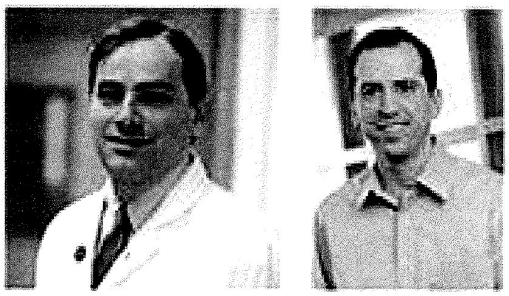
Ex. H

Class 41

MSK
Department of Surgery Grand Rounds

"The MSK-IMPACT™ assay for the surgeon"



Drs. Solit[a] and Berger[b]
[a]Geoffrey Beene Chair,
Marie-Josee and Henry R. Kravis
Center for Molecular Oncology
(CMO);
[b]Associate Director of the CMO and
Attending Geneticist, Pathology

3 November 2014
Zuckerman Auditorium, 0800-0900

TRACK 5: MUTATION ANALYSIS FOR CLINICAL BIOMARKERS AND DIAGNOSTICS

Thursday, May 1

1:00-2:00 Conference Registration

CLINICAL UTILITY OF "ACTIONABLE" MUTATIONS

1:55-2:00 Chairperson's Opening Remarks
Marc Ladanyi, M.D., William Ruane Chair in Molecular Oncology; Molecular Diagnostics Service and Human Oncology Pathogenesis Program, Memorial Sloan-Kettering Cancer Center

2:00-2:25 High-Throughput Clinical Cancer Genotyping Based in Next-Generation Sequencing: New Paradigm, New Challenges

Marc Ladanyi, M.D., William Ruane Chair in Molecular Oncology; Molecular Diagnostics Service and Human Oncology Pathogenesis Program, Memorial Sloan-Kettering Cancer Center

2:25-2:50 Mining Genetic Data on an Entire Nation
Kári Stefánsson , M.D., CEO, deCODE Genetics

2:50-3:15 Validation of NGS Cancer Panels for Clinical Somatic Mutation Profiling — Identification of Source of Variations and Artifacts Using FFPE Tissues
Ken Chang, Ph.D., Senior Principal Scientist, Clinical Biomarkers and Diagnostics, Merck Research Labs

3:20-4:15 Refreshment Break in the Exhibit Hall with Poster Viewing
Chairperson's Opening Remarks
Michael Berger, Ph.D., Assistant Professor, Pathology, Memorial Sloan-Kettering Cancer Center

4:15-4:40 Broad-Based Clinical Genotyping in Personalizing Cancer Therapy

Darrell R. Borger, Ph.D. , Co-Director, Translational Research Laboratory; Director, Biomarker Laboratory, Massachusetts General Hospital and Harvard Medical School
This talk will address lessons learned from five years of implementing tumor mutational profiling as a component of cancer patient care. Advantages of a broad-based profiling approach that has been equally applied across diverse cancers will be highlighted, indicating how this has revealed new molecular signatures and has been used to foster a genotype-directed approach to clinical trial design. This has provided the foundation for expansion into next-generation sequencing approaches.

4:40-5:05 Biomarkers in Cutaneous Melanoma
Victor Prieto, M.D., Ph.D., Professor, Pathology and Dermatology, MD Anderson Cancer Center
This talk will discuss the recent developments on biomarkers in melanocytic lesions. In particular we will discuss the application of biomarkers to the diagnosis of melanocytic lesions (differentiation between nevus and melanoma by use of immunohistochemistry, CGH, FISH, and mass spectrometry), prognosis of melanoma (immunohistochemistry and FISH), and treatment (mutation analysis).

