BIOMARKERS & IMMUNO-ONCOLOGY

WORLD CONGRESS 2018

The Leading Annual Meeting Where Big Pharma and Biotech Drive Innovation and Collaboration in Biomarkers, Diagnostics, and Immunotherapy

June 11 - 13, 2018 • Westin Boston Waterfront • Boston, MA

June 11 - 12

- Immuno-Oncology Biomarkers 1: Predictive Biomarkers and Companion Diagnostics
- Combination Immunotherapy

June 12 - 13

- Immuno-Oncology Biomarkers 2: Immune Profiling and Immune Monitoring
- Intrinsic and Acquired Resistance to Immunotherapy

BIOMARKERS

- Clinical and Translational Biomarkers
- Digital Biomarkers: Biosensors, Wearables, and mHealth

DISTINGUISHED SPEAKERS

- Roy D. Baynes, SVP and Chief Medical Officer, Merck
- Robert A. Anders, Co-Director, Tumor Microenvironment Center, Johns Hopkins University
- Stefan J. Scherer, VP & Head, Early Development, Novartis
- George Poste, Chief Scientist, Complex Adaptive Systems, Arizona State University
- George A. Green, IV, Head, Pharmacodiagnostics, Bristol-Myers Squibb
- Arnold B. Gelb, MD, MS, FASCR, FCAP, Advisor, Companion Diagnostic Development, Merck
- Christopher M. Hartshorn, Director, Cancer Treatment and Diagnosis, NCI, NIH
- Shirin Khambata Ford, Global Head, Biomarkers and Diagnostics, Merck
- Daniel Karlin, Head, Experimental Medicine, Pfizer
- Cecilia Schott, VP, Precision Medicine, AstraZeneca
- Mark E. Curran, VP and Head, Companion Diagnostics, Janssen Immunology
- Christian Gossens, Global Head, Early Development, Roche
- Marc Ladanyi, Chair, Molecular Oncology & Diagnostics, Memorial Sloan-Kettering
- Fred Ramsdell, VP, Research, Parker Inst. for Cancer Immunotherapy

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- Literature Distribution (Tote Bag Insert or Chair Drop)
- Padfolios
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- And More!

Looking for additional ways to drive leads to your sales team?
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- Whitepapers
- Webinars
- Custom Market Research Surveys
- Podcasts

2017 Attendee Demographics

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## Conference-at-a-Glance

### Sunday, June 10
- 4:30-6:30 pm: Short Course Registration and Conference Registration
- 5:00-8:30 pm: Dinner Short Course (SC1): Fit for Purpose Biomarker Assay Development and Validation (*Separate registration required)

### Monday, June 11
- 7:00 am: Conference Registration and Morning Coffee
- 8:00-9:10 am: Opening Plenary Session: Emerging Approaches for Cancer
- 9:10-9:55 am: Coffee Break in the Exhibit Hall with Poster Viewing
- 9:55-12:00 pm: Patient Selection Biomarkers and Companion Diagnostics in Immuno-Oncology
  - Biomarkers to Predict Response to Immunotherapy
  - Rational Combination Immunotherapy Strategies
  - Liquid Biopsy for Precision Medicine
  - Biosensors and Wearables as Biomarkers in Clinical Development
- 12:00-1:25 pm: Luncheon Presentation*
  - Sponsored by
- 1:25-3:30 pm: Biomarkers to Predict Response to Immunotherapy Continues
  - Combination Immunotherapy with Personalized Vaccines
  - Liquid Biopsy for Precision Medicine Continues
  - Biosensors and Wearables as Biomarkers in Clinical Development Continues
- 3:30-4:10 pm: Refreshment Break in the Exhibit Hall with Poster Viewing
- 4:10-5:45 pm: Biomarkers to Predict Response to Immunotherapy Continues
  - Combination Immunotherapy with Personalized Vaccines
  - Liquid Biopsy for Precision Medicine Continues
  - Biosensors and Wearables as Biomarkers in Clinical Development Continues
- 5:45-6:45 pm: Welcome Reception in the Exhibit Hall with Poster Viewing

### Tuesday, June 12
- 7:25-8:25 am: Interactive Breakout Discussion Groups with Continental Breakfast
- 8:25-10:30 am: Liquid Biopsy for Immuno-Oncology
  - Targeting the Tumor Microenvironment: Activating the Immune System for Better Response to Immunotherapy
- 10:00-11:10 am: Coffee Break in the Exhibit Hall with Poster Viewing
- 11:10-12:45 pm: Tumor Neoantigens as Biomarkers and Targets
  - Assay Development and Clinical Implementation for Genomic Tests
  - Clinical Applications of Smartphones: New Source of Digital Biomarkers
- 1:00 pm: Conference and Think Tank Registration
- 1:55-3:30 pm: Microsatellite Instability and Mismatch Repair Deficiency Biomarkers
  - Mechanism of Non-Response: Resistance or Lack of Efficacy
  - Implementing Precision Medicine
- 3:30-4:30 pm: Refreshment Break in the Exhibit Hall. Last Chance for Poster Viewing
- 4:30-6:00 pm: Tumor Microenvironment Profiling
  - Mechanism of Non-Response: Resistance or Lack of Efficacy (Cont.)
  - Implementing Precision Medicine (Cont.)
- 6:30-9:00 pm: Dinner Short Course (SC2): Multiplexed Analysis of Tumor Tissues Using Spatially Resolved and Quantitative Platforms (*Separate registration required)

### Wednesday, June 13
- 7:25-8:25 am: Interactive Breakout Discussion Groups with Continental Breakfast
- 8:25-10:00 am: Integrated Biomarker Analysis for Precision Immuno-Oncology
  - Combination Immunotherapy to Overcome Resistance
  - Companion and Complementary Diagnostics
- 10:00-10:30 am: Networking Coffee Break
- 10:30-12:00 pm: Integrated Biomarker Analysis for Precision Immuno-Oncology (Cont.)
  - Emerging Targets and Therapeutic Strategies to Address Resistance
  - Companion and Complementary Diagnostics (Cont.)
- 12:00-1:25 pm: Luncheon Presentation (Sponsored by)
  - Lunchen Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own
- 1:25-3:00 pm: Immune Monitoring: Biomarkers of Response and Resistance
  - Mutation Analysis to Guide Therapy
- 3:00 pm: Close of Conference

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**Now in Boston!**
Now in Boston!

**To Register!**

**Cover**

Sponsor & Exhibit Opportunities

**Conference-at-a-Glance**

Distinguished Speakers

**Short Courses**

Immu-Oncology Biomarkers 1

Immu-Oncology Biomarkers 2

Combination Immunotherapy

Intrinsic and Acquired Resistance to Immunotherapy

Clinical and Translational Biomarkers

Biomarkers for Patient Selection

Digital Biomarkers: Biosensors, Wearables, and mHealth

Hotel & Travel Information

Registration Information

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**Distinguished Speakers**

John L. Allison, FBIBMS, Vice President, Biomarker Services, Biologics Development Services, Tampa Bay

Robert A. Anders, MD, PhD, Associate Professor, Pathology & Director, Tumor Microenvironment Center, Bloomberg-Kimmel Institute for Cancer Immunotherapy, Johns Hopkins University

Jiri Auberch, PharmD, PhD, Senior Director, Translational Biomanufacturing Development, Pfizer

Xinfeng Bao, PhD, Director, Immuno-Oncology, Eisai

J. Carl Barrett, PhD, Vice President, Oncology Translational Sciences, Astra Zeneca

Roy D. Baynes, MD, PhD, Senior Vice President and Head, Global Clinical Development, CMG, Merck

Research Laboratories

Robert A. Beckman, MD, Professor, Oncology, Biostatistics, Bioinformatics, and Biomathematics, Ludwig Institute for Cancer Research, City of Hope National Medical Center

Arnold Gelb, MD, MS, FASCP FCAP, Advisor, Companion Diagnostic Development

Marios Giannakos, MD, PhD, Medical Oncologist & Clinical Investigator, Dana-Farber Cancer Institute, National Cancer Institute

Fujinon St. Foundation for Parkinson’s Research

Morganna Freeman, MD, Clinical Oncologist, Immunotherapeutics, The Angeles Clinic and Research Institute

Jianjun Gao, MD, PhD, Assistant Professor, Genitourinary Medical Oncology, The University of Texas MD Anderson Cancer Center

Nina Farber Garabedian, PhD, Director of Clinical Treatment Center, Researcher, Broad Institute of MIT and Harvard

Daniel Karlin, MD, MA, Head, Clinical, Immunological and Hematology/Oncology, Immunology, Icahn School of Medicine at Mount Sinai

Christian Gossens, PhD, MBA, Global Head, Early Development Workflows, pRED Informatics, Roche Pharmaceuticals Research and Early Development

Daniel Grant, PhD, Director, Early Development Lead, Novartis

George A. Green, IV, PhD, Head, Pharmacodynamics, Bristol-Myers Squibb

Abdel B. Haliim, PharmD, PhD, DABCC, FAAC, Vice President, Translational Medicine, Biomarkers & Diagnostics, Celldex Therapeutics

Gerard Hall, PhD, Principal Research Scientist, Experimental and Translational Immunology-Oncology: Biomarkers, Eli Lilly

Samar Hanash, MD, PhD, Director, McCombs Institute for Cancer Early Detection and Treatment, MD Anderson Cancer Center

Brent A. Hanks, MD, PhD, Assistant Professor, Cancer Immunology/Immunotherapy, Duke Cancer Institute

Christopher M. Hartsough, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

Elena Izmalkov, PhD, Senior Director, Novel Data Streams and Devices, Data Science Institute, Takeda Pharmaceuticals International, Inc.

Vladimir Jankovic, MD, PhD, Director, Early Clinical Development & Experimental Sciences, Regeneron

Felix Janku, MD, PhD, Associate Professor, Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center

Sarah Javaid, PhD, Associate Principal Scientist, Merck & Co.

John Milburn Jessup, MD, Scientific Director, Precision Cancer Care Program, Inova Schar Cancer Institute; Professor, Systems Biology, Krasnow Institute of Advanced Study, George Mason University

Bruce E. Johnson, MD, Professor of Medicine, Harvard Medical School

Karin Jooss, PhD, CSO, Gritstone Oncology

Pawel Kalinski, MD, PhD, Professor, Oncology, Vice-Chair, Translational Research, Roswell Park Cancer Institute

Maria Karasirides, PhD, Executive Director, Immuno-Oncology, Regeneron Pharmaceuticals

Daniel Karlin, MD, MA, Head, Clinical, Immunological and Hematology/Oncology, Immunology, Icahn School of Medicine at Mount Sinai

Frank Kramer, PhD, Director & Biomarker Strategist, Cardiovascular Diseases, Bayer AG

Mark Lackner, PhD, Director and Principal Scientist, Genentech

Marc Ladanyi, MD, William J. Ruane Chair in Molecular Oncology, Molecular Diagnostics Service and Human Oncology & Pathogenesis Program, Memorial Sloan-Kettering Cancer Center

Rebecca Leary, PhD, Lab Head, Next Generation Diagnostics, Novartis Institutes for BioMedical Research

Joel Lefferts, PhD, Assistant Professor, Pathology, Assistant Director, Genomic Diagnostics and Research, Advanced Technology (CGAT), Geisel School of Medicine at Dartmouth, Dartmouth-Hitchcock Medical Center

Andrey Loboda, PhD, Director, Genetics and Pharmacogenomics, Merck

Christina Lockwood, PhD, Associate Professor, Director, Genetics and Solid Tumors Laboratory, University of Washington

Patricia LoRusso, DO, Director, Medical Oncology, Yale University

Rajkumar (Raja) Luthra, PhD, Director, Molecular Diagnostics Laboratory; Director, Molecular Diagnostics Program, Professor, Division of Pathology and Laboratory Medicine, The University of Texas MD Anderson Cancer Center

Christopher Major, PhD, Scientific Director, Diagnostic Development, Janssen

Rajat Mandal, MD, Head and Neck Surgical Oncologist, Memorial Sloan Kettering Cancer Center

Sanjeev Mariathasan, PhD, Senior Scientist, Oncology Biomarker Department, Genentech

James R. Mault, MD, FACS, Senior Vice President and CMO, Qualcomm Life

Jennifer J.D. Morrissette, PhD, Scientific Director, Clinical Cancer Cytogenetics, Clinical Director, Center for Personalized Diagnostics, University of Pennsylvania

Unik B. Nielsen, PhD, President and Co-Founder, Torque

Carol Anne Ogden, PhD, Senior Manager and ADECTRIS Biomarker Lead, Diagnostics and Biomarkers, Seattle Genetics, Inc.

