testing has never been more important. This discussion will focus on specimen types, laboratory parameters and their relationship with library content. Tumor specimens can differ substantially, from fresh tissue to formalin fixed paraffin embedded tissue, and from biopsy specimens to fine needle aspirations. Decisions for sequencing and the ability to detect clinically useful mutations rely on the biology of these specimens, each with their own advantages and disadvantages. Due to the intrinsic variability in neoplastic tissue, the management of specimens entering into the laboratory for sequencing, the quantity and quality of the nucleic acid and appropriate tumor percentage is critical in the relationship to mutation detection. The diversity and availability of input DNA molecules governs the logistics of sequencing and the implications to detect low abundance mutations and tumor heterogeneity.

4:15 Capturing the Broad Spectrum of Pathogenic Mutations with NGS: Challenges in Assay Development and Validation

Stephen Lincoln, Scientific Affairs, Invitae

Technically challenging variants are a substantial fraction (10% or more) of findings in routine clinical testing. These can include CNVs affecting only a single exon, either large indels or complex variants, or alterations in low-complexity, highly conserved or extreme-GC regions. Novel biochemical and bioinformatics methods can help address many of these although supplementary assays are sometimes required. Published validation studies often omit these variants, and benign SNPs dominate most sensitivity calculations. In part this may be due to difficulty obtaining positive controls. We thus have developed and tested, in multiple laboratories, synthetic controls containing a diverse set of challenging mutations in commonly tested genes

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4:45 Panel Discussion: Assay Validation Tips and Tricks

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

- Validation and Implementation of NGS Diagnostic Assays Bringing up NGS Assays in the CLIA Lab Selection
- Development and Analytical Validation of a Targeted NGS Assay for the Support of the NCI-MATCH Trial
- Validation and Implementation of NGS Assays within the Framework of CAP Accreditation and Proficiency Testing Requirements

5:15 Close of Conference Program

Cambridge Healthtech Institute's Second Annual

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE

Advancing Molecular Diagnostics to Improve Detection and Patient Outcome

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

NEXT GENERATION SEQUENCING FOR INFECTIOUS DISEASES

11:50 Chairperson's Opening Remarks
Andrew Bryan, M.D., Ph.D., Acting Assistant Professor, Assistant Director, Clinical Microbiology, Department of Laboratory Medicine, University of Washington

12:00 pm Emerging Assays for Infectious Diseases in Diagnosis and Outbreak Surveillance
Charles Chiu, M.D., Ph.D., Associate Professor, Lab Medicine and Infectious Diseases; Director, UCSF-Abbott Viral Diagnostics and Discovery Center; Associate Director, Clinical Microbiology Laboratory, University of California, San Francisco

Advances in technology, genomics, and bioinformatics and the vast increases in the size of reference databases have made comprehensive diagnosis of infectious diseases practical. Here we will discuss the promise, challenges, and experience with clinical validation and implementation of a metagenomic next-generation sequencing (mNGS) assay for identification of pathogens in hospitalized patients. We will also discuss the use of new technologies, including nanopore sequencing and transcriptome profiling, for surveillance of epidemics such as the 2015-2016 Zika virus outbreak in the Americas.

12:30 Implementation of Metagenomic Next-Generation Sequencing for Pathogen Detection in the Clinical Laboratory
Samia Naccache, PhD, Clinical Microbiology Fellow, Pathology and Lab Medicine, Children's Hospital Los Angeles

Metagenomic next-generation sequencing (mNGS) for pathogen detection allows for unbiased identification of infectious agent nucleic acid in clinical samples. We have implemented this assay in the UCSF clinical laboratory for diagnosis of meningitis / encephalitis using optimized library preparation and bioinformatics processing steps, with case discussion and decision support through the Microbial Sequencing Board. This talk will outline the mNGS assay performance, clinical utility and effect on patient management decisions.

1:00 Session Break

Sponsored by FRY

1:15 Years On the Bench: Design and Implementation of a Microbial NGS Clinical Diagnostics System
Jeremy Ellis, Ph.D., Research Director, Laboratory Manager, Research & Development, Fry Laboratories, LLC

Translating research-based NGS methods into the clinical diagnostics laboratory poses several unique challenges. Experience with a microbial NGS diagnostics assay will be reviewed in addition to design requirements. Our system, RIDI™, will be used to explore challenges and opportunities.

2:10 Session Break

2:30 Chairperson's Remarks
Jennifer Dien Bard, Director of the Clinical Microbiology Laboratory, Assistant Professor of Clinical Pathology, Keck School of Medicine of the University of Southern California

2:40 The Role of Deep Sequencing for Clinical Diagnoses of Polymicrobial Bacterial Infections
Andrew Bryan, M.D., Ph.D., Acting Assistant Professor, Assistant Director, Clinical Microbiology, Department of Laboratory Medicine, University of Washington

Bacterial identification and susceptibility testing in clinical microbiology laboratories relies on an array of diagnostic methods ranging from classic culture, rapid commercial molecular platforms, MALDI-TOF mass spectrometry, and sequencing methods. While each of these technologies brings valuable contributions to patient care, deep sequencing of polymicrobial bacterial infections has the potential to accurately de-convolute these complex infections and identify clinically significant organisms not detected by classical or Sanger-based sequencing methods.

3:10 Challenges and Approaches for Assuring the Quality of Next-Generation Sequencing in Clinical Laboratories Sequencing Human or Pathogen DNA
Ira M. Lubin, Ph.D., FACMG, Division of Laboratory Systems/CSELS, Office of Public Health Scientific Service, The Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention published practice recommendations developed by multidisciplinary workgroups for the integration of next-generation sequencing into clinical laboratory settings. Although targeted at the analysis of human genomic DNA, general principles were identified relevant to the analysis of pathogens. Common challenges and approaches faced by laboratories, whether sequencing human or pathogen DNA, will be discussed.

DIAGNOSTICS CHANNEL

3:40 Panel Discussion: Challenges in Implementing and Using NGS in Clinical Laboratories
Moderator: Andrew Bryan, M.D., Ph.D., Acting Assistant Professor, Assistant Director, Clinical Microbiology, Department of Laboratory Medicine, University of Washington
Panelists: Session Speakers

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session **(please see page 4 for details)**

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session **(please see page 4 for details)**

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

MOLECULAR DIAGNOSTICS FOR ZIKA

10:05 Chairperson's Remarks
Gerrit Van Roekel, Senior Program Officer, Business Development, Bill & Melinda Gates Foundation

10:15 Development of a Zika Diagnostic in a Laboratory Setting
James Musser, M.D., Ph.D., Professor of Pathology and Genomic Medicine, Institute for Academic Medicine, Houston Methodist

10:45 Minimally-Instrumented, Point-of-Care Molecular Detection of Zika Virus
Changchun Liu, Ph.D., Research Assistant Professor, Department of Mechanical Engineering and Applied Mechanics, University of Pennsylvania
Zika virus (ZIKV) is currently causing a large outbreak in the Americas. Rapid and reliable diagnostics for ZIKV are vital. Since immunoassays lack adequate sensitivity and selectivity, molecular diagnostics is an effective means to detect ZIKV soon after infection and throughout pregnancy. In this talk, I will present our recent effort towards the development of an inexpensive minimally-instrumented smart cup for molecular detection of ZIKV at the point-of-care.

POINT-OF-CARE TESTING FOR INFECTIOUS DISEASE: A NEW PARADIGM

11:15 A New Paradigm in Infectious Disease Testing: Molecular Point-of-Care Testing
Omai Garner, Ph.D., D(ABMM), Assistant Professor, Pathology and Laboratory Medicine, UCLA
Point-of-care testing for infectious disease has always suffered from poor sensitivity due to the usage of lateral flow based assays. Recently, the FDA has made a couple of molecular based influenza diagnostics CLIA waived. This talk will detail the sensitivity and specificity of these new tests as compared to in-lab molecular diagnostics, and will discuss the many challenges involved in implementing molecular testing within a physician's office.

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE

11:45 FlashDirect - 12 min (or less) Sample-to-Answer Molecular Diagnostics
Sponsored by THERMAL GRADIENT
Robert Juncosa, CEO, Thermal Gradient, Inc.
Thermal Gradient will introduce its rapid sample prep and quantitative PCR technology and three instrument systems capable of full very rapid sample-to-answer molecular diagnostics. The FlashDirect instruments and disposable cartridges support a wide variety of specimens and nucleic acid targets.

12:15 pm Session Break

12:25 Luncheon Presentation: Portable System for Mulitplexed Immunoassays in Complex Sample Matrices
Sponsored by m·bio DIAGNOSTICS
Michael Lochhead, Ph.D., CTO, MBio Diagnostics, Inc.
MBio Diagnostics has developed a portable assay system that enables multiplexed, quantitative immunoassays using a disposable cartridge and simple fluorescence reader. This presentation will focus on demonstrations of MBio's unique ability to run complex sample matrices without pre-processing.

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

POINT-OF-CARE TESTING FOR INFECTIOUS DISEASE: A NEW PARADIGM (CONT.)

2:00 Chairperson's Remarks
Gerrit Van Roekel, Senior Program Officer, Business Development, Bill & Melinda Gates Foundation

2:10 PANEL DISCUSSION: Point-of-Care Molecular Diagnostics Platforms in Global Health – Does Current Technology Meet the Needs?
Moderator: Gerrit Van Roekel, Senior Program Officer, Business Development, Bill & Melinda Gates Foundation
Panelists: Mickey S. Urdea, Ph.D., Founder, Partner, Halteres Associates, LLC
Bernhard H. Weigl, Principal Investigator, Flow Based Diagnostics, Intellectual Ventures/Global Good, Affiliate Professor, Department of Bioengineering, University of Washington
Judi Tilghman, Ph.D., Vice President, Technology Assessment, Quidel
We'll see a plethora of sample-to-answer point-of-care diagnostics platforms come online in the coming years, which should help to address the need for diagnostic testing in global health settings, and emerging markets for diagnostic testing in low and middle income countries are projected to grow exponentially. But does the current technology adequately address global health needs? In this panel we will feature presentations on the need for diagnostics in global health settings and the technologies addressing those needs, followed by Q&A with the panelists.

DIAGNOSTICS CHANNEL

3:10 Research Developments in Point-of-Care Testing for the DoD Chem/Bio Defense Program

Richard Schoske, GS-15, Ph.D., Chief, Diagnostics, Detection and Threat Surveillance Div (CBA), Chemical and Biological Technologies Department (J9/CB), Defense Threat Reduction Agency

The Chem/Bio Defense Program is developing prototype Point-of-Care devices and assays for the identification of biological threat agents for the multiplex identification of pathogens and the determination of host biomarkers of early warning of exposure using Molecular and Immuno-diagnostic methods. The underlying design goal is the development of tools for the differential diagnosis of syndromic panels for diseases for which the initial symptoms and presentation is generic that are: sensitive and specific, CLIA-waiver compatible, robust for use in austere environments, rapid, and cost-effective.

Sponsored by Streck

3:40 20-Minute Genetic ID of Resistant Bacteria to Improve Surveillance and Antimicrobial Stewardship

Michael van Waes, Ph.D., Director, Molecular Products, Molecular Technology, Streck

Rapid testing strategies characterize antibiotic resistant organisms and improve antimicrobial stewardship programs. The Streck Zulu RT instrument, in combination with the ARM-D real-time PCR kits, can screen samples for the presence of genes that mediate resistance in 20 minutes.

Sponsored by Seegene

3:55 Presentation to be Announced

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

ANTIMICROBIAL RESISTANCE AND SUSCEPTIBILITY TRAINING

10:50 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

MOLECULAR DIAGNOSTICS FOR INFECTIOUS DISEASE

11:00 Emerging Technologies for Rapid Susceptibility Testing

Jennifer Dien Bard, Director of the Clinical Microbiology Laboratory, Assistant Professor of Clinical Pathology, Keck School of Medicine of the University of Southern California

Despite significant advances in the approaches to pathogen identification directly from clinical specimens, antimicrobial susceptibility testing is mainly performed by conventional methods, delaying results by 2-5 days. There is an unmet need for rapid, phenotypic approaches to susceptibility testing directly from clinical specimens. The current multiplexed molecular panels available identify organisms directly from positive blood cultures and detect the presence of resistance markers. This session will summarize the current and emerging technologies for rapid phenotypic susceptibility testing.

11:30 Sizing Up Your Enemy: The Use of Molecular Tests to Predict Antimicrobial Resistance in *Neisseria Gonorrhoeae*

Peera Hemarajata, M.D., Ph.D., D(ABMM), Clinical Instructor, Pathology and Laboratory Medicine, David Geffen School of Medicine, UCLA

Neisseria gonorrhoeae has become a serious threat due to high prevalence of antimicrobial resistance. Prospective susceptibility testing enables physicians to use antimicrobials other than those recommended for empirical treatment, and could potentially delay emergence of resistance to recommended antibiotics. Few laboratories routinely perform culture and susceptibility testing for *N. gonorrhoeae*. We will discuss molecular assays that may be able to predict susceptibility directly from specimens without the need for culture.

12:00 pm Insights into Antimicrobial Resistance Learned from NGS

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

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

SEPSIS AND BLOOD STREAM INFECTIONS

1:50 Chairperson's Remarks

Matthew Faron, PhD, Research Scientist, Clinical Microbiology, Medical College of Wisconsin

2:00 Next-Generation Sequencing Diagnostics of Blood Stream Infections

Kai Sohn, Ph.D., Group Leader, MBT, Fraunhofer IGB

Bloodstream infections remain one of the major challenges in intensive care units leading to sepsis or septic shock. Due to the lack of timely diagnostic approaches with sufficient sensitivity, mortality rates of sepsis are still unacceptably high. We describe the establishment of a complete diagnostic workflow for the identification of infectious microorganisms from seven septic patients based on unbiased sequence analyses of free circulating DNA from plasma by next-generation

sequencing.

2:25 Performance of PCR-REBA Assay for Screening and Identifying Pathogens Directly in Whole Blood of Patients with Suspected Sepsis

Hyeyong Lee, Ph.D., Professor, Biomedical Laboratory Science, Yonsei University, Wonju Campus

The present study investigated blood samples from 882 patients who matched the criteria of systemic inflammatory response syndrome with suspected bacterial or fungal infection. In brief, the results from this study showed that the concordance rate of blood culture and PCR-REBA was 83.0% (95% confidence interval [CI], 79.8-84.8, p<0.0001). The results also showed that PCR-REBA positive patients had higher CRP or PCT levels than PCR-REBA negative and blood culture negative patients.

OUTCOME STUDIES

2:50 Designing Studies to Evaluate How Infectious Disease Diagnostics Affect Patient Care and Outcomes

Christopher R. Polage, M.D., MAS, Director, Clinical Microbiology Laboratory, Associate Professor of Clinical Pathology and Infectious Diseases, Pathology and Laboratory Medicine, University of California, Davis Health System

Molecular tests for infectious diseases are increasingly used for patient care but few studies investigate their impact on patient care and outcomes. This presentation examines selected clinical outcome studies to identify characteristics of successful and unsuccessful tests and studies with the goal of providing a road map to designing studies to accurately evaluate and maximize the impact of new tests on patient care.

3:10 A First In, First Out (FIFO) Respiratory Virus Testing Algorithm Significantly Impacts ICU Patient Outcomes

Raquel Marie Martinez, Ph.D., D(ABMM), Director, Clinical and Molecular Microbiology, Laboratory Medicine, Geisinger Health System

Nucleic acid amplification and detection of respiratory virus (RV) pathogens is rapid and sensitive, but multiplex methods can be costly. Implementation of molecular methods can promote improvements in laboratory workflow; however, few studies assess the impact of rapid results on downstream patient outcomes. The purpose of this study was to assess the impact of rapid multiplex RV testing for an ICU patient population.

3:30 Session Break

NOVEL APPROACHES TO INFECTIOUS DISEASE DIAGNOSIS

3:40 Chairperson's Remarks

Raquel Marie Martinez, Ph.D., D(ABMM), Director, Clinical and Molecular Microbiology, Laboratory Medicine, Geisinger Health System

3:45 Automated Plate Reading and Quantitation: Can a Computer that Learns Replace Human Plate Reading?

Matthew Faron, PhD, Research Scientist, Clinical Microbiology, Medical College of Wisconsin

Digital imaging in microbiology has revolutionized the microbiology laboratory and significantly reduced turnaround of culture results. Most recently, we have partnered to developed software that can automatically read plates and interpret chromogenic media, only requiring human intervention for positive specimens and reducing the hands-on time for plate reading by 80%. We now report on the ability to read blood plates and quantify the number of colonies present on a plate.

4:10 Accelerating Diagnosis and Therapy of Infectious Diseases Using Public Heterogeneous Data

Purvesh Khatri, Ph.D., Assistant Professor, Medicine, Stanford University

Public availability of large amounts of heterogeneous molecular data for infectious diseases presents unprecedented opportunities for identifying novel diagnostic and prognostic markers, while accounting for the real world patient population heterogeneity observed across the world. I will discuss a novel framework and results obtained using the framework for diagnosis and prognosis of multiple infectious diseases including TB, dengue, influenza, and sepsis.

4:35 Digital Detection of Infectious Agents in Unprocessed Blood Using Blood Droplet PCR

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 detection of infectious agents in blood remains an unmet challenge. The current systems are often not sensitive enough to detect low-abundance pathogens. Moreover, these techniques usually require culture and sample processing steps that are not suited for routine testing. I will present a new method that integrates droplet digital detection and direct blood PCR, which allows us to rapidly detect target cells at single cell sensitivity in unprocessed samples.

4:55 What Is Life? Real-Time Molecular Assessment of Microbial Viability and Growth in Samples

Gerard Cangelosi, Ph.D., Professor, Environmental and Occupational Health Sciences, University of Washington

Viable pathogen cells are usually more significant to human health than dead ones. Similarly, normally harmless commensal microorganisms can cause disease when they begin to proliferate unchecked. These distinctions are important but challenging for molecular and clinical microbiologists who rely on nucleic acid-based testing methods. This presentation describes new PCR-based methods that differentiate viable from inactivated microbial cells, and related methods that assess ongoing microbial growth in samples.

5:15 Close of Conference Program

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Cambridge Healthtech Institute's Second Annual

CANCER IMMUNOTHERAPY

Emerging Biology, New Targets, Development Strategies and Clinical Studies

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MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

EMERGING CHECKPOINTS, COMBINATIONS AND CLINICAL STUDIES

11:50 Chairperson's Opening Remarks
Christopher Shelton, Ph.D., Manager, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

12:00 pm TACTI-mel, Two ACTive Immunotherapies in Melanoma: Combination of IMP321 (LAG-3Ig) with an Anti-PD-1 Antagonist in a Phase I Trial
Frédéric Triebel, M.D., Ph.D., CSO & CMO, Prima BioMed Ltd.
IMP321 (LAG-3Ig) binds to MHC class II molecules on the surface of antigen-presenting cells and activates the cellular immune response mechanisms known to mediate tumor recognition and killing. Inducing more TILs at the tumor site with an APC activator like IMP321 while releasing the PD-1 brake on TILs may lead to greater anti-tumor efficacy than anti-PD-1 alone. A Phase I trial called TACTI-mel for Two ACTive Immunotherapies in melanoma has been started in 2016 combining a low-dose agonist (IMP321) with a high-dose antagonist (pembrolizumab) in advanced or metastatic melanoma.

12:30 CPI-444 – A Novel Oral Checkpoint Inhibitor of Adenosine-Mediated Suppression of Tumor Immunity
Ian McCaffery, Ph.D., Vice President, Translational Sciences, Corvus Pharmaceuticals
CPI-444 is a novel, selective inhibitor of adenosine 2A receptor (A2AR), the key mediator of adenosine-mediated immune suppression. CPI-444 is being evaluated in a multicenter Phase I/Ib clinical trial in patients with various solid tumors both as a single agent and in combination with TECENTRIQ™ (atezolizumab), Genentech's investigational cancer immunotherapy that targets PD-L1. Insights into the underlying biological mechanisms of adenosine activity in tumors from ongoing preclinical and clinical studies of CPI-444 will be discussed.

1:00 Session Break

1:10 Luncheon Presentation I: Hypothesizing Co-Immuno-therapy Targets for Tumor Infiltrating Myeloid Derived Suppressor Cells
Matthew E. Wampole, Ph.D., Solution Scientist, Clarivate Analytics (formerly the IP & Science division of Thomson Reuters)
This presentation will overview the field of cancer immunotherapies and look at how data and knowledge driven approaches are being used to find potential new targets for treating resistant populations.

1:40 Luncheon Presentation II *(Sponsorship Opportunity Available)*

2:10 Session Break

TARGETING MACROPHAGE CHECKPOINTS FOR NEW IMMUNOTHERAPIES AND COMBINATIONS

2:30 Chairperson's Remarks
Christopher Shelton, Ph.D., Manager, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

2:40 TTI-621 (SIRPαFc): A Checkpoint Inhibitor of the Innate Immune System that Blocks the CD47 "Do Not Eat" Signal
Bob Uger, Ph.D., CSO, Trillium Therapeutics Inc.
CD47 binds to SIRPα on the surface of macrophages and delivers a "do not eat" signal that suppresses phagocytosis. There is strong evidence that many tumors express high levels of CD47 to escape macrophage-mediated immune surveillance. Trillium Therapeutics is developing TTI-621 (SIRPαFc), a fusion protein consisting of the CD47-binding domain of human SIRPα linked to the Fc region of human IgG1. This presentation will discuss the preclinical rationale and emerging clinical data for this novel innate immune system checkpoint inhibitor.

3:10 The Anti-CD47 Antibody Hu5F9-G4 Is a Novel Innate Immune Checkpoint Inhibitor with Broad Anti-Tumor Activity
Mark Chao, M.D., Ph.D., Co-Founder and Medical Director, Forty Seven Inc.
The anti-CD47 antibody Hu5F9-G4 is a first-in-class therapeutic that blocks CD47 signaling and eliminates tumors through phagocytosis. This anti-tumor activity is demonstrated across many solid tumor and hematologic malignancies in preclinical models. Furthermore, Hu5F9-G4 is able to combine with multiple cancer therapeutic classes to induce a synergistic anti-tumor effect. First-in-class, first-in-human Phase I trials have been initiated in solid tumors and acute myeloid leukemia. During this talk, preclinical data for monotherapy and combination therapy efficacy with Hu5F9-G4 will be presented as well as data from ongoing clinical studies.

3:40 Targeting SIRPα to Control Myeloid-Derived Suppressor Cells and Tumor-Associated Macrophages

Bernard Vanhove, Ph.D., COO, OSE Immunotherapeutics

We recently developed Effi-dem, a new anti-SIRPα antagonist IgG4 mAb. In contrast with agents targeting CD47, Effi-dem and other surrogate mAbs prevent M2 polarization of monocyte-derived macrophages differentiated with M-CSF + IL-4 while increase pro-inflammatory M1 cytokines. Anti-SIRPα mAbs also induce differentiation of MDSC into non-suppressive mature myeloid cells overexpressing CD80, CD86 and CD103. This *in vitro* activity of anti-SIRPα mAbs revealed a therapeutic potential in preclinical models of orthotopic hepatocellular carcinoma (HCC), melanoma and breast cancer models.

