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

IMMUNO-ONCOLOGY

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

J. Carl Barrett
VP, Oncology Translational Sciences
AstraZeneca

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, FASCP, FCAP; Advisor, Companion Diagnostic Development

Christopher M. Hartshorn
Director, Cancer Treatment and Diagnosis
NCl, 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 Ladanyii
Chair, Molecular Oncology & Diagnostics
Memorial Sloan-Kettering

Fred Ramsdell
VP, Research
Parker Inst. for Cancer Immunotherapy
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2017 Attendee Demographics

COMPANY TYPE
- IVD and Pharma: 51%
- Pharmaceutical: 22%
- Healthcare/Hospital: 10%
- Academic/Government: 9%
- CRO: 3%
- Services/Societies: 3%
- Other: 2%

TITLE TYPE
- Executive/Director: 44%
- Sales/Marketing: 20%
- Scientist/Technologist: 19%
- Professor: 8%
- Manager: 8%
- Other: 1%

For additional sponsorship, exhibit & lead generation information, please contact:
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Register by March 16
SAVE up to $350!

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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
- 12:00-1:25 pm: Luncheon Presentation
- 1:25-3:30 pm: Biomarkers to Predict Response to Immunotherapy (Cont.)
  - Combination Immunotherapy with Personalized Vaccines
  - Liquid Biopsy for Precision Medicine (Cont.)
- 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 (Cont.)
  - Combining Immunotherapy with Personalized Vaccines
  - Liquid Biopsy for Precision Medicine (Cont.)
- 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
- 8:25-10:00 am: Liquid Biopsy for Immuno-Oncology
  - Targeting the Tumor Microenvironment: Activating the Immune System for Better Response to Immunotherapy
  - Liquid Biopsy for Immuno-Oncology
  - Mobile Health in Clinical Trials
- 10:00-10:30 am: Coffee Break in the Exhibit Hall with Poster Viewing
- 10:30-12:00 pm: Integrated Biomarker Analysis for Precision Immuno-Oncology
  - Emerging Targets and Therapeutic Strategies to Address Resistance
  - Companion and Complementary Diagnostics (Cont.)
- 12:00-1:25 pm: Luncheon 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 Close of Conference

### 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
  - 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 (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own
- 1:25-3:00 pm: Immune Monitoring: Biomarkers of Response and Resistance
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Cover
Sponsor & Exhibit Opportunities
Conference-at-a-Glance
Distinguished Speakers
Short Courses
Immuno-Oncology Biomarkers 1
Immuno-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

