

**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

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| 7:00 a.m. – 8:00 a.m. <i>Ballroom Foyer</i> | Registration |
| 8:00 a.m. - 12:00 p.m. <i>Salon F-H</i> | Early Detection Research Network (EDRN) and Food and Drug Administration (FDA) Workshop on Diagnostic Biomarkers |
| 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. |
| <i>8:10 a.m. – 8:20 a.m.</i> | <i>FDA Pre-submission Process - Overview</i> |
| <i>8:20 a.m. – 8:35 a.m.</i> | Steven Skates, Ph.D., Massachusetts General Hospital |
| <i>8:35 a.m. – 8:50 a.m.</i> | Jeffrey Seidman, M.D., Medical Officer, OIR/DMGP Anand Pathak, M.D., Ph.D., M.P.H., Medical Officer, OIR/DMGP |
| <i>8:50 a.m. – 9:00 a.m.</i> | 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. |
| <i>9:00 a.m. – 9:15 a.m.</i> | David Ransohoff, M.D., University of North Carolina at Chapel Hill |
| <i>9:15 a.m. – 9:35 a.m.</i> | Gene Pennello, Ph.D., Team Leader, Biostatistics, OSB/DBS, FDA |
| <i>9:35 a.m. – 9:50 a.m.</i> | Discussion |
| 9:50 a.m. – 10:10 a.m. | Break |

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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
Salon F-H** **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, DMGP,
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., Ph.D., M.P.H., 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

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Tuesday, March 6, 2018 Continued

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| 12:00 p.m. – 1:00 p.m. <i>White Oak B</i> | EDRN Executive Committee Meeting (closed session) |
| 8:00 a.m. – 1:00 p.m. <i>Ballroom Foyer</i> | Registration |
| 1:00 p.m. – 1:10 p.m. <i>Salon F-H</i> | Welcoming Remarks 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 <u>Impressions of a New NCI Director</u> Norman Sharpless, M.D., Director, National Cancer Institute |
| <i>1:45 p.m. – 1:50 p.m.</i> | Q&A |
| 1:50 p.m. – 3:40 p.m. | <u>Session I: Innovative and Novel Technologies</u> <i>Session Chairs</i> <ul style="list-style-type: none">○ Chair: Scott Tomlins, M.D., Ph.D., University of Michigan○ Co-Chair: Joshua LaBaer, M.D., Ph.D., Arizona State University/The Biodesign Institute |
| <i>1:50 p.m. – 1:55 p.m.</i> | Introduction to Session Chair/Co-Chair |

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Tuesday, March 6, 2018 Continued

Session I: Innovative and Novel Technologies Continued

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| <i>1:55 p.m. – 2:20 p.m.</i> <i>Salon F-H</i> | Plenary Lecture <u>A Review of Seed Investments at the Knight Cancer Institute for Early Detection Research</u> Sadik Esener, Ph.D., Oregon Health & Science University's Knight Cancer Institute |
| <i>2:20 p.m. – 2:25 p.m.</i> | Q&A |
| <i>2:25 p.m. – 2:45 p.m.</i> | <u>Liquid Biopsy for the Earlier Detection of Cancer</u> Kenneth Kinzler, Ph.D., Johns Hopkins University |
| <i>2:45 p.m. – 2:50 p.m.</i> | Q&A |
| <i>2:50 p.m. – 3:10 p.m.</i> | <u>Multiplex Screening and Evaluation of Plasma Protein Biomarkers for Early detection of Colorectal Cancer Using Proximity Extension Assay</u> Ida Grundberg, Ph.D., Olink Proteomics |
| <i>3:10 p.m. – 3:15 p.m.</i> | Q&A |
| <i>3:15 p.m. – 3:35 p.m.</i> | <u>Biomarker Quantification by Compensated Interferometry: Lowering the LOQ to Improve Case-Control Separation for IPNs</u> Darryl Bornhop, Ph.D., Vanderbilt University |
| <i>3:35 p.m. – 3:40 p.m.</i> | Q&A |
| 3:40 p.m. – 4:00 p.m. | Break |
| 4:00 p.m. – 5:50 p.m. <i>Salon F-H</i> | <u>Session II: Accelerating Validation and Implementation of Biomarkers</u> <i>Session Chairs</i> <ul style="list-style-type: none">○ Chair: John Wei, M.D., University of Michigan○ Co-Chair: Anirban Maitra, M.B.B.S., The University of Texas MD Anderson Cancer Center |