Shuj Ogino, MD, PhD, Professor (Pathology & Epidemiology), Brigham & Women’s Hospital, Dana-Farber Cancer Institute, Harvard Medical School, Harvard T.H. Chan School of Public Health; Associate Member, Broad Institute of MIT and Harvard

Tushar Paritkar, PhD, Product Manager, Verily Life Sciences

Bakul Patel, Associate Director, Digital Health, FDA

Tracy Petrie, PhD, MolleMapper Product Manager, Oregon Health & Science University

Robert Pierce, MD, Scientific Director, Immunopathology Core, Fred Hutchinson Cancer Research Center

Katerina Politi, PhD, Associate Professor, Pathology, Yale School of Medicine

George Poste, DVM, PhD, Chief Scientist, Complex Adaptive Systems, Regents’ Professor and Del E. Webb Chair in Health Innovation, Arizona State University

Laszlo Radiavny, PhD, Senior Vice President & Senior Global Scientific Advisor, Immuno-Oncology, EMD Serono

Osama Rahma, MD, Assistant Professor, Medicine, Dana-Farber Cancer Institute, Harvard Medical School

Fred Ramsdell, PhD, Vice President, Parker Institute for Cancer Immunotherapy

Susanne K. Rhoades, PhD, Director, Diagnostics Development, Tailored Therapeutics, Eli Lilly and Company

David L. Rimm, PhD, Professor, Pathology, Yale University

David B. Roth, MD, PhD, Simon Flexner Professor and Chair, Department of Pathology and Laboratory Medicine Director, Penn Center for Precision Medicine

Kurt Schalper, PhD, Assistant Professor, Pathology and Medicine (Medical Oncology), Yale School of Medicine

Stefan J. Scherer MD, PhD, Vice President & Head, Early Development, Strategy and Innovation, US Oncology, Amgen

Emmett Schmidt, MD, Assistant Professor, Cancer Immunology, AstraZeneca

Sadhna Shankar, MD, MPH, Senior Director, Clinical Research & Development, MacroGenics

Peter M. Shaw, PhD, Head, Clinical Pharmacogenetics, Merck

Daniel Stetson, PhD, Associate Principal Scientist, AstraZeneca

Zhen Su, MD, MBA, CMG, North America, EMD Serono, Inc.

Ryan J. Sullivan, MD, Assistant Professor, Hematology & Oncology, Massachusetts General Hospital; Assistant Professor, Medicine, Harvard Medical School

Elizabeth Thompson, MD, PhD, Assistant Professor, Pathology and Oncology, The Johns Hopkins University School of Medicine

Gregory Tsongalis, PhD, Professor, Pathology & Laboratory Medicine, Dartmouth College

Shannon J. Turley, PhD, Principal Scientist, Cancer Immunology, Genentech

Gabriel Vargas, MD, PhD, Executive Medical Director, Digital Health & Neuroscience, CareDigm Therapeutic Area Health, Early Development, Amgen

Sylvie Vincent, PhD, Associate Director, Translational Medicine, Takeda

Dan E. Webster, PhD, Principal Scientist of Digital Health, Sage Bionetworks

Glen J. Weiss, MD, MBA, Director, Phase I Clinical Development, Beth Israel Deaconess Medical Center, Boston

Theresa L. Whiteside, PhD, Professor, Pathology, Immunology and Otolaryngology, University of Pittsburgh Cancer Institute

Wendy Winkler, PhD, Executive Director, Next Generation Diagnostics, Novartis Institutes for Biomedical Research

 Timothy Yap, MD, PhD, Associate Professor, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center

Jiandie Yuan, MD, PhD, Senior Director, Translational Oncology, Early Clinical Oncology Development, Merck Research Labs
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**SUNDAY, JUNE 10, 5:00-8:30 PM**

**DINNER SHORT COURSE**

**SC1: Fit-for-Purpose Biomarker Assay Development and Validation**

Instructors:
John L. Allinson, FIBMS, Vice President, Biomarker Services, Biosigns Development Services, Tampa Bay Viswanath Devanarayanan, PhD, Global Head of Statistics & Data Sciences, Charles River Laboratories

This tutorial will provide recommendations on the “fit-for-purpose” best practices in the development and validation of biomarker assays for exploratory or advanced biomarker applications. Strategies for different applications at various phases of biomarker development will be described. Key elements in the method of development and validation will be illustrated with examples, including reference to standard material, sample stability and collection integrity, validation and QC samples, validity of reference standards, calibration curve fitting methods, method optimization and feasibility studies. Special challenges in protein biomarker assays will be discussed, including strategies for moving from biomarker panels in the exploratory phase to the few markers chosen to support clinical trials, cross-validation of biomarker assays, etc.

**Outline:**
1. Introduction: Nomenclature, types of biomarker methods/assays, method development and validation road-map, fundamental validity, similarity and differences from PK assays and diagnostic applications
2. Pre-analytical and biochemical elements: Target range, standards, validation and QC samples, stability, matrix effect, specificity and relative selectivity
3. Calibration curve model selection, evaluation and weighting
4. Method feasibility and optimization with precision profiles
5. Evaluation of some pre-study validation characteristics such as precision, bias, sensitivity and quantification limits
6. Use of sample controls for in-study performance monitoring and conformance testing among laboratories
7. Special considerations for multiplex assays, cross-validation of assays, etc.
8. Method comparisons

**TUESDAY, JUNE 12, 6:30-9:00 PM**

**DINNER SHORT COURSE**

**SC3: Multiplexed Analysis of Tumor Tissues Using Spatially Resolved and Quantitative Platforms**

Instructor:
Kurt A. Schalper, MD, PhD, Assistant Professor: Pathology and Medicine (Medical Oncology), Yale School of Medicine; Director, Translational Immunology-Oncology Laboratory, Yale Cancer Center

In this course we will discuss novel strategies to simultaneously analyze multiple biomolecules/analytes such as protein and mRNA targets in tumor tissues using diverse platforms including multispectral fluorescence, mass spectrometry imaging and barcoding-based signal detection systems. We will review the technical principles, practical aspects, determinants for optimal performance and possible uses in oncology research.

**Outline:**
1. Introduction: Current state of tissue biomarker analysis, major clinical/research uses. Value of spatial context and quantitative output
2. Platforms for multiplexed/quantitative measurement of tissue biomarkers
3. Principles and practical considerations of multiplexed tissue analysis
4. Sample preparation, assay validation strategies and reproducibility assessment
5. Use of multiplexed analysis for biomarker assessment

**TUESDAY, JUNE 12, 1:45-5:30 PM**

**Executive ThinkTank**

**SC2: Digital Biomarker Implementation Strategies**

Discussion Leader:
Daniel Karlin, MD, MA, Head, Clinical, Informatics and Regulatory Strategy, Digital Medicine and the Pfizer Innovation Research Lab

Panelists:
Michael J. Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision and Digital Medicine, R&D Chief Regulatory Office, GlaxoSmithKline
Peter Bergethon, MD, Vice President, Quantitative Medicine and Clinical Technologies, Biogen
Yu-Feng Yvonne Chan, MD, PhD, Associate Professor, Genetics and Genomics Sciences & Emerging Medicine; Director, Center for Digital Health, Icahn Institute for Genomics and Multiscale Biology, Icahn School of Medicine at Mount Sinai
Ieuan Clay, PhD, Group Lead, Digital Endpoints, Translational Medicine, Novartis Institute for Biomedical Research

Christian Gossens, PhD, MBA, Global Head, Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development
Daniel Grant, PhD, Director, Early Development Lead, Novartis
Gabriel Vargas, MD, PhD, Executive Medical Director, Digital Health & Neuroscience Therapeutic Area Head, Early Development, Amgen

**1:15-1:45 Introductions and Lunch Provided**

**1:45 Roundtable: Choosing Digital Endpoints in Clinical Trials**

- How are digital biomarkers different from traditional biomarkers?
- What clinical evidence is required for using digital biomarkers as clinical outcome measure in clinical trials?
- What is the value proposition for digital endpoints?
- How to progress digital endpoints beyond the exploratory phase?
- How to deal with clinical meaningfulness and regulatory acceptability of digital biomarker data?
- How to choose and validate a digital biomarker for a new application when there is no current biomarker for reference?
- What are the emerging applications for digital biomarkers?

**3:00 Networking Refreshment Break**

**3:45 Roundtable: Technology Advances in Biosensors, Wearables and mHealth for Clinical Applications**

- How to validate digital biomarkers?
- What would be sufficient qualification for regulatory acceptance?
- What evidence is needed for market access and payer acceptance?
- What are the challenges and opportunities for using wearables, biosensors and smartphones in clinical development?
- Can technology and analytics keep up with endpoint development?
- What data sharing and data standards are needed to enable progression?
- Is there a consortium validation model for digital biomarkers?
- Where will the technology and implementation stand in 5 years?

**5:00 Close of ThinkTank**
**OPENING PLENARY SESSION: EMERGING APPROACHES FOR CANCER**

8:05 Chairperson’s Opening Remarks
George A. Green, IV, PhD, Head, Pharmacodiagnostics, Bristol-Myers Squibb

8:10 Clinical Genomic Profiling Using the MSK-IMPACT™ Large Panel NGS Assay to Guide Patient Selection for Targeted and Immune Therapies
Marc Ladanyi, MD, William J. Ruane Chair in Molecular Oncology, Molecular Diagnostics Service and Human Oncology & Pathogenesis Program, Memorial Sloan-Kettering Cancer Center

As the centerpiece of an institutional initiative in clinical cancer genomics, we have implemented large scale genomic profiling for targetable cancer drivers and other cancer-relevant alterations in all patients with advanced solid cancers. Since 2014, over 23,000 patients have been profiled using the MSK-IMPACT™ targeted large panel, capture-based DNAseq assay. MSK-IMPACT™, which received FDA clearance in 2017, allows robust detection of somatic mutations in all known cancer genes, copy number changes and select cancer fusion gene rearrangements, as well as assessing overall tumor mutation burden and microsatellite instability. Patients are also screened for oncogenic fusions by targeted RNAseq and for germline cancer predisposition alleles and evidence of clonal hematopoiesis.

8:40 Widgets to Cancer Patient-Specific Digits: The Case for Out-of-Clinic Objective Measures and Their Potential Impact to Remote Patient Monitoring in Precision Oncology and Discovery
Christopher M. Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

Albeit the case for long-term, out-of-clinic monitoring has been obvious for many chronic diseases, the case for cancer has not been as clear. The National Cancer Institute has begun piloting and funding various aspects to enable an Internet of Cancer Medical Things. This talk will focus on these efforts currently and prospectively as well as the overall vision to coordinate a much broader initiative to improve our understanding of cancer progression and improve the delivery of cancer care.

9:10 Coffee Break in the Exhibit Hall with Poster Viewing

**PATIENT SELECTION BIOMARKERS AND COMPANION DIAGNOSTICS IN IMMUNO-Oncology**

9:55 Chairperson’s Remarks
Shirin Khambata Ford, PhD, Global Head, Biomarkers and Diagnostics, Executive Director, Oncology Global Medical Affairs, Merck

10:00 Patient Selection Strategies for Making Precision Medicine a Reality for Immuno-Oncology
Shirin Khambata Ford, PhD, Global Head, Biomarkers and Diagnostics, Executive Director, Oncology Global Medical Affairs, Merck

This talk will highlight the development and implementation of the PD-L1 IHC testing globally to select patients for pembrolizumab treatment across different tumor types. It will also focus on some of the more recent biomarker approaches that are being utilized to optimally select patients who will benefit from anti-PD1 therapies such as microsatellite instability/mismatch repair deficiency assessment and tumor mutation burden.

