

**10<sup>th</sup> 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**

- |   |   |
|---|---|
| <b>7:00 a.m. – 8:00 a.m.</b><br><i>Ballroom Foyer</i> | <b>Registration</b>   |
| <b>8:00 a.m. - 12:00 p.m.</b><br><i>Ballroom F-H</i>  | <b>Early Detection Research Network (EDRN)<br/>and Food and Drug Agency (FDA) Workshop<br/>on Diagnostic Biomarkers</b>   |
| <b>8:00 a.m. – 8:10 a.m.</b>                          | <b>Welcome and Charge to Participants</b><br>Sudhir Srivastava, Ph.D., M.P.H., National<br>Cancer Institute<br>Kelly Oliner, Ph.D., Deputy Division Director,<br>OIR/DIHD, FDA  |
| <b>8:10 a.m. – 9:00 a.m.</b>                          | <b>Discussion Topic: Establishing a pathway for<br/>investigators for an FDA pre-submission on<br/>proposed design(s) for prospective early<br/>detection and/or diagnostic studies -<br/>without necessarily having an industry<br/>partner.</b> |
| <i>8:10 a.m. – 8:25 a.m.</i>                          | Steven Skates, Ph.D., Massachusetts General<br>Hospital   |
| <i>8:25 a.m. – 8:45 a.m.</i>                          | Jeffrey Seidman, M.D., Medical Officer,<br>OIR/DMGP, FDA  |
| <i>8:45 a.m. – 9:00 a.m.</i>                          | Discussion  |
| <b>9:00 a.m. – 9:50 a.m.</b>                          | <b>Discussion Topic: Exploration of the use of<br/>banked samples from large cohorts, such as<br/>WHI and PLCO, for submission to FDA for<br/>claims of early detection.</b>  |
| <i>9:00 a.m. – 9:15 a.m.</i>                          | Ziding Feng, Ph.D., The University of Texas MD<br>Anderson Cancer Center  |
| <i>9:15 a.m. – 9:35 a.m.</i>                          | Gene Pennello, Ph.D., Team Leader,<br>Biostatistics, OSB/DBS, FDA   |
| <i>9:35 a.m. – 9:50 a.m.</i>                          | Discussion  |
| <b>9:50 a.m. – 10:10 a.m.</b>                         | <b>Break</b>  |

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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  
technology platform approval/clearance,  
with a focus on proteomics and mass  
spectrometry.**  
*Ballroom F-H*

*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., 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**

<b>12:00 p.m. – 1:00 p.m.</b> <i>White Oak B</i>	<b>EDRN Executive Committee Meeting (closed session)</b>
<b>8:00 a.m. – 1:00 p.m.</b> <i>Ballroom Foyer</i>	<b>Registration</b>
<b>1:00 p.m. – 1:10 p.m.</b> <i>Ballroom F-H</i>	<b>Welcoming Remarks</b> Barnett S. Kramer, M.D., M.P.H., Director, Division of Cancer Prevention, National Cancer Institute
<b>1:10 p.m. – 1:15 p.m.</b>	<b>Welcome and Charge to Participants</b> Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute
<b>1:15 p.m. – 1:20 p.m.</b>	<b>Network Consulting Team’s Perspective on the EDRN</b> Larry Norton, M.D., Chair EDRN Network Consulting Team, Memorial Sloan Kettering Cancer Center
<b>1:20 p.m. – 1:45 p.m.</b>	<b>Plenary Lecture</b> <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
<b>1:50 p.m. – 3:40 p.m.</b>	<b><u>Session I: Innovative and Novel Technologies</u></b> <i>Session Chairs</i> <ul style="list-style-type: none"><li>○ Chair: Scott Tomlins, M.D., Ph.D., University of Michigan</li><li>○ Co-Chair: Joshua LaBaer, M.D., Ph.D., Arizona State University/The Biodesign Institute</li></ul>
<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**