4:10 Test Validation to Predict Response to Checkpoint Inhibitors

Sponsored by OmniSeq

Carl Morrison, M.D., DVM, President, CSO & Founder, OmniSeq Precision Medicine

Testing for response to checkpoint inhibitors is a current and future target of immunotherapy. Our approach to this problem is the development of a multianalyte assay algorithm analysis (MAAA) using a targeted RNA-seq panel of immune related genes. A requirement of the validation of this assay, Immune Advance, was to meet regulatory requirements of NYS Clinical Laboratory Evaluation Program. In this talk, we will discuss the fundamental aspects of analytical validation, clinical validation, and clinical utility.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session **(please see page 4 for details)**

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session **(please see page 4 for details)**

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

ADVANCES IN NK CELL-BASED THERAPY

10:05 Chairperson's Remarks

Hans Klingemann, M.D., Ph.D., Vice President, Research & Development, NantKwest, Inc.

10:15 FEATURED PRESENTATION: Novel Ways to Target and Activate NK Cells to Treat Cancer

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

The major limitation of NK cells is their lack of specificity and their inability to proliferate when targeted through antibody dependent cellular cytotoxicity. IL-15, a natural cytokine that is critical for NK cell development and homeostasis, will be discussed. We have recently developed a class of molecules that combine antigen specificity and IL-15's proliferative activity together into a novel class of multifunctional molecules we call trispecific killer engagers (TriKEs). Lastly, we have discovered a new subset of NK cells termed adaptive with properties of immunologic memory.

10:45 Adoptive Immunotherapy with Expanded NK Cells - The Impact of STAT3 Signaling and Crosstalk with Adaptive Immunity

Dean Anthony Lee, M.D., Ph.D., Professor, Pediatrics; Director, Cellular Therapy and Cancer Immunotherapy Program, Nationwide Children's Hospital; James Comprehensive Cancer Center/Solove Research Institute, The Ohio State University

We developed a system for *ex vivo* NK cell expansion based on genetically modified feeder cells expressing IL-21, which through STAT3 signaling induces robust activation and proliferation of NK cells from normal donors, patients, cord blood, and embryonic/pluripotent stem cells. We established the GMP infrastructure to manufacture clinical-grade NK cells using this approach, and infused expanded NK cells into patients as monotherapy, in single or repeated infusions, or in combination with chemotherapy or stem cell transplantation, delivering ~200 infusions to over 60 patients at doses up to 108 cells/kg, with no infusion-related or dose-limiting toxicities observed.

11:15 Off the Shelf, Engineered Allogeneic Natural Killer Cell Therapeutics: aNK, haNK, taNK

Hans Klingemann, M.D., Ph.D., Vice President, Research & Development, NantKwest, Inc.

NantKwest has developed the NK cell line NK-92 into an "off the shelf" activated NK (aNK) cell therapeutic. The safety of aNK as well as their activity against a broad range of cancers have been confirmed in several Phase I clinical trials in the U.S., Canada and Europe. The aNK cells can be administered in the outpatient setting and serve as a universal cell-based therapy without need for individualized patient matching. Moreover, the aNK cell platform has been bioengineered to incorporate a high-affinity antibody binding Fc-receptor (haNK). Both aNK and haNK cells can be equipped with CARs.

11:45 Cells of The Immune System and Cancer: Friends or Foe

Sponsored by charles river

Winfried Elis, Project Manager, Discovery Charles River

The rise of immune-oncology has necessitated the development of experimental *in vivo* platforms to support the drug discovery process. The strengths and weaknesses of genetically engineered and syngeneic mouse models as well as of humanized PDX models will be discussed.

12:15 pm Session Break

12:25 Beyond PD-L1 IHC: A Gene Expression-Based Test in Development for Anti-PD-1 Response the nCounter® Dx Analysis System
Sponsored by nanoString TECHNOLOGIES
Sarah Warren, Ph.D., Senior Scientist, Immune Oncology, NanoString Technologies Inc.
NanoString Technologies is collaborating with a major pharmaceutical partner to develop an anti-PD-1 response assay that digitally measures a multi- gene expression signature and thus circumvents many of the difficulties associated with PD-L1 IHC.

12:55 Leveraging Genomics-Based Assays for Immuno-Oncology in Clinical Research
Sponsored by illumina
Victor Weigman, Ph.D., Associate Director, Translational Genomics, Biomarker Discovery and Clinical Assay Development, Q2 Solutions – EA Genomics a Quintiles Quest Joint Venture
Innovative technologies to investigate immune associated gene targets are being used in multiple facets of clinical research. This talk will outline results from genomic profiling of immune signatures (B/T cell repertoire, IGVH, HLA) for biomarker identification in multiple cancer indications with comparisons to existing clinical research assays.

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

AGONIST – PD-1 COMBINATION STUDIES

2:00 Chairperson's Remarks
Ezio Bonvini, M.D., Senior Vice President, Research, MacroGenics, Inc.

2:10 Engaging Innate and Adaptive Immunity to Fight Cancer
Martin Treder, Ph.D., CSO, Affimed
Bispecific immune cell engagers developed through Affimed's proprietary antibody platform are well differentiated not only through their bivalent, high avidity binding and specificity, but also due to their limited competition with circulating IgGs, resulting in significantly stronger activation and modulation of NK- or T-cells. Preclinical experiments for Affimed's lead candidate, AFM13, a prototypic NK-cell engager currently in Phase II clinical development, have demonstrated synergistic efficacy of AFM13 in combination with checkpoint modulators such as anti-PD-1 antibodies, resulting in activation of both innate and adaptive immunity.

2:40 Development of an Agonist Antibody Targeting ICOS
Jennifer Michaelson, Ph.D., Executive Program Leader and Senior Director, Preclinical Development, 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.

3:10 Circulating Stromal Cells for Immunotherapy
Sponsored by Creatv MicroTech
Daniel Adams, Senior Research Scientist, Creatv MicroTech, Inc.

3:25 Multiscalar Systems Modeling to Design Rational Cancer Immunotherapy Combinations
Sponsored by Systems Imagination
Spyro Mousses, Ph.D., President, Systems Imagination, Inc.
This case study will describe the mining and modeling of disparate types of information ranging from WGS data to deep clinical phenotype data including pathological and radiological images. Results identified hidden insights that can be leveraged to design safer and more effective drug combinations for cancer immunotherapy.

3:40 Immunotherapy Potency Analysis Using Cellular Impedance
Sponsored by ACEA Biosciences Inc.
Brandon Lamarche, Ph.D., Research Scientist, ACEA Biosciences
The kinetics of cancer cell destruction by diverse immunotherapies is monitored in a label-free manner using the xCELLigence instruments. Examples of analyzing potency and serial killing capacity, and optimizing constructs/conditions for treating both liquid and solid tumor targets are provided.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

EMERGING APPROACHES FOR CHECKPOINT INHIBITOR COMBINATION IMMUNOTHERAPY

10:50 Chairperson's Remarks
Gordon J. Freeman, Ph.D., Professor, Medicine, Division of Hematologic Malignancies, Department of Medical Oncology, Dana-Farber Cancer Institute, Harvard Medical School

10:55 PD-1 Cancer Immunotherapy
Gordon J. Freeman, Ph.D., Professor, Medicine, Division of Hematologic Malignancies, Department of Medical Oncology, Dana-Farber Cancer Institute, Harvard Medical School
My laboratory studies the role of costimulatory signals in the development of an immune response. T cell activation requires two signals. Specificity is provided by TCR recognition of peptide-MHC complexes but a second, costimulatory signal is required for full T cell activation. Recently, we have cloned two novel members of the B7 gene family. These new B7s bind to receptors expressed on activated

T cells and further regulate the development of an immune response. We are currently focusing on the function of these novel B7 genes and their interactions with the B7/CD28-CTLA4 pathway.

11:20 Computational Identification of Novel Immune Checkpoints: The Progression from Database to Drug

John Hunter, Ph.D., Site Head and Vice President, Antibody R&D, Compugen USA, Inc.

The B7/CD28 immune checkpoint proteins CTLA4, PD1, and PDL-1 play critical roles in T cell regulation, and have emerged as exciting drug targets for cancer immunotherapy. Utilizing Compugen's predictive discovery platform, we identified a number of novel checkpoint candidates that were then assessed as potential antibody targets for cancer treatment. Candidates meeting these validation criteria are being moved forward for therapeutic antibody development at Compugen, with CGEN-15029 the most advanced program in the therapeutic pipeline.

11:45 Imprime PGG - A Yeast-Derived Pathogen-Associated Molecular Pattern (PAMP) Triggers the Anti-Cancer Immunity Cycle to Potentiate the Efficacy of Immune Checkpoint Inhibitors

Jeremy R. Graff, Ph.D., CSO and Senior Vice President, Research, Biothera Pharmaceuticals, Inc.

Imprime PGG is being developed as a novel cancer immunotherapeutic. Imprime has been safely administered to >400 human subjects. Imprime triggers a cascade of immune activating events that re-polarize the immunosuppressive tumor microenvironment and elicit maturation of antigen presenting cells. Unlike other PAMPs (TLR and STING agonists), Imprime is administered systemically. In preclinical tumor models, Imprime robustly enhances the anti-tumor efficacy of CPIs. Accordingly, Imprime is now being explored in multiple Phase II clinical trials in combination with pembrolizumab.

12:10 pm The Immune Repertoire Capture (IRC) Technology Platform

Daniel Emerling, Ph.D., Senior Vice President, Research, Atreca, Inc.

Atreca's proprietary Immune Repertoire Capture™ (IRC™) technology delivers high-fidelity data from the active and clinically productive anti-cancer immune responses of patients who respond well to checkpoint inhibition or other immuno-modulatory treatments. By analyzing these quantitative data, such robust anti-cancer immune responses are mined to generate biotherapeutics that provide the "engine and steering" in combination with checkpoint inhibitors and immune activators, driving anti-cancer immune responses more robustly and specifically to improve treatment outcomes.

12:35 Session Break

12:40 Luncheon Presentation: Syngeneic and Tumor-Bearing Humanized Mouse Models to Address Efficacy of Novel Compounds or their Combination

Sponsored by Oncodesign

Philippe Slos, Director, Scientific Operations, Operations, Oncodesign

Recent breakthroughs in treating malignancies with antibodies harnessing self-immunity against neoplastic cells showed a great promise of immunotherapy for cancer therapy. Oncodesign will discuss case studies and relevant preclinical mouse models to address efficacy of novel compounds or their combination.

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

EMERGING TARGETS AND STRATEGIES: TREGS AND NEO-ANTIGENS

1:50 Chairperson's Remarks

Denise Faustman, M.D., Ph.D., Director, Immunobiology & Associate Professor, Medicine, Immunobiology, Massachusetts General Hospital/Harvard Medical School

1:55 Dominant Antibody Antagonists: A Novel Immunotherapy Approach Targeting the TNFR2 Receptor for Direct Oncogene-Targeted Cancer Killing and Selective Tumor Treg Killing

Denise Faustman, M.D., Ph.D., Director, Immunobiology & Associate Professor, Medicine, Immunobiology, Massachusetts General Hospital/Harvard Medical School

Tumor necrosis factor receptor 2 (TNFR2) is a target protein with restricted expression on the most potent Tregs of the tumor infiltrate and on human tumors as a newly discovered human oncogene. We characterized the effect of TNFR2 antibody antagonists via TNFR2 in human samples from ovarian ascites compared to healthy controls, finding that dominant TNFR2 antagonists demonstrate tumor-specific Treg depletion. Further, blocking TNFR2 signaling with antagonist antibodies also creates a novel tool to possibly eliminate tumors expressing the TNFR2 oncogene and to more potently suppress Tregs.

2:20 Intratumoral mAb and IL2 with Local Radiotherapy as an "*in situ* Vaccine"

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 identified a cooperative interaction between local radiation and intratumoral injection of hu14.18-IL2 immunocytokine (IC, anti-GD2 antibody linked to IL2) in mice bearing a single subcutaneous tumor, resulting in 71% complete regression. However, when two tumors of the same type are present and only one is treated with RT and IT-IC, the enhanced response is not seen. The non-treated tumor induces a systemic suppressive effect on the efficacy of RT and IT-IC. Our recent data indicate that this "concomitant immune tolerance" is, at least in part, a tumor-specific effect of Tregs.

2:45 Fully Individualized Tumor Neo-Antigen-Based Vaccine Approaches to Cancer Therapy

Karin Jooss, Ph.D., CSO, Gritstone Oncology

Genetic instability in tumors generates tumor-specific neo-antigens which have been identified as the targets of new T cells in patients responding to checkpoint inhibitor therapy. Predicting neo-antigens by sequencing routine clinical biopsy material, and then incorporating them into therapeutic cancer vaccines, is an attractive concept being developed by Gritstone Oncology. The complexities of neo-antigen prediction will be discussed, together with insights into how vaccine vectors are selected and designed.

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3:10 Immune Designs Discovery Platforms: Targeting Dendritic Cells and the Tumor Microenvironment for Systemic and *in situ* Cancer Immunotherapy

Jan ter Meulen, M.D., Dr.habil., DTM&H, CSO, Immune Design

Immune Design is developing the dendritic cell-targeting viral vector platform ZVex® for systemic therapy and the synthetic TLR4 agonist platform GLAAS™ for intratumoral therapy. These two novel technologies are currently being tested in several Phase I through II trials alone and in combination with each other and other IO modalities. Supportive mechanistic preclinical studies and updated clinical data demonstrating the potency of these approaches will be presented.

3:25 Session Break

NEXT-GENERATION ANTIBODIES FOR CANCER IMMUNOTHERAPY

3:40 Chairperson's Remarks

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

3:45 From DART® to TRIDENT™: Flexible Multispecific Antibody-Based Molecules for Multiple Clinical Applications

Ezio Bonvini, M.D., Senior Vice President, Research, MacroGenics, Inc.

The presentation will focus on the DART® and TRIDENT™ platforms and their applications as a means to redirect effector cells against tumors and/or to engage multiple checkpoint molecules to enhance the immune response in cancer. MacroGenics's preclinical pharmacology and development experience will be discussed.

4:15 Monoclonal Antibody Drug Discovery for Cancer Immunotherapy

Christopher Shelton, Ph.D., Manager, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

4:45 Anti-CD20/CD3 T Cell Dependent Bispecific Antibody (TDB) as Potential Therapy for B Cell Malignancies

Liping Laura Sun, Ph.D., Principal Scientific Researcher, Translational Oncology, Genentech, Inc.

The anti-CD20/CD3 T cell recruiting bispecific antibody (CD20-TDB) is a full-length, fully humanized IgG1 molecule currently under clinical investigation in B cell malignancies. CD20-TDB can have broad clinical applicability, either combining with chemo reagents to enable flexible treatment strategies to incorporate CD20-TDB into current standard of therapy for B cell malignancies or with immune checkpoint inhibitors such as anti-PD-L1/PD-1 to improve upon single-agent efficacy.

5:15 Close of Conference Program

Cambridge Healthtech Institute's Fifth Annual

COMBINATION IMMUNOTHERAPY DESIGN MODELS

Models and Approaches to Bring Combination Therapies to the Clinic

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

TRANSLATIONAL IMMUNO-ONCOLOGY

11:50 Chairperson's Opening Remarks
Terri McClanahan,Ph.D., Executive Director, Molecular Discovery, Biologics, Merck Research Laboratories

12:00 pm KEYNOTE PRESENTATION: Rational Development of Combination Therapies in Immuno-Oncology
Michael Kalos, M.D., CSO, Cancer Immunobiology, Eli Lilly
Treatment of patients with combinations of agents, such as CTLA4 and PD1, has provided additional benefit to patients, along with increased toxicity, highlighting the value for developing combination therapies. In this session, we will discuss preclinical and translational strategies and approaches to support the rational development of more effective combination strategies that lead to increased clinical benefit for patients.

12:30 Biomarker Development for the Era of Combination Cancer Immunotherapy
Terri McClanahan,Ph.D., Executive Director, Molecular Discovery, Biologics, Merck Research Laboratories
Keytruda® (pembrolizumab), a PD-1-specific monoclonal antibody, is approved in the U.S. for advanced melanoma, NSCLC and SCCHN, and is being studied in >30 cancers. Efforts are now underway to extend the benefit of cancer immunotherapy to more patients through the use of anti PD-1-based combination regimens. However, significant challenges remain to identify the best combinations that provide true immune synergy, and to target the right combinations to the right patients who will experience unambiguous clinical benefit. Biomarker and translational research-driven strategies can guide the future state of the field, ultimately allowing for the development of precision medicine approaches to combination cancer immunotherapy.

1:00 Session Break

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

2:10 Session Break

PRECLINICAL TO CLINICAL STUDIES: HUMANIZED MODELS TO INFORM TRIALS DESIGN

2:30 Chairperson's Remarks
Pamela N. Munster, M.D., Professor, Medicine, Program Leader, Development Therapeutics, Director, Early Phase Clinical Trials Program, Helen Diller Cancer Center, University of California, San Francisco

2:40 Designing and Executing Cancer Immunotherapy Clinical Trials
Pamela N. Munster, M.D., Professor, Medicine, Program Leader, Development Therapeutics, Director, Early Phase Clinical Trials Program, Helen Diller Cancer Center, University of California, San Francisco
A breakdown 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 certain cancers such melanoma, lung and other cancers. However, many cancers, including breast cancers, appear less responsive. We are exploring the roles of tumor lymphocyte infiltration, T cell differential, epigenetic modifiers and the co-operative involvement of other immune pathways to induce responses in immune silent tumors. Translating preclinical findings into early phase clinical studies, we will describe recent advances in how to determine safety, feasibility and efficacy of integrating immunotherapy into targeted therapy and chemotherapy.

3:10 Driving Efficiency in I/O Clinical Trials by Leveraging Patient Matched Primary 3D Ex Vivo Cultures
Matthew R. Gevaert, Ph.D., CEO, KIYATEC, Inc.

3:40 Talimogene Laherparepvec in Combination with Checkpoint Inhibitors: From Bench to Bedside
Pedro J. Beltran, Ph.D., Research Director, Oncology Research, Amgen, Inc.
Checkpoint inhibitors and viral immunotherapy with talimogene laherparepvec have shown significant therapeutic benefit in melanoma patients when used as monotherapies. As these two forms of approved immunotherapy act mostly on different parts of the immunity cycle, studying their combination pre-clinically and clinically informs their future development. We have used 3 syngeneic murine models to study the pharmacodynamic and efficacy changes driven by the combination of talimogene laherparepvec and blockade of CTLA-4 or PD-1/PD-L1. Clinical trials testing these combinations in the clinic are currently ongoing.

Sponsored by MACS Miltenyi Biotec

4:10 Complete Workflows Improve the Isolation and Analysis of Tumor-Infiltrating Immune Cell Subpopulations
Cesar Evaristo, Ph.D., Research & Development Team Coordinator, Research & Development Immune Responses, Tumor Immunology, T cells, Miltenyi Biotec GmbH
Tumor-infiltrating leukocytes (TILs) constitute a fraction of highly complex and variable tumor tissue, complicating the analysis of individual subpopulations. By combining optimized tissue dissociation with specific pre-enrichment of TILs, we significantly increased the quality of data obtained from TIL analysis.

4:25 Sponsored Presentation *(Opportunity Available)*

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session (please see page 4 for details)

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

TUMOR MODELS FOR CANCER IMMUNOTHERAPY

10:05 Chairperson's Remarks
Gavin Thurston, Vice President, Oncology and Angiogenesis Research, Regeneron Pharmaceuticals

10:15 Mouse Models to Test Human Cancer Immuno-Therapeutics
Gavin Thurston, Vice President, Oncology and Angiogenesis Research, Regeneron Pharmaceuticals
Preclinical *in vivo* tumor models are essential to test anti-tumor activity and side-effect profiles of novel immunotherapeutics. However, antibody-based therapies often do not cross-react with the corresponding murine targets, making such tests difficult. We have utilized Regeneron's capabilities in murine genetic engineering to develop several approaches of combining functional immune cells with preclinical tumor models. We have used these approaches for preclinical testing of both checkpoint inhibiting antibodies and T cell-engaging bispecific antibodies.

10:45 Characterization of Molecular and Cellular Properties of Murine Syngeneic Models to Aid Model Selection and Biomarker Discovery for Immune-Oncology Programs
Wenyan Zhong, Ph.D., Senior Principal Scientist, Oncology R&D Group, Pfizer
Preclinical *in vivo* models for most immuno-oncology (IO) programs require the use of immunocompetent mice bearing syngeneic tumors. To facilitate model selection for use in preclinical efficacy studies, we characterized a panel of mouse tumor cell lines and syngeneic tumor tissues. In this talk, we will discuss molecular and cellular properties of these models.

11:15 Case Study: Blockade of Phosphatidylserine-Mediated Tumor Immune Suppression to Enhance Immune Checkpoint Therapies
Bruce Freimark, Ph.D., Research Director, Pre-Clinical Oncology, Peregrine Pharmaceuticals, Inc.
Phosphatidylserine (PS) exposure in tumors induces non-inflammatory signals which contribute to an immunosuppressive environment. Antibody blockade of PS activates immune responses by promoting M1 macrophages, maturation of dendritic cells and inducing adaptive T-cell responses. PS targeting antibodies enhance the anti-tumor activity of checkpoint antibodies in preclinical tumor models.

Sponsored by MI Bioresearch

11:45 Methods and Models for Preclinical Immuno-Oncology
Dylan Daniel, Ph.D., Director, Scientific Development, MI Bioresearch
MI Bioresearch has characterized an array of syngeneic immuno-oncology models to support *in vivo* pharmacology drug discovery. Our characterization includes comprehensive lymphoid and myeloid flow cytometry immune profiling, and model responses to checkpoint inhibitors and focal beam radiotherapy combinations.

Sponsored by EXEMPLAR GENETICS

12:00 pm Genetically Engineered Miniswine Models of Cancer
John Swart, Ph.D., President, Exemplar Genetics
Current preclinical models of cancer fail to accurately recapitulate human disease and do not effectively translated to the clinic. Recently, Exemplar Genetics has developed a genetically engineered miniature swine model that contains a conditional KRAS mutation on the background of TP53-targeted pigs, the ExeGen® TP53+/R167H& KRAS+/G12D miniswine model. This model should allow for the inducement of human-like tumors in a tissue specific manner. Initial characterization of induced tumors demonstrates the transformative nature of this model.

12:30 Session Break

Sponsored by MITRA BIOTECH

12:35 Luncheon Presentation to be Announced
Parker Cassidy, MBA, Chief Commercial Officer, Mitra Biotech

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

ADVANCING TRANSLATION WITH NOVEL APPROACHES AND INDUSTRY-ACADEMIA PARTNERSHIPS

2:00 Chairperson's Remarks
Lawrence B. Schook, Ph.D., Gutsgell Professor, Animal Sciences and Radiology, University of Illinois

2:10 Collaboration for Translation: Academic-Industry Partnerships to Explore Novel Opportunities in the Area of Immuno-Oncology
Joseph Dal Porto, Ph.D., Director, Pfizer Center for Therapeutic Innovation
The Center for Therapeutic Innovation (CTI) -San Francisco is a direct partnership

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between Pfizer and leading academic institutions, including UC San Francisco, UC San Diego, Stanford University and others, to establish open collaborations designed to rapidly identify targets and develop therapeutic NMEs. The long-term goal is to substantially reduce the time required to translate promising bio-medical research into new medications and therapies. Most recently, CTI has joined with academic oncology and immunology researchers to understand the translatability of emerging targets in the Immuno-Oncology therapeutic arena.