10:30 Transitioning from Exploratory Tumor Mutation Burden Assays to IVD Platforms for Immuno-Oncology
George A. Green, IV, PhD, Head, Pharmacodiagnostics, Bristol-Myers Squibb

A range of methods exist for measuring tumor mutation burden (TMB), including whole exome sequencing (WES) and genomic profiling assays (e.g. FoundationOne®). While WES is used in research, more efficient methods, such as FoundationOne®, are being assessed for clinical use. Therefore, harmonization of various tests will be essential to establish diagnostics. This discussion will expand on previous data demonstrating concordance between WES and FoundationOne® in pursuit of an IVD assessing TMB.

11:00 Differential Response of Target Germline Variation Reveals Patient Enrichment Strategy for a Novel Cancer Immunotherapy
Xingfeng Bao, PhD, Director, Immuno-Oncology, Eisai

In the discovery and development of cancer immunotherapy, the polymorphic nature of immune therapeutic targets and limited translatability of mouse models make prediction of human response to an immunotherapy challenging. In this presentation, we will discuss an application of human germline genetics and primary human tumor tissues for the characterization and translational biomarker discovery of a novel drug candidate.

11:30 CO-PRESENTATION: Proteomic Profiling of Biomarkers for Response to Immunotherapy in Melanoma Patients Using Proximity Extension Assay
Ida Grundberg, PhD, Business Development Manager, Sales, Olink Proteomics
Marjana Rucevic, PhD, Business Development Manager, Sales, Olink Proteomics

Checkpoint immunotherapy has greatly improved clinical outcomes in the subset of melanoma patients which urges a need to develop biomarkers for therapy response. Olink’s Proximity Extension Assay was applied to profile around 1,000 validated plasma proteins in 58 melanoma patients treated with anti-PD-1 or anti-PDL-1 (44 responders and 14 non-responders). Results demonstrate significant changes in around 100 protein biomarkers over the course of treatment and six proteins were identified as potential markers of therapy response.
12:00 pm Luncheon Presentation: Validation of an RNA-Based Immune Profiling Assay for Limiting & Diverse Patient Samples
Natalie LaFranzo, Director, Scientific Projects and Market Development, Cofactor Genomics

The success of immunotherapy development relies on robust approaches for characterizing and interpreting a patient’s immune system; specifically, the microenvironment surrounding a tumor. Using RNA-seq and machine-learning informatics, Cofactor’s Paragon assay overcomes current challenges associated with commonly used methods, even for limiting and degraded samples. Complex molecular signals are measured and reported in an easy to interpret report. Case study data with control samples and patient materials will be discussed.

BIOMARKERS TO PREDICT RESPONSE TO IMMUNOTHERAPY

1:25 Chairperson’s Remarks
David L. Rimm, MD, PhD, Professor, Pathology, Yale University

1:30 Immunophenotyping to Differentiate Responder and Non-Responder Patients in Cancer Immunotherapy
George Poste, DVM, PhD, Chief Scientist, Complex Adaptive Systems, Regents’ Professor and Del E. Webb Chair in Health Innovation, Arizona State University

The clinical benefits of immune checkpoint inhibitors in a variety of malignancies are unprecedented. Unfortunately, the level of positive therapeutic response is not consistent across different tumor classes and even in responsive tumor lineages non-responders still dominate. The need for comprehensive immunophenotyping to identify the mechanisms underlying these differential responses and better predict responder patients is an urgent clinical and economic imperative.

2:00 Dual Biomarker Strategy to Understand Novel Translational Biomarkers to Stratify Patients Effectively for Personalized Cancer Immunotherapy
Jianda Yuan, MD, PhD, Senior Director, Translational Oncology, Early Clinical Oncology Development, Merck Research Labs

Immune checkpoint blockade therapies are revolutionizing the standard cancer treatment. Despite the current success of these therapies, not all patients respond to immunotherapy, and even those that do often experience toxicities. Combination approaches are the keys to improving clinical response. High throughput next-generation sequencing technologies enable us to explore the mechanisms of responses as well as resistance. Emerging dual biomarkers (tumor mutational burden and gene expression profile) allow us to understand novel translational biomarkers to stratify patients effectively for personalized cancer immunotherapy.

2:30 Predicting Response to Immunotherapy: PD-L1 and Beyond
David L. Rimm, MD, PhD, Professor, Pathology, Yale University

Prediction of response to PD-1 axis drugs began with simple IHC-based assessment of PD-L1 with different assays matched to different drugs. More recently, assessment of DNA MMR has gained its first approval as a predictive assay. This presentation will discuss these tests and future more sophisticated tests for protein, including expression in the microenvironment and the tumor, mRNA, as expression signatures, and DNA, including tumor mutational burden.

3:00 Mitigating Risk when Navigating the Journey from Biomarker Assay Validation to the Commercial Deployment of a CDx
Cindy Spittle, PhD, Vice President, Development and Scientific Affairs, MolecularMD

Multiple biomarker assays and methodologies are being explored for use in I/O studies. Examples of methods currently being used for MSI, TMB and gene expression analysis will be reviewed. Insights regarding the technical, regulatory and operational factors that should be evaluated when selecting an assay for implementation in a clinical trial and co-development as a companion diagnostic will be discussed.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:10 Chairperson’s Remarks
David L. Rimm, MD, PhD, Professor, Pathology, Yale University

4:15 The New Precision Medicine: The Role of Dynamic Tumor and Immune Sampling in Immunotherapy
Margonna Freeman, DO, Medical Oncologist, Immunotherapeutics, The Angeles Clinic and Research Institute

4:45 The Genomic and Immunologic Determinants of Response to Cancer Immunotherapy
Rajarsi Mandal, MD, Head and Neck Surgical Oncology Fellow, Memorial Sloan Kettering Cancer Center

Immune checkpoint blockade is a promising approach for the treatment of human malignancies and has led to improved response rates and durable clinical benefit in a subset of patients. However, the extent to which patients derive benefit is diverse and the determinants of response to therapy are ill-defined. We have sought to define the genomic and immunologic 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 the tumor immune landscape help dictate clinical response to immune-based therapies.

5:15 Tumor Microenvironment as Biomarker for Immunotherapy
Kien Thiam Tan, PhD, Vice Director, Medical Informatics, ACT Genomics

The success of immune checkpoint inhibitors in a subset of cancer patients has led to major efforts in identifying predictive biomarkers. In addition to PD-L1 staining and tumor mutational burden, factors such as immune cell compositions and checkpoint molecule profiles, antigen presenting machinery and immune resistance signals, should also be considered when evaluating a patient for immunotherapy. In this talk, a novel chip-based assay to monitor tumor microenvironment using FFPE tissue will be presented.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

TUESDAY, JUNE 12

7:25 am Interactive Breakout Discussion Groups with Continental Breakfast
This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific discussion group.
group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

**LIQUID BIOPSY FOR IMMUNO-ONCOLOGY**

8:25 Chairperson's Remarks
Theresa L. Whiteside, PhD, Professor, Pathology, Immunology and Otolaryngology, University of Pittsburgh Cancer Institute

8:30 Tumor-Derived Exosomes as Potential Biomarkers of Cancer Progression and Immune Dysfunction in Cancer
Theresa L. Whiteside, PhD, Professor, Pathology, Immunology and Otolaryngology, University of Pittsburgh Cancer Institute

Plasma-derived exosomes are emerging as promising non-invasive correlates of cancer progression. In patients with solid tumors or hematological malignancies, plasma exosomes carry a cargo enriched in immunosuppressive proteins. As immune suppression is one of the hallmarks of cancer progression, circulating exosomes rich in inhibitory molecules are implicated in mediating systemic immune suppression.

9:00 Profiling the Tumor Immune Microenvironment by Means of Liquid Biopsy
Samir Hanash, MD, PhD, Director, McCombs Institute for Cancer Early Detection and Treatment, MD Anderson Cancer Center

Interest in liquid biopsy has largely focused on ctDNA. However, plasma has a rich content in cells, extra-cellular vesicles and biomolecules that inform about tumor features, the microenvironment and the status of the immune response. Progress in defining the tumor microenvironment in solid tumors by means of liquid biopsy will be presented.

9:30 Clinical Applications of cfDNA for Targeted and Immune Therapies
Rebecca Leary, PhD, Lab Head, Next Generation Diagnostics, Novartis Institutes for BioMedical Research

Circulating tumor DNA (ctDNA) provides an opportunity for non-invasive assessment of tumor genotype, and may enable rational use of targeted and/or immune modulating therapies at several clinical milestones. Implementation of ctDNA-based assays across clinical and research settings highlights important assay characteristics and suggests future clinical applications.

10:00 Molecular Analysis of an Adaptive T Cell Response against an IL-12 Adjuvanted Vaccine: From Molecule to Mechanism
Wyatt McDonnell, Graduate Fellow, Pathology, Microbiology and Immunology, Vanderbilt University School of Medicine

The cytokine IL-12 is known to enhance the function and quality of cytotoxic T lymphocytes (CTLs) against antigens, especially in the context of vaccines. In this study, we analyzed samples from the HIV Vaccine Trial Network (HVTN) study 087. We report the enhancement of the cellular response in individuals receiving IL-12 and identify several potential markers of successful IL-12 adjuvanted vaccination.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing
TUESDAY, JUNE 12

12:15 pm Conference Registration

12:55 Luncheon Presentation: Diagnostic Solutions for Multi-Arm I-O Clinical Trials

Steven Walker, PhD, Head, Internal Product Management, Almac Diagnostics

During this talk participants will learn about Almac Diagnostics’ - Novel strategy for patient stratification in Basket & Umbrella trials - Solution to enable multiple biomarkers to be evaluated from one sample - Cancer panel solutions for both DNA & RNA - Unique product offering for Immuno-Oncology - Customised patient reporting enabling simple interpretation of molecular data.

1:25 Session Break

MICROSATELLITE INSTABILITY AND MISMATCH REPAIR DEFICIENCY BIOMARKERS

1:55 Chairperson's Opening Remarks

Kenneth Emancipator, MD, Executive Medical Director and Head of Companion Diagnostics, Merck & Co.

2:00 Biomarkers for Mismatch Repair Deficiency in Cancer

Robert A. Anders, MD, PhD, Associate Professor, Pathology; Co-Director, Tumor Microenvironment Center, Bloomberg-Kimmel Institute for Cancer Immunotherapy, Johns Hopkins University

The program presents an overview of microsatellite instability (MSI) and mismatch repair defect (MMRD) in colorectal cancer. While much work has focused on the tumor immune microenvironment of established cancers, little is known about the immune response to the earliest stages of tumor development. This talk will explore the immune microenvironment of neoplastic precursor lesions using ductal and lobular carcinoma in situ of the breast and pancreatic intraepithelial neoplasia and intraductal papillary mucinous neoplasm of the pancreas as models.

2:30 The First Biomarker-Defined Tumor Indication: FDA Approval of Pembrolizumab for MSI-High Cancer

Kenneth Emancipator, MD, Executive Medical Director and Head of Companion Diagnostics, Merck & Co.

The program presents an overview of microsatellite instability (MSI) and mismatch repair defect (MMRD), and how it fits into the tumor immunogenicity-inflammation pathway. It reviews the history and clinical evidence for MSI and MMRD as a predictive biomarker for response to pembrolizumab. It discusses the unprecedented – and unorthodox – path to FDA approval of pembrolizumab. Finally, it discusses MSI and MMRD in the broader context of biomarkers in immune-oncology.

3:00 The Power of Single Molecule Counting (SMC™): The Future of Immunoassays

Antaben Tailor, PhD, SMC Technology & Application Advancement Lead, Research & Development, MilliporeSigma

Single Molecule Counting (SMC™) uses the power of high definition technology to help accelerate biomarker research. Data generated with customers demonstrates picogram to femtogram quantification limits applicable to low abundance biomarkers. With the SMCxPro® Immunoassay System, even the smallest changes in biomarker levels can be measured, allowing researchers to gain unprecedented insights into complex disease, drug efficacy and drug safety.

3:30 Refreshment Break in the Exhibit Hall. Last chance for poster viewing.

