10th Early Detection Research Network (EDRN) Scientific Workshop
Cancer Biomarkers in Precision Medicine
March 6-8, 2018
Bethesda North Marriott Hotel & Conference Center
Bethesda, Maryland

Tuesday, March 6, 2018

7:00 a.m. – 8:00 a.m.  Registration
Ballroom Foyer

8:00 a.m. - 12:00 p.m.  Early Detection Research Network (EDRN) and Food and Drug Agency (FDA) Workshop on Diagnostic Biomarkers
Ballroom F-H

8:00 a.m. – 8:10 a.m.  Welcome and Charge to Participants
Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute
Kelly Oliner, Ph.D., Deputy Division Director, OIR/DIHD, FDA

8:10 a.m. – 9:00 a.m.  Discussion Topic: Establishing a pathway for investigators for an FDA pre-submission on proposed design(s) for prospective early detection and/or diagnostic studies - without necessarily having an industry partner.

8:10 a.m. – 8:25 a.m.  Steven Skates, Ph.D., Massachusetts General Hospital
8:25 a.m. – 8:45 a.m.  Jeffrey Seidman, M.D., Medical Officer, OIR/DMGP, FDA
8:45 a.m. – 9:00 a.m.  Discussion

9:00 a.m. – 9:50 a.m.  Discussion Topic: Exploration of the use of banked samples from large cohorts, such as WHI and PLCO, for submission to FDA for claims of early detection.

9:00 a.m. – 9:15 a.m.  Ziding Feng, Ph.D., The University of Texas MD Anderson Cancer Center
9:15 a.m. – 9:35 a.m.  Gene Pennello, Ph.D., Team Leader, Biostatistics, OSB/DBS, FDA
9:35 a.m. – 9:50 a.m.  Discussion

9:50 a.m. – 10:10 a.m.  Break
Tuesday, March 6, 2018 Continued

EDRN and FDA Workshop on Diagnostic Biomarkers Continued

10:10 a.m. – 11:00 a.m. Discussion Topic: FDA requirements for technology platform approval/clearance, with a focus on proteomics and mass spectrometry.

10:10 a.m. – 10:25 a.m. Daniel Chan, Ph.D., Johns Hopkins University
10:25 a.m. – 10:45 a.m. Doug Jeffery, Ph.D., Branch Chief, OIR/DIHD/IMFB, FDA
10:45 a.m. – 11:00 a.m. Discussion

11:00 a.m. – 11:50 a.m. Discussion Topic: FDA requirements for analyte approval/clearance (analyte panel and classifiers).

11:00 a.m. – 11:15 a.m. Zhen Zhang, Ph.D., Johns Hopkins University
11:15 a.m. – 11:35 a.m. Aaron Schetter, Ph.D., M.P.H., OIR, DMPG, FDA
11:35 a.m. – 11:50 a.m. Discussion

12:00 p.m. Adjourn

FDA Participants
Reena Philip, Ph.D., Division Director OIR/DMGP
Lea Carrington, MS, MBA, MT (ASCP), Division Director OIR/DIHD
Kelly Oliner, Ph.D., Deputy Division Director, OIR/DIHD
Meijuan Li, Ph.D., Branch Chief, OSB/DBS
Eunice Lee, Ph.D., Branch Chief, OIR/DMGP
Doug Jeffery, Ph.D., Branch Chief, OIR/DIHD
Gene Pennello, Ph.D., Team Leader, Biostatistics, OSB/DBS
Changhong Song, Ph.D., Team Leader, Biostatistics, OSB/DBS
Anand Pathak, M.D., Medical Officer, OIR/DMGP
Jeffrey Seidman, M.D., Medical Officer, OIR/DMGP
Majda Haznadar, Ph.D., Scientific Reviewer, OIR/DIHD
Ozan Aygun, Ph.D., Scientific Reviewer, OIR/DMGP

OIR: Office of In Vitro Diagnostics and Radiological Health
DMGP: Division of Molecular Genetics and Pathology
DIHD: Division of Immunology and Hematology
OSB: Office of Surveillance and Biometrics
DBS: Division of Biostatistics
Tuesday, March 6, 2018 Continued