5:05-5:30 Genomic Approaches for Discovering and Profiling Biomarkers of Drug Response in Cancer
Michael Berger, Ph.D., Assistant Professor, Pathology, Memorial Sloan-Kettering Cancer Center
Massively parallel sequencing of tumors enables the discovery of genomic biomarkers that correlate with clinical outcomes and the prospective identification of these biomarkers in cancer patients. We have developed a

targeted, deep coverage sequencing assay to comprehensively characterize several classes of genomic alterations in 341 cancer genes (MSK-IMPACT) and have deployed this assay both retrospectively and prospectively on tumors from more than 1,500 patients at MSKCC. I will describe examples in which our group has identified genomic biomarkers predictive of drug response and resistance in a variety of tumor types.

6:00-9:00 Dinner Course*
Next-Generation Sequencing as a Clinical Test
(*Separate registration required)

Friday, May 2

7:30-8:15 am Breakfast Presentation *(Sponsorship Opportunity Available)* or Morning Coffee

NGS AND MUTATION ANALYSIS FOR PATIENT SELECTION

8:25-8:30 Chairperson's Opening Remarks
Scott D. Patterson, Ph.D., Executive Director, Medical Sciences, Amgen

8:30-8:55 Exploring Tumor Somatic Mutations to Further Refine the Responding Patient Population
Scott D. Patterson, Ph.D., Executive Director, Medical Sciences, Amgen
Rigorous hypothesis testing is a key final element in demonstrating the clinical validity of a biomarker. But to get to that stage, a sufficient level of evidence has to be generated to gain the confidence of key stakeholders to test a given biomarker hypothesis. Further, as the implementation of a therapeutic is usually intended to be global in nature, considerations for global diagnostic implementation should be taken into account. Biomarkers of the EGFR pathway will be described in tihs context.

8:55-9:20 Talk Title to be Announced
Xiaolan Hu, Ph.D., Head, Clinical Genetics, Bristol-Myers Squibb

9:20-9:45 Utilization of Point-of-Care Genotyping Technologies to Actively Recruit into a Genotype-Stratified Three Period Crossover Experimental Medicine Trial

Charles J. Cox, Ph.D., Head, Genetics Experiment Design and Delivery, GlaxoSmithKline

9:45-10:00 Panel Discussion
Moderator: Saumya Pant, Ph.D., Research Fellow, Merck

10:00-10:50 Coffee Break in the Exhibit Hall with Poster Viewing

10:50-11:15 Molecular Diagnostics of Cancer for Precision Medicine: Strategies and Challenges for Improving Clinical Outcome
Towia Libermann, Ph.D., Associate Professor, Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School; Director, BIDMC Genomics, Proteomics, Bioinformatics, and Systems Biology Center and DF/HCC Cancer Proteomics Core
Advances in NGS are unraveling cancer mutations, providing opportunities for developing precision medicine diagnostics. Growing understanding of cancer pathways combined with innovative targeted therapies enable discovery of actionable mutations in individual patients. Strategies to tailor therapy based on each patient's genetic characteristics are postulated to change the course of cancer. While an attractive concept, tumor heterogeneity and clinical trial complexities are major challenges for improving clinical outcome. Advances and challenges in cancer diagnostics for precision medicine will be discussed.

11:15-11:40 Next-Generation Sequencing Strategies for Selecting Patients Who May Benefit from PARP Inhibitor Therapy
Mitch Raponi, Ph.D., Senior Director, Molecular Diagnostics, Clovis Oncology
The discussion will address the following questions: What biomarkers should we be focusing on to identify appropriate patients who will likely benefit from PARP inhibitors? How can we apply next-generation sequencing technologies to identify all patients who will respond to the PARP inhibitor rucaparib? What regulatory challenges are we faced with for approval of NGS companion diagnostics?

11:40-12:05 pm Talk Title to be Announced
Saumya Pant, Ph.D., Research Fellow, Merck

12:05-12:30 The Use of Targeted NGS Assays to Identify Tumor Molecular Defects and Support Treatment Selection in NCI-Sponsored Clinical Trials
Jason Lih, Ph.D., Principal Scientist, Molecular Characterization & Clinical Assay Development Laboratory, Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research

12:30 Close of Conference

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