2:40 An Example of a Collaboration between Industry and Academia for Testing Combination Therapies in Preclinical Patient-Derived Xenograft Models of Glioblastoma

Anderson Clark, Ph.D., Director, Translational in vivo Pharmacology, Oncology, EMD Serono Research & Development Institute

John De Groot, Associate Professor, Chair Ad Interim, Neuro-Oncology, The University of Texas MD Anderson Cancer Center

The use of patient-derived xenograft (PDX) models of cancer has increased over the past decade, both in industry and academia, providing preclinical data to support both drug development and basic oncology research.

3:10 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.

Sponsored by CHAMPIONS ONCOLOGY

3:40 Late Breaking Presentation

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

TRANSLATIONAL BIOMARKERS IN CANCER IMMUNOTHERAPY DEVELOPMENT

10:50 Chairperson's Remarks

Jianda Yuan, M.D., Ph.D., Director, Translational Immuno-Oncology Research, Early Clinical Oncology Development, Merck & Co., Inc.

11:00 Next Generation Biomarkers for the Era of Combination Cancer Immunotherapy

Sarah Javaid, Ph.D., Senior Scientist, Discovery Pharmacogenomics, Genetics and Pharmacogenomics, Merck & Co., Inc.

Combination approaches are the keys to improving clinical response. From preclinical immune-oncology mouse models to patients enrolled on clinical trials, novel high throughput technologies enable us to understand the mechanisms underlying the complex interactions between the immune system and cancer, identify predictive biomarkers for the patients who will most likely benefit from current immunotherapies, avoid immune-related adverse events and guide the future combination cancer immunotherapy.

11:30 Biomarker Strategy to Inform Clinical Development of ImmTACTM Molecules (Immune Mobilising TCRs Against Cancer)

David Krige, Ph.D., Head of Biomarkers, Immunocore

A comprehensive biomarker strategy has been developed to compliment clinical studies with IMCgp100, an ImmTAC that targets malignant melanoma. This biomarker strategy is vital for evaluating ongoing trials as well as informing the clinical development of other ImmTAC molecules, either as single agents or in combination with checkpoint inhibitors.

12:00 pm Utility of Quantifying Circulating Lymphocyte Populations as Pharmacodynamic Biomarkers in Trials of Immune Oncology Therapeutics

Nathan Standifer, Ph.D., Scientist II, Clinical Pharmacology and DMPK, MedImmune

Immune oncology (IO) therapeutics are directed at inducing immune responses against tumor cells. Intrinsic to this mechanism of action is the activation of circulating immune cells, which can be most effectively monitored using flow cytometry-based assays. In this presentation, aspects of assay development, validation, implementation and analysis of clinical flow cytometry datasets will be discussed. Results from clinical trials of IO as single agents or in combination with other IO will be shown and strategies for interpretation and post-hoc analyses will be detailed.

12:30 Session Break

Sponsored by CELLECTA Discovery is Yours.

12:40 Luncheon Presentation to be Announced

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

CELLULAR MODELS FOR COMBINATION THERAPY DESIGN

1:50 Chairperson's Remarks

Scott Martin, Senior Scientific Manager, Group Lead, Functional Genomics, Discovery Oncology, Genentech

2:00 Understanding and Predicting Cellular Response through Chemical and Functional Genomic Profiling of Well-Characterized Cancer Cell Lines

Scott Martin, Senior Scientific Manager, Group Lead, Functional Genomics, Discovery Oncology, Genentech

Determining relationships between genomic features and drug sensitivity is central to the concept of personalized medicine and indication selection. Many studies have highlighted the value of integrating omics data with drug activity across cell lines to identify predictors of response. Here we extend upon these studies with numerous chemical and genetic perturbations to explore such relationships. Data reveals both known and novel correlations, and was also used to explore best experimental and computational practices.

2:30 Beyond Genomics: Identifying Treatment Options for Refractory Cancer Patients Using Real Time Functional Assays and FDA Approved Drug Combinations

Matthew De Silva, CEO, Founder, Notable Labs

Refractory cancer patients often have resistant disease that does not respond to single agent therapy. Combination strategies are promising, but patient heterogeneity makes clinical trial design difficult. Next generation functional phenotypic assays using a patient's cancer cells can identify potentially synergistic treatments in a matter of days, but the combinatorial space is often larger than the available cells. *In silico* models that employ 'omic data from a patient can prioritize which combinations to test *ex vivo*. If the agent(s) of choice are approved, physicians can then prescribe them

3:00 Generation of *ex vivo* Tumor Models from PDX Tumors as a Platform for Clinically Relevant Anticancer Drug Discovery

Geoffrey A. Bartholomeusz, Ph.D., Associate Professor and Director, siRNA Core Facility, Department of Experimental Therapeutics, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center

Monolayer cell cultures platforms inadequately represent the complex tumor microenvironment and drugs identified by these systems have failed when translated into the clinics. Clinically relevant PDX systems are both costly and time consuming. We have developed a clinically relevant *ex vivo* tumor tissue system derived from a PDX tumor, and preliminary data confirms its potential to serve as a platform for clinically relevant drug discovery in a time and cost effective manner.

3:30 Session Break

CRISPR FOR TUMOR MODELING, INTERNATIONAL INITIATIVES

3:40 Chairperson's Remarks

Monte Winslow, Ph.D., Assistant Professor, Genetics, Stanford University

3:45 Cancer Modeling with *in vivo* CRISPR/Cas9 Genome Editing

Monte Winslow, Ph.D., Assistant Professor, Genetics, Stanford University

Conventional genetically engineered mouse models of human cancer have been instrumental in our understanding of all aspects of cancer development. However, these models are much too labor-intensive, expensive, and slow to perform the extensive molecular analyses needed to adequately comprehend this disease. I will discuss our ongoing work to employ CRISPR/Cas9-mediated genome editing to generate cancer models and illuminate gene function during cancer progression within the natural *in vivo* setting.

4:15 Tailored Pre-Clinical Models with CRISPR-Based Genome Editing

Lukas Edward Dow, Assistant Professor, Medicine, Weill Cornell Medicine

CRISPR/Cas9 genome editing has changed the way we design and execute *in vivo* experiments. We are using CRISPR-based genome editing in stem cells and in adult mice to generate tailored pre-clinical models. This allows both a deeper understanding of the genetic underpinnings of cancer progression and provides a platform to interrogate new therapeutic strategies in specific genetic contexts, which is key for realizing the potential of personalized medicine.

4:45 The Human Cancer Model Initiative

Louis M. Staudt, M.D., Ph.D., Director, Center for Cancer Genomics, Co-Chief, Lymphoid Malignancies Branch, National Cancer Institute, National Institutes of Health

The Human Cancer Model Initiative (HCMI) aims to generate 1000 new cancer cell lines directly from patient biopsy material using a variety of technologies, including organoids and conditionally reprogrammed cells. Each cell line will be genomically characterized and clinical diagnostic and therapeutic data will be gathered from the participating patients. The new cell lines and their associated data will be made available to the research community to promote a deeper understanding of cancer and its response or resistance to therapy.

5:15 Close of Conference Program

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INFORMATICS CHANNEL

- **Bioinformatics for Big Data**
- **Integrated Pharma Informatics**

Cambridge Healthtech Institute's Sixth Annual

BIOINFORMATICS FOR BIG DATA

Creating Actionable Data

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

DATA ANNOTATION AND RETRIEVAL - STANDARDS, ACCESSIBILITY FROM THE CLOUD AND SECURITY

11:50 Chairperson's Opening Remarks

John Mattison, M.D., Assistant Medical Director, Chief Medical Information Officer, Kaiser Permanente, SCAL

12:00 pm Making Experimental Results Findable, Accessible, Interoperable and Reusable: The CEDAR Technology for Managing Online Biomedical Metadata

Mark Musen, M.D., Ph.D., Professor, Biomedical Informatics at Stanford University, Director of the Stanford Center for Biomedical Informatics Research

The Center for Expanded Data Annotation and Retrieval (CEDAR) develops information technology to ease the authoring and management of the metadata that investigators need to make sense of online datasets. The approach aids the verification of experimental results, the secondary analysis of biomedical data, and the integration of online datasets.

12:30 Conducting Cancer Research in a Distributed Cloud Environment

Anthony R. Kerlavage, Ph.D., Chief, Cancer Informatics Branch, National Cancer Institute, Center for Biomedical Informatics & Information Technology

The NCI has launched the Genomic Data Commons and Cancer Genomics Cloud Pilots as a secure ecosystem to provide a repository for the growing amount of cancer genomic and related clinical data, and an analytics platform to conduct research on large cancer datasets. Together, these form the foundational elements of a Cancer Knowledge System.

1:00 Enjoy Lunch on Your Own

BIOINFORMATICS IN THE PRACTICE OF HEALTHCARE: FROM DATA TO CLINICAL ACTION

2:30 Chairperson's Opening Remarks

John C. Earls, MS, Graduate Research Assistant, Nathan Price Lab, Institute for Systems Biology

2:40 From Big Data to Actionability: Lessons from the Pioneer 100 Project and Beyond

John C. Earls, MS, Graduate Research Assistant, Nathan Price Lab, Institute for Systems Biology

Lee Hood and I have recently launched a large-scale wellness project that integrates genomics, proteomics, transcriptomics, microbiomes, clinical chemistries and wearable devices of the quantified self to monitor wellness and disease, which is scaling now to thousands of people. I will present results from our proof-of-concept pilot study.

3:10 Integrating Multi-Omics Data for Clinical Actions

Han Liang, Ph.D., Associate Professor and Deputy Chair, Department of Bioinformatics and Computational Biology, Associate Professor, Department of Systems Biology, The University of Texas MD Anderson Cancer Center

Cancer omics data has been accumulated at a fascinating speed, and one key question is how to use these data to facilitate clinical decisions for precision cancer medicine. I will present the resource of cancer proteomics data based on reverse-phase protein arrays and discuss their utility in predict patient survival and drug options. I will also discuss how to identify driver mutations by using high-throughput functional assays.

3:40 From Bits to Bedside: Translating Big Data into Precision Medicine and Digital Health

Dexter Hadley, M.D., Ph.D., Assistant Professor of Pediatrics, Institute for Computational Health Sciences, University of California, San Francisco

In this talk, I will use examples from my research using big data analytics to define ideals of precision medicine and digital health across a variety of diseases. Specifically, I will introduce the audience to my work in large-scale population-wide analysis with public and private data sources, and my work on using mobile technology and digital health to foster these two ideals and improve patient care.

Sponsored by SevenBridges

4:10 Democratizing Cancer Data to Accelerate Discovery

Gaurav Kaushik, Ph.D., Scientific Product Manager, Seven Bridges

The Cancer Genomics Cloud (CGC) democratizes access to The Cancer Genome Atlas. The CGC removes the need to download data, enables easy querying, and much more. We discuss its design and the avenues of discovery it enables.

INFORMATICS CHANNEL

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session (please see page 4 for details)

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session (please see page 4 for details)

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

PERSONALIZED MEDICINE STRATEGIES

10:05 Chairperson's Remarks

Anthony R. Kerlavage, Ph.D., Chief, Cancer Informatics Branch, Center for Biomedical Informatics & Information Technology, National Cancer Institute

10:15 Sharing Data for Genomic Medicine

David Haussler, Ph.D., Professor of Biomolecular Engineering, UC Santa Cruz & Scientific Director, UC Santa Cruz Genomics Institute

Every human disease is a rare disease at the molecular level. No single institute has enough patients to understand any particular molecular subtype. For genomics to benefit medicine and science, we must share data. I outline the data standards and Application Programming Interfaces developed by the Global Alliance for Genomics and Health (GA4GH) that are intended to address this issue, and highlight a few global genomics projects that use them.

10:45 Health Systems as Translational Research Partners

Gregory J. Tranah, Ph.D., Director of Precision Medicine & Senior Scientist, Sutter Health; Ad-junct Professor, Epidemiology and Biostatistics, University of California, San Franciso

Precision medicine is empowered by access to diverse data, patients, and provider networks. This presentation will describe the role of health systems as translational research partners that can drive: 1) molecular discoveries; 2) provider and patient engagement through an interoperable platform; and 3) rapid translation of discoveries to clinical practice.

11:15 A Closed-Loop, Multilevel Modeling of Glucose Homeostasis

Corrado Priami, Professor & CEO, The Microsoft Research - University of Trento COSBI

T2DM is one of the major diseases affecting western society that is diagnosed at phenotypic level by inspecting fasting glucose. An understanding of the links between phenotype and molecular signaling is fundamental to control the disease progression. We exploit multi-level dynamical modeling to improve existing whole-body model of glucose metabolism and connect them with molecular insulin signaling in adipose cells.

11:45 Accelerating Big Data Research in the Cloud

Sponsored by aspera an IBM company

Anand Basu, MS, MBA, Senior Vice President, ESAC Inc.

Sharing omics data with researchers around the world is a challenge given the growing size of datasets. Learn how ESAC leveraged Aspera high-speed transfer software to enable fast, secure online sharing of large proteomic data for a critical NCI initiative.

12:15 Enjoy Lunch on Your Own

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

PLATFORMS FOR EXPLORING MULTI-OMICS DATA

2:00 Chairperson's Remarks

Xianghong Jasmine Zhou, Ph.D., Professor, Pathology and Laboratory Medicine, University of California, Los Angeles

2:10 Structure-Function Mapping of 3D Human Genome

Xianghong Jasmine Zhou, Ph.D., Professor, Pathology and Laboratory Medicine, University of California at Los Angeles

Here we report an approach to comprehensively identify 3D chromatin clusters that each occurs frequently across a population of genome structures. Applying our method to a population of genome structures (at the macrodomain resolution) of lymphoblastoid cells, we identify an atlas of stable inter-chromosomal chromatin clusters.

2:40 Multi-Omics Data Analysis Tools for Biologists and Clinicians

Bing Zhang, Ph.D., Professor, Department of Molecular and Human Genetics, Lester & Sue Smith Breast Center, Baylor College of Medicine

A major challenge in the multi-omics era is to enable biologists and clinicians to directly use the complex, interconnected, and high-dimensional data. This talk will introduce two web applications that attempt to address this challenge. NetGestalt provides a network-based framework for multi-omics data visualization and analysis. LinkedOmics enables the discovery of novel associations between genomic, proteomic, and clinical attributes.

3:10 3'-UTR Shortening Represses Tumor Suppressors in Trans by Disrupting ceRNA Crosstalk

Wei Li, Ph.D., Associate Professor, Division of Biostatistics, Duncan L. Cancer Center-LI, Baylor College of Medicine

Widespread mRNA 3'-UTR shortening promotes tumor growth *in vivo*, yet its underlying mechanism remains largely unknown. Here, our big data analysis followed by experimental validation suggest that the major role of 3'-UTR shortening in tumorigenesis is to direct the release of microRNAs to repress tumor suppressor competing-endogenous RNA (ceRNA) in trans, such as PTEN.

3:40 Next-Generation Image Mining and Data Analysis Provides Real-Time Decision on Patient Stratification

Sponsored by DEFINIENS the tissue phenomics company

Ralf Huss, M.D., CMO, Definiens

Extraction of information & biological insights provided from tissue is challenging and has to be represented in a meaningful way. Virtual multiplexing of multiple immunohistochemistry stains into a multi-dimensional virtual image is crucial to

BIOINFORMATICS FOR BIG DATA

successful image mining and data analysis

3:55 Talk Title to be Announced
John Mattison, M.D., Assistant Medical Director, Chief Medical Information Officer, Kaiser Permanente, SCAL

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

BIOINFORMATICS IN THE PRACTICE OF HEALTHCARE: FROM DATA TO CLINICAL ACTION (CONT.)

10:50 Chairperson's Remarks
Peng Yue, Associate Director, Research Bioinformatics, Gilead Sciences

11:00 Learning Real-World Evidence of Drug Efficacy and Safety from the EHR
Nigam Shah, Ph.D., Associate Professor of Medicine (Biomedical Informatics), Stanford University, Assistant Director, The Center for Biomedical Informatics Research
With the widespread availability of Electronic Health Records (EHR), it is possible to examine the outcomes of decisions made by doctors during clinical practice to identify patterns of care-generating evidence from the collective experience of millions of patients. We will discuss methods that transform EHR data into real world evidence for comparative effectiveness, drug safety and Phase IV surveillance studies for a learning health system.

11:30 Bioinformatics Approaches for Functional Interpretation of Genome Variation
Kai Wang, Ph.D., Associate Professor, Biomedical Informatics, Institute for Genomic Medicine, Columbia University
We developed Phenolyzer, which analyzes clinical phenotypes on a given patient and predicts the most likely candidate genes that are responsible for the phenotypes, by integrating multiple sources of gene-pathway-disease-phenotype information. Based on Phenolyzer, we also developed iCAGES (integrated CAncer GEnome Score), which is an effective tool for prioritizing cancer driver genes for a patient using genome sequencing data. We illustrate case studies where iCAGES can facilitate selection of optimal treatment strategies based on predicted personal driver genes.

12:00 Visualization, Characterization and Mining of Real-World Patient Data
Andreas Matern, Vice President, Partnerships & Innovation, BioReference Laboratories, GeneDX
Real World Patient Data (RWPD) is plagued with a lack of data management strategy. In this talk, I will discuss the construction of a data repository and visualization tools used to mine and characterize RWPD from clinical patient records. The discussion will include overcoming the complexities of RWPD, modeling the data for use in clinical and pharmaceutical research, and visualizations and data mining techniques used to allow end users to interrogate the data in ways never before possible.

TRANSLATIONAL INFORMATICS: CLINICAL DATA DRIVING PRECLINICAL RESEARCH

12:10 pm Connecting Tumor Genomics with Therapeutics through Multi-Dimensional Network Modules
Sourav Bandyopadhyay, Ph.D., Assistant Professor, Bioengineering and Therapeutic Sciences, University of California, San Francisco
Recent efforts have catalogued genomic, transcriptomic, epigenetic and proteomic changes in tumors and a challenge is to integrate these data to identify a consensus catalog of the unique molecular events or modules in cancers and connect them with new therapeutics. We present a new approach called MAGNET to integrate such data based on functional networks. Evaluation of network modules in cancer cell lines reveals a preserved subset that can be used for biomarker development.

12:30 Enjoy Lunch on Your Own

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

TRANSLATIONAL INFORMATICS: CLINICAL DATA DRIVING PRECLINICAL RESEARCH (CONT.)

1:50 Chairperson's Remarks
Farida Kopti, Ph.D., Director, Chemistry/Pharmacology/HTS Informatics IT, Merck Research Labs, Merck & Co.

2:00 Leveraging 'Omics Data from Deeply Phenotyped Clinical Studies to Inform Target and Biomarker Validation
Janna Hutz, Ph.D., Senior Director, Head, Human Biology & Data Science Engine, Eisai AiM Institute, Eisai, Inc.
Beyond oncology, there have been few documented successes in using genome scale sequencing from clinical trials to inform design of subsequent trials. Rather, it is emerging that these datasets' greatest value may lie in feeding back into earlier stages of drug discovery. I will share Eisai's efforts to use NGS data from well-characterized clinical cohorts for target validation and biomarker identification.

BIOINFORMATICS FOR BIG DATA

INFORMATICS CHANNEL

2:30 Disease Signatures to Drug Discovery
Deepak K. Rajpal, Ph.D., Director, Computational Biology-Target Sciences, GSK
We present how we have used clinical transcriptomics-based generation of disease signatures and their application in drug discovery. We have identified disease areas of interest and then clinical transcriptomics datasets from published literature associated with the diseases of interest. We have then generated disease signatures and by integrative informatics approaches, and have applied these datasets in our drug discovery efforts. We present here a case study in dermatological disease area.

3:00 Target Identification and Validation Using Genomics and Genetics
Vinod Kumar, Ph.D., Senior Scientific Investigator, Computational Biology (US), Target Sciences, R&D, GSK
In practice, the identification of a novel disease target is an integrative step combining many lines of evidence, but may often be triggered by a key, highly publicized finding. Though relatively little attention has been paid to systematically evaluate the multiple lines of evidence that have proven effective in choosing a successful target for that disease. I will present how we use informatics approaches to leverage genetic, genomics and phenotypic data to prioritize targets and validate them experimentally.

3:30 Session Break

WRESTLING WITH BIG DATA: IMPLICATIONS FOR DISCOVERY, REIMBURSEMENT, REGULATION, AND CLINIC

3:40 Chairperson's Remarks
Andrew C. Fish, J.D., Executive Director, AdvaMedDx

3:45 Big Data – The Devil's in the Details
Elaine K. Jeter, M.D., J1 MolDx Medical Director, Palmetto GBA
Linking effective therapies and expanded trial designations are the expected benefit of the ever expanding capabilities of genomic biomarker and gene expression identification. More and more data is being generated every day. Keeping that data 'valuable' will require we maintain a critical focus on the quality and comparative values of the data, especially in the area of genomics and more specifically outcomes. Other questions will arise around where the data is collected, how it is curated, and who has access. As a Medicare payer, we support the concept of data collection/aggregation if that data can be effectively mined to create ever improving treatment protocols and more importantly improved outcomes.

4:00 Efficiently Leveraging Commercial and Open Source Bioinformatics Tools for Clinical Interventions and Research Discoveries from Very Large Datasets
Ben Busby, Ph.D., Genomics Outreach Coordinator, NCBI, NLM/NIH
In precision medicine, it is often the case that efficacy does not depend on the appropriate computational intervention, but on the morphology of the data that informs the problem. For example, different strategies should be employed when calling short variants in stable versus unstable regions of the human genome, or when looking for pathogenic effectors in well-characterized versus newly discovered bacterial or viral pathogens. Pragmatic solutions from existing commercial and open source resources will be presented.

4:15 From Bits to Bedside: Developing a Learning Digital Health System to Evaluate Pigmented Skin Lesions
Dexter Hadley, M.D., Ph.D., Assistant Professor, Pediatrics, Institute for Computational Health Sciences, University of California, San Francisco
Melanoma accounts for less than one percent of skin cancer cases but the vast majority of skin cancer deaths. Early screening and diagnosis significantly improves patient outcomes, yet no systematic framework exists for clinical evaluation of common pigmented lesions for risk of melanoma. In this talk, I will describe our approach to develop a learning health system focused on precision screening and diagnosis of skin cancer. We first leverage medical students in the clinics to capture digital samples of pigmented skin lesions at scale with mobile health technology. We then leverage this clinical big data to train state-of-the-art deep learning image classification algorithms to better screen for cancer. Our work translates routinely documented electronic health data into an impactful digital health initiative to directly improve clinical outcomes and advance clinical knowledge.

4:30 PANEL DISCUSSION

5:15 Close of Conference Program

Cambridge Healthtech Institute's Ninth Annual

INTEGRATED PHARMA INFORMATICS

Driving Translational Research & Precision Medicine in the Era of Digital Health

MONDAY, FEBRUARY 20

10:30 am Conference Program Registration Open

INTEGRATED INFORMATICS FOR COLLABORATION, DECISION MAKING, AND PRECISION MEDICINE

11:50 Chairperson's Opening Remarks
Tom Plasterer, Ph.D., Director, US Cross-Science, AstraZeneca

12:00 pm All-in-One or One-for-All? Reckoning with the Diversity and Commonality of Research Information Technologies
Peter Covitz, Ph.D., Senior Director, Research & Translational IT, Research and Development IT, Biogen

Biopharmaceutical research is increasingly enabled by information technology. At the same time, life science companies are under increasing pressure to boost R&D productivity without adding significant cost. One example is the choice between consolidating around a limited number of integrated platforms that receive higher levels of investment versus supporting a greater variety of point solutions that serve specific niche requirements. This presentation will discuss the trade-offs inherent in such choices and make some suggestions on which way to lean for different situations.