12:00 p.m. – 1:00 p.m.  EDRN Executive Committee Meeting (closed session)
  White Oak B

8:00 a.m. – 1:00 p.m.  Registration
  Ballroom Foyer

1:00 p.m. – 1:10 p.m.  Welcoming Remarks
  Ballroom F-H
  Barnett S. Kramer, M.D., M.P.H., Director,
  Division of Cancer Prevention, National Cancer Institute

1:10 p.m. – 1:15 p.m.  Welcome and Charge to Participants
  Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute

1:15 p.m. – 1:20 p.m.  Network Consulting Team’s Perspective on the EDRN
  Larry Norton, M.D., Chair EDRN Network Consulting Team,
  Memorial Sloan Kettering Cancer Center

1:20 p.m. – 1:45 p.m.  Plenary Lecture
  Impressions of a New NCI Director
  Norman Sharpless, M.D., Director, National Cancer Institute

  1:45 p.m. – 1:50 p.m.  Q&A

1:50 p.m. – 3:40 p.m.  Session I: Innovative and Novel Technologies
  Session Chairs
  o Chair: Scott Tomlins, M.D., Ph.D.,
    University of Michigan
  o Co-Chair: Joshua LaBaer, M.D., Ph.D.,
    Arizona State University/The Biodesign Institute

  1:50 p.m. – 1:55 p.m.  Introduction to Session Chair/Co-Chair
**10\textsuperscript{th} Early Detection Research Network (EDRN) Scientific Workshop**

**Cancer Biomarkers in Precision Medicine**

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**Bethesda, Maryland**

**Tuesday, March 6, 2018 Continued**

**Session I: Innovative and Novel Technologies Continued**

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| 1:55 p.m. – 2:20 p.m. | **Plenary Lecture**
|                | Ballroom F-H                                                          |
|                | A Review of Seed Investments at the Knight Cancer Institute for Early Detection Research
|                | Sadik Esener, Ph.D., Oregon Health & Science University's Knight Cancer Institute |
| 2:20 p.m. – 2:25 p.m. | Q&A                                                                    |
| 2:25 p.m. – 2:45 p.m. | **Liquid Biopsy for the Earlier Detection of Cancer**
|                | Kenneth Kinzler, Ph.D., Johns Hopkins University                      |
| 2:45 p.m. – 2:50 p.m. | Q&A                                                                    |
| 2:50 p.m. – 3:10 p.m. | **Multiplex Screening and Evaluation of Plasma Protein Biomarkers for Early detection of Colorectal Cancer Using Proximity Extension Assay**
|                | Ida Grundberg, Ph.D., Olink Proteomics                                |
| 3:10 p.m. – 3:15 p.m. | Q&A                                                                    |
| 3:15 p.m. – 3:35 p.m. | **Biomarker Quantification by Compensated Interferometry: Lowering the LOQ to Improve Case-Control Separation for IPNs**
|                | Darryl Bornhop, Ph.D., Vanderbilt University                         |
| 3:35 p.m. – 3:40 p.m. | Q&A                                                                    |
| 3:40 p.m. – 4:00 p.m. | **Break**                                                             |
| 4:00 p.m. – 5:50 p.m. | **Session II: Accelerating Validation and Implementation of Biomarkers**
|                | **Session Chairs**                                                    |
|                | ○ Chair: John Wei, M.D., University of Michigan                       |
|                | ○ Co-Chair: Anirban Maitra, M.B.B.S., The University of Texas MD Anderson Cancer Center |
Tuesday, March 6, 2018 Continued

Session II: Accelerating Validation and Implementation of Biomarkers Continued

4:00 p.m. – 4:05 p.m.  ---  Introduction to Session
Ballroom F-H  ---  Chair/Co-Chair

4:05 p.m. – 4:30 p.m.  ---  Plenary Lecture
The Continuum of Risk Assessment and Early Detection through Blood Based Biomarkers
Samir Hanash, M.D., Ph.D., The University of Texas MD Anderson Cancer Center

4:30 p.m. – 4:35 p.m.  ---  Q&A

4:35 p.m. – 4:55 p.m.  ---  By Design Approach in Biomarker Development, Validation, and Clinical Implementation
Zhen Zhang, Ph.D., Johns Hopkins University