4:25 Chairperson's Remarks

Marios Giannakis, MD, PhD, Medical Oncologist & Clinical Investigator, Dana-Farber Gastrointestinal Cancer Treatment Center; Researcher, Broad Institute of MIT and Harvard Medical School

4:30 Genetic Mechanisms of Immune Evasion in Colorectal Cancer

Marios Giannakis, MD, PhD, Medical Oncologist & Clinical Investigator, Dana-Farber Gastrointestinal Cancer Treatment Center; Researcher, Broad Institute of MIT and Harvard Medical School

We molecularly characterized 1,211 colorectal cancers (CRCs) and demonstrated that WNT-signaling and immune-related genes are significantly mutated in CRC. We also showed immuno-editing in microsatellite-instability high (MSI-H) tumors through biallelic antigen-presentation machinery mutations. In both microsatellite stable and MSI-H CRCs, we used transcriptional and immunohistochemical orthogonal analyses to demonstrate exclusion of an effective immune infiltrate through an active WNT-signaling pathway. These results can inform novel immunotherapy trials in CRC patients.

4:55 Bioinformatics and Clinical Applications of Immune Profiling

Marios Giannakis, MD, PhD, Medical Oncologist & Clinical Investigator, Dana-Farber Gastrointestinal Cancer Treatment Center; Researcher, Broad Institute of MIT and Harvard Medical School

We have developed a bioinformatic pipeline to analyze immune profiling data and have applied it to understand the clinical impact of various biomarkers. This talk will feature case studies that illustrate the power of combining clinical data with immune profiling to inform patient selection in clinical trials.

5:30 The Immune Microenvironment of Neoplastic Precursor Lesions

Elizabeth Thompson, MD, PhD, Assistant Professor, Pathology and Oncology, The Johns Hopkins University School of Medicine

While much work has focused on the tumor immune microenvironment of established cancers, little is known about the immune response to the earliest stages of tumor development. This talk will explore the immune microenvironment of neoplastic precursor lesions using ductal and lobular carcinoma in situ of the breast and pancreatic intraepithelial neoplasia and intraductal papillary mucinous neoplasm of the pancreas as models.

6:30 Dinner Short Course*

SC3: Multiplexed Analysis of Tumor Tissues Using Spatially Resolved and Quantitative Platforms

*Separate registration required

WEDNESDAY, JUNE 13

7:25 am Interactive Breakout Discussion Groups with Continental Breakfast

This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.
INTEGRATED BIOMARKER ANALYSIS FOR PRECISION IMMUNO-ONCOLOGY

8:25 Chairperson’s Remarks
Andrey Loboda, PhD, Director, Genetics and Pharmacogenomics, Merck

8:30 Paired and Dynamic Multiplex Analyses of Tissue Markers for Biomarker Discovery
Sacha Gnjatic, PhD, Associate Professor, Tisch Cancer Institute, Hematology/Oncology, Immunology, Icahn School of Medicine at Mount Sinai

With immunotherapy rapidly becoming standard of care for a variety of tumor types, including non-small cell lung, head and neck, and urothelial carcinoma, the new frontier is to understand mechanisms and identify biomarkers that explain why so many patients still fail to experience clinical benefit. The study of immune recognition of tumors is therefore of central importance, not only as a baseline measurement of immunocompetence that may be harnessed by immunomodulatory drugs, but also as a predictive biomarker of response with dynamic changes over time. Some of the most interesting biomarkers so far are based on intrinsic tumor immunogenicity, including cancer/testis antigens and neoantigens, as well as presence of a variety of immune cells that recognize these antigens or modulate immunity at the tissue site. Through development of novel high-dimensional approaches to investigate the tumor microenvironment in unprecedented depth, with the help of single cell technologies and dedicated deep-learning data analysis tools, a composite picture of the tumor microenvironment should help map the complexity of factors interacting locally that collectively have personalized prognostic or predictive value.

9:00 Integrating Data from High-Throughput, High-Content Platforms for Informative MOA Analysis of Single Agent and Combination Immunotherapies in Preclinical Models
Gerald Hall, PhD, Principal Research Scientist, Experimental and Translational Immuno-Oncology: Biomarkers, Eli Lilly

The use of biomarkers in preclinical immuno-oncology is critical for comprehensive hypothesis testing and generating insightful new MOA hypotheses in early preclinical development. The use of multiple integrated high-throughput, high-content cellular and molecular platforms, as well as model systems, allows for the interrogation of biological processes involved in drug treatment and generation of novel ideas regarding MOA, off target effects, and rational drug combinations.

9:30 Getting Closer to the Picture and Data for Immuno-Oncology Assays Using the Celigo Image Cytometer
Leo Chan, Technology Research & Development Manager, Nexcelom Bioscience LLC

Immuno-oncology assays are conducted by release assays, but can be inaccurate due to indirect supplant measurement. We demonstrated the detection of antibody/cell-mediated cytotoxicity in 2D/3D models using the Celigo. The image cytometer could analyze live cells to measure time/dose-dependent cytotoxicity. The proposed method can perform high-throughput cancer drug screening.

9:45 Tumor Immunogenomic Profiling: High-Content Assays and Analytics
Christelle Johnson, MS, PhD, Senior Field Applications Scientist, Cancer Genomics & Immuno-Oncology, Personalis, Inc.
Few platforms support multidimensional biomarker analysis. This talk will highlight ACE Immunio™ as a universal platform for biomarker discovery that enables comprehensive variant detection, neoantigen identification, and characterization of tumor immunogenomics. We will feature a case study demonstrating the platform’s ability to identify tumor escape mechanisms for cancer immunotherapy.

10:00 Networking Coffee Break

10:30 Molecular Mechanisms and Biomarkers Predictive of Response to Keytruda
Andrey Loboda, PhD, Director, Genetics and Pharmacogenomics, Merck
The talk will address molecular biomarkers of response to pembrolizumab, including the role of tumor antigenicity, as measured by mutational load (ML) and T cell inflamed microenvironment in predicting the response to pembrolizumab. Data will be presented that prospectively validates the utility of both biomarkers as tumor type agnostic and orthogonal measures of response. These findings provide a biomarker framework for development of pembrolizumab as a monotherapy and for characterizing responses to novel immunotherapy regimens.

11:00 Precision Immunology through Deeper Single-Cell Profiling
Pratip Chattopadhyay, PhD, Associate Professor, Pathology; Director, Precision Immunology Incubator, Isaac and Laura Perlmuter Cancer Center, New York University Langone Medical Center
Three trends have dominated biomedical research over the last decade. The first, the NIH Roadmap’s Single Cell Analysis Program, was founded on the principle that cells are extremely heterogenous, and that this heterogeneity is important in health and disease. For this reason, cells must be characterized individually, rather than by insensitive and misleading analysis of bulk cell populations. This trend renewed appreciation for cellular heterogeneity, and incited a revolution of new technologies that could comprehensively analyze single cells (the second trend, deep profiling). Finally, a third biomedical research trend was sparked by President Obama’s Precision Medicine Initiative, which aims to define genomic and proteomic differences between patient groups, and use this information to inform treatment decisions. In this talk, I will discuss my work at the intersection of these three trends, and demonstrate the value of new technologies for comprehensive and complete cellular analysis. I will provide examples of how deep knowledge about immune responses can be attained, using examples drawn from our recent work in immunotherapy and fundamental immunology. This talk will highlight our work developing 30 parameter flow cytometry, single-cell RNA sequencing, CITE-Seq (for simultaneous measurement of protein and transcripts), and new bioinformatic tools.

11:30 Integrative Analyses of Environment, Microbiota, and Tumor Immunity Can Inform Immuno-Oncology Research
Shuji Ogino, MD, PhD, Professor (Pathology & Epidemiology), Brigham & Women’s Hospital, Dana-Farber Cancer Institute, Harvard Medical School, Harvard T.H. Chan School of Public Health; Associate Member, Broad Institute of MIT and Harvard
The integrative field of “immunology-MPE” (molecular pathological epidemiology) is an emerging paradigm, and can investigate influences of the exposome (dietary, lifestyle, environmental, microbial, pharmacological, and other exposures) on tumor-immune interactions, thereby informing immunotherapy research. Using over

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BiomarkerWorldCongress.com
1,000 colorectal cancer cases with rich data on immune response, whole exome sequencing (tumor and normal DNA), tumor neoantigens, and clinical outcomes, proof-of-principle immuno-MPE studies have shown great promise for precision prevention and immuno-oncology.

**12:00 pm Luncheon Presentation: Enabling Multidimensional Translational Data Management & Analysis for Biomarkers Discovery and Patients Stratification**

Eduardo Gonzalez, Bioinformatics Product Strategist, Informatics, PerkinElmer

In this presentation, we will show how domain experts, like oncologists, can directly gain insight by exploring and analyzing complex translational datasets in a rich visual environment connected to the Cloud. Advanced analytics for biomarker discovery facilitate self-service data exploration to empower scientists using embedded, well-established analytics, allowing the direct exploration and analysis of complex datasets—including omics data—to progress biomarker projects.

**IMMUNE MONITORING: BIOMARKERS OF RESPONSE AND RESISTANCE**

1:25 Chairperson's Remarks

1:30 Response and Resistance in CAR-T Therapy

Elena Orlando, PhD, Bioinformatics Investigator, Novartis Institutes for BioMedical Research

2:00 Molecular Determinants for Sensitivity and Resistance to Immunostimulatory Therapies in Cancer

Kurt Schalper, MD, PhD, Assistant Professor, Pathology and Medicine (Medical Oncology), Yale School of Medicine

2:30 Cancer Immunotherapy Biomarkers for Selection and Monitoring

Glen J. Weiss, MD, MBA, Director, Phase I Clinical Research, Beth Israel Deaconess Medical Center, Boston

There are now multiple monoclonal antibody immunotherapies available for clinical use to treat advanced cancers. However, just a fraction of these patients experience an impressive durable response. How are these therapies selected and how is efficacy monitored? This lecture will highlight current data on biomarkers being used and evaluated for treatment selection and monitoring.

3:00 Close of Conference
BIOMARKERS FOR COMBINATION IMMUNOTHERAPY

9:55 Chairperson's Remarks
Carol Anne Ogden, PhD, Senior Manager and ADCETRIS Biomarker Lead, Diagnostics and Biomarkers, Seattle Genetics, Inc.

10:00 Looking under the Spotlight: Evaluation of Biomarkers in an ADC + CPI Combination Clinical Trial
Carol Anne Ogden, PhD, Senior Manager and ADCETRIS Biomarker Lead, Diagnostics and Biomarkers, Seattle Genetics, Inc.

Brentuximab vedotin (BV) is an antibody-drug conjugate directed against CD30, a receptor expressed by malignant Reed-Sternberg (RS) cells present in classical Hodgkin lymphoma. Treatment with BV may result in inflammatory activity due to RS destruction by immunogenic cell death. Nivolumab blocks the programmed death-1 (PD-1) receptor, inhibiting the binding of PD-1 ligands, and together with the inflammatory activation activity of BV, restores the antitumor immune response.

10:30 Considerations for PK/PD Analysis in Optimal Dose Selection of Novel Immune Checkpoint Combinations
Vladimir Jankovic, MD, Director, Precision Medicine, Early Clinical Development & Experimental Sciences, Regeneron

As the expanding portfolio of novel immune checkpoint combinations enters the clinic, investigating a broad dose combination matrix in Phase II efficacy studies will not be efficient. Novel PK/PD analysis approaches to narrow down the range of safe and effective IO combination regimens during Phase I dose escalation are needed to streamline the proof-of-concept studies.

11:00 Forward and Reverse Strategies to Support the Clinical Development of the Anti-PD-1 Antibody Pembrolizumab
Sarah Javaid, PhD, Associate Principal Scientist, Merck

Immune checkpoint blockade therapies are revolutionizing the standard cancer treatment. Despite the current success of these therapies, not all patients respond to immunotherapy and even those that do often experience toxicities. Combination approaches are the keys to improving clinical response. 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 reduce treatment costs for those unlikely to respond.

11:30 From a Test Tube to a Business Opportunity - The Power of an Intelligence Platform
Shlomi Madar, Vice President, Life Sciences, Signals Analytics

Soon, the doubling time of medical knowledge will reach 75 days! This new reality requires a whole new mindset. Connected Intelligence is a new concept that allows the decision maker to assume control over big data and convert it into meaningful, actionable insights. Learn more @ Signals Analytics' talk.