1:55 p.m. – 2:20 p.m. <i>Ballroom F-H</i>	<b>Plenary Lecture</b> <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 Q&A
2:20 p.m. – 2:25 p.m.	Q&A
2:25 p.m. – 2:45 p.m.	<u>Liquid Biopsy for the Earlier Detection of Cancer</u> Kenneth Kinzler, Ph.D., Johns Hopkins University Q&A
2:45 p.m. – 2:50 p.m.	Q&A
2:50 p.m. – 3:10 p.m.	<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 Q&A
3:10 p.m. – 3:15 p.m.	Q&A
3:15 p.m. – 3:35 p.m.	<u>Biomarker Quantification by Compensated Interferometry: Lowering the LOQ to Improve Case-Control Separation for IPNs</u> Darryl Bornhop, Ph.D., Vanderbilt University Q&A
3:35 p.m. – 3:40 p.m.	Q&A
<b>3:40 p.m. – 4:00 p.m.</b>	<b>Break</b>
<b>4:00 p.m. – 5:50 p.m.</b> <i>Ballroom F-H</i>	<b><u>Session II: Accelerating Validation and Implementation of Biomarkers</u></b> <i>Session Chairs</i> <ul style="list-style-type: none"><li>○ Chair: John Wei, M.D., University of Michigan</li><li>○ Co-Chair: Anirban Maitra, M.B.B.S., The University of Texas MD Anderson Cancer Center</li></ul>

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**Tuesday, March 6, 2018 Continued**

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

<i>4:00 p.m. – 4:05 p.m.</i> <i>Ballroom F-H</i>	Introduction to Session Chair/Co-Chair
<b>4:05 p.m. – 4:30 p.m.</b>	<b>Plenary Lecture</b> <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>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
<b>5:50 p.m.</b>	<b>Adjourn for the Day</b>

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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.**  
*Ballroom 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.  
Ballroom 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.**  
*Ballroom 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**

**12:30 p.m. – 3:10 p.m.**  
*Ballroom 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

*1:25 p.m. – 1:30 p.m.*

Q&A

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**Wednesday, March 7, 2018 Continued**

**Session IV: Imaging and Early Detection Continued**

<i>1:30 p.m. – 1:50 p.m.</i> <i>Ballroom 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
<b>3:10 p.m. – 4:00 p.m.</b> <i>Ballroom E</i>	<b>Poster Viewing Session 2</b>

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**Wednesday, March 7, 2018 Continued**

**4:00 p.m. – 5:30 p.m.**  
*Ballroom 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**  
*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

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**Thursday, March 8, 2018 Continued**

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

<i>9:55 a.m. – 10:00 a.m.</i> <i>Ballroom 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
<b>10:50 a.m. – 11:10 a.m.</b>	<b>Break</b>
<b>11:10 a.m. – 12:50 p.m.</b> <i>Ballroom F-H</i>	<b><u>Breast Cancer</u></b> <i>Session Chairs</i> <ul style="list-style-type: none"><li>○ Jeff Marks, Ph.D., Duke University Medical School</li><li>○ Alexander Borowsky, M.D., University of California, Davis</li></ul>
<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**

<i>12:00 p.m. – 12:20 p.m.</i> <i>Ballroom 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>	
<b>12:50 p.m. – 2:00 p.m.</b>	<b>Lunch (On Your Own)</b>
<b>2:00 p.m. – 3:40 p.m.</b> <i>Ballroom F-H</i>	<b><u>Lung Cancer</u></b> <i>Session Chairs</i> <ul style="list-style-type: none"><li>○ Harvey Pass, M.D., New York University School of Medicine</li><li>○ Avrum Spira, M.D., M.Sc., Boston University</li></ul>
<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
<i>2:20 p.m. – 2:25 p.m.</i>	Q&A
<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
<i>2:45 p.m. – 2:50 p.m.</i>	Q&A

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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.*

*Ballroom 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

Q&A

*3:35 p.m. – 3:40 p.m.*

**3:40 p.m. – 4:00 p.m.**

**Break**

**4:00 p.m. – 5:00 p.m.**

*Ballroom 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**