12:30 How Highly Integrated Informatics Platforms Contribute to Our Drug Portfolio
Juergen Hammer, Ph.D., MBA, Global Head Data Science, Pharma Research and Development Informatics, Roche Innovation Center New York

In a world where genetics, sensor, real-world and image data increasingly influence clinical decision-making, well-designed and highly integrated informatics platforms supporting structured data capturing, integration, and analytics become essential for effective drug development. I will discuss how these informatics platforms are being applied at Roche. Furthermore, I will discuss some of the principles in designing these platforms, and contrast our current approach to previous approaches in biomedical informatics.

1:00 Session Break

1:10 Luncheon Presentation: Agile Data Access to Speed Discovery of Scientific Insights
Sponsored by CERTARA
Quan Nguyen, Senior Director, Client Technology Solutions, Certara

A key bottleneck in discovery and development is the ability to access and understand complex biological, chemical, pre-clinical data from many sources. Thousands of scientists rely on D360 Scientific Informatics Platform to access and analyze data for better informed decisions.

2:10 Session Break

2:30 Chairperson's Remarks
Ajay Shah, Director, Research Informatics and Systems, Office of Chief Informatics Officer, Beckman Research Institute, City of Hope National Medical Center

2:40 Edge Informatics and FAIR (Findable, Accessible, Interoperable and Reusable) Data
Tom Plasterer, Ph.D., Director, US Cross-Science, Research & Development Information (RDI), AstraZeneca

Edge Informatics is an approach to accelerate collaboration in the BioPharma pipeline. By combining technical and social solutions, knowledge can be shared and leveraged across the multiple internal and external silos participating in the drug development process. This is accomplished by making data assets findable, accessible, interoperable and reusable (FAIR). Public consortia and internal efforts embracing FAIR data and Edge Informatics will be highlighted, in both preclinical and clinical domains.

3:10 Enabling Genomics Beyond the Pipelines
Boris Umylny, Ph.D, CTO, Smpl Bio

As genomic analysis gains widespread commercial acceptance, it is important for analytical tools to evolve from their current siloed setup to become an integral part of the corporate computation-al environment. In this talk we introduce Kratos – a cutting-edge application that combines capa-bilities for bulk as well as single-cell NGS data analysis with secure, world-wide collaboration and unparalleled ability to integrate and thrive in real-world setting.

3:40 Integrated Informatics Approaches to Enable Immuno-Oncology
Yun Li, Head, R&D Informatics, R&D Business Technology, Pfizer San Francisco

The advancement of Immuno-Oncology brings new hope for cancer patients but also presents new challenges in several areas of Informatics. This presentation will highlight some of the approaches R&D Business Technology at Pfizer has taken to overcome those challenges.

4:10 Integration from the Ground Up: Transforming Biologics R&D Informatics with Benchling
Sponsored by Benchling
Sajith Wickramasekara, Founder & CEO, Benchling

Most R&D processes are scattered across disparate software. Benchling unifies experiment workflows, ensuring that cutting-edge science is never held back by obsolete software. We will describe how we worked with scientists to streamline biologics R&D workflow on a single platform.

INFORMATICS CHANNEL

4:25 The Paradigm Shift in Integrated Informatics

Sponsored by CORE INFORMATICS

Marc Siladi, Senior Business Analyst, Core Informatics

This presentation will discuss the convergence between big data and drug discovery driving the neo "Cambrian Healthcare explosion." This vertex is creating a new landscape with new approaches and tools for healthcare including informatics, analytics, and data management strategies.

4:40 Refreshment Break and Transition to Plenary Session

5:00 Plenary Keynote Session **(please see page 4 for details)**

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

7:30 Close of Day

TUESDAY, FEBRUARY 21

7:30 am Registration Open and Morning Coffee

8:00 Plenary Keynote Session **(please see page 4 for details)**

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

DATA INTEGRATION AND ANALYSIS

10:05 Chairperson's Remarks

Boris Umylny, Ph.D, CTO, Smpl Bio

10:15 Universal Registration: Centralized Data Management and an Intelligent Network of Relationships between Records

Farida Kopti, Ph.D., Director, Chemistry/Pharmacology/HTS Informatics IT, Merck Research Labs, Merck & Co.

Merck intends to capture and secure the intellectual property around our various entities in the course of drug discovery. Hierarchical and other pipeline driven relationships can be identified between these entities, plus direct links to assay test results depicting the functional activity of the entities. This will enable traceability, lower the cost associated with duplicate production of the entity, and allow scientific data to be accessed in real time across the research organization. Scientists will be able to make decisions based on a more complete set of data that is not broken down by application silos.

10:45 Alexion's Content Analysis Project: Mining Content for Actionable Insight

Martin Leach, Vice President R&D IT, Enterprise Data Management & Analytics, IT, Alexion Pharmaceuticals

Unlocking content from internal and external sources is key for many different use cases. Competitive analysis, business development, external scouting, patient identification and just making sense of the vast amount of information within an organization. In our presentation, we will share some of our findings and methods for doing this at Alexion using off the shelf technology and approaches with advanced data visualizations that help explain information sources.

INTEGRATED PHARMA INFORMATICS

INFORMATICS FOR BIG DATA

11:15 SPIRIT-SA: Machine Learning Platform for Scientific Data Analysis

Ajay Shah, Director, Research Informatics and Systems, Office of Chief Informatics Officer, Beckman Research Institute, City of Hope National Medical Center

SPIRIT (Software Platform for Integrated Research Information and Transformation) seeks to integrate basic, clinical and translational data and analytic tools. SPIRIT-SA (Scientific Analytics) component of SPIRIT platform provides data normalization, data cleanup, and results validation using multiple machine learning algorithms simultaneously. The latest version of SPIRIT-SA guides the users to the most suitable algorithms for their dataset and the ideal visualization methods.

Sponsored by PerkinElmer

11:45 Aligning Data Analytics for Translational and Personalized Medicine

Dan Weaver, Ph.D., Senior Product Manager, PerkinElmer

PerkinElmer Signals for Translational helps discover, analyze & align high-dimensional datasets with clinical outcomes. We will elaborate on functional components, simplified data loading model supporting structured and unstructured data and TIBCO Spotfire visualizations designed to answer Translational Researcher's questions.

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

2:00 Chairperson's Remarks

Peter Covitz, Ph.D., Senior Director, Research & Translational IT, Research and Development IT, Biogen

2:10 Presentation to Be Announced

INFORMATICS FOR TARGET VALIDATION

2:40 ADC Target Identification and Validation

Sean Liu, Ph.D., Global Head, Translational Science Systems, Research IT, Takeda Pharmaceuticals

Takeda developed an analysis pipeline to use publicly available microarray and RNASeq data for antibody-drug conjugate (ADC) target identification and data integration and visualization platform to validate and prioritize targets based upon biological relevance and druggability. This presentation will discuss considerations and criteria for ADC target identification and public data sources to address each of the criteria.

3:10 Drug Target Validation Using Genomics and Data Mining

Peng Yue, Associate Director, Research Bioinformatics, Gilead Sciences

Target validation using *in vivo* animal models is a critical step in drug discovery at the pre-clinical stage. However, the poor predictive value of animal models often correlates with the lack of efficacy in clinical trials. The ever-growing collection of big data offers a complementary way to validate the biological role of a given

target in human. This talk will discuss the challenges and potential of such an *in silico* way for target validation.

Sponsored by Clarivate Analytics

3:40 New Approaches to Target Identification

Richard K. Harrison, Ph.D., CSO, Clarivate Analytics (Formerly the IP & Science business of Thomson Reuters)

This talk will highlight the use of omic and pathway based analysis for identifying new targets and the use of new analytical tools and analytics to rapidly triage targets to identify the most promising from both scientific and commercial perspectives.

4:10 Hollywood Oscar Dessert Reception in the Exhibit Hall with Poster Viewing

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

6:00 Close of Day

WEDNESDAY, FEBRUARY 22

7:00 am Registration Open

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

8:00 Plenary Keynote Session (please see page 4 for details)

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

BIOINFORMATICS IN THE PRACTICE OF HEALTHCARE: FROM DATA TO CLINICAL ACTION (CONT.)

10:50 Chairperson's Remarks

Peng Yue, Associate Director, Research Bioinformatics, Gilead Sciences

11:00 Learning Real-World Evidence of Drug Efficacy and Safety from the EHR

Nigam Shah, Ph.D., Associate Professor of Medicine (Biomedical Informatics) at Stanford University, Assistant Director of the Center for Biomedical Informatics Research

With the widespread availability of Electronic Health Records (EHR), it is possible to examine the outcomes of decisions made by doctors during clinical practice to identify patterns of care-generating evidence from the collective experience of millions of patients. We will discuss methods that transform EHR data into real world evidence for comparative effectiveness, drug safety and Phase IV surveillance studies for a learning health system.

11:30 Bioinformatics Approaches for Functional Interpretation of Genome Variation

Kai Wang, Ph.D., Associate Professor, Biomedical Informatics, Institute for Genomic Medicine, Columbia University

INTEGRATED PHARMA INFORMATICS

We developed Phenolyzer, which analyzes clinical phenotypes on a given patient and predicts the most likely candidate genes that are responsible for the phenotypes, by integrating multiple sources of gene-pathway-disease-phenotype information. Based on Phenolyzer, we also developed iCAGES (integrated CAncer GEnome Score), which is an effective tool for prioritizing cancer driver genes for a patient using genome sequencing data. We illustrate case studies where iCAGES can facilitate selection of optimal treatment strategies based on predicted personal driver genes.

12:00 Visualization, Characterization and Mining of Real-World Patient Data

Andreas Matern, Vice President, Partnerships & Innovation, BioReference Laboratories, GeneDX

Real World Patient Data (RWPD) is plagued with a lack of data management strategy. In this talk, I will discuss the construction of a data repository and visualization tools used to mine and characterize RWPD from clinical patient records. The discussion will include overcoming the complexities of RWPD, modeling the data for use in clinical and pharmaceutical research, and visualizations and data mining techniques used to allow end users to interrogate the data in ways never before possible.

12:10 pm Connecting Tumor Genomics with Therapeutics through Multi-Dimensional Network Modules

Sourav Bandyopadhyay, Ph.D., Assistant Professor, Bioengineering and Therapeutic Sciences, University of California San Francisco

Recent efforts have catalogued genomic, transcriptomic, epigenetic and proteomic changes in tumors, and a challenge is to integrate these data to identify a consensus catalog of the unique molecular events or modules in cancers and connect them with new therapeutics. We present a new approach called MAGNET to integrate such data based on functional networks. Evaluation of network modules in cancer cell lines reveals a preserved subset that can be used for biomarker development.

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

TRANSLATIONAL INFORMATICS: CLINICIAL DATA DRIVING PRECLINICAL RESEARCH (CONT.)

1:50 Chairperson's Remarks

Farida Kopti, Ph.D., Director, Chemistry/Pharmacology/HTS Informatics IT, Merck Research Labs, Merck & Co.

INFORMATICS CHANNEL

2:00 Leveraging 'Omics Data from Deeply Phenotyped Clinical Studies to Inform Target and Biomarker Validation

Janna Hutz, Ph.D., Senior Director, Head, Human Biology & Data Science Engine, Eisai AiM Institute, Eisai, Inc.

Beyond oncology, there have been few documented successes in using genome scale sequencing from clinical trials to inform design of subsequent trials. Rather, it is emerging that these datasets' greatest value may lie in feeding back into earlier stages of drug discovery. I will share Eisai's efforts to use NGS data from well-characterized clinical cohorts for target validation and biomarker identification.

2:30 Disease Signatures to Drug Discovery

Deepak K. Rajpal, Ph.D., Director, Computational Biology-Target Sciences, GSK

We present how we have used clinical transcriptomics based generation of disease signatures and their application in drug discovery. We have identified disease areas of interest and then clinical transcriptomics datasets from published literature associated with the diseases of interest. We have then generated disease signatures and by integrative informatics approaches, and have applied these datasets in our drug discovery efforts. We present here a case study in dermatological disease area.

3:00 Target Identification and Validation Using Genomics and Genetics

Vinod Kumar, Ph.D., Senior Scientific Investigator, Computational Biology (US), Target Sciences, R&D, GSK

In practice, the identification of a novel disease target is an integrative step combining many lines of evidence, but may often be triggered by a key, highly publicized finding. Though relatively little attention has been paid to systematically evaluate the multiple lines of evidence that have proven effective in choosing a successful target for that disease. I will present how we use informatics approaches to leverage genetic, genomics and phenotypic data to prioritize targets and validate them experimentally.

3:30 Session Break

WRESTLING WITH BIG DATA: IMPLICATIONS FOR DISCOVERY, REIMBURSEMENT, REGULATION, AND CLINIC

3:40 Chairperson's Remarks

Andrew C. Fish, J.D., Executive Director, AdvaMedDx

3:45 Big Data – The Devil's in the Details

Elaine K. Jeter, M.D., J1 MolDx Medical Director, Palmetto GBA

Linking effective therapies and expanded trial designations are the expected benefit of the ever expanding capabilities of genomic biomarker and gene expression identification. More and more data is being generated every day. Keeping that data 'valuable' will require we maintain a critical focus on the quality and comparative values of the data, especially in the area of genomics and more specifically outcomes. Other questions will arise around where the data is collected, how it is curated, and who has access. As a Medicare payer, we support the concept of data collection/aggregation if that data can be effectively mined to create ever improving treatment protocols and more importantly improved outcomes.

4:00 Efficiently Leveraging Commercial and Open Source Bioinformatics Tools for Clinical Interventions and Research Discoveries from Very Large Datasets

Ben Busby, Ph.D., Genomics Outreach Coordinator, NCBI, NLM/NIH

In precision medicine, it is often the case that efficacy does not depend on the appropriate computational intervention, but on the morphology of the data that informs the problem. For example, different strategies should be employed when calling short variants in stable versus unstable regions of the human genome, or when looking for pathogenic effectors in well-characterized versus newly discovered bacterial or viral pathogens. Pragmatic solutions from existing commercial and open source resources will be presented.

4:15 From Bits to Bedside: Developing a Learning Digital Health System to Evaluate Pigmented Skin Lesions

Dexter Hadley, M.D., Ph.D., Assistant Professor, Pediatrics, Institute for Computational Health Sciences, University of California, San Francisco

Melanoma accounts for less than one percent of skin cancer cases but the vast majority of skin cancer deaths. Early screening and diagnosis significantly improves patient outcomes, yet no systematic framework exists for clinical evaluation of common pigmented lesions for risk of melanoma. In this talk, I will describe our approach to develop a learning health system focused on precision screening and diagnosis of skin cancer. We first leverage medical students in the clinics to capture digital samples of pigmented skin lesions at scale with mobile health technology. We then leverage this clinical big data to train state-of-the-art deep learning image classification algorithms to better screen for cancer. Our work translates routinely documented electronic health data into an impactful digital health initiative to directly improve clinical outcomes and advance clinical knowledge.

4:30 PANEL DISCUSSION

5:15 Close of Conference Program

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- **New Frontiers in CRISPR-Based Gene Editing**
- **Circulating Cell-Free DNA**
- **Point-of-Care Diagnostics**
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- **Commercialization of Molecular Diagnostics**

Cambridge Healthtech Institute's Third Annual

NEW FRONTIERS IN CRISPR-BASED GENE EDITING

Developing Faster, Better Ways to Precisely and Efficiently Edit Genes

THURSDAY, FEBRUARY 23

7:00 am Registration and Morning Coffee

CRISPR FOR DRUG DISCOVERY

8:25 Chairperson's Opening Remarks
Bruce R. Conklin, M.D., Investigator, Gladstone Institute of Cardiovascular Disease and Professor, Division of Genomic Medicine, University of California, San Francisco

8:30 FEATURED PRESENTATION: CRISPR-Based Screens in Human Cardiac Disease Models
Bruce R. Conklin, M.D., Investigator, Gladstone Institute of Cardiovascular Disease and Professor, Division of Genomic Medicine, University of California, San Francisco
We have developed efficient methods to edit one residue at a time in human iPS cells. These "isogenic" lines form models that are yielding phenotypes that help to explain the molecular basis of several human diseases. Recently, we developed CRISPR-inhibition (CRISPRi) cell lines for high-throughput gene inactivation of thousands of genes. CRISPRi screens could help us construct more mature human tissues and improved disease models.

9:00 Development and Optimization of CRISPR Gene Editing for Drug Discovery Applications
John Feder, Ph.D., Associate Director, Genome Biology and Emerging Technologies, Department of Genetically Defined Diseases and Genomics, Bristol-Myers Squibb
New CRISPR systems, modalities and methods are being discovered and published at an unprecedented pace such that unbiased and agnostic comparisons and protocol optimizations are warranted if the promise of genome engineering is to be realized in the pharmaceutical setting. We will present our results to date for generating highly optimized method for gene editing in induced pluripotent stem cells.

9:30 Tailored Pre-Clinical Models with CRISPR-Based Genome Editing
Lukas Edward Dow, Assistant Professor, Medicine, Weill Cornell Medicine
CRISPR/Cas9 genome editing has changed the way we design and execute *in vivo* experiments. We are using CRISPR-based genome editing in stem cells and in adult mice to generate tailored pre-clinical models. This allows both a deeper understanding of the genetic underpinnings of cancer progression and provides a platform to interrogate new therapeutic strategies in specific genetic contexts, which is key for realizing the potential of personalized medicine.

Sponsored by SYNTHEGO

10:00 Use of Synthetic sgRNA to Improve CRISPR Editing Efficiency
Kevin Holden, Ph.D., Head, Synthetic Biology, Synthego
CRISPR has made genome editing accessible for a wide range of cell-types. However, obtaining consistent editing efficiencies remains a challenge. Synthego has developed novel RNA synthesis technology to produce 100-mer sgRNA for CRISPR at a practical scale and price. We demonstrate that Synthego sgRNA produces consistent and superior genome editing.

10:15 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break with Exhibit and Poster Viewing

11:15 Whole-Genome CRISPR Screening for Necroptosis Resistance and Tumor Suppressor Synthetic Lethality
Mike Costa, Ph.D., Senior Scientific Manager, Department of Discovery Oncology, Genentech Research & Early Development
We have developed efficient whole-genome pooled gRNA libraries and applied them to positive and negative selection screens. Screening for resistance to necroptotic cell death identifies known necrosome components and additional hits that reveal new regulators. Screens in cancer cell lines detect novel dependencies conferred by mutations in tumor suppressors. We will discuss successful strategies for increasing screen throughput, computational identification of hits, and hit validation.

11:45 Genome Editing on iPSCs for Drug Discovery
Nazish Sayed M.D., Ph.D., Instructor, Cardiovascular Institute, Stanford University School of Medicine
This presentation will describe the use of genome editing technology for assessing the pathogenicity related to variant of uncertain significance (VUS). In addition, we will describe examples of how control vs. genome-edited iPSC-derived cardiomyocytes are being used for drug screening and drug discovery applications.

12:15 pm Nucleofection, Genome Editing, and the Transfection of Clinically-Relevant Cells
Sponsored by Lonza
Greg Alberts, Ph.D., Lonza Walkersville, Inc
The LV Nucleofector is the latest addition to the Nucleofector platform, and can transfect up to 2 billion cells, with the same performance of other Nucleofector devices. Nucleofection is a proven choice for genome modification applications like CRISPR, and is poised to play a comprehensive role in new innovative therapies.

12:30 Session Break

Sponsored by CELLECTA Discovery is Yours.

12:40 Luncheon Presentation: Functional Genome-Wide Analysis Using Optimized CRISPR Pooled Screens
Paul Diehl, Ph.D., COO, Cellecta, Inc.

1:15 Session Break

SYMPOSIA

CRISPR FOR DISEASE MODELING & TARGET IDENTIFICATION

1:50 Chairperson's Remarks
Michael Bassik, Ph.D., Assistant Professor, Department of Genetics, Stanford University

2:00 Fixing the Broken Heart by Myoediting
Chengzu Long, Ph.D., Assistant Professor, Division of Cardiology, New York University School of Medicine
Using CRISPR-mediated genomic editing, we successfully prevented muscular dystrophy in the germline and postnatal muscles of *mdx* mouse model (Long *et al. Science* 2014; Long *et al. Science* 2016). Recently, we have advanced it to novel strains of humanized mice and patients' cardiomyocytes. This has enabled us to optimize the correction of DMD mutations, providing a path toward a potential cure of the disease in patients.

2:30 Precise Gene Editing in Human Pluripotent Stem Cells
Krishanu Saha, Ph.D., Assistant Professor, Department of Biomedical Engineering, & Wisconsin Institute for Discovery, University of Wisconsin, Madison
Human pluripotent stem cells are important resources for drug discovery, toxicology, disease modeling, tissue engineering and regenerative medicine. Recently, we developed new CRISPR-Cas9 strategies to correct pathogenic point mutations and introduce transgenes precisely using homology-directed DNA repair. These strategies reduce and, in some cases, eliminate undesired allelic modifications associated with non-homologous end joining.

3:00 High Throughput Screening: Best Technology and Practices
Sponsored by MilliporeSigma
Caroline Beckett, Global CRISPR Product Manager, MilliporeSigma
CRISPR revolutionized gene editing, but multi-target screening remains a complex goal. MilliporeSigma shares best approaches learned over years of genome editing. We also explore the best CRISPR tools from small gene panels to whole genome pooled and arrayed screening libraries.

3:30 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

4:15 Development of New CRISPR/Cas9-Based Tools to Study Drug Interactions through Knockout and Directed Evolution
Michael Bassik, Ph.D., Assistant Professor, Department of Genetics, Stanford University
We have used parallel shRNA and CRISPR screening to explore the biology of essential and non-essential genes, and have identified the target and mechanism of action of a novel host-targeting antiviral drug. More recently, we have used pairwise expression of sgRNAs to identify synergistic combinations of drug targets, and adapted our screening systems for new applications in mutagenesis and directed evolution.

4:45 Applying Inducible and Multiplexed CRISPR/Cas System in Functional Cancer Genetic Studies
Jian Cao, Ph.D., Associate Research Scientist, Department of Pathology, Yale University

NEW FRONTIERS IN CRISPR-BASED GENE EDITING

We have developed a highly efficient doxycycline-inducible Cas9 system for uniform temporal control and efficient gene disruption even in a polyclonal setting. We also established a simple one-step cloning approach for multiple-sgRNA expression in an improved vector. By combining our inducible and multiplex genome editing approaches, we performed functional studies to identify cancer driver genes.