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
Jin Aubrecht, PharmD, PhD, Senior Director, Translational Biomanufacturing, Teal Genomics
Xingfeng Bao, PhD, Director, Immuno-Oncology, Eisai
J. Carl Barrett, PhD, Vice President, Oncology Translational Sciences, Astrella
Roy D. Baynes, MD, PhD, Senior Vice President and Head, Global Clinical Development, CMG, Merck Research Laboratory
Robert A. Beckham, MD, Professor, Oncology, Biostatistics, Bioinformatics, and Biomathematics, Lombardi Cancer Center; Perioperative Comprehensive Cancer Center and Innovation Institute for Biomedical Informatics, Georgetown University Medical Center
Michael J. Benecchi, PhD, Senior Director, Global Regulatory Affairs, Precision and Inflammatory Medicine, R&D Chief Regulatory Office, GlaxoSmithKline
Peter Berghozen, MD, Vice President, Quantitative Medicine and Clinical Technologies, Biogen
Erhan Bilal, PhD, Researcher, IBM T.J. Watson Research/Computational Biology Center
Manjo Bilusic, MD, PhD, Associate Research Physician, National Cancer Institute, National Institutes of Health
Darrel R. Borger, PhD, Scientific Director, Immuno-Profiling Laboratory, Director, Translational Research/Biomanufacturer Laboratory, Massachusetts General Hospital Cancer Center
Michael E. (Ted) Burczynski, PhD, PPM Expert, Director, Personalized & Predictive Medicine, Analytics & Big Data, Teva Pharmaceuticals
Yu-Feng Yvonne Chan, MD, PhD, Associate Professor; Genetics and Genomics Science & Emergency Medicine; Director, Center for Digital Health, Icahn Institute for Genomics and Multiscale Biology; Icahn School of Medicine at Mount Sinai
Pratip Chattopadhyay, PhD, Associate Professor, Pharmacology, Director, Precision Immunology Incubator, Isaac and Laura Perlmuter Cancer Center, New York University Langone Medical Center
Ieuan Clay, PhD, Group Lead Broad Endpoints, Translational Medicine, Novartis Institutes for Biomedical Research
Carolyn Compton, MD, PhD, Professor, Life Science, Arizona State University, CMG, ASU Complex Adaptive Systems Institute; CMG, National Biomarker Development Alliance
Mark E. Curran, PhD, Vice President and Head of Companion Diagnostics, Janssen Immunology Viswanath Devanarayan, PhD, Global Head of Statistics & Data Sciences, Charles River Laboratories
Kenneth Emanuelczyk, MD, Executive Medical Director and Head of Companion Diagnostics, Merck & Co.
Steven Fling, PhD, Senior Staff Scientist, Vaccine & Infectious Disease Division, Fred Hutchinson Cancer Research Center, Director, Cancer Immunotherapy Trials Network Immunology
Shrin Kambhata Ford, PhD, Global Head, Biomarkers and Diagnostics, Executive Director, Oncology Global Medical Affairs, Merck
Bernard A. Fox, PhD, Harder Family Chair for Cancer Research, Member and Chief, Laboratory of Molecular and Tumor Immunology, Robert W. Franz Cancer Center, Earle A. Chiles Research Institute, Portland Portland Medical Center; CEO, UbVac
Mark Frasier, PhD, Senior Vice President, Research Programs, The Michael J. Fox Foundation for Parkinson’s Research
Morganna Freeman, MD, Digital Oncological Immunologist, The Angeles Clinic and Research Institute
Jianjun Gao, MD, PhD, Assistant Professor, Genentherapy Medical Oncology, The University of Texas MD Anderson Cancer Center
Arnold Gelb, MS, MD, FASCP FCAP, Advisor, Companion Diagnostic Development
Marios Giannakos, MD, PhD, Medical Oncologist & Clinical Investigator; Dana Farber Barrow Gaitan Cancer Treatment Center; Researcher, Broad Institute of MIT and Harvard
Christopher Major, PhD, Scientific Director, Diagnostic Development, Janssen
Rajiv Jandial, MD, Head and Neck Surgical Oncology Fellow, Memorial Sloan Kettering Cancer Center
Sanjeev Mariathasan, PhD, Senior Scientist, Oncology Biomarker Department, Genentech
Gajraj R. Naik, MD, FACP, Senior Vice President and CMG, Qualcomm Life
Jennifer J.D. Morrisette, PhD, Scientific Director, Clinical Cancer Cytogenetics, Clinical Director, Center for Personalized Diagnostics, University of Pennsylvania
Unnik B. Nielsen, PhD, President and Co-Founder, Toquate
Carol Anne Ogden, PhD, Senior Managing and ADCETRIS Biomarker Lead, Diagnostics and Biomarkers, Genentech, Inc.
Shigui Ogi, 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 Parlikar, PhD, Product Manager, Verity Life Sciences
Bakul Patel, Associate Director, Digital Health, FDA
Tracy Petrie, PhD, MoleMapper Product Manager, Oregon Health & Science University
Robert Pierce, MD, Scientific Director, ImmunoPET 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 Radvanyi, 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, Research, Parker Institute for Cancer Immunotherapy
Susanne K. Rhoades, PhD, Director, Diagnostics Development, Tailored Therapeutics, Eli Lilly and Company
David L. Rimm, MD, 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, MD, 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, Inc.
Emmett Schmidt, PhD, Distinguished Scientist & Executive Director, Merck Research Labs
Ceccia Schott, PharmD, MBA, Vice President, Precision Medicine, AstaraZeneca
Sadhana Shankar, MD, MPH, Senior Director, Clinical Research & Development, MacroGenics
Peter M. Shaw, PhD, Head, Clinical Pharmacogenomics, 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 & Laboratory Medicine, Dartmouth College
Shannon J. Turley, PhD, Principal Scientist, Cancer Immunology, Genentech
Gregory Tsongalis, PhD, Professor, Pathology & Laboratory Medicine, Dartmouth College
Glen J. Weiss, MD, MBA, Clinical Associate Professor, University of Arizona College of Medicine, Phoenix
Theresa L. Whiteside, PhD, Professor, Pathology, Immunology and Otolaryngology, University of Pittsburgh Cancer Institute
Wendy Wickler, 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
Jianda 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. Allison, FIBMS, Vice President, Biomarker Services, Biologics Development Services, Tampa Bay Viswanath Devanarayan, 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 bioanalytical 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 (Medicine Oncology), Yale School of Medicine; Director, Translational Immuno-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
1:45-2:15 Introductions and Lunch Provided
2:15 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
• Where to prioritize investment for optimum clinical trial process
• What are the emerging applications for digital biomarkers?
3:30 Networking Refreshment Break
4:15 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?
5:30 Close of ThinkTank

Please visit www.BiomarkerWorldCongress.com for detailed course descriptions

*Separate registration required
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, Pharmacodiagnosics, 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, Pharmacodiagnosics, 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 Presentation to be Announced
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
Morganna 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
Shu-Jen Chen, PhD, CSO, 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 group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available in 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
Samar 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
Cirulating 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.