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Tuesday, March 6, 2018 Continued

**Session II: Accelerating Validation and Implementation of Biomarkers
Continued**

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| <i>4:00 p.m. – 4:05 p.m.</i> <i>Salon F-H</i> | Introduction to Session Chair/Co-Chair |
| 4:05 p.m. – 4:30 p.m. | Plenary Lecture <u>The Continuum of Risk Assessment and Early Detection through Blood Based Biomarkers</u> Samir Hanash, M.D., Ph.D., The University of Texas MD Anderson Cancer Center |
| <i>4:30 p.m. – 4:35 p.m.</i> | Q&A |
| <i>4:35 p.m. – 4:55 p.m.</i> | <u>By Design Approach in Biomarker Development, Validation, and Clinical Implementation</u> Zhen Zhang, Ph.D., Johns Hopkins University |
| <i>4:55 p.m. – 5:00 p.m.</i> | Q&A |
| <i>5:00 p.m. – 5:20 p.m.</i> | <u>Challenges in Moving Biomarkers from Bench to Bedside</u> John Wei, M.D., University of Michigan |
| <i>5:20 p.m. – 5:25 p.m.</i> | Q&A |
| <i>5:25 p.m. – 5:45 p.m.</i> | <u>From Bench to Boardroom to Bedside: an Airway Gene-expression Biomarker's Journey</u> Avrum Spira, M.D., M.Sc., Boston University |
| <i>5:45 p.m. – 5:50 p.m.</i> | 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.
Ballroom Foyer

Registration

8:00 a.m. – 10:15 a.m.
Salon F-H

**Session III: Precision Detection of Early
Stage Cancers**

Session Chairs

- Chair: Amanda Paulovich, M.D., Ph.D., Fred Hutchinson Cancer Research Center
- Co-Chair: Kenneth Kinzler, Ph.D., John Hopkins University

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

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Wednesday, March 7, 2018 Continued

Session III: Precision Detection of Early Stage Cancers

*9:50 a.m. – 10:10 a.m.
Salon F-H*

Prostate Cancer as a Model for the Challenges
of Precision Early Detection

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.
Salon E

Poster Viewing Session 1

11:30 a.m. – 12:30 p.m.

Lunch Break (On Your Own)

11:30 a.m. – 12:30 p.m.
White Oak B

**Pancreatic Cancer Investigator Meeting
(Closed Session)**

12:30 p.m. – 3:10 p.m.
Salon F-H

Session IV: Imaging and Early Detection
Session Chairs

- Chair: Eugene Koay, M.D., Ph.D., The
University of Texas MD Anderson Cancer
Center
- Co-Chair: Pierre Massion, M.D., Vanderbilt-
Ingram Cancer Center

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
Q&A

1:25 p.m. – 1:30 p.m.

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Wednesday, March 7, 2018 Continued

Session IV: Imaging and Early Detection Continued

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

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Wednesday, March 7, 2018 Continued

4:00 p.m. – 5:30 p.m.
Salon F-H

**Session V: Building Alliances with Other
Consortia**

Session Chairs

- Chair: Karen Anderson, M.D., Ph.D., Arizona State University
- Co-Chair: Denise Aberle, M.D., University of California, Los Angeles

4:00 p.m. – 4:05 p.m.

Introduction to Session
Chair/Co-Chair

4:05 p.m. – 4:25 p.m.

Alan Pollack, M.D., Ph.D., University of Miami,
Consortium of Imaging and Biomarkers

4:25 p.m. – 4:45 p.m.