5:15 HOT TOPIC DISCUSSION: The Role of FDA in Regulating Gene Editing
Fyodor Urnov, Ph.D., Associate Director, Altius Institute for Biomedical Sciences and Adjunct Professor, Department of Molecular & Cell Biology, University of California Berkeley

5:45 Reception with Exhibit and Poster Viewing

6:45 Close of Day

FRIDAY, FEBRUARY 24

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

8:00 Registration Open

GENE EDITING: NEW THERAPIES AND NEW OPPORTUNITIES

8:25 Chairperson's Remarks
Mark A. Kay, M.D., Ph.D., Dennis Farrey Family Professor, Departments of Pediatrics and Genetics, Vice Chair for Basic Research (Pediatrics), Stanford University

8:30 FEATURED PRESENTATION: Novel AAV Vectors for Classical and Genome Editing-Based Gene Therapy
Mark A. Kay, M.D., Ph.D., Dennis Farrey Family Professor, Departments of Pediatrics and Genetics, Vice Chair for Basic Research (Pediatrics), Stanford University
Recombinant AAV vectors show promise in gene therapy. However, vector selection based on animal studies is not necessarily predictive of human outcomes. I will discuss approaches to improve these predictions, and novel methods to create/select rAAV vectors with enhanced properties. We have also developed an AAV promoterless site-specific gene targeting approach without the use of nucleases and show preclinical efficacy in animal models of human disease.

9:00 *In vivo* Genome Editing via CRISPR-Cas9 Mediated Homology-independent Targeted Integration
Keiichiro Suzuki, Ph.D., Research Associate, Laboratory of Dr. Juan Carlos Izpisua Belmonte, Gene Expression Laboratory, The Salk Institute for Biological Studies
Non-dividing cells, the major constituents of adult tissues, are inaccessible for targeted knock-in with current technologies. We have developed a robust homology-independent targeted integration (HITI) strategy that allows for efficient targeted knock-in in both dividing and non-dividing cells *in vitro* and *in vivo*. Using this method, we achieved the therapeutic efficacy of a rat model of blindness retinitis pigmentosa *in vivo*.

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9:30 Development of a CRISPR/Cas9 and Stem Cell Platform for Duchenne Muscular Dystrophy

April Pyle, Ph.D., Associate Professor, Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research, Department of Microbiology, Immunology and Molecular Genetics, David Geffen School of Medicine, University of California, Los Angeles

We have developed a platform to restore the reading frame using CRISPR/Cas9 in patients with Duchenne Muscular Dystrophy (DMD). CRISPR/Cas9 mediated deletion of dystrophin up to 725kb in hiPSCs represents a therapeutic strategy applicable to up to 60% of DMD patients. Current efforts are aimed at translating this platform using stem cell mediated delivery of corrected skeletal muscle progenitor cells in animal models of DMD.

10:00 An Arrayed CRISPR Library for Individual, Combinatorial and Multiplexed Gene Knockout

Simon R.V. Knott, Ph.D., Assistant Professor and Associate Director, Center for Bioinformatics and Functional Genomics, Cedars-Sinai Medical Institute

We have combined a machine-learning approach with other strategies to optimize the efficiency of sgRNAs for CRISPR screens and have constructed a genome-wide, sequence-verified, arrayed CRISPR library. This incorporates expression strategies to facilitate multiplexed or combinatorial screening. By conducting parallel loss-of-function screens, we compare our approach to existing sgRNA design and expression strategies.

10:30 Coffee Break with Exhibit and Poster Viewing

11:15 *In vivo* Genome Engineering via CRISPR-Cas Systems

Prashant Mali, Ph.D., Assistant Professor, Department of Bioengineering, University of California San Diego

The CRISPR-Cas systems have emerged as a powerful toolset for targeted genome engineering. Development of safe and efficient gene transfer platforms for these will transform our ability to study biological processes in their native *in vivo* settings and also target various human diseases. In this talk I will describe some of our ongoing efforts to improve *ex vivo* and *in vivo* genome engineering.

11:45 Mechanism and Therapeutic Application of RNA-Guided Immune Systems

Christof Fellmann, Ph.D., Postdoctoral Fellow, Laboratory of Dr. Jennifer Doudna, Department of Molecular and Cell Biology, University of California, Berkeley

12:15 pm Pooled CRISPR Screens in the Noncoding Genome

Neville Sanjana, Ph.D., Core Faculty Member, New York Genome Center and Assistant Professor, Department of Biology & Center for Genomics and Systems Biology, New York University

We have recently adapted CRISPR forward genetic screens into noncoding regions of the genome, where it can be challenging to identify functional elements. We find that mutations at specific noncoding elements lead to changes in transcription factor occupancy and that these changes coincide with modulation of gene expression. These results expand the potential of CRISPR screens for fundamental genomic discovery, gene regulation, and therapeutic development.

12:45 Close of Symposium

Cambridge Healthtech Institute's Fourth Annual

CIRCULATING CELL-FREE DNA

Overcoming Technical Challenges to Provide Clinical Solutions

THURSDAY, FEBRUARY 23

7:00 am Registration and Morning Coffee

FEATURED SESSION: ACHIEVING EARLY DETECTION

8:25 Chairperson's Opening Remarks
Abhijit Patel, M.D., Ph.D., Assistant Professor, Yale University School of Medicine

8:30 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.

9:15 Cell Free Tumor Derived DNA as a Diagnostic Tool for Human Malignancies
Chetan Bettegowda, M.D., Ph.D., Assistant Professor, Neurosurgery and Oncology, Johns Hopkins University School of Medicine
Neoplasms have been shown to shed cell free molecules of DNA into various biofluids. The detection and quantification of tumor-derived DNA (tDNA) in these biofluids can be exploited for diagnostic benefit. The applications of tDNA detection with regards to screening, diagnosis and disease monitoring will be discussed in a variety of cancer types.

Sponsored by Biological Dynamics

10:00 Novel AC Electrokinetic Platform for Isolating Cell-Free DNA & Exosome Biomarkers for Clinical Applications
Raj Krishnan, Ph.D., California CEO, Biological Dynamics
Biological Dynamics have developed a novel lab-on-a-chip AC Electrokinetics platform that offers a rapid and affordable way to isolate and quantify cell-free nanoparticles (cfDNA, proteins & exosomes) directly from biofluids, with the overall goal of improving precision medicine in oncology.

Sponsored by seracare

10:15 Improved Material for Developing, Validating, and Monitoring Liquid Biopsy Assays
Dale Yuzuki, MA, M.Ed, Director, Market Development – Oncology, SeraCare Life Sciences
Random ultrasonication-based fragmentation methods have inherent weaknesses. Current needs for liquid biopsy assay development, validation, and monitoring include standards that are more commutable to native samples, highly multiplexed, and behave in library preparation close to native plasma ctDNA.

10:30 Coffee Break with Exhibit and Poster Viewing

MONITORING TREATMENT RESPONSE AND DETECTING RESISTANCE MUTATIONS

11:15 Technological Challenges and Clinical Applications of ctDNA
Abhijit Patel, M.D., Ph.D., Assistant Professor, Yale University School of Medicine
Our group has developed an NGS-based assay that applies novel molecular and computational error suppression techniques to enable ultrasensitive measurement of ctDNA. Data will be presented from ongoing studies to establish the clinical utility of this technology, with a focus on monitoring of therapeutic response.

11:45 Liquid Biopsies in Precision Oncology
Filip Janku, M.D., Ph.D., Assistant Professor, Investigational Cancer Therapeutics (Phase I Program), MD Anderson Cancer Center
Unlike tissue biopsies, obtaining liquid biopsies such as samples of plasma-derived cell-free DNA is a minimally invasive approach. Plasma cell-free DNA can be used to assess molecular profile at different time points and provide valuable information about genetic changes that occur during the disease trajectory, as cancer progression is not a static process. In addition to identification of molecular targets for cancer therapy, molecular testing of cell-free DNA can provide additional information about prognosis, evaluate response to therapy, reveal disease progression or recurrence, and detect early emergence of molecular abnormalities that drive resistance to systemic therapy. Agreement rate between the molecular profile of cell-free DNA and archival tumor tissue is deemed to be acceptable and ranges from 70%-100%. Recently, both the European Medicines Agency and the United States Food and Drug Administration approved a PCR-based cell-free DNA test to detect EGFR mutations in NSCLC as an alternative to molecular testing of tumor tissue.

Sponsored by BIO-RAD

12:15 pm Digital PCR, a Highly Reproducible Method for the Detection of Rare Genetic Variants
Jim Hugget, Ph.D., Senior Lecturer, Analytical Microbiology, School of Bioscience and Medicine, Faculty of Health and Medical Science, University of Surrey
Digital PCR (dPCR) offers a potentially accurate method for the measurement of rare genetic variants using cell free DNA. This study investigated the performance of dPCR and evaluated its sensitivity and reproducibility, comparing 21 laboratories, when measuring KRAS mutations both as fractional abundance and absolute mutant copies.

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12:40 Luncheon Presentation: Robust NGS Target Enrichment and Ultra-Sensitive Digital PCR to Profile & Monitor Mutations in Circulating cfDNA

Sponsored by RainDance Technologies

Fraser Symmans, Ph.D., M.D., Professor and Director, Research Operations, Department of Pathology, Anderson Cancer Center

Jennifer Jackson, Ph.D., Senior Scientist, RainDance Technologies

Hear how the only unified NGS target enrichment and digital PCR platform is enabling researchers to profile and monitor critical mutations in blood with an easier and faster workflow than before.

1:15 Session Break

1:50 Chairperson's Remarks

Laura L. Elnitski, Ph.D., Principal Investigator, Genomic Functional Analysis, National Human Genome Research Institute

2:00 Featured Poster: Comprehensive Analysis of 13 Different Methods for Bisulfite Conversion of Circulating Cell-Free DNA

Mai-Britt Worm Orntoft, Student, Molecular Medicine, Aarhus University Hospital Skejby

Blood circulating cell-free DNA (cfDNA) is becoming a popular basis for novel biomarkers, and especially disease specific cfDNA methylation patterns have gained much attention. A significant challenge for the utilization of cfDNA methylation markers is the very limited amount of cfDNA present in blood that is reduced even further when cfDNA undergoes bisulfite conversion (BSC) prior to biomarker detection, which reportedly leads to significant cfDNA loss. Yet, only few efforts have focused on ensuring high cfDNA BSC efficiency and recovery, and few commercial kits are directed at this purpose. To identify the BSC method with the highest DNA recovery, this study compared 13 different methods, of which 6 are compatible with automation.

REGULATORS AND PAYORS: THEIR ROLE IN CLINICAL TRANSLATION

2:30 Clinical Applications of Liquid Biopsies: A Payer's Perspective

Girish Putcha, M.D., Ph.D., Director, Laboratory Science, Palmetto GBA (MolDX)

Liquid biopsies in oncology hold great promise for multiple clinical applications, from screening and diagnosis to monitoring for residual disease or resistance to the selection of both targeted and immuno-oncology therapies. Each use case presents different opportunities and challenges for payers, which will be discussed.

3:00 Standardizing Blood Collection for cfDNA Detection by Sample Stabilization with a New Plastic Cell-Free DNA BCT

Sponsored by Streck

Landon Olp, Ph.D., Research & Development, Scientist, Immunology & Biomarkers, Streck

The Cell-Free DNA BCT stabilizes nucleated blood cells up to 14 days, improving sample collection/transport logistics while minimizing variability of cfDNA preparation. Streck also introduces this same sample stabilization in a newly engineered plastic tube for greater safety.

3:15 Personalized Custom Panels for the Detection of Circulatory Tumor DNA Mutations

Sponsored by natera Conceive. Deliver.

Bernhard Zimmermann, Ph.D., Senior Director, Research & Development, Natera

We have developed an approach to detect cancer signatures in plasma by ultra-deep sequencing of custom multiplex PCR assays to mutations found in the tumor. We demonstrate detection of clonal and subclonal mutations in treatment naïve lung cancer patients, of MRD and relapse up to one year before clinical manifestation.

3:30 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

EPIGENETIC MODIFICATIONS OF cfDNA

4:15 KEYNOTE PRESENTATION: Novel Developments in Tracking Minor Fractions of Tissue and Tumor Epigenetic Signatures in Circulating-DNA

G. Mike Makrigiorgos, Ph.D., Professor, Radiation Oncology, Dana-Farber Cancer Institute, Harvard Medical School

Epigenetic marks in circulating DNA can be a powerful tool for tracking healthy tissue damage or for monitoring tumors during cancer therapy. Just as with mutated DNA, epigenetically altered DNA that provides clinically useful information is often masked by high excess of epigenetically 'normal' DNA. We present Methylation-Sensitive Nuclease-assisted Minor-allele Enrichment, MS-NaME, a simple and powerful approach that removes unaltered DNA in order to focus on clinically relevant DNA epigenetic changes. This single-step approach retains current sample preparation protocols almost unchanged and combines seamlessly with existing technologies like MS-HRM, Methylight and bisulfite sequencing. Application in clinical samples and liquid biopsies will be presented.

4:45 Peripheral Monitoring of Neurodegeneration Using cfDNA Methylation

Zac Chatterton, Ph.D., Postdoctoral Fellow, Neuroscience, Icahn School of Medicine, Mount Sinai

Neurodegeneration occurs in a variety of human diseases; however, molecular profiling of the brain is restrictive. Cell free DNA (cfDNA) derived from neurological tissue holds great promise for the detection and monitoring of neurodegeneration. Within our lab we exploit the unique DNA methylation profiles of brain cells to create molecular diagnostic assays capable of detecting peripheral neurological derived cfDNA.

5:15 Characterizing a DNA Methylation Locus of Pan-Cancer Importance for Use in Biofluid Diagnostics

Laura L. Elnitski, Ph.D., Principal Investigator, Genomic Functional Analysis, National Human Genome Research Institute

Cancer diagnostics is moving into noninvasive screening and rapid detection methods through the isolation of circulating tumor cells and circulating tumor DNA. We measured the magnitude of differential methylation of the ZNF154 CpG island in TCGA data and colon, lung, breast, stomach, and endometrial tumors and found all tumor types hypermethylated at this locus. As shown through experimental and computational analyses, this biomarker has demonstrated potential for blood-based cancer screening.

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5:45 Reception with Exhibit and Poster Viewing

6:45 Close of Day

FRIDAY, FEBRUARY 24

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

8:00 Registration Open

MOVING cfDNA INTO CLINICAL PRACTICE

8:25 Chairperson's Remarks

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

8:30 Epigenetically Altered Circulating Nucleosomes - Validation of a New Diagnostic Approach for Colorectal Cancer

Jason Terrell, M.D., CMO, VolitionRx

In a retrospective training cohort of 4800 patients presenting with symptoms of Colorectal diseases generated a diagnostic NuQ® panel with sensitivity of 81% at a specificity of 80% in an age adjusted linear regression model for the detection of Colorectal cancer (CRC). In a subsequent pilot prospective study of 58 subjects, a sensitivity of 91% at 90% specificity was achieved for the detection of CRC. We present the results of a validation study in an independent cohort of symptomatic subjects for a novel NuQ® based CRC diagnostic test.

9:00 Building Evidence of Utility for cfDNA in Cancer Management

Phillip G. Febbo, M.D., CMO, Genomic Health, Inc.

Precision medicine in cancer care requires robust interrogation of an individual's tumor to guide therapy. Circulating cell-free DNA often includes tumor DNA and can enable genomic analysis when tumor tissue is unavailable or difficult to obtain. However, important clinical and technological limitations need to be acknowledged and addressed in order to develop a valid test that has clinical utility for an intended patient population.

9:30 Are Liquid Biopsies Ready for Routine Clinical Use?

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

Detection of actionable genomic alterations is a requisite component for NCCN guideline-compliant work-up of several tumor types, including NSCLC adenocarcinoma. Moreover, identification of acquired resistance mutations emergent at time of progression on targeted therapies is practical and, in some cases, required for patients to receive next-generation agents. Liquid biopsy, including analysis of circulating tumor DNA (ctDNA), offers a non-invasive mutation genotyping option when traditional biopsies are not feasible. The reliability and clinical utility of this approach will be discussed.

Sponsored by CareDx

10:00 Clinical Utility of Donor-Derived Cell-Free DNA in Transplantation

Robert Woodward, Ph.D., Senior Director, Research & Development, CareDx

AlloSure design, including judicious SNP selection, robust amplification strategy and a novel interpretative algorithm, enables accurate and reproducible clinical-grade results. Evidence supporting clinical validity and utility for multiple heart and kidney transplant indications will be described.

10:30 Coffee Break with Exhibit and Poster Viewing

11:15 Clinical Implementation of Digital PCR for Cancer Diagnostics and Monitoring

Alexander Dobrovic, Head/Group Leader, Translational Genomics, Olivia Newton-John Cancer Research Institute

This presentation will discuss digital PCR as a diagnostic and monitoring tool using liquid biopsies with insights from our clinical testing and research program.

USING cfDNA IN CLINICAL TRIALS

11:45 Ultra-Sensitive Mutational Analysis in Cell-Free DNA by Digital PCR and NGS Technologies

Rachel Tam, Senior Scientific Researcher, Oncology Biomarker Development, Genentech

Circulating cell-free DNA (cfDNA) in plasma offers a non-invasive approach to monitor tumor molecular profiling in real-time at multiple time-points, detection of emerging genomic alterations associated with drug resistance and clarifying cancer prognosis and diagnosis of cancer recurrence or progression. We developed an ultra-sensitive droplet digital PCR (ddPCR) approach to detect actionable cancer biomarkers in cfDNA. We compared this ddPCR approach to other orthogonal technologies, including qPCR and NGS, and achieved 100% concordance across these platforms.

12:15 pm Applications of Plasma Genotyping for Advanced Non-Small Cell Lung Cancer

Cloud P. Paweletz, Ph.D., Head, Translational Research Laboratory; Biomarker Lead, Belfer Institute for Applied Cancer Science, Dana-Farber Cancer Institute

Through collaboration between thoracic oncologists and biomarker scientists at DFCI, we have spent the recent years developing approaches for targeted genotyping of plasma cell-free DNA in advanced NSCLC. Our approach primarily focuses on rapid assays for clinical application, including droplet digital PCR and targeted NGS assays. We will review our approach to clinical validation and present ongoing clinical investigations using these assays to study response and resistance to targeted therapies.

12:45 Close of Symposium

Cambridge Healthtech Institute's Sixth Annual

POINT-OF-CARE DIAGNOSTICS

Realizing the Potential of Rapid Diagnostics to Transform Medicine

THURSDAY, FEBRUARY 23

7:00 am Registration and Morning Coffee

INTEGRATING POCT INTO HEALTH SYSTEMS

8:55 Chairperson's Opening Remarks

Susan Kretz, MHA, MT(ASCP), Manager, Point-of-Care Testing, PCL Alverno Clinical Labs

9:00 Standardizing Point-of-Care for Two Large Hospital Systems, Can It Be Done?

Susan Kretz, MHA, MT(ASCP), Manager, Point-of-Care Testing, PCL Alverno Clinical Labs

In most hospital systems Point-of-Care testing is overseen by the hospital. What happens to POC when operation is taken under laboratory control? We will discuss why the lab was granted oversight and why standardization is important in POC testing. We will look at the process of how devices were evaluated/selected and discuss the challenges that were seen by moving two very different hospital systems to one POC test and device menu.

9:30 How to Generate Health Economic Claims for POC Testing

Katherine Tynan, Ph.D., Business Development & Strategic Consulting for Diagnostics Companies, Tynan Consulting LLC

Point-of-care testing for a variety of disease states provides an excellent opportunity for many providers to expand patient care services while improving health at the patient and population level. Measuring those improvements and tying them to quality metrics is key in the world where providers will be paid for quality not quantity. 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, reduction in prescriptions for antibiotics, etc.) through health economic modeling. Examples of how to demonstrate these claims to convince stakeholders/payers to favor POC diagnostics over more traditional approaches will be discussed.

10:00 Three Essential Factors for Successful Development of a Microfluidic POC Diagnostic

Sponsored by miniFAB

Erol Harvery, Ph.D., CEO, MiniFAB

Three important factors for success of microfluidic POC diagnostics. Developments must be driven by user/market requirements. Devices must be designed with high integration and manufacturing simplicity. Representative integrated systems must be quickly achieved to facilitate assay testing and KOL feedback.

10:15 Designing for Humans in Point of Care Testing

Sponsored by Invetech

Cece O'Connor, Global Director, UX Strategy & Design, Invetech

Successful POCT integration into health systems incorporates a deep knowledge of the people involved. Human-Centered Design Research uncovers powerful insights into user needs, leading to innovative, intuitive workflows and digital interactions. We will outline challenges faced with POCT design along with UX techniques to drive differentiated, streamlined experiences.

10:30 Coffee Break with Exhibit and Poster Viewing

INTEGRATION AND IMPLEMENTATION CASE STUDIES

11:15 The Trials and Tribulations of POCT: A Clinical Biochemist's Perspective

Julie Shaw, Ph.D., Assistant Professor, Department of Pathology and Laboratory Medicine at The University of Ottawa - The Ottawa Hospital

This presentation will touch on practical challenges related to implementation of POCT. Specific challenges related to user compliance, order and result documentation, operator training and meeting accreditation requirements will be discussed.

11:45 Barriers to Point-of-Care HIV Testing - Evidence and Possible Solutions

Nitika Pant Pai, M.D., MPH, Ph.D., Associate Professor, Medicine, Divisions of Clinical Epidemiology & Infectious Diseases, McGill University

Point-of-care technologies offer a potential to expedite an initial screening/ potential diagnosis, and/or clinical decisions at the point of clinical care. However, barriers at various levels exist and posing a challenge to their ideal implementation. Using data from field settings, this talk will provide an overview of the barriers at four levels- health systems, providers, patients and technologies. Some potential innovative solutions to facilitate the integration of POCTs in global health will also be presented.

12:15 pm Laser-Diodes: A Cost-Effective Step Up from LEDs

Sponsored by B9 NORTH

Henry Schek, Ph.D., Chief Technical Officer, Chroma Technology Corp

Laser-diodes are an under-utilized resource for achieving some of the best performance features of LEDs and costly lasers. We review a platform for flexible, custom, cost-effective, laser-diode sources for broad application in research, diagnostics and treatment.

12:30 Session Break

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12:40 Luncheon Presentation: Handheld, Single Molecule Sensitive Diagnostic Platform

Sponsored by Two Pore Guys

Dan Heller, CEO, Two Pore Guys, Inc.

Presenting technology and use cases for a handheld PoC testing platform using a saliva-to-results demonstration of HIV antibody test. 2PG's nanopore-based platform supports a broad menu of assays that can be adapted from existing reagents used on lab-based systems.

1:15 Session Break

TELEHEALTH: IMPROVING ACCESS AT THE POINT-OF-CARE

1:50 Chairperson's Remarks

Donald Klepser, Pharm.D., MBA, Associate Professor, Pharmacy Practice, University of Nebraska Medical Center

2:00 Telemedicine for Acute Care Diagnostics in Resource-Constrained Settings: A New Paradigm

Alfred Papali, M.D., Assistant Professor, Pulmonary & Critical Care Medicine, Institute for Global Health, University of Maryland School of Medicine

Low- and middle-income countries (LMICs) carry a substantial burden of critical illness worldwide, but material and human resource constraints in these environments often limit accurate diagnosis. Telemedicine is an emerging modality that can help to overcome these limitations. Novel telemedicine applications, combined with task shifting and point-of-care ultrasound, may help to improve acute care diagnostics in LMICs if scaled up as part of an organized, collaborative approach among diverse interests.