12:00 pm Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own
RATIONAL COMBINATION IMMUNOTHERAPY STRATEGIES

1:25 Chairperson’s Remarks
Emmett Schmidt, PhD, Distinguished Scientist & Executive Director, Merck Research Labs

1:30 Drivers in the Clinical Development of Cancer Combination Therapy
Emmett Schmidt, PhD, Distinguished Scientist & Executive Director, Merck Research Labs

Immune checkpoint inhibition is emerging as a backbone for cancer therapy. Data from a broad range of combination trials containing such therapies have emerged in the last three years. Combination benefit by independent action and through molecular reasoning both fit portions of these developing results. A flexible approach of both approaches to future trial development seems likely to yield rewards in combination therapy development.

2:00 Shifting Perspectives on Combination Immunotherapy
Maria Karasarides, PhD, Executive Director, Immuno-Oncology, Regeneron Pharmaceuticals

This presentation will cover: 1) emerging immunotherapy combination data and meaningfulness of early data sets, 2) focus on PD-1 and CTLA-4 blockade – is this the most promising combination to date? 3) strategies to improve immunotherapy combinations development – is patient selection our best bet?

2:30 Dual Checkpoint Inhibition DART® Molecules
Edwin Rock, MD, PhD, Vice President, Clinical Research, MacroGenics, Inc.

Combinations of multiple checkpoint inhibitors have resulted in significantly enhanced benefit compared to the blockade of a single target. DART molecules are designed to simultaneously bind to two targets. MGD013 (co-blockade of PD-1 and LAG-3) and MGD019 (co-blockade of PD-1 and CTLA-4), are DART molecules that could deliver biological and clinical activity of combined checkpoint blockade using a single molecule with potential advantages in biology, clinical development and patient convenience.

3:00 The Impact of Patient-to-Patient Variability on Responses to Combination Therapies
Adam C. Palmer, PhD, Postdoctoral Fellow, Harvard Program in Therapeutic Science, Harvard Medical School

All cancer therapies have variable efficacy across patient populations. With combination therapies, different patients may be more or less responsive to different parts of the combination. This has two consequences that affect the design and interpretation of clinical trials. First, patient variability alone, without more ‘drug additivity’, explains the superiority of many FDA-approved combinations including PD1 + CTLA4 blockade. Second, when trials compare ‘treatment A’ vs ‘A+B’, improved survival curves can be equally explained by (1) most patients experiencing a small benefit or (2) few patients experiencing a large benefit; this imposes massive uncertainty on estimates of the rate and magnitude of survival benefit from adding treatment ‘B’.

3:30 Refreshment Break in the Exhibit Hall. Last chance for poster viewing.

PERSONALIZED VACCINES: POTENTIAL FOR COMBINATION IMMUNOTHERAPY

4:10 Chairperson’s Remarks
Emmett Schmidt, PhD, Distinguished Scientist & Executive Director, Merck Research Labs

 perform a Phase II trial of this strategy as adjuvant treatment for definitively treated NSCLC and document induction or boosting of immune response to a wide spectrum of proteins whose genes are overexpressed in NSCLC.

5:15 Dissecting Immune Correlates in Cancer Immunotherapy Clinical Trials
Steven Fling, PhD, Senior Staff Scientist, Vaccine & Infectious Disease Division, Fred Hutchinson Cancer Research Center; Director, Cancer Immunotherapy Trials Network Immunology Monitoring Laboratory

Our lab coordinates multi-parameter, immune monitoring of multi-center cancer immunotherapy trials. We recently reported clinical results from a vaccine therapy trial in cancer patients with advanced malignancies expressing NY-ESO-1, showing significantly increased humoral and cellular immunity resulting from the vaccine regimen. Here we report techniques and in-depth results dissecting multiple correlates associated with the enhanced immune response to vaccine, including gene signatures and delineation of antigen presenting cell subsets.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing
responses in the tumor and immune microenvironment. The Torque platform makes it possible to anchor powerful stimulatory cytokines, antibodies, and small molecules directly to immune cells to direct their activity and increase their efficacy and durability in the "hostile" tumor microenvironment, while controlling systemic exposure. Torque's lead product candidate is Deep IL-15, which is entering clinical development for hematologic and solid tumors.

9:00 Modulating Intratumoral Myeloid Cells to Prime Responses to Anti-PD-1 Blockade
Robert Pierce, MD, Scientific Director, Immunopathology Core, Fred Hutchinson Cancer Research Center

Anti PD-1 blockade is effective in many solid tumors, but response appears to be predicated on a preexisting anti-tumor T cell response. Immunologically quiescent tumors generally fail to respond. The tumor microenvironment (TME) of these poorly inflamed tumors are often dominated by myeloid-derived (MF) immunosuppressive cells. Using experimental mouse models and human tumor samples, we describe various immunosuppressive states of intratumoral MF and potential means to reverse the immunosuppressive TME through modulating these cells.

9:30 Activated B Cells in Human Primary Tumors Present Antigen and Increase Anti-Tumor Function of CD4 T Cells
Tullia Bruno, PhD, Research Assistant Professor, Immunology, University of Pittsburgh

10:00 Immunogenic Cell Death: An Agnostic Adjuvant for Mice and Men
John Milburn Jessup, MD, Scientific Director, Precision Cancer Care Program, Inova Schar Cancer Institute; Professor, Systems Biology, Krasnow Institute of Advanced Study, George Mason University

Immunogenic cell death is a form of necroptosis caused by viruses, select cytotoxic agents and radiation that causes the release of tumor antigens in association with eat me and take me signals that promote innate immunity as well as cross-prime adaptive immune responses to the tumor. The advantage of this approach is that it is agnostic to the specific tumor antigen and stimulates the host to determine what may be important as an immune response. Our approach in human and mouse colorectal carcinoma involves combining a viral therapeutic with a standard cytotoxic agent to induce cell-mediated immunity to tumor antigens that then may be augmented by checkpoint inhibitors.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

TUMOR NEOANTIGENS AS BIOMARKERS AND TARGETS

11:10 Chairperson's Remarks
Fred Ramsdell, PhD, Parker Institute for Cancer Immunotherapy

11:15 Neoantigens and Their Relationship to Mutational Load, Mismatch Repair and Immune Checkpoint Expression
Arnold Gelb, MD, MS, FASCP, FCAP, Advisor, Companion Diagnostic Development

The objectives of this presentation are: 1) to review the biological background by which somatic mutations can lead to the generation of private, highly immunogenic tumor antigens (neoantigens), 2) to discuss association of neoantigens with mutational burden, mismatch repair and immune checkpoint expression, and 3) to provide an outlook on clinical applications involving assessment of neoantigens and mutational load with regards to response to immune-checkpoint blockade in solid tumors.

11:45 Tumor Neoantigen Selection Alliance (TESLA): Towards Personalized Cancer Vaccines
Fred Ramsdell, PhD, Vice President, Research, Parker Institute for Cancer Immunotherapy

It is now accepted that mutation-derived neoantigens can elicit a tumor-specific immune response. Identifying neoantigens accurately from the exome sequence is a key parameter for the development of such responses and remains a significant variable of the overall process. TESLA is a consortium-based approach involving over 30 groups to identify key parameters in neoantigen prediction. An update on the progress of the program will be discussed.

12:15 pm Driving CD8+ T Cell Responses to Mutational Neoantigens in Tumors—Harnessing Immunogenic Viral Vectors in Combination with Immune Checkpoint Modulators
Karin Jooss, PhD, CSO, Gritstone Oncology

DNA damage may cause mutations in tumors that can generate new antigens, known as tumor-specific neo-antigens (TSNAs). Accurate prediction of TSNAs is key to generate potent TSNAs specific vaccine approaches. Viral vector-based vaccine platforms have shown to induce hi-titer, polyfunctional and durable CD4+ and CD8+ T cell responses in humans. The personalized vaccine is delivered in combination with immune checkpoint blockade, to keep TSNAs-induced T cells active in the immunosuppressive tumor microenvironment.

12:45 Close of Conference
Intrinsic and Acquired Resistance to Immunotherapy

**TUESDAY, JUNE 12**

1:00 pm **Conference Registration**

**MECHANISM OF NON-RESPONSE: RESISTANCE OR LACK OF EFFICACY**

1:55 **Chairperson's Opening Remarks**

Pawel Kalinski, MD, PhD, Professor, Oncology; Vice-Chair, Translational Research, Roswell Park Cancer Institute

2:00 **Genomic Signatures for Precision Immuno-Oncology**

Iman Tavassoly, MD, PhD, Research Fellow, Mount Sinai Institute for Systems Biomedicine, Icahn School of Medicine at Mount Sinai

Finding biomarkers for optimization of immunotherapy in cancer is of great importance. Genomic signatures of a patient’s immune system and the tumor tissue and their interactions are key regulators of responses to immunotherapy. I will present an integrative computational and mathematical framework to extract these genomic signatures and build a quantitative biomarker space which can be used for precision immunotherapy in cancer.

2:30 **The Stromal Microenvironment in Cancer Immunology and Immunotherapy**

Shannon J. Turley, PhD, Principal Scientist, Cancer Immunology, Genentech

This presentation will cover: understanding the role of stromal cells in the tumor microenvironment and the effect of cross-talk with immune cells; analyzing factors correlating with resistance to atezolizumab and reverse-translating this information to provide meaningful preclinical insights; and building tools to study mesenchymal cells and their impact on immuno-oncology across tumor types.

3:00 **Primary Resistance Mechanisms to Immunotherapy**

Sanjeev Mariathasan, PhD, Senior Scientist, Oncology Biomarker Department, Genentech

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:25 **Chairperson’s Remarks**

Pawel Kalinski, MD, PhD, Professor, Oncology; Vice-Chair, Translational Research, Roswell Park Cancer Institute

4:30 **COX2-PGE2-Orchestrated Secondary Suppression in the Course of Immunotherapy**

Pawel Kalinski, MD, PhD, Professor, Oncology; Vice-Chair, Translational Research, Roswell Park Cancer Institute

Immune checkpoint inhibition (ICI) provided new effective treatment option for patients with many types of advanced cancer, but the majority of patients still show primary or secondary resistance to ICI. The effectiveness of ICI and many other forms of cancer immunotherapy is regulated at the level of tumor microenvironments (TME) by the balance between type-1 immune cells, such as CD8+ cytotoxic T cells (CTLs), Th1 and NK cells and suppressive cells, such as regulatory T cells (Tregs) and myeloid-derived suppressor cells (MDSCs). We observed that the activation of CTLs or NK cells in TMEs of human cancers, results in a strong mobilization of “secondary” suppression, mediated by activated MDSCs and their production of COX2, IDO, and IL-10, which suppress CTL function.

5:00 The Stromal Microenvironment in Cancer Immunology and Immunotherapy

Roy D. Baynes, MD, PhD, Associate Professor, Hematology & Oncology, Massachusetts General Hospital; Assistant Professor, Medicine, Harvard Medical School

Immune checkpoint inhibitor therapy leads to durable responses in a significant minority of patients with solid tumors and may improve overall survival in select diseases. However, most patients who will not benefit and a significant percentage of patients who do respond, will develop acquired resistance. Proper antigen presentation is critical for initial and ongoing tumor immunity, and impaired antigen presentation machinery is an important mechanism of both intrinsic and acquired resistance.

5:30 Acquired Resistance to Immune Modulation in Lung Cancer

Katerina Politi, PhD, Associate Professor, Pathology, Yale School of Medicine

Immune checkpoint inhibitors have transformed the treatment landscape for lung cancer. However, most patients whose tumors initially respond to treatment eventually develop drug resistance disease. Emerging data indicate that lung tumors can escape treatment with immune checkpoint inhibitors by altering HLA Class I antigen presentation. Insights into how HLA Class I antigen presentation is disrupted in immune checkpoint inhibitor resistant tumors is critical to finding strategies to overcome drug resistance.

