BIOMARKERS CONSORTIUM
IMPROVING HEALTH THROUGH MEANINGFUL MEASUREMENTS

FNIH
Foundation for the National Institutes of Health

Cancer Steering Committee Annual Scientific Symposium

Bethesda Marriott Hotel
Bethesda, MD

Monday, November 4, 2019 11:00 am – 8:00 pm
Tuesday, November 5, 2019 7:30 am – 4:00 pm

Agenda

Monday, November 4	
11:00 am – 12:00 pm	**Registration and Lunch**
12:00 – 12:15 pm	**FNIH Welcome** – Stacey Adam and Dana Connors
12:15 – 12:45 pm	**Meeting Introduction and Overview** – Eric Rubin, Merck and Gary Kelloff, NCI
12:45 – 1:15 pm	**Keynote** – Monica Bertagnolli, Dana Farber Cancer Institute
1:15 – 2:45 pm	**Biomarkers in the Immunotherapy Landscape** Chair: Eric Rubin, Merck • **CRI Landscape Analysis of IO Trials and Biomarkers** Jun Tang, Cancer Research Institute • **Human Tumor Atlas** Bruce Johnson, Dana Farber Cancer Institute • **Perspectives on Biomarkers in IO Trials** — Priti Hegde, Foundation Medicine — Lyndsay Harris, NCI/Partnership for Accelerating Cancer Therapies — Theresa LaVallee, Parker Institute for Cancer Immunotherapy — Alessandra Cesano, Essa Pharma • **Discussion/Panel**
2:45 – 3:00 pm	**Coffee/Networking**

3:00 – 4:30 pm	**Challenges for Biomarker Development: Heterogeneity, Immunotherapy-related Toxicity, and Regulatory Approaches** Chair: Bruce Johnson, Dana Farber Cancer Institute • **ctDNA in Immuno-oncology** Alex Snyder, Merck • **Data-Driven Evidence of Intra- and Inter-tumor Heterogeneity** Kurt Schalper, Yale • **Immunotherapy-related Adverse Events—Infrastructure for Evaluation** Elad Sharon, NCI • **Regulatory Perspective** Marc Theoret, FDA • **Discussion/Panel**
4:30 – 4:45 pm	**Coffee/Networking**
4:45 – 6:30 pm	**Advanced Technologies in Biomarker Development** Chair: Greg Friberg, Amgen • **Proteotyping Human Cancers** Dan Liebler, Protypia • **The SCANT Method** Jonathan Carlson, Harvard • **Diagnostic Technologies to Guide Therapy Design and Follow Therapy Response in Immuno-oncology** James Heath, Institute for Systems Biology • **Epigenetic Signatures in the Immune Tumor Interface: Stratifying Melanoma Patients for Checkpoint Inhibitors** Claudio Carini and Peter Parker, King's College London • **Discussion/Panel**
6:30 – 7:00 pm	**Keynote** – Chi Van Dang, University of Pennsylvania
7:00 – 8:00 pm	**Reception**
8:00 pm	**Adjourn – Dinner on Your Own**

AGENDA: TUESDAY, NOVEMBER 5

Tuesday, November 5	
7:30 – 7:50 am	**Registration and Breakfast**
7:50 – 8:00 am	**Meeting Overview II –** Eric Rubin, Merck
8:00 – 8:30 am	**Keynote –** Chris Boshoff, Pfizer
8:30 – 8:45 am	**Break/Networking**
8:45 – 10:15 am	**Breakout Session A – The Microbiome** Chair: Yasmine Belkaid, NIAID and NIH Center for Human Immunology • **An Overview of the Science of the Microbiome** Yasmine Belkaid, NIAID • **Functional Microbiomic Signatures as Predictors of Pro-tumor Inflammatory State and Susceptibility to Immunotherapy** Leopoldo Segal, NYU • **Discussion/Panel**
8:45 – 10:15 am	**Breakout Session B – Measurable Residual Disease** Chair: Greg Reaman, FDA • **Statistical Considerations Regarding the Role of MRD** Don Berry, Berry Consulting • **Molecular Response and MRD in AML** Jerry Radich, University of Washington • **The Future of MRD in Multiple Myeloma** Ken Anderson, Dana Farber Cancer Institute • **Next Steps for MRD in Other Hematologic Cancers – AML** Robert Loberg, Amgen • **The Need for an Opportunity for MRD Standardization in AML** Kim Jessup, Unaffiliated • **Discussion/Panel**
10:15 – 10:30 am	**Coffee/Networking**

10:30 am – 12:25 pm	**Breakout Session C – Imaging Biomarkers** Chair: Annette Schmid, Takeda • **Imaging Biomarkers as Trial Endpoints** Greg Goldmacher, Merck • **Parameters Based on Tumor Growth and Regression** Tito Fojo, Columbia University • **Vol-PACT Project Read Out** Larry Schwartz, Columbia University • **Radiomic Feature Identification** Andrea Thiele and Bushi Wang, Boehringer Ingelheim • **Whole Organ Radiomics in Oncology: A Novel AI Based Approach** Nozha Boujemaa, Median Technologies • **Discussion/Panel**
10:30 am – 12:25 pm	**Breakout Session D – Liquid Biopsy** Chair: Carl Barrett, AstraZeneca • **Challenges in Establishing ctDNA Controls** Bob McCormack, Unaffiliated • **Standardization of Tumor Mutational Burden** Mark Stewart, Friends of Cancer Research • **Use of the Immunosequencing Platform with Cell-Free DNA** Lanny Kirsch, Adaptive Biotechnologies • **PD Assay Network and Other Collaborations** Howard Scher, Memorial Sloan Kettering Cancer Center • **Clinical Implementation Challenges** Stanley Hamilton, MD Anderson • **Collaborations and Initiatives to Validate Liquid Biopsy** — Lauren Leiman, BloodPAC — Reena Philip, FDA • **Discussion/Panel**
12:25 – 12:50 pm	**Lunch/Networking**
12:50 – 1:10 pm	**Lunch Session: Breakout Session Summaries** • **The Microbiome** Session Chair: Yasmine Belkaid, NIAID • **Measurable Residual Disease** Session Chair: Greg Reaman, FDA • **Imaging Biomarkers** Session Chair: Annette Schmid, Takeda • **Liquid Biopsy** Session Chair: Carl Barrett, AstraZeneca

1:10 – 1:30 pm	**Lunch Session: Pediatric Oncology Perspective** • **Pediatric Oncology Patient Advocate** Caitlyn Barrett, CureSearch • **Clinical Trial Access and Inclusion/Exclusion Criteria** Ann Ramer, Advocate
1:30 – 2:00 pm	**Keynote –** Gideon Blumenthal, FDA
2:00 – 3:50 pm	**Data Science and Machine Learning in Biomarker Development** Chair: Hisham Hamadeh, GenMab • **Leveraging the NCI Cancer Research Data Commons** David Patton, Center for Biomedical Informatics and Information Technology, NCI • **Machine Learning and the Use of AI, an update on INFORMED** Sean Khozin, FDA • **Data-driven Knowledge Graphs and AI for Biomarker Discovery and Patient Selection** Janusz Dutkowski, Data4Cure • **Machine-learning Systems and Discovery of Actionable Biomarkers for Clinical Development** Pratik Shah, MIT • **Use of RWD in Accelerating Biomarker Discovery** Shrujal Baxi, FlatIron Health • **Discussion/Panel**
3:50 – 4:00 pm	**Wrap-up and Adjourn**