2:30 Lessons Learned in the Spread and Scale of Telehealth at Massachusetts General Hospital

Ronald Dixon, M.D., Director, Virtual Practice Project, Massachusetts General Hospital

With the aging of the population and the increasing burden of chronic disease, new models of health care delivery are required to achieve the triple aim of improving the experience of care, improving the health of populations, and reducing per capita costs of health care. POCT may have a role in all aspects of this triple aim, with widespread adoption being essential to success. This session will highlight five key lessons learned from the virtual healthcare sphere to ensure sustainable clinical adoption. Lessons learned include: expect failure and pivot creatively, iterate and adapt relentlessly, welcome collaborators as "co-conspirators", embrace opposition, and provide continuous feedback.

3:00 Qorvo Biosensor Solution for Mobile and Point of Care Applications

Sponsored by Qorvo all around you

Bryan Bothwell, Director, Strategy and Business Development, Qorvo

Qorvo has developed a biosensor platform to enable a paradigm shift in point of care (POC) testing. By combining multi-GHz bulk acoustic wave detection arrays with microfluidics and electronics integration, the platform delivers centralized lab results at the POC, breaking the technological barrier limiting ubiquitous deployment of liquid-based biosensors across all markets.

3:30 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

POINT-OF-CARE IN THE PHARMACY

4:15 Implementing Collaborative, Community Pharmacy-Based Disease Management Programs Using CLIA-Waived POC Tests

Donald Klepser, Pharm.D., MBA, Associate Professor, Pharmacy Practice, University of Nebraska Medical Center

CLIA-waived POCT can provide useful information to the pharmacist as part of collaborative disease management programs. Data from the successful implementation of such programs and the role of POCT in these programs will be discussed.

4:45 Pharmacist Point-of-Care Testing: A State Law Framework

Alex J. Adams, Pharm.D., MPH, Executive Director, Idaho State Board of Pharmacy

****Presented by: Donald Klepser, Pharm.D., MBA, Associate Professor, Pharmacy Practice, University of Nebraska Medical Center****

Pharmacists must navigate a complex maze of federal and state laws in order to fully engage in point-of-care testing. This session will discuss federal CLIA laws, state-level restrictions on CLIA-waived testing, and Collaborative Practice laws that enable pharmacists to act on the results of tests.

5:15 CLIA-Waived Cholesterol Point-of-Care Tests for Community Pharmacies

Deanna Tran, Pharm.D., BCACP, Assistant Professor, Pharmacy Practice and Science, University of Maryland School of Pharmacy

CLIA-waived cholesterol point-of-care tests are used in community pharmacies to assist with improving health outcomes of patients by providing health screenings and referring patients with dyslipidemia for further evaluation. Studies including pharmacists' use of CLIA-waived cholesterol point-of-care devices and accuracy will be discussed.

5:45 Reception with Exhibit and Poster Viewing

6:45 Close of Day

FRIDAY, FEBRUARY 24

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

8:00 Registration Open

TESTING FOR ANTIMICROBIAL STEWARDSHIP

8:25 Chairperson's Remarks

Tharini Sathiamoorthy, Vice President, AdvaMedDx

8:30 Role of Pathogen Diagnostics in Antimicrobial Stewardship

Rangarajan Sampath, Ph.D., Senior Research Fellow and Senior Director, R&D, Ibis

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Biosciences, Abbott

The spread of multi-drug resistant organisms presents an increasing challenge to the management and treatment critical infections. Rapid and broad diagnostics are an unmet need. We describe a molecular method using PCR and electrospray ionization mass spectrometry (PCR/ESI-MS) that is capable of providing organism identifications for over 500 pathogens directly from patient specimens in less than 8 hours that has the potential to transform the way we use antimicrobials.

9:00 Influence of POC Testing on Antimicrobial Stewardship (AS) of Acute Exacerbation of Chronic Bronchitis (AECB) and Community-Acquired Pneumonia (CAP)

David N. Gilbert, M.D., Chief, Infectious Diseases, Providence Portland Medical Center and Professor of Medicine, Oregon Health & Sciences University

Increasing antibiotic resistance and a paltry pipeline of new, effective antibiotics is a crisis. Overuse of empiric antibiotics for respiratory tract infections is a major contributor to the problem. It is possible to reduce overuse by the POC use of multiplex PCR platforms to detect the presence of potential pathogens plus serum levels of procalcitonin. Procalcitonin levels can separate viral from bacterial infection and/or allow determination of whether detected bacteria are colonizing or invading. Two recent prospective studies will illustrate how this approach benefits AS.

9:30 Featured Poster: 30 Minute Phenotypic Antibiotic Susceptibility Test Directly from Clinical Samples

Travis Schlappi, Student, Chemical Engineering, California Institute of Technology

We used digital PCR (dPCR) to precisely measure DNA replication in bacteria exposed to antibiotics, and to shorten the required antibiotic exposure by allowing very high resolution quantification of DNA replication on timescales faster than cell division. Partitioning bacterial chromosomal DNA into many small volumes during dPCR enabled rapid AST via (i) precise quantification and (ii) a measure of how antibiotics affect the states of macromolecular assembly of bacterial chromosomes. This digital AST (dAST) determined susceptibility of clinical isolates from urinary tract infections (UTI) after 15 min of exposure for all four antibiotic classes relevant to UTIs. We then optimized the chemistries and performed the entire dAST workflow directly from clinical UTI samples in less than 30 min. This work lays a foundation for the development of a rapid, point-of-care AST that would improve patient outcomes and strengthen global antibiotic stewardship.

10:00 Panel with Session Speakers

10:30 Coffee Break with Exhibit and Poster Viewing

WHAT'S NEXT? EMERGING POINT-OF-CARE TECHNOLOGIES

11:15 Point-of-Care Diagnostics for Personalized, Precision Dosing of Biologic Drugs

Bradley Messmer, Ph.D., CEO, Abreos Biosciences, Inc.

Biologic drugs have proven highly efficacious in the treatment of cancer and numerous chronic diseases, but they are also very costly. Despite evidence of a relationship between circulating drug levels and clinical efficacy for the majority of these drugs, dosing usually follows a one-dose-fits-all approach. Direct monitoring of drug levels in patient blood samples would enable precise, personalized dosing that can improve outcomes, minimize side effects, and reduce costs.

11:45 A Point-of-Care Platform for the Detection of Plasma Circulating microRNAs in the Low Resource Setting

Jorge Soto, CTO, Miroculus

Miroculus has developed a low-cost microRNA detection platform designed for laboratory technicians without specialized training and in a low-resource setting. The platform encompasses: a) a molecular assay capable of semi-quantitative reporting of miRNAs in biofluids, b) an instrument that fully automates the assay and minimizes user effort to simple deposition sample in a digital microfluidics cartridge inlet, c) real-time data analysis through cloud computing. The first application is stomach cancer detection.

12:15 pm Ultra Low-Cost, Portable Smartphone Optosensors for Mobile Point-of-Care Diagnostics

Lei Li, Ph.D., Assistant Professor, Mechanical and Materials Engineering, Washington State University

Optical biosensing in point-of-care (POC) diagnostics, including fluorescence, luminance, absorbance or colorimetric, has been widely accepted in almost every area of diagnostics/detection. Currently, high-performance optical elements are expensive and become a barrier for developing low-cost POC diagnostics. We have developed a serial of optosensing platforms that covers a wide range of applications. Especially, we have developed a low-cost miniaturized multichannel smartphone optosensing platform with high accuracy and sensitivity. Our unique optomechanical system design and manufacturing process made our platforms appropriate for low-cost in-field applications.

12:45 Close of Symposium

POINT-OF-CARE DIAGNOSTICS

Cambridge Healthtech Institute's Third Annual

BIOMARKERS FOR CANCER IMMUNOTHERAPY

Next-Generation Biomarkers for Combination Therapies: Beyond PD-1 and PD-L1

THURSDAY, FEBRUARY 23

7:00 am Registration and Morning Coffee

BIOMARKER STRATEGIES FOR COMBINATION THERAPIES

8:25 Chairperson's Opening Remarks
Robert Anders, M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins

8:30 Biomarker Strategies for Cancer Immunotherapy Combination Studies
Jeffrey Wallin, Ph.D., Group Leader and Senior Scientist, Oncology Biomarker Development, Genentech, Inc.
The detection and destruction of malignant cells by cytolytic T effector cells is a hallmark of cancer immunotherapy. Although durable responses have been observed with immune checkpoint blockade in some cancers, combination approaches will be required to extend this benefit beyond a subset of patients. Combinations for cancer immunotherapy involve promotion of one or more steps of the cancer-immunity cycle and biomarkers can provide valuable diagnostic and mechanistic information for cancer immunotherapy clinical trials. This talk will focus on biomarker strategies that can be utilized to inform decision-making in cancer immunotherapy clinical trials.

9:00 Development of a Potential Companion Diagnostic (CDX) for Pembrolizumab on the Nanostring Ncounter® Dx Analysis System
Matt Marton, Ph.D., RAC, Director, Genomics and Companion Diagnostics, Translational Biomarkers, Merck & Co., Inc.
We describe the development of a gene expression biomarker that correlates with response to pembrolizumab in multiple cancer types. The 18-gene signature includes genes involved in cytokine signaling, antigen processing and immune checkpoint regulation. We will discuss analytical performance characteristics of the assay under investigation as a diagnostic device in multiple protocols in multiple indications for its ability to identify responders to pembrolizumab treatment.

9:30 Detecting Resistance before RECIST: The Role of Tumor Biomarkers in Immunotherapy
Morganna Freeman, D.O., Associate Director, Melanoma and Cutaneous Oncology Program, The Angeles Clinic and Research Institute
Over the last few years, immune-based cancer therapies have dramatically altered the treatment landscape in oncology. On the heels of those breakthrough therapies is intense immunoprofiling to predict and prognosticate clinical responses, however the immune system is just one half of the equation. Cancer biomarkers to detect adaptive resistance and early relapse have an emerging role in immunotherapy, the development and utilization of which will be discussed in detail here.

Sponsored by Quanterix

10:00 Simoa for the Ultra-Sensitive Measurement of Proteins as Biomarkers of Immuno-Oncology Therapeutics
David Duffy, Massachusetts Vice President, Research and Chief Technology Officer, Quanterix Corporation
We will describe the use of single molecule arrays (Simoa) to measure proteins that are emerging as important biomarkers for the effectiveness of immuno-oncology therapies. Immune-targeted therapies, e.g., checkpoint inhibitors, have emerged as the next generation approaches to treating cancer.

10:15 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break with Exhibit and Poster Viewing

PD-1 AND PD-L1: FUTURE DIRECTIONS

11:15 Biomarkers in the Tumor Microenvironment: What Is Working and How Can We Do Better?
Robert Anders, M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins
This lecture will discuss the status of immune based therapies and the state of the art in using predictive biomarkers to guide therapy. The use of PD-L1 as a biomarker will be discussed in the context of the tumor immune microenvironment. The results and interrogation of the colon cancer tumor microenvironment will also be summarized.

11:45 PD-1 and PD-L1 Blockade – Step 1. Bringing Immunotherapy to the Masses
Kathleen M. Mahoney, M.D., Ph.D., Clinical Instructor, Beth Israel Deaconess Medical Center; Research Fellow, Dana-Farber Cancer Institute
Blocking either the PD-1 receptor or its ligand PD-L1 has improved overall survival in Phase III trials in patients with melanoma, kidney cancer, and non-small cell lung cancer. Current clinical trials are investigating the toxicity and efficacy of combining PD-1 pathway blockade with other therapies, since the majority of patients fail to respond to PD-1 pathway blockade. However, a subset of patients develop significant, durable benefits from PD-1 pathway monotherapy.

12:15 pm Sponsored Presentation *(Opportunity Available)*

12:30 Session Break

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

SYMPOSIA

1:15 Session Break

CLINICAL CASE STUDIES

1:50 Chairperson's Remarks
Bernard A. Fox, Ph.D., Providence Cancer Center

2:00 AZD9150, a Therapeutic ASO that Modulates the Tumor Microenvironment
Patricia McCoon, Ph.D., Principal Scientist, Oncology Translational Science, AstraZeneca Pharmaceuticals
AZD9150 is a therapeutic antisense oligonucleotide targeting STAT3 that has shown clinical safety and efficacy in two Phase I clinical trials. Clinical biomarker analysis demonstrated STAT3 knockdown in immune cells accompanied by gene expression changes associated with better response to anti-PD(L)1 therapy. In mouse syngeneic tumors, combining STAT3 ASO treatment with immune checkpoint blockade improves efficacy. These data provided rationale for the current Phase Ib/II clinical trials exploring the combination of AZD9150 + anti-PDL1 (durvalumab).

2:30 Strategies to Induce and Monitor Anti-Cancer Immunity in Patients with Non-Small Cell Lung Cancer (NSCLC)
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
Patients who fail checkpoint blockade are thought to lack T cells capable of recognizing a broad spectrum of antigens expressed by all cancer cells. To address this hurdle we have developed a DC-targeted microvesicle cancer vaccine, DPV-001, that contains > 100 proteins over-expressed by NSCLC. Results of a Phase II study of DPV-001 in patients with NSCLC, document induction and/or boosting of immune responses against cancer antigens in every patient. Monitoring strategies employed and opportunities to stratify patients for next generation trials will be discussed.

3:00 The Novel Phase 2 Immunotherapeutic, Imprime PGG, Repolarizes the Tumor Immune Microenvironment and Activates Antigen Presentation to Drive an Integrated Anti-Cancer Immune Response with Checkpoint Inhibitors
Jeremy Graff, Ph.D., CSO, Senior Vice President, Research, Biothera Pharmaceuticals, Inc.
Imprime PGG is a systemically administered PAMP (Pathogen Associated Molecular Pattern) currently in phase 2 trials. As a PAMP, Imprime PGG binds directly to innate immune cells, triggering a cascade of immune activating events. These include the repolarization of the immune suppressive myeloid cells within the tumor microenvironment as well as the activation and maturation of dendritic cells, the immune system's professional antigen presenting cells. As a consequence, Imprime PGG treatment effectively stimulates T cell activation and synergizes with immune checkpoint inhibitors to enhance anti-tumor efficacy in multiple pre-clinical tumor models. A recently completed phase 1 study in healthy human volunteers has shown that Imprime PGG- mediated immune activation requires immune complex formation with naturally occurring anti-beta glucan IgG antibodies (ABA), levels of which vary across the human population. These ABA are now being used to pre-select patients for inclusion in a series of phase 2 studies in combination with pembrolizumab.

3:30 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

BEYOND CHECKPOINT INHIBITION: WHERE DO WE GO FROM HERE?

4:15 Utility of Teff Signature Assays in Plasma to Measure Pharmacodynamic Changes in Phase 1 Study of Atezolizumab and Cobimetinib in Melanoma
Vinita Gupta, Ph.D, Scientist, Cancer Immunotherapy, Genentech
As an exploratory objective of this phase 1a study, profiling of T cell activation markers was carried out in plasma of melanoma patients (n=22) at baseline and post dose that might act as indicators of immuno-modulatory effect of Cobimetinib with Atezolizumab. We qualified immunoassays for Teff signature panel as well as other immune-monitoring markers such as CCL2, IL-6, IL-18 and TNF-a on Simple-Plex and Quanterix platforms to study harmacodynamics of this drug combination. The assays exhibited CV<20% and accuracy within 70-130% range. The majority of patients show a spike in Teff signature markers at Cycle 1 Day 15 of the treatment as a pharmacodynamic response and suggesting a mechanism of action for these drugs.

4:45 Liquid Biopsies in Immuno-Oncology Drug Development
Shidong Jia, Ph.D., Founder & CEO, Predicine
Cancer immunotherapy offers great promise where biomarkers have been shown to predict therapy outcome in various types of cancer patients. The talk will describe the development of a next-generation sequencing-based liquid biopsy test to support drug development in cancer immunotherapy clinical trials .

5:15 Objective Measurement and Significance of IDO1, B7-H3 and B7-H4 in Hormone Receptor-Positive Breast Cancer
Daniel E. Carvajal-Hausdorf, M.D., Postdoctoral Associate, Pathology, Yale School of Medicine
Immunostimulatory therapies targeting immune suppressive pathways produce durable clinical responses in advanced solid tumors. However, PD-1/PD-L1 axis blockade has been in ineffective in hormone receptor positive breast cancer (HR+ BC). Here, we objectively assessed the expression of immunomodulatory enzyme IDO1 and immune checkpoint molecules B7-H3 and B7-H4, and their relationship with tumor-infiltrating lymphocytes in HR+ BC.

5:45 Reception with Exhibit and Poster Viewing

6:45 Close of Day

SYMPOSIA

FRIDAY, FEBRUARY 24

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

8:00 Registration Open

BEYOND CHECKPOINT INHIBITION (CONT.)

8:25 Chairperson's Remarks

Sandip Patel, M.D., Assistant Professor, Cancer Immunotherapy Program, Experimental Therapeutics, Thoracic Oncology; Assistant Director, Clinical Trials Office, Medicine/Hematology & Oncology, University of California, San Diego Moores Cancer Center

8:30 Novel T Cell Biomarkers for Response to Immune Checkpoint Therapies

Adil Daud, M.D., HS Clinical Professor, Medicine (Hematology/Oncology), University of California, San Francisco; Director, Melanoma Clinical Research, UCSF Helen Diller Family Comprehensive Cancer Center

9:00 Beyond PD-L1 as a Biomarker for Checkpoint Inhibition

Arnold Gelb, Head, Companion Diagnostic Development & US Site Head, EMD Serono

After briefly reviewing the current status of PD-L1 as a biomarker and Companion Diagnostic, including the limitations thereof, an overview of other candidate biomarkers for checkpoint inhibition will be presented. This overview will include select aspects of the tumor microenvironment, immune cell phenotyping, T cell repertoires, IFN-gamma gene signature, neoantigen burden, MSI status, and possible other "hot topics" that have been described in the interim.

9:30 Next-Generation Cancer Immunotherapy: Agents and Biomarkers

Sandip Patel, M.D., Assistant Professor, Cancer Immunotherapy Program, Experimental Therapeutics, Thoracic Oncology; Assistant Director, Clinical Trials Office, Medicine/Hematology & Oncology, University of California, San Diego Moores Cancer Center

Dr. Sandip Patel, M.D. will be discussing predictive biomarkers for immunotherapeutic response in cancer, with a focus on novel biomarker assays. He will be focusing on the nuances in the development of PD-L1 IHC with a focus on alternative predictive biomarkers that may better determine patient response to immune checkpoint modulation. Additionally, Dr. Patel will be discussing the next generation of cancer immunotherapeutics currently under development including cell-based approaches.

10:00 Highly Multiplexed IHC Assays to Examine Immune Checkpoints and Biomarkers for Immunotherapy

Jennifer Ziello, Senior Research Associate, Translation Diagnostics, Cell Signaling

The emergence of an increasing number of immunotherapy biomarkers and the importance of their context within the tumor microenvironment has resulted in a need for high-plex immunohistochemistry (IHC) assays. Using highly specific and validated antibodies developed for this purpose, we constructed several fluorescent multiplexed, TSA-based assays to examine the frequency, spatial localization, and proximity of immune cells within the tumor microenvironment. Our data demonstrates the feasibility of simultaneous detection of seven fluorochromes in order to visualize immunosuppressive receptors associated with the exhausted T cell phenotype, myeloid-derived suppressor cells, and the PD-1:PD-L1 axis. Our findings demonstrate the utility of multiplex IHC to deconvolute protein expression and interactions within the complex tumor microenvironment.

10:30 Coffee Break with Exhibit and Poster Viewing

ESTABLISHING COMPANION DIAGNOSTICS ACROSS TARGETED IMMUNOTHERAPIES

11:15 Precision Immunotherapy: The Challenge of Converting Complex Predictive Biomarkers into Practical Companion Diagnostics

Kenneth Emancipator, M.D., Executive Medical Director, Translational Medicine, Companion Diagnostics, Merck & Co.

Early immunotherapies have produced dramatic results for some patients, but future immunotherapies likely need to be guided by diagnostics to benefit more patients. Properly targeting immunotherapy requires incorporating into clinical practice complex diagnostics which can assess host immune response in addition to cancer biology itself. "Precision Immunotherapy" requires discovery of appropriate predictive biomarkers and incorporating them into practical companion diagnostics which will be adopted by practitioners.

11:45 Establishing Companion Diagnostics for Immunotherapies Including OPDIVO® (Nivolumab)

Neeraj Adya, Ph.D., Director, Pharmacodiagnostics Research and Development, Bristol-Myers Squibb

Clinical utility of single biomarker-based companion diagnostics (CDx) to select patients has been effectively demonstrated for mutation targeted therapies. An effective CDx for immunotherapies like OPDIVO® will likely require a set of biomarkers that serves as a surrogate for identifying immune status in patients. These biomarkers will need to meet the same analytical rigor as for a single biomarker. This talk leverages lessons learned from PD-L1 towards future CDx development.

12:15 pm Companion & Complementary Diagnostic Strategies for Cancer Immune Therapies

Andy Williams, Ph.D., Companion Diagnostics Franchise Lead, Cancer Immune Therapies, Oncology Biomarker Development & Companion Diagnostics, Genetech

This presentation highlights diagnostic strategies for cancer immune therapies. Based on a 2017 publication (Scheerens et al. 2017 Clinical and Translational Sciences, DOI:10.1111/cts.12455) considerations for companion and complementary diagnostics will be discussed with potential for broader application across other diseases. Relevant data from the 2016 approval of atezolizumab (Tecentriq) in NSCLC will be covered. Immunhistochemistry (IHC) and

12:45 Close of Symposium

Cambridge Healthtech Institute's Fourth Annual

NGS DIAGNOSTICS: KNOWLEDGE BASES, ANNOTATION AND INTERPRETATION

Reporting Solutions for NGS and Other Genomic Technologies

THURSDAY, FEBRUARY 23

7:00 am Registration and Morning Coffee

DATA SOLUTIONS TO ADVANCE GENOMIC MEDICINE

8:25 Chairperson's Opening Remarks

Mark E. Nunes, M.D., Associate Professor, Pediatrics, Division Chief, Medical Genetics, Kaiser Permanente

8:30 Data Sharing through the NCI Genomics Data Commons

Louis M. Staudt, M.D., Ph.D., Director, Center for Cancer Genomics, Co-Chief, Lymphoid Malignancies Branch, National Cancer Institute, National Institutes of Health

The National Cancer Institute (NCI) Genomic Data Commons (GDC) has been established to promote the sharing of cancer genomic and clinical data, with the aim to foster precision medicine approaches to the diagnosis and treatment of cancer. The GDC not only houses data collected from NCI-sponsored programs but is also open for any investigator who wishes to share cancer genomic and clinical data broadly. As the number of cases in the GDC grows, its explanatory power will increase, enabling the identification of low-frequency genetic drivers of cancer, an understanding of genomic determinants of therapeutic response, and potentially the constitution of clinical trial cohorts of patients with shared genetic lesions.

9:00 Has the Genomic Infrastructure Been Built to Allow Precision Medicine?

Mark E. Nunes, M.D., Associate Professor, Pediatrics, Division Chief, Medical Genetics, Kaiser Permanente

The Human Genome Project converged with the Digital Age to create the large-scale infrastructure needed to generate and analyze genomic "big data". The community infrastructure for sharing genomic data, and the personal/personnel infrastructure to exploit genomic data, have lagged. A clinician's perspective on the state of community and personal infrastructure, as providers and patients interface with electronic medical records, will ask: enough to overcome the personnel and knowledge gaps?