4:55 p.m. – 5:00 p.m.  ---  Q&A

5:00 p.m. – 5:20 p.m.  ---  Challenges in Moving Biomarkers from Bench to Bedside
John Wei, M.D., University of Michigan

5:20 p.m. – 5:25 p.m.  ---  Q&A

5:25 p.m. – 5:45 p.m.  ---  Bench to Boardroom to Bedside: an Airway Gene-expression Biomarker’s Journey
Avrum Spira, M.D., M.Sc., Boston University

5:45 p.m. – 5:50 p.m.  ---  Q&A

5:50 p.m.  ---  Adjourn for the Day
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Wednesday, March 7, 2018

7:00 a.m. – 8:00 a.m.  Registration
Ballroom Foyer

8:00 a.m. – 10:15 a.m.  Session III: Precision Detection of Early Stage Cancers
Ballroom F-H

8:00 a.m. – 8:05 a.m.  Introduction to Session Chair/Co-Chair

8:05 a.m. – 8:30 a.m.  Plenary Lecture
Genomic Studies of Advanced and Early Lung Cancer
Matthew Meyerson, M.D., Ph.D., Dana-Farber Cancer Institute

8:30 a.m. – 8:35 a.m.  Q&A

8:35 a.m. – 8:55 a.m.  Biomarker Driven Non-Endoscopic Early Detection for Barrett’s Esophagus
Sanford Markowitz, M.D., Ph.D., Case Western Reserve University

8:55 a.m. – 9:00 a.m.  Q&A

9:00 a.m. – 9:20 a.m.  Proteomic and Genomic Ovarian Cancer Biomarker Discovery and Validation
Steven Skates, Ph.D., Massachusetts General Hospital

9:20 a.m. – 9:25 a.m.  Q&A

9:25 a.m. – 9:45 a.m.  Early Detection of Pancreatic Cancer through the Evaluation of Pancreatic Cysts
Aatur Singhi, M.D., Ph.D., University of Pittsburgh

9:45 a.m. – 9:50 a.m.  Q&A
Wednesday, March 7, 2018 Continued

Session III: Precision Detection of Early Stage Cancers

9:50 a.m. – 10:10 a.m. Prostate Cancer as a Model for the Challenges of Precision Early Detection
Ballroom F-H
Scott Tomlins, M.D., Ph.D., University of Michigan

10:10 a.m. – 10:15 a.m. Q&A

10:15 a.m. – 11:30 a.m. Poster Viewing Session 1
Ballroom E

11:30 a.m. – 12:30 p.m. Lunch Break (On Your Own)

11:30 a.m. – 12:30 p.m. Pancreatic Cancer Investigator Meeting
White Oak B

12:30 p.m. – 3:10 p.m. Session IV: Imaging and Early Detection
Ballroom F-H

12:30 p.m. – 12:35 p.m. Introduction to Session Chair/Co-Chair

12:35 p.m. – 1:00 p.m. Plenary Lecture
High and Low Neuroendocrine Subtypes of Small Cell Lung Cancer and their Clinical Importance
Adi Gazdar, M.D., University of Texas Southwestern

1:00 p.m. – 1:05 p.m. Q&A

1:05 p.m. – 1:25 p.m. Habitat Risk Score in Prostate Cancer - Correlation with Histopathology from Radical Prostatectomy
Radka Stoyanova, Ph.D., University of Miami