Brian Wolpin, M.D., M.P.H., Dana-Farber
Cancer Institute, Pancreatic Cancer Detection
Consortium

4:45 p.m. – 5:05 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.
White Oak B

Discussion on International Collaborations

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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**
Salon 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

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Thursday, March 8, 2018 Continued

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

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| <i>9:55 a.m. – 10:00 a.m.</i> <i>Salon F-H</i> | Q&A |
| <i>10:00 a.m. – 10:20 a.m.</i> | <u>A Targeted Proteomics Strategy for the Development of Prostate Cancer Liquid- Biopsies</u> John Semmes, Ph.D., Eastern Virginia Medical School |
| <i>10:20 a.m. – 10:25 a.m.</i> | Q&A |
| <i>10:25 a.m. – 10:45 a.m.</i> | <u>Interrogating the Urinary Transcriptome to Refine Prostate Cancer Detection</u> Martin Sanda, M.D., Emory University |
| <i>10:45 a.m. – 10:50 a.m.</i> | Q&A |
| 10:50 a.m. – 11:10 a.m. | Break |
| 11:10 a.m. – 12:50 p.m. <i>Salon F-H</i> | <u>Breast Cancer</u> <i>Session Chairs</i> <ul style="list-style-type: none">○ Jeff Marks, Ph.D., Duke University Medical School○ Alexander Borowsky, M.D., University of California, Davis |
| <i>11:10 a.m. – 11:30 a.m.</i> | <u>Understanding the Landscape of DCIS</u> Laura Esserman, M.D., M.B.A., University of California, San Francisco Michael Campbell, Ph.D., University of California, San Francisco |
| <i>11:30 a.m. – 11:35 a.m.</i> | Q&A |
| <i>11:35 a.m. – 11:55 a.m.</i> | <u>Prediction of Progression and Recurrence in the Vermont Cohort of Screen-Detected Breast Cancer</u> Donald Weaver, M.D., University of Vermont |
| <i>11:55 a.m. – 12:00 p.m.</i> | Q&A |

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Thursday, March 8, 2018 Continued

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

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| <i>12:00 p.m. – 12:20 p.m.</i> <i>Salon F-H</i> | <u>Unique Approach Combining Avatar Mice and Targeted Mass Spectrometry to Identify Blood Biomarkers for Early Detection of Breast Cancer</u> Amanda Paulovich, M.D., Ph.D., Fred Hutchinson Cancer Research Center Q&A |
| <i>12:20 p.m. – 12:25 p.m.</i> | |
| <i>12:25 p.m. – 12:45 p.m.</i> | <u>Breast Cancer: Integrating Imaging and Molecular Diagnostics</u> Karen Anderson, M.D., Ph.D., Arizona State University Q&A |
| <i>12:45 p.m. – 12:50 p.m.</i> | |
| 12:50 p.m. – 2:00 p.m. | Lunch (On Your Own) |
| 2:00 p.m. – 3:40 p.m. <i>Salon F-H</i> | <u>Lung Cancer</u> <i>Session Chairs</i> <ul style="list-style-type: none">○ Harvey Pass, M.D., New York University School of Medicine○ Avrum Spira, M.D., M.Sc., Boston University |
| <i>2:00 p.m. – 2:20 p.m.</i> | <u>Immunity and Inflammation in the Pathogenesis of Lung Cancer</u> Steven Dubinett, M.D., University of California, Los Angeles Q&A |
| <i>2:20 p.m. – 2:25 p.m.</i> | |
| <i>2:25 p.m. – 2:45 p.m.</i> | <u>Distinguishing Indolent from Aggressive Lung Cancers using Quantitative Radiomic Features</u> Matthew Schabath, Ph.D., H. Lee Moffitt Cancer Center Q&A |
| <i>2:45 p.m. – 2:50 p.m.</i> | |

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

*2:50 p.m. – 3:10 p.m.
Salon F-H*

Whole Blood Gene Expression Can Accurately
Distinguish Benign from Malignant Lung
Nodules; Transitioning from Microarrays to the
NanoString™ Platform

Louise Showe, Ph.D., Wistar Institute
Q&A

3:10 p.m. – 3:15 p.m.

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.
Salon F-H

**Collaborative Opportunities between the
EDRN and MCL**

(Leadership of these two consortia to present
their vision for interacting with each other)

Session Chairs

- Karen Anderson, M.D., Ph.D., Arizona State University
- Martin Sanda, M.D., Emory University
- Laura Esserman, M.D., M.B.A., University of California, San Francisco
- James Brooks, M.D., Stanford University

5:00 p.m.

Adjourn EDRN/MCL Joint Meeting