9:30 Free the Data: One Laboratory's Approach to Knowledge-Based Genomic Variant Classification

Madhuri Hegde, Ph.D., FACMG, Adjunct Professor, Emory University, Vice President and Chief Scientific Officer, Global Laboratory Services, Diagnostics, PerkinElmer, Inc.

High quality accurate classification of the clinical significance of sequence variant identified is essential in releasing the full potential of genomic medicine. The amount of sequence generated within clinical laboratories has increased dramatically with the advent of lower-cost, more automated Sanger sequencing and next-generation sequencing technologies. We have developed a variant curation interface management suite: EmVar and EmVClass, which is used to store variants and facilitate variant classification.

10:00 Systematic Assessment of Clinical Actionability Associated with Genomic Variation

Elizabeth Webber, MS, Research Associate, Center for Health Research, Kaiser Permanente

ClinGen's Actionability Working Group developed a structured framework to assess clinical actionability of genes and associated disorders based upon the availability of clinical interventions that could improve future health outcomes in patients and their at-risk relatives. This framework provides support to the research and clinical community for making clear, streamlined, and consistent determinations of clinical actionability based upon transparent criteria to guide analysis and reporting of variation in genome-scale sequencing.

10:30 Coffee Break with Exhibit and Poster Viewing

DEVELOPING KNOWLEDGE RESOURCES

11:10 Chairperson's Remarks

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

11:15 Developing Knowledge Resources for the Diagnostic Lab Director

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

Exome and genome sequencing will eventually serve as a first line test for many genetic disorders. While the technology is no longer a barrier, developing and updating knowledge resources on large numbers of genes, variants and disorders is a major bottleneck. This presentation will discuss national efforts to develop and curate knowledge resources that will guide diagnostic laboratory directors in all aspects of genomic sequencing including test design, validation and interpretation.

SYMPOSIA

11:45 SOAR: Scalable OMICS Analysis and Reporting
Andrew Stubbs, Ph.D., Assistant Professor, Bioinformatics, Erasmus University Medical School
We have implemented, SOAR, a generalized and scalable open source solution for integrated analysis of clinical and "OMICs" data. SOAR provides biomarker discovery and validation, with the latest "OMICs" tools available via Galaxy (use.galaxy.org) to the medical researchers in clinical and translational research projects. SOAR uses our GalaxyFlow to access multiple Galaxy instances (including tools) via a single graphical user interface. GalaxyFlow ensures that SOAR platform provides FAIR (Findable, Accessible, Interoperable, and Reusable) data principles where possible. The utility of SOAR will be demonstrated with existing translational research projects at the Erasmus University Medical Center.

12:15 Sponsored Presentation *(Opportunity Available)*

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

1:15 Session Break

REFERENCE MODELS AND POPULATION-BASED SCREENING

1:50 Chairperson's Remarks
Susan Mockus, Ph.D., Manager, Clinical Analytics & Curation, The Jackson Laboratory for Genomic Medicine

2:00 Using Exome Aggregation (ExAC) Dataset for the Interpretation of Rare Variants in Mendelian Diseases
Monkol Lek, Ph.D., Research Fellow, Massachusetts General Hospital
Large-scale reference data sets of human genetic variation are critical for the medical and functional interpretation of DNA sequence changes. The ExAC data set contains variants from over 120,000 individuals aggregated from a variety of large-scale sequencing projects. In this presentation, we will provide a general overview of the production of the ExAC data set, recent updates and also discuss examples of how the data set has been used for the interpretation of rare variants and development of methods available to the community.

2:30 The 100,000 Genomes Project: Transforming the UK's National Health Service
Joanne Mason,Ph.D., Director of Sequencing and Sample Acquisition, Genomics England, Queen Mary University of London
The 100,000 genomes project is transforming the UK's National Health Services introducing whole genome sequencing as a standard of care test for rare disease and cancer patients. My talk will cover our approach and infrastructure to deliver this transformational program for patients in England and approaches to interpreting whole genome data on a population scale.

WES AND PANELS IN ONCOLOGY: INTERPRETATION AND REPORTING

3:00 Tackling the Task of Precision Immuno-Oncology in an Integrated Health System
Terence Rhodes, M.D.,Ph.D., Director of Immuno-Oncology, Intermountain Healthcare
Although an active area of research, the lack of current clinical biomarkers for cancer immunotherapy comes at a significant delay in effective treatments and increased costs for the majority of patients who do not benefit from immunotherapy. Intermountain Healthcare's unique resources will play a role in personalizing immuno-oncology

3:30 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

4:15 Creating Standards and Transparency for Interpretation of Somatic Variants
Susan Mockus, Ph.D., Manager, Clinical Analytics & Curation, The Jackson Laboratory for Genomic Medicine
Genomic tumor profiling enables insights into prognostic, diagnostic, and predictive biomarkers of disease. Somatic variants are often characterized by clinical actionability. Actionability is defined in a variety of ways ranging from variant pathogenicity to connection to targeted therapies and available clinical trials. Tier ranking systems have been commonly implemented, but none uniformly adopted. The need for interpretation standards and methods for providing transparency will be described.

4:45 Pushing the Limits - Challenges of Somatic Variant Detection
Robert Daber, Ph.D., Founder and CEO, Gnosity Consults
NGS continues to emerge as a powerful diagnostic methodology for the characterization of mutation status in a variety of tumors. Here we describe our experience detecting various complicated somatic mutation types across a variety of tumor types, including both low allele frequency mutations as well as complicated insertion and deletion events. We will also discuss our strategies for decreasing the lower limit of detection by customizing the limits of detection for each genomic loci independently.

5:15 Large-Scale, Cloud-Based Analysis of Cancer Genomes: Lessons Learned from the PCAWG Project
Brian O'Connor, Technical Director, Analysis Core Genomics Institute, UCSC
The PanCancer Analysis of Whole Genomes (PCAWG) project is a large-scale, highly distributed research collaboration designed to identify common patterns of mutations across 2,800 cancer genomes. The use of clouds, both public and private, was instrumental in analyzing this dataset using current best practice pipelines. This talk describes the technical infrastructure built for the project, how we leveraged cloud environments to perform the "core" analysis, and the lessons learned along the way. It will also explore the nature of the dataset and how it can be leveraged to support research and clinical applications.

5:45 Reception with Exhibit and Poster Viewing

SYMPOSIA

6:45 Close of Day

FRIDAY, FEBRUARY 24

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

8:00 Registration Open

GERMLINE MUTATIONS INTERPRETATION AND REPORTING

8:25 Chairperson's Remarks
Catherine Brownstein, Instructor, Genetics and Genomics, Boston Children's Hospital and Harvard Medical School

8:30 Annotation and Interpretation of Clinical Exome Sequencing
Wayne W. Grody, M.D., Ph.D., Professor, Medical Genetics and Molecular Pathology, Pathology & Lab Medicine, Pediatrics, Human Genetics, Director, Molecular Diagnostic Laboratories and Clinical Genomics Center, University of California Los Angeles School of Medicine
Our center has been performing clinical-grade whole-exome sequencing (WES) for the diagnosis of rare Mendelian disorders since January 2012. In addition to our in-house bioinformatics pipeline and externally available databases and algorithms, all mutations and variants are interpreted by a unique "Clinical Genomics Board" comprised of lab directors, technologists, bioinformaticists, genetic counselors, medical geneticists, and the ordering clinicians. We find that this approach provides the most "value-added" clinical insight for proper annotation and reporting of variants.

9:00 CLARITY Undiagnosed – Interpreting Clinical Variation
Catherine Brownstein, Instructor, Genetics and Genomics, Boston Children's Hospital and Harvard Medical School
Variant interpretation is a rapidly evolving field; there remains a great diversity in application of criteria and choices of genes and variants to be reported when clear cut pathogenic mutations are not immediately obvious. The CLARITY Challenges are an effective means for assessing current practices for using next-generation sequencing. The data collected during this contest will be used to accelerate broad dissemination of diagnostic sequencing practices that are suitable for clinical use.

9:30 Building a Framework for Consistent and Accurate Clinical Interpretation of Germline Sequence Variants
Keith Nykamp, Ph.D., Senior Scientist, Clinical Genomics Group, Invitae
With the ACMG ISV guidelines as a starting point, we developed a weighted, score-based classification system designed to be scalable across a large team of variant scientists. This system, which we call Sherloc, was implemented in our clinical reporting workflow and iteratively revised based on our experience with more than 15,000 variants. This presentation will discuss some of the challenges we encountered, and how the Sherloc system overcomes these challenges.

10:00 Mendel, meet Mendeleev: Why Genotypes Matter More than Variants -- and What You Can Do About It
Nathaniel Pearson, Ph.D., Senior Director, Scientific Engagement & Public Outreach, New York Genome Center

10:30 Coffee Break with Exhibit and Poster Viewing

FREENOME, MICROBIOME AND BEYOND

11:15 Adaptive Genomics Engine (AGE) for Cloud-Based Machine Learning of Cell-Free DNA (cfDNA) to Enable Computational Classification and Biomarker Discovery in Cancer Research
Gabriel Otte, Ph.D., CEO, Co-Founder, Freenome, Inc.
The underlying biology of cell-free DNA (cfDNA) and projected signatures in circulation are fundamentally different from tissue. Thus, tools are needed to facilitate the deconvolution of these novel cfDNA signatures. Freenome built the Adaptive Genomics Engine (AGE) for read-level transformation of cfDNA sequence data to enable computational classification with deep learning. AGE generates unique feature representations of cfDNA to define data structures independent of traditional mutation calling such as read length distributions. This method showed >95% accuracy for disease detection (n = 351) and estimated a reduced dimensional subspace that preserves divergence between tissues of origin in both early- and late-stage lung and prostate cancers, indicative of multi-cancer discrimination with AGE.

11:45 The Human Microbiome: Data Challenges and Solutions
Andreas M. Kogelnik, M.D., Ph.D., Open Medicine Institute
Examination of various human microbiomes is yielding valuable, clinically-relevant information; however, there is still much to learn. Human microbiome analysis is the study of microbial communities found in and on the human body. The goal of human microbiome studies is to understand the role of microbes in health and disease. High throughput methods have enabled increasingly relevant studies with increasing clinical impact that is both surprising and broad-reaching at times. There remains enormous work to be done for data analysis and for application of these technologies.

12:15 pm Public and Private Databases: Competition or Cooperation
Moderator: Catherine Brownstein, Instructor, Genetics and Genomics, Boston Children's Hospital and Harvard Medical School
Panelists:
Irene C. Blat, Ph.D., Scientific Director of Translational Genomics, Application Sciences, WuXi NextCODE Genomics
Speakers of the Day
- Is there a single nomenclature source for genes and variants that should be adopted across all databases?
- How should databases provide transparency to data collection sources and evaluation processes?
- What levels of evidence should be required for a new variant?

12:45 Close of Symposium

Cambridge Healthtech Institute's Inaugural

MICROBIOME-BASED PRECISION MEDICINE

Using the Microbiome as a Tool for Translating Science into Useful Therapeutics

THURSDAY, FEBRUARY 23

7:00 am Registration and Morning Coffee

THE GUT MICROBIOME IN HEALTH & DISEASE: RESEARCH & INDUSTRY TRENDS

8:25 Chairperson's Opening Remarks
Sudeep Basu, Ph.D., Practice Leader, TechVision-Innovation Services, Frost & Sullivan

8:30 Human Microbiome Market Analysis, Trends and Predictions
Sudeep Basu, Ph.D., Practice Leader, TechVision-Innovation Services, Frost & Sullivan

This presentation focuses on microbiome trends including a review of select technologies, markets and products. Additional insights will be provided on the policy and regulatory framework, in the context of the future pipeline - what companies and products are in clinical trials.

9:00 National Collaborations in Microbiome Research and Education
Alison Kim, Ph.D., Senior Director, Research and Innovation, American Gastroenterological Association (AGA)

The American Gastroenterological Association (AGA) established its Center for Gut Microbiome Research and Education in 2012 with a mission to advance research and education on the gut microbiome with the goal of improving human health. This talk will present the work of AGA and its center in organizing educational programs, publications, citizen science projects, and a national registry as a complement to the work of individual investigators and institutions studying the microbiome.

9:30 Presentation Moved from Friday & Replacement Presentation: The Mind-Gut Connection
Emeran Mayer, M.D., Ph.D., Executive Director, Oppenheimer Center for Stress and Resilience and Co-Director, Digestive Diseases Research Center, University of California at Los Angeles; Author, The Mind-Gut Connection: How the Hidden Conversation Within Our Bodies Impacts Our Mood, Our Choices, and Our Overall Health (published July 2016)

Presentation delivered via narrated powerpoint

Sponsored by METABOLON

10:00 The Essential Ingredients for Decoding the Microbiome with Metabolomics
Kirk Beebe, Ph.D., Director, Application Metabolomics, Metabolon

The microbiome has an important role in health but lack of mechanistic understanding hinders the practical use of this information. We will illustrate how, through surveying the metabolites that broker microbe-host interaction, metabolomics can enrich insights into this association.

10:30 Coffee Break with Exhibit and Poster Viewing

MICROBIOME SAMPLE PREPARATION, STORAGE, AND ANALYSIS CHALLENGES

11:15 Measuring Relevant Changes in the Microbiome
Colleen Cutcliffe, Ph.D., Co-Founder and CEO, Whole Biome

As various academic and commercial teams begin to develop interventions targeting the microbiome, we all find ourselves needing to answer two key questions: (1) Can we change an already existing microbial ecosystem in a predictable and desired way and (2) Can we change a person's disease or healthy state in predictable and desired ways? The keys to answering these questions lie in the interventions themselves, but also in the methods that are used to measure and monitor the microbiome. In this talk, I will share some of Whole Biome's learnings as we begin to explore the complexity of data acquisition and analytics required to enable us to answer these two key questions.

11:45 Standards for Pathogen Identification
Scott Jackson, Ph.D., Molecular Genetics and Microbial Genomics, National Institute of Standards and Technology

Sponsored by SECOND GENOME SOLUTIONS

12:15 pm Improving the Utility of Microbiome Research
Cheryl-Emiliane Chow, Ph.D., Bioinformatics, Scientist Solutions, Second Genome

Understanding which microbes influence health is critical to research in human biology. Through hardware and software development, Second Genome has built strategies to: achieve strain-level taxonomic resolution, improve functional insights, and achieve reproducible results. Through identification of key microbes, these findings can be applied to develop microbiome-based diagnostics and therapeutics.

12:30 Session Break

SYMPOSIA

Sponsored by charles river

12:44 LUNCHEON PANEL DISCUSSION: The Charles River Microbiome Think Tank

Moderators: *Iva Morse, CSO, Vice President, Charles River*
John Ho, M.D.,CSO, Corporate Senior Vice President, Charles River
Panelists:
Kirk Beebe, Ph.D., Director, Application Science, Metabolon
Lynn Bry, M.D., Ph.D., Associate Professor, Pathology and Director, Massachusetts Host-Microbiome Center + Crimson Core, Brigham & Women's Hospital
David Cook, Ph.D., Executive Vice President of R&D and CSO, Seres Health
Audrey Goddard, Ph.D., Vice President, Research and Development, uBiome
Christiane Honisch, Ph.D., Director, Microbiology Markets, Illumina
Mohan S. Iyer, Chief Business Officer, Second Genome
Scott Jackson, Ph.D., Molecular Genetics and Microbial Genomics, National Institute of Standards and Technology
Andreas M. Kogelnik, M.D., Ph.D., Director, Open Medicine Institute
Deepak K. Rajpal, Ph.D., Director, Computational Biology-Target Sciences, GSK
This Microbiome Think Tank Luncheon Panel Discussion features leading researchers and thought leaders from microbiome therapeutic and biopharma companies discussing novel research towards clinical applications to improve disease treatment and human health.

1:45 Session Break

NOVEL RESEARCH TOWARDS TRANSLATIONAL INTERVENTIONS & CLINICAL APPLICATIONS

2:20 Chairperson's Remarks
Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360

2:20 Precision Microbiome Engineering in Agriculture and Beyond
Nick Conley, Ph.D., CEO & Co-Founder, EpiBiome
In lieu of small-molecule antibiotics, EpiBiome deploys bacterial viruses known as phages, which are abundant in nature and kill about half of the bacteria on the planet every two days. This talk provides an understanding of how modern tools of molecular and microbiology, such as high-throughput discovery methods and next-generation sequencing, can give an old idea (phage therapy) new life.

3:00 Rapid Detection of Enteric Pathogens and Characterization of the Intestinal Microbiome in Health and Disease
Rita R. Colwell, Ph.D., D.Sc., Distinguished Professor, Center for Bioinformatics and Computational Biology and University of Maryland Institute of Advance, University of Maryland College Park
High-throughput sequencing, combined with high-resolution metagenomic analysis, provides a powerful diagnostic tool for clinical management of enteric disease. A retrospective case control study comprising samples of known and unknown etiology, as well as healthy individual samples will be discussed. The results of this study showed that the intestinal microbiome could differentiate healthy, diseased, and asymptomatic carriers, as well as individuals in the early stages of infection and disease.

3:30 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

4:15 New Presentation: Challenges in Microbiome Therapeutic Development
Emma Taylor, M.D., Co-founder and CEO, Naked Biome
Naked Biome is developing live biologic therapeutics for skin disease with a focus on acne. Their company is harnessing information from the human microbiome project and translating this into the first science-based topical live biologic therapeutic using healthy skin bacteria. This is a novel therapeutic area without precedence and the company is navigating challenges in several of the areas below to develop antibiotic alternatives and effective microbiome-based therapies for dermatologic conditions. Discussed will be: challenges in microbial therapeutic development, strain selection, intellectual property, RX vs DTC, manufacturing, formulation, regulatory strategy, and clinical trial.

4:45 The Oral Microbiome, Autoimmunity and Personalized Nutrition
Bonnie Feldman, D.D.S., MBA, Digital Health Analyst and Chief Growth Officer, DrBonnie360
Advances in big data analytics, next-generation sequencing, and systems immunology are fueling our understanding of the human microbiome. This emerging science is changing our understanding and approach toward oral health and systemic immunity. Bacteria in the mouth seed the GI tract to the tune of 1 trillion bacteria every day. The status of our oral health may be an early indicator of other systemic diseases such as diabetes, heart disease, and rheumatoid arthritis.

5:15 Diversity of Key Players in the Microbial Ecosystems of the Human Body
Corrado Priami, Ph.D., Professor, Computer Science, The University of Trento; President and CEO, The Microsoft Research - University of Trento Centre for Computational and Systems Biology (COSBI)
Coexisting bacteria form various microbial communities in human body parts. We analyze the interaction network among bacterial OTUs in 11 locations of the human body. Beyond identifying the key players and discussing their biological relevance, we also quantify and compare the properties of the 11 networks.

5:45 Reception with Exhibit and Poster Viewing

6:45 Close of Day

SYMPOSIA

FRIDAY, FEBRUARY 24

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

8:00 Registration Open

NOVEL RESEARCH TOWARDS TRANSLATIONAL INTERVENTIONS & CLINICAL APPLICATIONS

8:25 Chairperson's Remarks
Take Ogawa, Director, Second Genome, Inc.

8:30 Microbiome-Based Precision Medicine Tools for Personalized Treatment Approaches
Purna C. Kashyap, MBBS, Assistant Professor of Physiology and Assistant Professor of Medicine, Division of Gastroenterology and Hepatology, Mayo Clinic
Every individual harbors a unique gut microbiome. The inter-individual differences make it difficult to design treatment strategies targeting the microbiome that would apply to all individuals; rather, it highlights the need for personalized therapies. At the same time, inter-individual differences in microbiome may be predictive of individual susceptibility to microbiota related disease, drug therapy and pathogenic infections, hence serving as a diagnostic and therapeutic biomarker. Microbiome represents an important component of the next generation of precision medicine tools.

9:00 The Human Skin Microbiome: Metagenomes to Therapeutics
Julia Oh, Ph.D., Assistant Professor, The Jackson Laboratory
Metagenomic analyses of the human skin demonstrate that contrasting forces of the skin's biogeography and individuality shape the skin microbiome and its temporal dynamics. Striking changes in the skin's microbiome are observed in skin disease and other host factors like age or immunodeficiency. Understanding the function, structure, and dynamics of the microbiome is important to design therapeutics that precisely target the pathogen of interest, yet spare the surrounding beneficial microbiota.

9:30 Skin Microbiome
Larry Weiss, M.D., CMO, AOBiome, LLC
AOBiome is exploring the role of Ammonia Oxidizing Bacteria (AOB) as an ancestral human skin commensal. The company is developing live topical therapeutic and cosmetic formulations on *Nitrosomonas eutropha* for the prevention and treatment of inflammatory disorders of the skin. This presentation will discuss discovery of AOB as skin commensals; biology of *Nitrosomonas eutropha*; clinical development of AOB as a dermatologic therapeutic, and consumer products as a tool in therapeutic development.

10:00 High-Resolution Taxonomic Profiling to Enhance Translational Microbiome Research
James Robert White, Ph.D., Founder, Resphera Biosciences
Despite advancements in high-throughput DNA sequencing technologies, current microbiome profiling strategies often suffer from insufficient taxonomic characterization, thus hindering identification of reliable biomarkers and the design of follow-up experiments. This presentation will describe a new method for high-resolution taxonomic assignment of 16S rRNA sequence data and highlight two recent collaborative studies with FDA that employ this approach for detection of Salmonella enterica and Listeria monocytogenes. We will further report on applications in the context of Clostridium difficile infection and colorectal cancer.

10:30 Coffee Break with Exhibit and Poster Viewing

11:15 Talk Title to be Announced
David Cook, Ph.D., Executive Vice President of R&D and CSO, Seres Health

PHYSICIAN-SCIENTIST APPLICATIONS OF THE MICROBIOME TO PRECISION MEDICINE & HEALTH

11:45 Bioactive Small Molecules from the Human Gut Microbiome
Dylan Dodd, M.D., Ph.D., Instructor of Pathology, Sonnenburg Lab, Department of Microbiology and Immunology, Stanford University School of Medicine
The bacteria within our gut synthesize many small molecules that have important effects on our bodies including modulating drug metabolism, altering the immune system, and predisposing to cardiovascular disease. Targeting the production of these compounds represents an important new strategy to treat human disease. To achieve this, we need to understand how these molecules are produced and develop strategies to predictably alter their levels.

12:15 pm New Presentation: The Human Microbiome: Data Challenges and Solutions
Andreas M. Kogelnik, M.D., Ph.D., Open Medicine Institute
Examination of various human microbiomes is yielding valuable, clinically-relevant information; however, there is still much to learn. Human microbiome analysis is the study of microbial communities found in and on the human body. The goal of human microbiome studies is to understand the role of microbes in health and disease. High throughput methods have enabled increasingly relevant studies with increasing clinical impact that is both surprising and broad-reaching at times. There remains enormous work to be done for data analysis and for application of these technologies.

12:45 Close of Symposium

Cambridge Healthtech Institute's Third Annual

COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS

Addressing Challenges and Fostering Investment in Innovative Diagnostics

THURSDAY, FEBRUARY 23

7:00 am Registration and Morning Coffee

THE ECONOMICS OF PRODUCT DEVELOPMENT

8:25 Chairperson's Opening Remarks
Noa Ghersin, Analyst, Lux Research, Inc.