1:25 p.m. – 1:30 p.m. Q&A
### Session IV: Imaging and Early Detection Continued

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<td>1:30 p.m. – 1:50 p.m.</td>
<td>Feature Characterization of Indeterminate Lung Nodules</td>
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<td>Ballroom F-H</td>
<td>Denise Aberle, M.D., University of California, Los Angeles</td>
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<td>1:50 p.m. – 1:55 p.m.</td>
<td>Q&amp;A</td>
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<td>1:55 p.m. – 2:15 p.m.</td>
<td>Multi-parametric Image Processing for Early Detection of Cancer</td>
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<td>Eugene Koay, M.D, Ph.D., The University of Texas MD Anderson Cancer Center</td>
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<td>2:15 p.m. – 2:20 p.m.</td>
<td>Q&amp;A</td>
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<tr>
<td>2:20 p.m. – 2:40 p.m.</td>
<td>Strategies to Provide Temporal/Spatial High-resolution Mapping of Biologically Aggressive Breast Cancers</td>
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<td>Victoria Seewaldt, M.D., City of Hope</td>
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<td>2:40 p.m. – 2:45 p.m.</td>
<td>Q&amp;A</td>
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<td>2:45 p.m. – 3:05 p.m.</td>
<td>Radiomics</td>
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<td>Robert Gillies, Ph.D., H. Lee Moffitt Cancer Center</td>
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<td>3:05 p.m. – 3:10 p.m.</td>
<td>Q&amp;A</td>
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<td><strong>3:10 p.m. – 4:00 p.m.</strong></td>
<td><strong>Poster Viewing Session 2</strong></td>
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Wednesday, March 7, 2018 Continued

4:00 p.m. – 5:30 p.m.  Session V: Building Alliances with Other Consortia
Ballroom F-H

Introduction to Session Chair/Co-Chair

4:00 p.m. – 4:05 p.m.
Alan Pollack, M.D., Ph.D., University of Miami, Consortium of Imaging and Biomarkers

4:05 p.m. – 4:25 p.m.
Brian Wolpin, M.D., M.P.H., Dana-Farber Cancer Institute, Pancreatic Cancer Detection Consortium

4:25 p.m. – 4:45 p.m.
Stephen Pandol, M.D., Cedars- Sinai, Chronic Pancreatitis, Diabetes and Pancreatic Cancer Consortium

5:05 p.m. – 5:15 p.m.
Barbara Kenner, Ph.D., Kenner Family Research Fund

5:15 p.m. – 5:30 p.m.
Cancer Research UK’s Strategy and Activities in Early Detection Research
David Crosby Ph.D., Cancer Research UK

5:30 p.m.  Adjourn for the Day

7:00 p.m. – 9:00 p.m.  Discussion on International Collaborations
White Oak B
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Thursday, March 8, 2018

7:30 a.m. – 8:30 a.m.  Registration
Ballroom Foyer

Joint Meeting of the EDRN and Molecular and Cellular Characterization of Screen-Detected Lesions (MCL) Consortium

8:30 a.m. – 3:40 p.m.  Interdisciplinary Organ-Specific Research on Early Cancer Detection and Overdiagnosis
Ballroom F-H

8:30 a.m. – 8:40 a.m.  Welcome and Introductory Remarks
Dinah Singer, Ph.D., Director, Division of Cancer Biology, National Cancer Institute
Barnett S. Kramer, M.D., M.P.H., Director, Division of Cancer Prevention, National Cancer Institute

8:40 a.m. – 9:05 a.m.  Plenary Lecture
GRAIL’s Approach to Early Cancer Detection
Elizabeth Mansfield, Ph.D., GRAIL
9:05 a.m. – 9:10 a.m.  Q&A

9:10 a.m. – 10:50 a.m.  Prostate Cancer
Session Chairs
- Shiv Srivastava, Ph.D., Center for Prostate Disease Research
- Angelo DeMarzo, M.D., Ph.D., Johns Hopkins University

9:10 a.m. – 9:30 a.m.  Genomic Studies of Prostate Cancer Evolution
James D. Brooks, M.D., Stanford University
Robert West, M.D., Ph.D. Stanford University
9:30 a.m. – 9:35 a.m.  Q&A

9:35 a.m. – 9:55 a.m.  Prostate Cancer Precursor Lesions: Rethinking What We Know
Angelo DeMarzo, M.D., Ph.D., and Srinivasan Yegnasubramanian, M.D., Ph.D., Johns Hopkins University
Thursday, March 8, 2018 Continued

Interdisciplinary Organ-Specific Research on Early Cancer Detection and Overdiagnosis - Prostate Cancer -Continued

9:55 a.m. – 10:00 a.m.  Q&A
Ballroom F-H

10:00 a.m. – 10:20 a.m.  A Targeted Proteomics Strategy for the Development of Prostate Cancer Liquid-Biopsies
John Semmes, Ph.D., Eastern Virginia Medical School