9:35 Panel Discussion on Tumor Neoantigens as Biomarkers and Targets

10:00 Presentation to be Announced

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, Vice President, Research, 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) 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 TSNA 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 TSNA-induced T-cells active in the immunosuppressive tumor microenvironment.

12:45 Session Break

12:55 Luncheon Presentation to be Announced

1:25 Close of Conference
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.

5:00 Leveraging RNA Expression Profiling to Direct Evaluation into Complex Tumor–Immune Associations
Darrell R. Borger, PhD, Scientific Director, Immuno-Profiling Laboratory; Director, Translational Research/Biomarker Laboratory, Massachusetts General Hospital Cancer Center

The complexity of the tumor-immune environment is underscored by the diversity of cell types, signaling processes, and secreted factors that can modulate how a patient responds to immunotherapy. This talk will highlight integration of RNA expression profiling to identify relevant immune escape mechanisms, cytokine pathway activation, and infiltrating immune signatures. Together with MSI testing and multispectral imaging, specific targetable immune signatures across cancer types will be presented.

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  See Page 5 for detailed information

TUESDAY, JUNE 12

12:15 pm Conference Registration
12:55 Luncheon Presentation to be Announced
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

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 immunology.

3:00 The Power of Single Molecule Counting (SMC™): The Future of Immunoassays
Antaben Tailor, PhD, SMC Technology & Application Advancement Lead, Research & Development, MilliporeSigma

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

TUMOR MICROENVIRONMENT PROFILING

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

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

We molecularly characterized 1,211 colorectal cancers (CRCs) and demonstrated that WNT-signaling and immune-related genes are significantly mutated in CRC.

INTEGRATED BIOMARKER ANALYSIS FOR PRECISION IMMUNO-ONCOLOGY

8:25 Chairperson’s Remarks
Andrey Loboda, PhD, Director, Genetics and Pharmacogenomics, Merck
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
Prapti Chattopadhyay, PhD, Associate Professor, Pathology; Director, Precision Immunology Incubator; Isaac and Laura Perlmutter 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 heterogeneous, 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 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 (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own
IMMUNE MONITORING: BIOMARKERS OF RESPONSE AND RESISTANCE

1:25 Chairperson’s Remarks
Wendy Winckler, PhD, Executive Director, Next Generation Diagnostics, Novartis Institutes for Biomedical Research

1:30 Response and Resistance in CAR-T Therapy
Wendy Winckler, PhD, Executive Director, Next Generation Diagnostics, 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, Clinical Associate Professor, University of Arizona College of Medicine, Phoenix

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
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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 Sponsored Presentation (Opportunity Available)

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
PERSONALIZED VACCINES: POTENTIAL FOR COMBINATION IMMUNOTHERAPY

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

4:15 Cancer Vaccines: Advances, Challenges and Opportunities
Marijo Blusic, MD, PhD, Associate Research Physician, National Cancer Institute, National Institutes of Health

Therapeutic cancer vaccines are unlikely to impact treatment outcomes as monotherapy. There is growing preclinical and clinical data that combination with other treatment modalities like chemotherapy, hormone therapy or immunotherapy can enhance treatment efficacy and induce immunogenic endosome with minimal additional toxicity. It seems that therapeutic vaccines with checkpoint inhibitors hold the greatest potential for improving clinical outcomes.

4:45 The Next Wave: Combination Immunotherapy with Vaccines Targeting a New Class of Cancer Antigens, Combined with T Cell Agonists and Checkpoint Blockers
Bernard A. Fox, PhD, Harder Family Chair for Cancer Research, Member and Chief, Laboratory of Molecular and Tumor Immunology, Robert W. Franz Cancer Center, Earle A. Chiles Research Institute, Providence Portland Medical Center, CEO, UbiVac

Using a microvesicle vaccine composed of SLiPs and DRiPs, and termed DRibbles (DRiPs in Belbs), in a tumor model that lacks apparent immunogenicity, and where anti PD-L1 has no effect, we find that DRibble vaccination combined with anti-OX40 can substantially boost therapeutic efficacy and result in apparent cure of animals. We have performed 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 Immune 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 dissection 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
TUESDAY, JUNE 12