8:30 Disruptive and Open Innovation in Market Strategies for Precision Medicine
Winston Patrick Kuo, D.M.Sc., Chief Technology Officer, Head, Global Business Development, CloudHealth Genomics, Ltd.
The goal of President Obama's Precision Medicine Initiative was to enable disruptive technologies like next-generation sequencing (NGS) and innovations to improve patient care, diagnose disease at the early onset, using big data to guide therapies and therapeutics - bringing the American healthcare ecosystem into the 21st century. However, many important issues pertaining to the FDA remain unaddressed; NGS, on the FDA's regulatory purview, Laboratory Developed Tests (LDTs), pending FDA guidelines and reimbursement for NGS-based LDTs. Predicine's innovative marketing strategy is organized around engaging/leveraging the global community including and not limited to academia/industry, government and strategic partnerships. Predicine will shed some insight in overcoming some of these issues, and yet, providing value to the American market.

9:00 Advanced Diagnostic Laboratory Test (ADLT) Commercialization in a Post-PAMA Era
John Hanna, Vice President, Marketing & Managed Care, Veracyte, Inc.
The PAMA final rule sets specific criteria for New ADLT designation beginning in 2018. This session will cover considerations of the criteria for the ADLT designation, Medicare coverage and coding requirements, and commercialization strategies to effectively synchronize these activities.

9:30 Development of Decentralized Multiplexed Molecular Diagnostics for Precision Oncology
Sean Ferree, Ph.D., Vice President, Diagnostic Development, Nanostring Technologies, Inc.

10:00 Novel Diagnostic Technologies: Coverage Today and Coverage in the Future
Sponsored by XIFIN
Kyle Fetter, MBA, Vice President & General Manager, Diagnostic Services Operations, MDx Support Services, Xifin, Inc.
Early stage diagnostic and wearable diagnostic device companies face greater hurtles to commercialization and reimbursement than ever before. The combination of clinical, market adoption, and reimbursement hurdles make it imperative to synch up all efforts within an organization for diagnostic providers from early-stage product development to commercialization and payor contracting. During this session, we will explain the current challenges and how diagnostics companies are positioning themselves for success in light of those challenges.

10:15 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break with Exhibit and Poster Viewing

REIMBURSEMENT HURDLES FOR NEW TECHNOLOGIES

11:15 Molecular Diagnostics & Reimbursement: Lessons, Opportunities, and Challenges. The Clinical Laboratory Perspective
Thomas Neuwerth CQA(ASQ), MB(ASCP)CM, Quality Assurance, Intermountain Precision Genomics
Precision medicine has unique challenges and opportunities. Discussion will include the status of reimbursements in advanced diagnostics, evolving standards from accrediting/standards issuing agencies, economic impact data from an Intermountain Healthcare retrospective patient study, and the impact of MolDx on large panel somatic oncology tests from a laboratory research and development and validation perspective as part of the larger regulatory and reimbursement conversation within the precision medicine community.

11:45 Show Me the Money: Navigating the Reimbursement Process for Molecular Diagnostics
Lon Castle, M.D., CMO, Molecular Genetics, Specialty Drug and Personalized Medicine, eviCore healthcare
Analytic Validity…check. Clinical Validity…check. Clinical Utility…check. You've checked all the boxes as you launched your new test, so what's left to do? Plenty—if you want to get paid. Learn about the nuances of the reimbursement process and what to expect once your test is moved from "I&E" to "covered."

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

SYMPOSIA

REGULATORY AND LEGAL CONSIDERATIONS

1:50 Chairperson's Remarks
Lon Castle, M.D., CMO, Molecular Genetics, Specialty Drug and Personalized Medicine, eviCore healthcare

2:00 The Practical Effect of Myriad on Patent Claims
John Liddicoat, Ph.D., Philomathia Research Fellow, Faculty of Law, University of Cambridge
I will present a detailed quantitative study of how the Supreme Court decision of Association for Molecular Pathology v. Myriad Genetics Inc. has affected claims to naturally occurring nucleotides as composition of matter. This study focuses on patent applications that were pending when the case was decided and how the applicants have amended their claims to comply with the holding in Myriad. A descriptive statistical analysis of how claims have changed post-Myriad will be presented, as well as several case studies demonstrating these changes.

2:30 How Can We Go from Innovative Research to an FDA-Approved Diagnostic Test in the Market Place?
Debra J. Rasmussen, MBA, Global Regulatory Affairs Diagnostic Leader, Janssen Pharmaceuticals
Now is the time when increased innovation and novel healthcare models are driving a new way of addressing global health. One of the challenges is the transition from innovative research to an FDA-approved commercial product. This presentation will highlight regulatory considerations in Companion Diagnostics and explore strategies to move from research through feasibility, investigational trials, FDA approval/clearance, and market access.

3:00 Diagnostic Inventions – Dilemmas for Protection and Enforcement of Patent Rights
Erica Pascal, Ph.D., J.D., Partner, Intellectual Property & Technology, DLA Piper LLP (US)
Patent protection for diagnostics can be tricky. Methods claims may include steps carried out by a collection of entities – including the manufacturen an infringer comes on the scene. Protection for diagnostic assays and reagents may also raise questions as to how to extract the value from these inventions through licensing, enforcement and other manners of IP protection. This talk will explore the interplay between evolving IP laws and business considerations.

3:30 Refreshment Break and Poster Competition Winner Announced in the Exhibit Hall

MODELS FOR SUCCESSFUL PARTNERSHIPS

4:15 Effective Companion Diagnostic Partnerships with a Focus on Drug Approvals
Dan Snyder, President & CEO, Executive Management, MolecularMD
Applying traditional approaches of IVD development and commercialization to a companion diagnostic (CDx) program is not likely to result in a successful outcome for the corresponding drug development program. Collaborators need to be reminded that there is no commercialization of the companion diagnostic without the approval of the targeted therapy. In drug diagnostic co-development, the requirements for the diagnostic must be fully aligned with the investigational therapeutic clinical indication. The early stage alignment of the co-development strategy is pivotal in the overall success of the program. Case studies and insights will be shared that will illustrate and highlight best practices in forging effective partnerships between biopharma and diagnostic assay developers.

COMMERCIALIZATION OF MOLECULAR DIAGNOSTICS

4:45 Companion Diagnostics for Immunotherapy – The Man Behind the Curtain
M. Allen Northrup, Ph.D., FRSC, CEO, MIODx
Ideally, one would have a 100% predictive companion diagnostic to ensure that a therapy would work to save money, time, and the patients that be can selected. In clinical trials, it would be best to de-select patients that don't respond, smoothing the path to FDA approval. However, is there a simple gene or other marker to accurately predict a response to a therapy in such a complex and dynamic system as the human immune system? In any case, some degree of trial and error must be followed to even get to the ability to pre-diagnose responding patients. In the absence of a precise and predictive companion diagnostic, to prevent unforeseen negative effects or ineffective treatments, and to understand the biological response, immunotherapies benefit from real-time patient immune system monitoring.

5:15 Commercialization of Companion Diagnostics- Critical Success Factors and Lessons Learned
Reinhard Ortmann, Director, Companion Diagnostics, QIAGEN
Development of Companion Diagnostics (CDx) has been extensively analyzed; however, commercialization is often put aside until the registrational study begins. Getting a CDx developed and approved is indeed a critical and necessary step for commercial access; however, implementing the newly approved Companion Diagnostics is equally important. This presentation will discuss the importance of preparation for the successful launch and implementation of a newly approved Companion Diagnostic into the clinical laboratory

5:45 Reception with Exhibit and Poster Viewing

6:45 Close of Day

FRIDAY, FEBRUARY 24

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

8:00 Registration Open

GLOBAL CHALLENGES ON DRUG-DIAGNOSTIC CO-DEVELOPMENT

8:25 Chairperson's Remarks
William Pignato, Founder and Principal, W. J. Pignato & Associates

8:30 PANEL DISCUSSION: Recent Thinking, Development, and Initiatives
Moderator: William Pignato, Founder and Principal, W. J. Pignato & Associates

SYMPOSIA

Laura T. Housman, MPH, MBA, CEO, Founder, Access Solutions Consulting
Patricia Carrigan, Ph.D., Head,Translational Assay Technology, Pharmaceuticals Division, Bayer Pharma
Peggy Carter, Ph.D., Global Head, Drug Regulatory Affairs, Novartis Companion Diagnostics

This panel will cover:

- Regulatory issues
- Breakthrough therapies
- Timing of CDx integration
- Pre- and post-marketing challenges
- Implications of new technologies (e.g., NGS, "liquid biopsy")
- FDA-centric approach vs. global CDx initiatives
- Central CLIA lab vs. IVD platform choices

ESTABLISHING COMPANION DIAGNOSTICS ACROSS TARGETED IMMUNOTHERAPIES

10:00 PD-L1 Testing as a Model for the Impact of Biomarker Adoption on Drug Launch Success.
Peter Krein, Ph.D., Managing Director, Diaceutics
Due to the variety of antibodies and testing methodologies, as well as interpretation variation, the introduction of testing for PD-L1 expression presented numerous challenges, not only for pathologists, but also for clinicians intending to treat patients with I-O therapies. A better understanding of the specific factors that influence biomarker testing adoption for each country, and implementation of programs to overcome these barriers, would improve access to novel biomarker testing and streamline the therapy launch. This in turn would increase the number of patients eligible for precision therapies and help to eliminate variability in access to new therapeutics.

10:30 Coffee Break with Exhibit and Poster Viewing

11:15 Precision Immunotherapy: The Challenge of Converting Complex Predictive Biomarkers into Practical Companion Diagnostics
Kenneth Emancipator, M.D., Executive Medical Director, Translational Medicine, Companion Diagnostics, Merck & Co.
Early immunotherapies have produced dramatic results for some patients, but future immunotherapies likely need to be guided by diagnostics to benefit more patients. Properly targeting immunotherapy requires incorporating into clinical practice complex diagnostics which can assess host immune response in addition to cancer biology itself. "Precision Immunotherapy" requires discovery of appropriate predictive biomarkers and incorporating them into practical companion diagnostics which will be adopted by practitioners.

11:45 Establishing Companion Diagnostics for Immunotherapies Including OPDIVO® (Nivolumab)
Neeraj Adya, Ph.D., Director, Pharmacodiagnostics Research and Development, Bristol-Myers Squibb
Clinical utility of single biomarker-based companion diagnostics (CDx) to select patients has been effectively demonstrated for mutation-targeted therapies. An effective CDx for immunotherapies like OPDIVO® will likely require a set of biomarkers that serves as a surrogate for identifying immune status in patients. These biomarkers will need to meet the same analytical rigor as for a single biomarker. This talk leverages lessons learned from PD-L1 towards future CDx development.

12:15 pm Companion & Complementary Diagnostic Strategies for Cancer Immune Therapies
Andy Williams, Ph.D., Companion Diagnostics Franchise Lead, Cancer Immune Therapies, Oncology Biomarker Development & Companion Diagnostics, Genetech
This presentation highlights diagnostic strategies for cancer immune therapies. Based on a 2017 publication (Scheerens et al. 2017 Clinical and Translational Sciences, DOI:10.1111/cts.12455) considerations for companion and complementary diagnostics will be discussed with potential for broader application across other diseases. Relevant data from the 2016 approval of atezolizumab (Tecentriq) in NSCLC will be covered. Immunhistochemistry (IHC) and

12:45 Close of Symposium

DINNER SHORT COURSES*

WEDNESDAY, FEBRUARY 22, 2017 | 6:00 - 9:00 PM -- THE MOSCONE SOUTH CONVENTION CENTER

SC25: Technologies, Applications and Commercialization of Point-of-Care Diagnostics
Holger Becker, Ph.D., Founder & CSO, microfluidic ChipShop GmbH

SC26: Detection and Characterization of Circulating Biomarkers
Catherine Alix-Panabières, Ph.D., Director, Laboratory of Rare Human Circulating Cells (LCCRH), Cellular and Tissular Biopathology of Cancers, University Medical Center of Montpellier
Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf, University of Hamburg

SC27: A Primer to Gene Editing: Tools and Applications
Fuguo Jiang, Ph.D., Damon Runyon Research Fellow, Laboratory of Dr. Jennifer Doudna, Molecular and Cell Biology, University of California, Berkeley
Michael Bassik, Ph.D., Assistant Professor, Department of Genetics, Stanford University
Krishanu Saha, Ph.D., Assistant Professor, Department of Biomedical Engineering, & Wisconsin Institute for Discovery, University of Wisconsin-Madison

SC28: Genomics in the Service of Cancer Immunotherapy - Connecting DNA Repair, Mutational Processes and Genotoxic Therapy to Successful Cancer Immunotherapy
Zoltan Szallasi, Ph.D., M.D., Senior Research Scientist, Children's Hospital Informatics Program, Children's Hospital Boston, Harvard Medical School; Assistant Professor, Pediatrics, Harvard Medical School; Assistant Professor, Pediatrics, Boston Children's Hospital

** See registration page for pricing options.*

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STUDENT FELLOWSHIPS

Full time graduate students and Ph.D. Candidates are encouraged to apply for the Molecular Medicine Tri-Conference Student Fellowship. Applications are due by November 18, 2016.

- Interested students must complete the application for the 2017 Student Fellowship.
- Fellows are required to present a scientific poster. A poster title and abstract are due at the time of the application.
- All applications will be reviewed by the scientific review committee and the accepted students will be notified by December 2, 2016 if they were accepted for the 2017 Student Fellowship.
- Accepted 2017 Student Fellows will receive a discounted conference registration rate of $195*, which must be paid by in full by December 23, 2016. (Payment is requested at the time of the application but will not be charged until the application is approved.)
- This fellowship is limited to 20 students and is for the Main Conference Only. (Excludes Symposia Posters Hall)
- All accepted 2017 Student Fellows will be asked to help promote the conference onsite at their college, and throughout their social media networks.
- Students not accepted for the 2017 Student Fellowship can register at a discounted rate of $295*, and will not be required to present a poster.

**** This discounted Fellow rate cannot be combined with any other discounts for this event. Your discounted registration does not grant access to any of the short courses or symposia. It also does not include hotel, travel or meals.***

NEW FOR 2017!!

Early Innovator Award

DiagnosticsWorld

This year the 2017 Tri-Conference Student Fellowship Applicants are invited to enter the Inaugural Diagnostics World Early Innovator Award. The Award recognizes innovation and creativity in effectively recognizing and solving a real-world clinical, scientific or organizational problem through the application of a unique solution.

A panel of industry experts will review each Student Fellowship application and choose the Early Innovator Award winner based on the complexity of the problem; the uniqueness, elegance, and effectiveness of the solution; and proposed next steps.

To learn more about entering for Diagnostics World Early Innovator Award, visit: TriConference.com/Student-Fellowship

DiagnosticsWorld *Diagnostics World and the bi-weekly Diagnostics World Weekly Update newsletter deliver insights on the tools, innovations and breakthroughs that will emerging from the expanding field of diagnostics. As molecular technologies let us peer into the pathways of disease, 21st century diagnostics are posed to change the way our illnesses are found, treated, and even defined.*

For more info: DiagnosticsWorldNews.com

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Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in specific conference materials, your abstract must be submitted, approved and your registration paid in full by the following deadlines:

December 23, 2016
Poster abstracts submitted and approved by December 23, 2016 will be included in the Printed Program Guide and Electronic Program Materials.

January 13, 2017
Poster abstracts submitted and approved between December 24, 2016 and January 13, 2017 will be not included in the Printed Program Guide, but will be included in the Electronic Program Materials.

All poster abstracts are due no later than January 13, 2017.

Register online for Regular or All Access, or by phone, fax or mail. Please indicate that you would like to present a poster. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. Please see below for more information.

Reasons you should present your research poster at this conference:

- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes
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- $50 off your registration fee**

CONFERENCE PROGRAM POSTERS
At the Moscone North Convention Center - February 20-22, 2017

- Your Poster will be available to over 3,000 delegates
- Posters will be on display for three days in the exhibit hall
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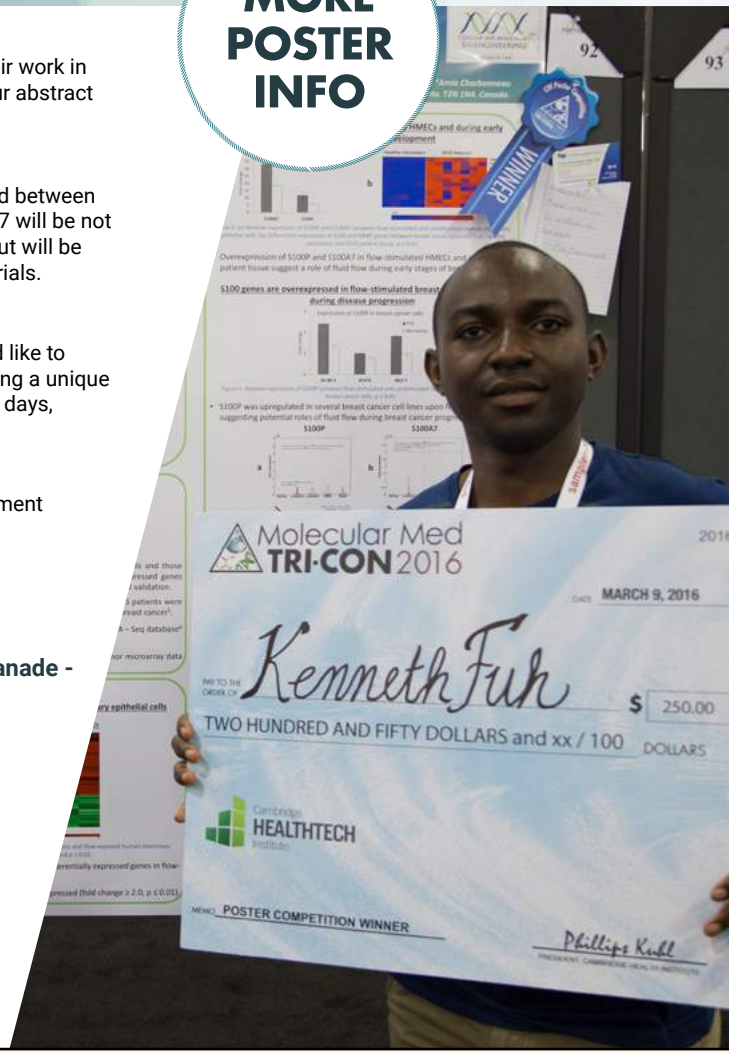
SYMPOSIA POSTERS
At the Moscone Center South, Esplanade - February 23-24, 2017

- Topic-specific poster sessions
- Targeted audience
- Automatically entered into the poster competition

People's Choice Poster Awards

- Two Conference Program award winners and one Symposia award winner will each receive $250.

MORE POSTER INFO



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

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

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Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, lunch, or separate from the main agenda within a pre-conference workshop. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly, so sign on early to secure your talk!

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Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

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Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, 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

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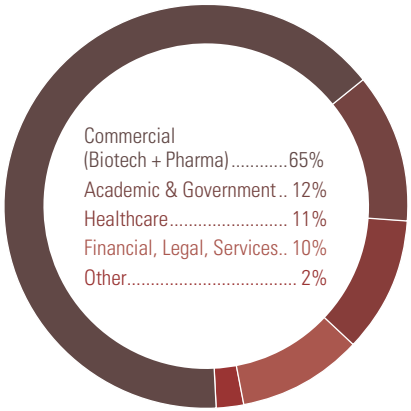
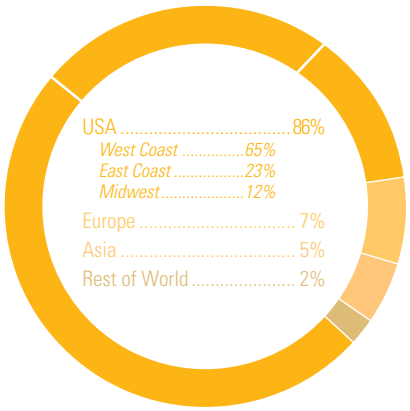


COMPANY TYPE



GEOGRAPHIC LOCATION

DELEGATE TITLE

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

Companies A-K
Jon Stroup, Sr Business Development Manager
781-972-5483 | jstroup@healthtech.com

Companies L-Z
Joseph Vacca, M.S., Director, Business Development
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The Moscone North Convention Center
747 Howard Street
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www.moscone.com

Symposia Conference Venue:
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San Francisco, CA 94103
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Host Hotel:
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Reservations:
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Discounted Room Rate:
$299 s/d

Discounted Room Cut-off Date:
January 20, 2017

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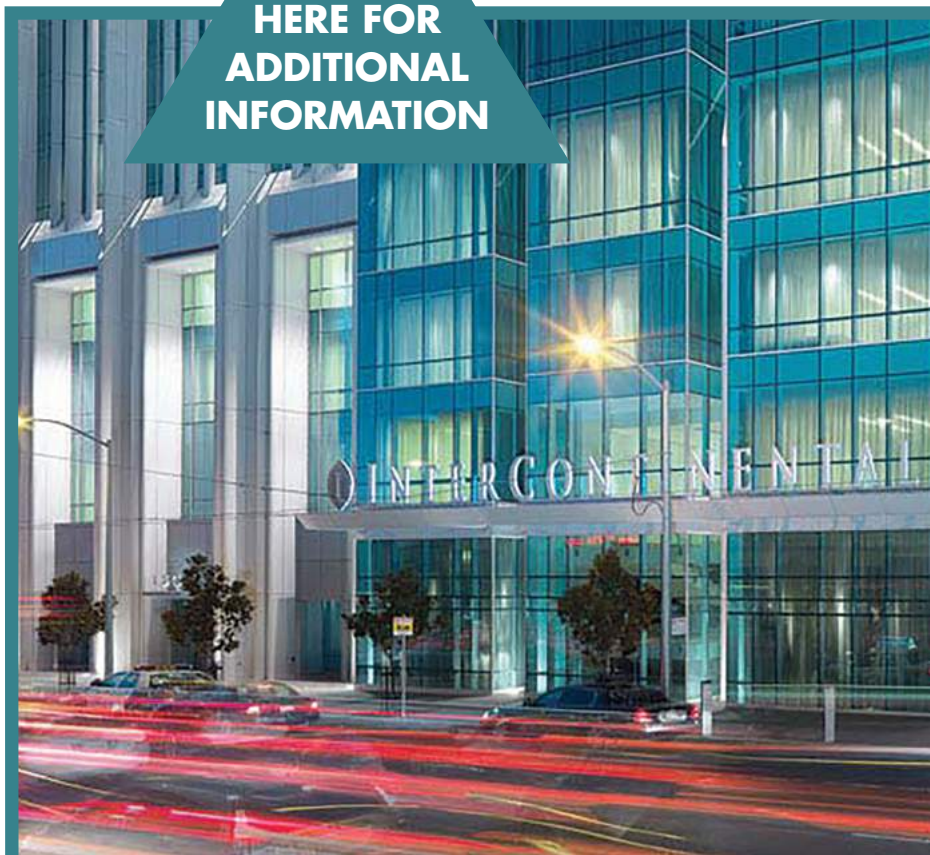

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FEBRUARY 19-24, 2017
SAN FRANCISCO, CA
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Sunday, February 19
2:00 – 5:00 PM & 5:30 – 8:30 PM

Monday, February 20
8:00 – 11:00 AM

Wednesday, February 22
6:00 – 9:00 PM

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(P8) Clinical NGS Diagnostics
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How to Register: TriConference.com

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All poster abstracts are due no later than January 13, 2017.

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