6:30 Dinner Short Course*

SC3: Multiplexed Analysis of Tumor Tissues Using Spatially Resolved and Quantitative Platforms

*Separate registration required

**WEDNESDAY, JUNE 13**

7:25 am **Interactive Breakout Discussion Groups with Continental Breakfast**

This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

**COMBINATION IMMUNOTHERAPY TO OVERCOME RESISTANCE**

8:25 **Chairperson's Remarks**

Roy D. Baynes, MD, PhD, Senior Vice President and Head, Global Clinical Development; CMO, Merck Research Laboratories
Intrinsic and Acquired Resistance to Immunotherapy
Immuo-Oncology Therapeutic Strategies and Predictive Biomarkers for Non-Responders

8:30 PD-1 Antibody Therapy: Approaches to Primary Resistance
Roy D. Baynes, MD, PhD, Senior Vice President and Head, Global Clinical Development; CMO, Merck Research Laboratories
PD-1 antibody therapy has shown broad spectrum activity across an array of solid malignancies. Informative biology helped identify those cancer types for initial exploration. A majority of patients however appear to exhibit primary resistance to such therapy. Precision medicine approaches help identify those patients most likely to respond to monotherapy, those patients who should be considered for further clinical research and potentially suggest combination approaches to address primary resistance.

9:00 Intrinsic Resistance to Immune Checkpoint Therapy and Potential Approaches to Overcome Resistance in Genitourinary Malignancies
Jianjun Gao, MD, PhD, Assistant Professor, Genitourinary Medical Oncology, The University of Texas MD Anderson Cancer Center
This presentation will focus on both genomic and tumor microenvironment resistance mechanisms of immune checkpoint therapy; rationale for designing combinational approaches to overcome resistance using genitourinary malignancies including prostate, kidney and bladder cancer as models; and preliminary data on some of these combination therapy clinical trials.

9:30 Combination Immunotherapy Strategies to Overcome Resistance to PD-1 Therapy
Osama Rahma, MD, Assistant Professor, Medicine, Dana-Farber Cancer Institute, Harvard Medical School
Primary and adaptive resistance to PD-1 therapy represents a major challenge in immunotherapy drug development. Primary resistance could be driven by a defect in antigen presentation or priming the T-cells while secondary resistance could be related to the co-expression of many immune checkpoints. This presentation will explore immunotherapy combination strategies to overcome both primary and secondary resistance.

10:00 Networking Coffee Break

EMERGING TARGETS AND THERAPEUTIC STRATEGIES TO ADDRESS RESISTANCE

10:30 Targeting Soluble TNF in Tumor Microenvironment (TME) to Reverse Resistance to Immunotherapy
Raymond Tesi, MD, President and CEO, Acting CMO, ImmunBio
Checkpoint inhibitors do not work in a majority of patients. The most important predictor of resistance to CPI is MDSC in blood and/or TME. MDSC requires TNF to proliferate. Selective elimination of soluble TNF (with preservation of trans-membrane TNF) in blood and TME will reverse the immunologic factors that cause resistance to CPI and other immunotherapies.

11:00 Targeting the DNA Damage Response to Enhance Immunotherapeutics
Timothy Yap, MD, PhD, Associate Professor, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center
DNA damage response agents, such as PARP inhibitors, are widely used in clinical oncology and exploit deficiencies in tumor DNA repair. Given the expanding role of immune checkpoint inhibitors in cancer medicine, the interaction of tumor DNA damage with the immune system has recently come into focus. It is now clear that the tumor DNA repair landscape has a key role in driving antitumor response to immune checkpoint blockade.

11:30 Investigating the Role of Innate Immunity in Adaptive Resistance to Cancer Immunotherapy
Brent A. Hanks, MD, PhD, Assistant Professor, Cancer Immunology/Immunotherapy, Duke Cancer Institute
We will explore recently identified mechanisms that cancers have evolved to suppress T cell-mediated immunity as an adaptive response to checkpoint inhibitor immunotherapy. Further discussion will address strategies to inhibit these mechanisms and augment the efficacy of currently available checkpoint inhibitor regimens.

12:00 pm Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own
Clinical and Translational Biomarkers

SUNDAY, JUNE 10

4:30-6:30 pm Short Course and Conference Registration

5:00-8:30 Dinner Short Course*

SC1: Fit-for-Purpose Biomarker Assay Development and Validation

*Separate registration required    See Page 5 for detailed information

MONDAY, JUNE 11

7:00 am Conference Registration and Morning Coffee

8:00 Organizer’s Welcome

OPENING PLENARY SESSION: EMERGING APPROACHES FOR CANCER

8:05 Chairperson’s Opening Remarks
     George A. Green, IV, PhD, Head, Pharmacodiagnostics, Bristol-Myers Squibb

8:10 Clinical Genomic Profiling Using the MSK-IMPACT™ Large Panel NGS Assay to Guide Patient Selection for Targeted and Immune Therapies
     Marc Ladanyi, MD, William J. Ruane Chair in Molecular Oncology, Molecular Diagnostics Service and Human Oncology & Pathogenesis Program, Memorial Sloan Kettering Cancer Center

As the centerpiece of an institutional initiative in clinical cancer genomics, we have implemented large scale genomic profiling for targetable cancer drivers and other cancer-relevant alterations in all patients with advanced solid cancers. Since 2014, over 23,000 patients have been profiled using the MSK-IMPACT™ targeted large panel, capture-based DNAseq assay. MSK-IMPACT™, which received FDA clearance in 2017, allows robust detection of somatic mutations in all known cancer genes, copy number changes and select cancer fusion gene rearrangements, as well as assessing overall tumor mutation burden and microsatellite instability. Patients are also screened for oncogenic fusions by targeted RNAseq and for germline cancer predisposition alleles and evidence of clonal hematopoiesis.

8:40 Widgets to Cancer Patient-Specific Digits: The Case for Out-of-Clinic Objective Measures and Their Potential Impact to Remote Patient Monitoring in Precision Oncology and Discovery
     Christopher M. Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

Albeit the case for long-term, out-of-clinic monitoring has been obvious for many chronic diseases, the case for cancer has not been as clear. The National Cancer Institute has begun piloting and funding various aspects to enable an Internet of Cancer Medical Things. This talk will focus on these efforts currently and prospectively as well as the overall vision to coordinate a much broader initiative to improve our understanding of cancer progression and improve the delivery of cancer care.

9:10 Coffee Break in the Exhibit Hall with Poster Viewing

BIOMARKER-DRIVEN CLINICAL TRIALS

9:55 Chairperson’s Remarks
     Robert A. Beckman, MD, Professor, Oncology, Biostatistics, Bioinformatics, and Biomathematics, Lombardi Comprehensive Cancer Center and Innovation Center for Biomedical Informatics, Georgetown University Medical Center

10:00 Clinical Monitoring of Biomarkers to Guide Informed Treatment
     Brittany Bahamon, PhD, Scientist, Takeda

De novo and acquired resistance mechanisms remain a persistent problem to long-term treatment benefit. To understand the molecular and biological mechanisms underlying the response and resistance to the mTOR inhibitor, TAK-228, a variety of human specimens collected at baseline, during treatment and at progression were analyzed with diverse approaches such as immunochemistry, sequencing or circulating tumor cell enumeration. In a clinical trial testing the combination of hormonal therapy with TAK-228 in patients with advanced or metastatic estrogen receptor positive breast cancer, sequencing of plasma ctDNA at baseline uncovered mutations typical from repeated exposure to hormonal therapies. At treatment relapse, drastic increase in mutation and molecular alterations in a subset of patients suggested novel acquired escape mechanisms, possibly linked to impaired genome integrity surveillance that would support the rational use of immuno-therapy. Continuous monitoring of biomarkers in clinical practice should warrant better treatment options for cancer patients.

10:30 Novel Adaptive Design for a Confirmatory Basket Trial and Best Practices for Application
     Robert A. Beckman, MD, Professor, Oncology, Biostatistics, Bioinformatics, and Biomathematics, Lombardi Comprehensive Cancer Center and Innovation Center for Biomedical Informatics, Georgetown University Medical Center

Increasingly, tumors are defined based on molecular subtypes, which if shared across histologies, may be pooled into basket trials, facilitating development of agents targeted at small molecular subgroups. To date, basket trials have been used either for exploratory early development, or for confirmation only in cases where a transformational benefit is anticipated. This presentation discusses a confirmatory basket trial design that is generally applicable to all beneficial therapies.

11:00 High Definition Multiplexing for Biomarker Strategies
     Louis Levy, Director, Corporate and Business Development, Ultivue

Biomarker discovery in immuno-oncology requires the analysis of multiple protein markers (n>4) with their spatial relationships at an amenable throughput. The scrutiny of the tumor micro-environment demands whole-slide multiplexed images featuring immune and tumor cells. Ultivue’s InSituPlex platform fulfills this need with the data reproducibility relevant to CDx.

11:30 The Application of a Novel Biomarker of Cell Division and Disruption in Drug Discovery and Development
     Martin Shaw, Business Development Manager, AroCell AB

AroCell TK210 ELISA is a novel, sensitive and specific assay for serum Thymidine Kinase 1, a well-known biomarker of cell division and disruption. Data will be presented on its application to in vitro drug discovery and clinical studies. Data will be presented on both solid and hematological malignancies.
11:45 Role of Biomarkers in Drug Development and Clinical Practice for the Treatment and Management of NSCLC
Michael Lieberman, PhD, Scientific Advisor, Excelra Knowledge Solutions
Clinical research should address the entire disease process of NSCLC, from risk, through diagnosis to treatment and outcome. The true value of a biomarker database should be measured by the critical questions that it can address for the success of the clinical trials and accelerating drug development.

12:00 pm Luncheon Presentation: Ultra-Sensitive Detection of Proteomic and Genomic Immuno-Oncology Biomarkers Using SIMOA (Single Molecule Array)
Dan Sikkema, Vice President, Accelerator Services, Quanterix
Advances in immuno-oncology in recent years have benefited from the appropriate selection of biomarkers for diagnosis and predicting treatment benefit, as well as monitoring efficacy and safety post-treatment. Use of readily available specimen types such as serum or saliva will permit more frequent and cost-effective monitoring of health status. The ability to measure low-frequency proteins combined with direct detection of genomic (ctDNA, microRNA) material with a single technology will provide new advancements to the field.

LIQUID BIOPSY FOR PRECISION MEDICINE

1:25 Chairperson’s Remarks
Carolyn Compton, MD, PhD, Professor, Life Science, Arizona State University; CMO, National Biomarker Development Alliance

1:30 Development of Next-Generation Sequencing Assays for Oncology Translational and Clinical Research
Ambar Ahmed, Senior Scientific Manager, Oncology Translational Sciences, AstraZeneca
Recent studies report discordance in somatic variants between tissue and plasma from the same patient. We designed a replicate study using clinical plasma samples analyzed through four commercial NGS vendors to examine factors contributing to discordance, including the same biological and technical aspects. Substantial variability in variant calling among the ctDNA assays was observed and comparison of results to tumor sequencing revealed a range of sensitivity (41-94%) and positive predictive value (33-89%).

2:00 Yin and Yang of Real-Time Oncology
Stefan J. Scherer MD, PhD, Vice President & Head, Early Development, Strategy and Innovation, US Oncology, Novartis Pharmaceuticals Corporation
Cancer is a heterogeneous disease and personalized therapy relies on the ability to characterize the tumor every time new treatment is needed. Potential detection of circulating tumor cells (CTCs) or circulating free tumor DNA (ctDNA) to provide molecular characterization and guide patient treatment offers a potential path forward to address this challenge.

2:30 Comprehensive Molecular Profiles of Circulating Tumor DNA from Breast and Lung Cancer Clinical Trials: Implications for Biomarker Development
Mark Lackner, PhD, Director and Principal Scientist, Genentech
Cell-free DNA (cfDNA) released by tumor cells into the blood stream provides a non-invasive way to study genomic alterations in cancer patients. I will discuss low-pass whole genome sequencing (LP-WGS) on cfDNA from clinical cohorts of breast and lung cancer patients and show that tumor DNA fraction in the blood shows dynamic changes over time and treatment. These results have implications for the identification of resistance mechanisms and real-time monitoring of disease.

3:00 Extracellular Vesicles and Platelets: A Strong Friendship in CancerLand Detection
Bakhos A. Tannous, PhD, Associate Professor, Neurology, Harvard Medical School; Director, Experimental Therapeutics and Molecular Imaging Lab; Director, Interdepartmental Neuroscience Center; Director, MGH Viral Vector Development Facility, Massachusetts General Hospital

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:10 Chairperson’s Remarks
Carolyn Compton, MD, PhD, Professor, Life Science, Arizona State University

4:15 Liquid Biopsies in Precision Medicine in Cancer
Filip Janku, MD, PhD, Associate Professor, Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center
Molecular testing of liquid biopsies utilizing plasma cell-free DNA is a promising tool for minimally invasive molecular diagnostics and monitoring. As tumor DNA comprises a small fraction of total cell-free DNA, highly sensitive and accurate techniques are required for cancer mutation detection. PCR-based technologies can detect a low frequency of molecular aberrations in cfDNA, but these approaches cannot sample many target sites. NGS can cover a variety of targets, but at higher cost and possibly lower sensitivity.

4:45 Preanalytical Variables and the Liquid Biopsy: The CAP, ASCO and the Moonshot BloodPAC Assess the Need for Standards
Carolyn Compton, MD, PhD, Professor, Life Science, Arizona State University; CMO, ASU Complex Adaptive Systems Institute; CMO, National Biomarker Development Alliance
The Beau Biden Moonshot Blood Profiling Atlas in Cancer (BloodPAC) group consisting of industry and academic partners has published their recommendations for core data elements that are essential for genomic databases built on liquid biopsy assays, including essential preanalytical factors. These have been reviewed by the FDA with the objective of facilitating product development in the future. The widespread adoption of the guidelines of these two authoritative groups would help to ensure the necessary molecular quality and consistency of liquid biopsy analysis results and reduce the problem of employing blood specimens of unknown provenance in clinical studies and clinical application.

5:15 Liquid Biopsies: An Emerging Non-Invasive Approach for Interrogating Toxicity and Disease
Jiri Aubrecht, PharmD, PhD, Senior Director, Clinical and Translational Biomarkers, Pfizer
MicroRNAs (miRNAs) released into the peripheral circulation upon cellular injury have shown promise as a new class of biomarkers. Our study demonstrates for the first time that signatures of circulating miRNAs show specificity for liver injury phenotypes in humans and, once validated, might become useful for diagnosis of organ pathologies as “liquid biopsies.”

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing
The cytokine IL-12 is known to enhance the function and quality of cytotoxic T lymphocytes (CTLs) against antigens, especially in the context of vaccines. In this study, we analyzed samples from the HIV Vaccine Trial Network (HVTN) study 087. We report the enhancement of the cellular response in individuals receiving IL-12 and identify several potential markers of successful IL-12 adjuvanted vaccination.
TUESDAY, JUNE 12

1:00 pm Conference Registration

IMPLEMENTING PRECISION MEDICINE

1:55 Chairperson's Opening Remarks
David B. Roth, MD, PhD, Simon Flexner Professor and Chair, Department of Pathology and Laboratory Medicine Director, Penn Center for Precision Medicine

2:00 Leveraging Pharmacogenetics in Drug Development
Peter M. Shaw, PhD, Head, Clinical Pharmacogenetics, Merck
This presentation will focus on routine collection of samples and generating genetic data “in life” from clinical studies to inform on drug development strategy and new targets. Case examples will be provided on improving benefit-risk considerations by identifying response variants, and understanding the contribution of ADME PGx in development programs.

2:30 Genomic and Proteomic Evaluation of Migraine
Michael E. (Ted) Burczynski, PhD, PPM Expert, Director, Personalized & Predictive Medicine, Analytics & Big Data, Teva Pharmaceuticals
This talk will describe exploratory biomarker screening activities in migraine using both large-scale genomic and proteomic approaches. The challenges and methods for sampling, data generation and analysis will be reviewed and preliminary data analyses will be discussed.

3:00 Corgenix - Your Partner for Liquid Biopsy Protein Diagnostics
Dawn McHugh, Vice President, Business Development, Personalized Diagnostics, Corgenix, Inc.
Corgenix has more than 25 years developing Liquid Biopsy Protein Diagnostics. We offer our expertise and services to Pharma to support their Personalized Medicine strategies. If you are looking to convert your soluble protein biomarker to an IVD or CDx, look to Corgenix.

3:30 Refreshment Break in the Exhibit Hall. Last chance for poster viewing.

4:25 Chairperson's Remarks
David B. Roth, MD, PhD, Simon Flexner Professor and Chair, Department of Pathology and Laboratory Medicine Director, Penn Center for Precision Medicine

4:30 Putting Precision Medicine into Clinical Practice
David B. Roth, MD, PhD, Simon Flexner Professor and Chair, Department of Pathology and Laboratory Medicine Director, Penn Center for Precision Medicine
At Penn we have focused on bringing promising new scientific developments in precision medicine to clinical practice, in oncology and other areas. The talk will cover the latest developments in several areas of our work in precision medicine.

5:00 Expanding the Reach of Precision Medicine in Non-Small Cell Lung Cancer
Bruce E. Johnson, MD, Professor of Medicine, Harvard Medical School
Fourteen years have passed since the discovery of the epidermal growth factor receptor (EGFR) mutation and its sensitivity to EGFR-tyrosine kinase inhibitors (TKIs) in approximately 15% of patients with NSCLC. The 2007 discovery of ALK rearrangements in 5% of patients with NSCLC led to both EGFR mutants and ALK rearranged NSCLC being treated with 4 different approved EGFR and ALK inhibitors. ROS1 rearrangements and BRAF V600E mutations have also been recently discovered, each representing 1% of lung cancer. Therefore, currently more than 20% of NSCLC can be treated with targeted agents.

5:30 Cut-Point Signatures for Patient Selection and Precision Medicine
Viswanath Devanarayan, PhD, Global Head of Statistics & Data Sciences, Charles River Laboratories
The underlying relationship between a disease/clinical outcome and candidate predictors such as biomarkers, demographics and baseline clinical status is usually unknown and must be deduced empirically from experimental data. Such relationships enable the development of prognostic and predictive biomarker signatures for the implementation of optimal patient selection and precision medicine strategy in clinical trials. For easier implementation in practice, having such multivariate signatures in terms of cut-points on predictors is preferable. In this talk, we will review our recently published algorithms for developing such signatures. Results from simulations and case study illustration will be provided.

6:30-9:30 Dinner Short Course*
SC3: Multiplexed Analysis of Tumor Tissues Using Spatially Resolved and Quantitative Platforms
*Separate registration required See Page 5 for detailed information

WEDNESDAY, JUNE 13

7:25 am Interactive Breakout Discussion Groups with Continental Breakfast
This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

COMPANION AND COMPLEMENTARY DIAGNOSTICS

8:25 Chairperson's Remarks
Susanne K. Rhoades, PhD, Director, Diagnostics Development, Tailored Therapeutics, Eli Lilly and Company

8:30 Follow-on CDx Application in Clinical Practice: Is There a Gap?
Cecilia Schott, PharmD, MBA, Vice President, Precision Medicine, AstraZeneca

9:00 From Clinical Trial Assays to IVD Companion Diagnostics: Lessons Learned from Bridging Studies
**9:30 Expanding CDx Strategy Options with RNAscope®, a Clinically-Validated, Quantitative in situ RNA Biomarker Platform**

**Christopher Bunker, PhD, Vice President, Business Development, Advanced Cell Diagnostics**

RNAscope is a clinically validated in situ hybridization assay that enables multiplexed tissue expression analysis in routine clinical biopsy tissues. RNAscope is the most sensitive and specific platform for tissue-based expression analysis. It is enabling faster, robust and wide dynamic range tissue-based biomarker expression analysis for accurate correlation to treatment outcome and selection of responsive patient for clinical trial enrollment and CDx.

**10:00 Networking Coffee Break**

**10:30 Qualification of a Biomarker for Patient Selection – Opportunity and Challenges**

**Abdel B. Halim, PharmD, PhD, DABCC, FAACC, Vice President, Translational Medicine, Biomarkers & Diagnostics, Celldex Therapeutics**

Incredibly high failure rate in the pharmaceutical industry has been positioning biomarkers and personalized medicine in the frontline as optimistic rescuers. Successful development and implementation of biomarkers and companion diagnostic strategies will likely mark the difference between winners and losers in this crowded space. To achieve this ambitious goal, some prerequisites should be fulfilled, principally, embracing an effective biomarker strategy as early as possible during the drug development phase and implementation of the right processes.

**11:00 Improving Outcomes in Auto-Immune Disease: Progress toward Prediction and Prognosis**

**Mark E. Curran, PhD, Vice President and Head of Companion Diagnostics, Janssen Immunology**

Auto-immune disease including rheumatoid arthritis and inflammatory bowel disease dramatically impacts quality of life for patients. Despite advances in treatment there remains a significant unmet clinical need for new therapies, companion diagnostics and integrated treatment solutions. Our team is focused on transforming treatment of these diseases by applying systems pharmacology, precision medicine and digital health to create new treatment paradigms. Progress toward these objectives will be discussed.

**11:30 Selecting Patients Using Investigational Companion/Complementary Diagnostics in Clinical Trials**

**Susanne K. Rhinoes, PhD, Director, Diagnostics Development, Tailored Therapeutics, Eli Lilly and Company**

Incorporating an investigational in vitro diagnostic that has potential to be a companion or complementary diagnostic into a clinical trial for a therapeutic product adds complexities and unique aspects that must be carefully considered. These considerations and impact on study initiation activities and clinical trial implementation will be discussed.

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

**MUTATION ANALYSIS TO GUIDE THERAPY**

1:25 Chairperson's Remarks

**Jennifer J.D. Morrissette, PhD, Scientific Director, Clinical Cancer Genomics; Clinical Director, Center for Personalized Diagnostics, University of Pennsylvania**

1:30 Somatic Mutation Testing: Beyond NGS

**Gregory Tsongalis, PhD, Professor, Pathology & Laboratory Medicine, Dartmouth College**

Precision medicine has impacted cancer patient management by allowing for more tailored therapeutic strategies to be selected based on the tumor cell genotype. More often, laboratories use next-generation sequencing (NGS) to obtain a molecular profile for use in this therapeutic selection process. Here we will discuss the limitations of NGS and alternative technical strategies to obtaining actionable mutation data.

**2:00 Association of Cytogenetic Risk Categories with Functional Categories of Mutations in AML**

**Jennifer J.D. Morrissette, PhD, Scientific Director, Clinical Cancer Genomics; Clinical Director, Center for Personalized Diagnostics, University of Pennsylvania**

We have studied the diagnostic specimens of over 350 patients with acute myeloid leukemia (AML) that have had routine cytogenetic studies and were sequenced using the hematological-NGS panel. Analysis of the data shows that there are different mutational profiles based on the functional genetic categories in patients with different cytogenetic profiles. The strategies proposed in this talk will inform the audience about the functional categories of mutations associated with different cytogenetic abnormalities at diagnosis in AML.

**2:30 Genome-Wide Somatic Copy Number Alteration Assessment in Diagnosing and Treating Cancer**

**Joel Lefferts, PhD, Assistant Professor of Pathology; Assistant Director, Clinical Genomics and Advanced Technology (CGAT), Department of Pathology and Laboratory Medicine, Geisel School of Medicine at Dartmouth, Dartmouth-Hitchcock Medical Center**

Gene amplifications and other copy number alterations (CNAs) are well-established biomarkers in oncology that can be invaluable in arriving at a definitive diagnosis as well as determining appropriate drug targets for cancer patients. In the clinical setting testing for CNAs is most common for specific targets in specific tumor types but the use of comprehensive, genome-wide CNA detection by a variety of techniques is growing. This CNA data is used in differentiating related tumor types at diagnosis and can also provide information regarding deregulated pathways that may predict response to targeted therapies that are currently available as well as those in development or in clinical trials.