7:25 am Interactive Breakout Discussion Groups with Continental Breakfast

TARGETING THE TUMOR MICROENVIRONMENT: ACTIVATING THE IMMUNE SYSTEM FOR BETTER RESPONSE TO IMMUNOTHERAPY

8:25 Chairperson’s Remarks
John Milburn Jessup, MD, George Mason University

8:30 Deep Primed™ Immunotherapy: Controlling the Microenvironment in T Cell Therapy
Ulrrik B. Nielsen, PhD, President and Co-Founder, Torque

Torque is developing Deep Primed™ cell therapies that direct and evoke immune 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.
Cambridge Healthtech Institute's Second Annual
Combination Immunotherapy

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 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.

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
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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 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

Submit a Poster
Cambridge Healthtech Institute encourages attendees to gain further exposure by sharing their work in the poster sessions.

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- Your poster abstract will be published in our conference materials

To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by April 27, 2018.
Intrinsic and Acquired Resistance to Immunotherapy
Immu-no-Oncology Therapeutic Strategies and Predictive Biomarkers for Non-Responders

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 Targeting the Tumor Microenvironment: Understanding Resistance Mechanisms in IO-Refractory Patients
Zhen Su, MD, MBA, CMO, North America, EMD Serono, Inc.

With the advent of IO therapy in oncology, we have seen significant improvements in the response rates and overall survival of cancer patients. However, the challenges to identify responsive patient populations, as well as understand mechanisms of resistance, continue to dampen our progress. Recent advances and preliminary combination regimens present a promising path forward; however, will this be enough to ensure durable responses in patients, especially in real-world settings?

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 Sponsored Presentation (Opportunity Available)

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 Antigen Presentation Defects and Resistance to Checkpoint Inhibitor Therapy
Ryan J. Sullivan, MD, Assistant 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 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 machinery 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  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.
10:30 Targeting TGF-Beta in Intrinsic and Acquired Resistance to Cancer Immunotherapy
Laszlo Radvanyi, PhD, Senior Vice President & Senior Global Scientific Advisor, Immuno-Oncology, EMD Serono

11:00 Sponsored Presentation (Opportunity Available)

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

IMMUNE MONITORING: BIOMARKERS OF RESPONSE AND RESISTANCE

1:25 Chairperson's Remarks
Wendy Winckler, PhD, Executive Director, Next Generation Diagnostics, Novartis Institutes for Biomedical Research

1:30 Response and Resistance in CAR-T Therapy
Wendy Winckler, PhD, Executive Director, Next Generation Diagnostics, 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, Clinical Associate Professor, University of Arizona College of Medicine, Phoenix

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
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Cambridge Healthtech Institute's Eighth Annual
Clinical and Translational Biomarkers

SUNDAY, JUNE 10

4:30-6:30 pm Short Course and Conference Registration
5:00-8:30 pm 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 am Organizer's Welcome

OPENING PLENARY SESSION: EMERGING APPROACHES FOR CANCER

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

8:10 am 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 am 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 am Coffee Break in the Exhibit Hall with Poster Viewing

BIOMARKER-DRIVEN CLINICAL TRIALS

9:55 am 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 am Clinical Monitoring of Biomarkers to Guide Informed Treatment
Sylvie Vincent, PhD, Associate Director, Translational Medicine, 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 immunohistochemistry, sequencing or circulating tumor cell numeration. 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 am 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 am 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.

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LIQUID BIOPSY FOR PRECISION MEDICINE

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

1:30 ctDNA Utility and Challenges
J. Carl Barrett, PhD, Vice President, Oncology Translational Sciences, AstraZeneca
Circulating tumor DNA (ctDNA) is becoming increasingly used in clinical practice and clinical/translational research. Examples of this utility will be given for patient selection, monitoring disease response and elucidating mechanisms of resistance to targeted therapies. Despite the common use in many commercial and academic labs, issues remain with sensitivity and specificity of some assays, and this will be discussed in this and other talks from our laboratories.