10:20 a.m. – 10:25 a.m.  Q&A

10:25 a.m. – 10:45 a.m.  Interrogating the Urinary Transcriptome to Refine Prostate Cancer Detection
Martin Sanda, M.D., Emory University

10:45 a.m. – 10:50 a.m.  Q&A

10:50 a.m. – 11:10 a.m.  Break

11:10 a.m. – 12:50 p.m.  Breast Cancer
Ballroom F-H

Session Chairs
- Jeff Marks, Ph.D., Duke University Medical School
- Alexander Borowsky, M.D., University of California, Davis

11:10 a.m. – 11:30 a.m.  Understanding the Landscape of DCIS
Laura Esserman, M.D., M.B.A., University of California, San Francisco
Michael Campbell, Ph.D., University of California, San Francisco

11:30 a.m. – 11:35 a.m.  Q&A

11:35 a.m. – 11:55 a.m.  Prediction of Progression and Recurrence in the Vermont Cohort of Screen-Detected Breast Cancer
Donald Weaver, M.D., University of Vermont

11:55 a.m. – 12:00 p.m.  Q&A
Thursday, March 8, 2018 Continued

Interdisciplinary Organ-Specific Research on Early Cancer Detection and Overdiagnosis - Breast Cancer - Continued

12:00 p.m. – 12:20 p.m.
**Ballroom F-H**

Unique Approach Combining Avatar Mice and Targeted Mass Spectrometry to Identify Blood Biomarkers for Early Detection of Breast Cancer
Amanda Paulovich, M.D., Ph.D., Fred Hutchinson Cancer Research Center

12:20 p.m. – 12:25 p.m.  Q&A

12:25 p.m. – 12:45 p.m.

Breast Cancer: Integrating Imaging and Molecular Diagnostics
Karen Anderson, M.D., Ph.D., Arizona State University

12:45 p.m. – 12:50 p.m.  Q&A

12:50 p.m. – 2:00 p.m.

**Lunch (On Your Own)**

2:00 p.m. – 3:40 p.m.
**Ballroom F-H**

**Lung Cancer**

*Session Chairs*

- Harvey Pass, M.D., New York University School of Medicine
- Avrum Spira, M.D., M.Sc., Boston University

2:00 p.m. – 2:20 p.m.

Immunity and Inflammation in the Pathogenesis of Lung Cancer
Steven Dubinett, M.D., University of California, Los Angeles

2:20 p.m. – 2:25 p.m.  Q&A

2:25 p.m. – 2:45 p.m.

Distinguishing Indolent from Aggressive Lung Cancers using Quantitative Radiomic Features
Matthew Schabath, Ph.D., H. Lee Moffitt Cancer Center

2:45 p.m. – 2:50 p.m.  Q&A
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Thursday, March 8, 2018 Continued

Interdisciplinary Organ-Specific Research on Early Cancer Detection and Overdiagnosis - Lung Cancer - Continued

2:50 p.m. – 3:10 p.m. Whole Blood Gene Expression Can Accurately Distinguish Benign from Malignant Lung Nodules; Transitioning from Microarrays to the NanoString™ Platform
   Ballroom F-H
   Louise Showe, Ph.D., Wistar Institute

3:10 p.m. – 3:15 p.m. Q&A

3:15 p.m. – 3:35 p.m. Approaches to Improving DNA Methylation Detection
   James Herman, M.D., University of Pittsburgh School of Medicine

3:35 p.m. – 3:40 p.m. Q&A

3:40 p.m. – 4:00 p.m. Break

4:00 p.m. – 5:00 p.m. Collaborative Opportunities between the EDRN and MCL
   (Leadership of these two consortia to present their vision for interacting with each other)
   Ballroom F-H
   Session Chairs
   o Karen Anderson, M.D., Ph.D., Arizona State University
   o Martin Sanda, M.D., Emory University
   o Laura Esserman, M.D., M.B.A., University of California, San Francisco
   o James Brooks, M.D., Stanford University

5:00 p.m. Adjourn