**3:00 Close of Conference**
SUNDAY, JUNE 10

4:30-6:30 pm Short Course and Conference Registration
5:00-8:30 Dinner Short Course*
SC1: Fit-for-Purpose Biomarker Assay Development and Validation
*Separate registration required See Page 5 for detailed information

MONDAY, JUNE 11

7:00 am Conference Registration and Morning Coffee
8:00 Organizer’s Welcome

OPENING PLENARY SESSION: EMERGING APPROACHES FOR CANCER

8:05 Chairperson’s Opening Remarks
George A. Green, IV, PhD, Head, Pharmacodiagnostics, Bristol-Myers Squibb

8:10 Clinical Genomic Profiling Using the MSK-IMPACT™ Large Panel NGS Assay to Guide Patient Selection for Targeted and Immune Therapies
Marc Ladanyi, MD, William J. Ruane Chair in Molecular Oncology, Molecular Diagnostics Service and Human Oncology & Pathogenesis Program, Memorial Sloan-Kettering Cancer Center
As the centerpiece of an institutional initiative in clinical cancer genomics, we have implemented large scale genomic profiling for targetable cancer drivers and other cancer-relevant alterations in all patients with advanced solid cancers. Since 2014, over 23,000 patients have been profiled using the MSK-IMPACT™ targeted large panel, capture-based DNAseq assay. MSK-IMPACT™, which received FDA clearance in 2017, allows robust detection of somatic mutations in all known cancer genes, copy number changes and select cancer fusion gene rearrangements, as well as assessing overall tumor mutation burden and microsatellite instability. Patients are also screened for oncogenic fusions by targeted RNAseq and for germline cancer predisposition alleles and evidence of clonal hematopoiesis.

8:40 Widgets to Cancer Patient-Specific Digits: The Case for Out-of-Clinic Objective Measures and Their Potential Impact to Remote Patient Monitoring in Precision Oncology and Discovery
Christopher M. Hartshorn, PhD, Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health
Albeit the case for long-term, out-of-clinic monitoring has been obvious for many chronic diseases, the case for cancer has not been as clear. The National Cancer Institute has begun piloting and funding various aspects to enable an Internet of Cancer Medical Things. This talk will focus on these efforts currently and prospectively under the overall vision to coordinate a much broader initiative to improve our understanding of cancer progression and improve the delivery of cancer care.

9:10 Coffee Break in the Exhibit Hall with Poster Viewing

9:55 Chairperson’s Remarks
Peter Bergethon, MD, Vice President, Quantitative Medicine and Clinical Technologies, Biogen

10:00 The Path toward Meaningful Novel Digital Endpoints in Clinical Trials
Daniel Karlin, MD, MA, Head, Clinical, Informatics and Regulatory Strategy, Digital Medicine and the Pfizer Innovation Research Lab
Dan will walk through how the Digital Medicine group at Pfizer and a number of consortia have been using theory and experience in the digital biomarker space to develop the science of novel digital endpoints and think about clinical meaningfulness of these measures. He will consider the variety of uses of digital endpoints and the ways in which these measures can inform the drug development paradigm from internal decision making through regulatory and market acceptance.

10:30 Digital Biomarkers from Parkinson’s Disease to Melanoma
Dan E. Webster, PhD, Principal Scientist of Digital Health, Sage Bionetworks
Smartphones contain sensors that can monitor disease symptoms, drug response, and potentially predict health outcomes. The mPower Parkinson’s Disease Study uses phone-based measurements to assess tremor, gait, phonation, and more to monitor participant symptoms. To find digital biomarkers predictive of disease from this data, teams competed in the Parkinson’s Disease Digital Biomarker DREAM Challenge. The Mole Mapper app uses a smartphone camera to map and quantitatively measure skin lesions over time to detect markers of progression to melanoma.

11:00 Regulatory Considerations for Digital Health
Bakul Patel, Associate Director, Digital Health, FDA

11:30 StepWatch™ Accuracy and Reliability Means Greater Probability to Detect Changes in Walking
Teri Chou, PhD, CEO, Modus Health LLC
The accuracy of walking monitors vary widely from consumer products such as Fitbit™ to medical devices such as StepWatch™. This presentation uses independent published studies about the most used walking monitors to emphasize how monitor accuracy and reliability can affect number of study participants needed to detect walking improvements.

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

CHOOSING DIGITAL ENDPOINTS IN CLINICAL TRIALS

BIOSENSORS AND WEARABLES AS BIOMARKERS IN CLINICAL DEVELOPMENT

1:25 Chairperson’s Remarks
Mark Frasier, PhD, Senior Vice President, Research Programs, The Michael J. Fox Foundation for Parkinson’s Research

1:30 Patient Centered Doesn’t Have to Mean Subjective: The Role of Digital Sensors in Refocusing Clinical Development on the Patient
Daniel Grant, PhD, Director, Early Development Lead, Novartis
Traditionally, the assessment of the impact of treatments on patients outside of the clinic has been dependent on questionnaires. As standards for data quality have
become higher, clinical studies are becoming progressively more focused on hard clinically measured endpoints. Alternatively, digital sensors in wearable devices and smart phones present the opportunity for the collection of objective data directly from patients in the real world.

2:00 Wearable Devices in Clinical Trials: Methodological Approaches and a Real-Life Experience
Elena Izmailova, PhD, Senior Director, Novel Data Streams and Devices, Data Science Institute, Takeda Pharmaceuticals International, Inc.

Development of wearable digital technologies in the form of sensors and cell phone apps has opened unprecedented opportunities for health data collection and remote medical care. Multiple applications for wearable technologies have been identified for patient care management and drug development. These applications range from basic physiological data collection to discovery of novel endpoints specific for certain disease areas. This presentation will highlight the methodological approaches and the experience in wearable data collection, analysis and interpretation in clinical trials.

2:30 When You Hear Digital, Think Dynamics: Time and Trajectories in Quantitative Medicine
Peter Bergethon, MD, Vice President, Quantitative Medicine and Clinical Technologies, Biogen

Medicine is systems science in which the patient is a system and their health state is characterized by measurable properties. The change in state over time (dynamics) allows characterization of a sequence of states as a trajectory through growth development, health and disease phases of life. Dynamic transitions define the trajectory from health to illness and with therapeutic intervention to recovery. Capturing time dependence is the power of digital technology.

3:00 Digital Biomarkers in Drug Development – Exploiting the Digital Armamentarium to Fight Heart Failure
Kunjal R. Patel, MHA, MBA, Senior Study Manager, Clinical Sciences, Bayer US

Worldwide, approximately 26 million people suffer from heart failure (HF). The disease has a high impact on patients’ quality of life and life expectancy with an annual mortality of approximately 30%. The use of emerging technologies, which allow remote and continuous patient monitoring will lead to a paradigm shift in the conduct of clinical trials in HF. Opportunities and challenges in this field will be discussed in the presentation.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Designing Wearables for Clinical Trials
Tushar Parlikar, PhD, Product Manager, Verily Life Sciences

In this talk, Tushar Parlikar will discuss Verily Life Sciences’ investigational device, Study Watch, and its use in clinical trials such as Verily’s Project Baseline.

5:15 Human Movement Analytics for Parkinson’s Disease
Erhan Bilal, PhD, Researcher, IBM T.J. Watson Research/Computational Biology Center

Current standards for evaluating the motor symptoms of Parkinson's patients are based on episodic assessments, such as UPDRS part III, performed by trained physicians in the clinic. Lately, there has been an effort in the field to develop continuous, objective measures of motor symptoms based on wearable sensors and other remote monitoring devices. This talk will focus on current approaches and the progress made towards this goal.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

TUESDAY, JUNE 12

7:25 am Interactive Breakout Discussion Groups with Continental Breakfast

MOBILE HEALTH IN CLINICAL TRIALS

8:25 Chairperson’s Remarks
Kunjal R. Patel, MHA, MBA, Senior Study Manager, Clinical Sciences, Bayer US

8:30 Regulatory Aspects for Mobile Medical App Development for Commercial and Clinical Trial Use Cases
Michael J. Benecky, PhD, Senior Director, Global Regulatory Affairs, Precision and Digital Medicine, R&D Chief Regulatory Office, GlaxoSmithKline

The presentation will discuss the regulatory aspects for two specific GSK mobile apps: MyAsthma and PARADE. MyAsthma is designed to help people living with asthma manage their condition. The GSK PARADE Study (Patient Rheumatoid Arthritis Data from Real World Study) is the first industry study to utilize the Apple Research Kit. Topics of discussion will include: 1) mobile medical apps are defined as medical devices from its intended use shown through labeling claims, advertising materials, or oral or written statements; 2) mobile medical app regulation is health risk based to balance patient safety and barriers to technological innovation; 3) quality management for mobile medical apps.

9:00 Lessons Learned from Conducting a Non-Interventional Virtual Trial in Migraine Patients
Gabriel Vargas, MD, PhD, Executive Medical Director, Digital Health & Neuroscience Therapeutic Area Head, Early Development, Amgen

The increasing costs of modern drug development have stimulated industry to identify novel approaches in the conduct of clinical trials. One area of great interest is the incorporation of digital health technologies into our clinical trials to enable faster recruitment, provide larger and richer data sets and promote more patient centric trials. This talk will discuss some examples of how Amgen has incorporated digital health into our trials and will describe how taking advantage of the tremendous progress made in consumer electronics over the last several years we have designed a “virtual” trial to understand the relationship between migraines and activity level as measured by an Apple Watch in a migraine patient population using a trial design which has no actual physical sites or study visits.
9:30 Impact of a Smartphone Application on Pain Severity in Patients with Cancer-Related Pain
Amanda J. Centi, PhD, Research Program Manager, Connect Health Innovation, Partners HealthCare

10:00 Internet of Medical Things: Making Intelligent Care Everywhere a Reality
James R. Mault, MD, FACS, Senior Vice President and CMO, Qualcomm Life

The Internet of Medical Things (IoMT) is a transformational era for health care that will shape technology, business culture and the practice of medicine. As this interoperable health care network develops and matures, there will be a number of defining inflection points that will shape the IoMT fabric. Dr. Mault will be sharing benchmarks and early examples covering: 1) parallels and pitfalls from the scaling of the Internet of Things that can inform the IoMT, 2) the investment and return for consumers, manufacturers and health systems; and 3) the stages and advancements, both structured and organic, that will accelerate a viable IoMT fabric.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

CLINICAL APPLICATIONS OF SMARTPHONES: NEW SOURCE OF DIGITAL BIOMARKERS

11:10 Chairperson's Remarks
Christian Gossens, PhD, MBA, Global Head, Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development

11:15 Digital Biomarkers Collected with Smartphones in Clinical Trials: How Relevant Are They?
Christian Gossens, PhD, MBA, Global Head, Early Development Workflows, pRED Informatics, Roche Pharmaceutical Research and Early Development

Mobile sensors are rapidly becoming part of everybody’s lives, and enhancing clinical trials with real world data is now increasingly possible. This allows for more objective, precise and continuous measurements. Roche has been pioneering a smartphone-based monitoring system since 2014. We share our first real-world digital biomarker results based on active tests and passive monitoring data from several neuroscience clinical trials.

11:45 The Asthma Mobile Health Study
Yu-Feng Yvonne Chan, MD, PhD, Associate Professor, Genetics and Genomics Sciences & Emergency Medicine; Director, Center for Digital Health, Icahn Institute for Genomics and Multiscale Biology, Icahn School of Medicine at Mount Sinai

The Mount Sinai Center for Digital Health team led the pioneering application of Apple's ResearchKit framework to enable a large-scale clinical research study of asthma, with over 10,000 research participants. The study helped demonstrate the value and utility of consumer-engagement in research, enabled by personal smartphones, with longitudinal, multi-dimensional data collected and analyzed from participants from 3 countries.

12:15 Pixels as Digital Biomarkers: Machine Learning and Beyond with MoleMapper
Tracy Petrie, PhD, MoleMapper Product Manager, Oregon Health & Science University

Smartphones are facilitating the Machine Learning revolution both as data collection devices and inference engines. In recent years, we’ve moved away from telling algorithms what to look for and are now training them to find the relevant and interesting features. Recent successes in classification efforts have fueled the work on Melanoma detection and triage algorithms but the next wave is arriving: supplementing single images with the appropriate context. The primary goal of this effort is to enable early detection of melanosomas resulting in decreased mortality rates. With the MoleMapper project, which uses Apple's ResearchKit platform, we’re building a dataset that includes context while asking, “Is there more we can learn from the data than just the ability to classify lesions?”

12:45 Close of Conference

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