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 Sponsored Presentation (Opportunity Available)

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
miRNAs (miRNAs) released into the peripheral circulation upon cellular injury have shown a 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
TUESDAY, JUNE 12

7:25 am Interactive Breakout Discussion Groups with Continental Breakfast

LIQUID BIOPSY FOR IMMUNO-ONCLOGY

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 Presentation to be Announced

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

ASSAY DEVELOPMENT AND CLINICAL IMPLEMENTATION FOR GENOMIC TESTS

11:10 Chairperson's Remarks
Rajyalakshmi (Raja) Luthra, PhD, Director, Molecular Diagnostics Laboratory; Director, Molecular Genetics Pathology Fellowship Program; Professor, Division of Pathology and Laboratory Medicine, The University of Texas MD Anderson Cancer Center

11:15 Integration of Circulating Cell-Free DNA (cfDNA) Mutation Testing into Precision Medicine Paradigm
Rajyalakshmi (Raja) Luthra, PhD, Director, Molecular Diagnostics Laboratory; Director, Molecular Genetics Pathology Fellowship Program; Professor, Division of Pathology and Laboratory Medicine, The University of Texas MD Anderson Cancer Center

Mutation analysis of circulating cell-free DNA (cfDNA) from plasma is slowly being integrated into cancer patient management as a minimally invasive alternative to tissue based genotyping. However, implementation of cfDNA testing for patient care is faced with several pre-analytical and analytical challenges. This talk addresses potential role and limitations of cfDNA mutation testing using NGS and digital PCR platforms in a molecular diagnostic laboratory for cancer patient management.

11:45 Technical Aspects of NGS Assays for Oncology Translational and Clinical Research
Daniel Stetson, PhD, Associate Principal Scientist, AstraZeneca

The increased acceptance of liquid biopsies for precision medicine demonstrates a critical need for a sensitive and specific assay platform. Next Generation Sequencing (NGS) has the capability of detecting multiple types of genetic aberrations and can be used with many sample types including ctDNA. The technical aspects of improving sensitivity and specificity of NGS assays will be discussed including library preparation from cfDNA, unique molecular barcoding, and comprehensive variant calling.

12:15 pm Precision Oncology: Practical Strategies for Genomic Test Implementation with Case Vignettes
Christina Lockwood, PhD, Associate Professor, Director, Genetics and Solid Tumors Laboratory, University of Washington

Next-generation sequencing is a valuable tool for generating patient-specific genetic information for clinical diagnostics and optimal therapy selection. The heterogeneous somatic mutational landscape in cancer makes NGS particularly appealing due to the ability to accurately and simultaneously detect multiple mutations across many genes, even if present in a minority of cells. The complexity of NGS assays necessitates unique quality control and validation considerations that integrate informatics and variant interpretation.

12:45 Close of Conference
**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 **Talk Title to be Announced**

Dawn McHugh, Vice President, Business Development, Personalized Diagnostics, Corgenix, Inc.

3:15 **Sponsored Presentation** (Opportunity Available)

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.

**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**

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

Commercial-ready companion diagnostic assays are not available to initiate potential registrational therapeutic trials. As such, it is often necessary to initiate registrational therapeutic trials using a prototype Clinical Trial Assay (CTA), followed by a migration to commercial-ready companion diagnostic assay, via a
biodrug study. This session will present Janssen's recent experience in bridging from CTA's to companion diagnostics for global submission.

**9:30 Sponsored Presentation (Opportunity Available)**

**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 repositioning biomarkers and personalized medicine in the forefront 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. Rhoades, 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 Cytogenetics; 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 Cytogenetics; 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 in 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 dysregulated 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 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
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 Sponsored Presentation (Opportunity Available)

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

4:15 A Roadmap to Digital Endpoints for Parkinson’s Disease Using Sensors and Wearable Devices
Mark Frasier, PhD, Senior Vice President, Research Programs, The Michael J. Fox Foundation for Parkinson’s Research

Parkinson’s disease is a complex heterogeneous neurodegenerative condition characterized by motor and non-motor symptoms affecting millions worldwide. Disease symptoms include tremor, bradykinesia, dyskinesia, sleep disturbance and cognitive impairment. Finding sensitive and objective metrics to track disease progression is difficult. Wearable devices and sensors open the possibility of objectively measuring disease progression. The talk will present a possible roadmap to finding these metrics.

4:45 pm 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
9:30 Digital Biomarkers in Drug Development – Exploiting the Digital Armamentarium to Fight Heart Failure
Frank Kramer, PhD, Director & Biomarker Strategist, Cardiovascular Diseases, Bayer AG
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.

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

11:00 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 pm 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.

12:45 Pixels as Digital Biomarkers: Machine Learning and Beyond with MoleMapper
Tracy Petrie, PhD, MoleMapper Product Manager, Oregon Health & Science University
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.

1:15 Close of Conference
Conference Venue and Hotel:
Westin Boston Waterfront
425 Summer Street
Boston, MA 02210
Phone: 617-532-4600
Discounted Room Rate: $309 s/d
Discounted Room Rate Cut-off Date: May 14, 2018
Please visit the travel page of www.biomarkerworldcongress.com to make your reservation and reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel.