

11th Early Detection Research Network (EDRN) Scientific Workshop
Pre-Workshop Meeting: Biomarkers and Regulatory Science
Monday, September 9, 2019
Bethesda North Marriott Hotel & Conference Center
Bethesda, Maryland

Room: White Flint Amphitheater

Co-Organizers:

- Carolina Livi, Ph.D. Agilent Technologies
- Daniel W. Chan, Ph.D., Johns Hopkins University

Monday, September 9, 2019

- 12:00 p.m. – 1:00 p.m. Registration/Check-In**
- 1:00 p.m. – 1:15 p.m. Opening Remarks**
Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute
- 1:15 p.m. – 1:45 p.m. What's New? FDA IVD Initiatives and Regulations
Timothy Stenzel, M.D., Ph.D., Director, Office of Health Technology, In Vitro Diagnostics and Radiological Health, CDRH, Food and Drug Administration (FDA)
- 1:45 p.m. – 2:15 p.m. FDA Regulatory Requirements for Successful Biomarkers Application
Anand Pathak, M.D., Ph.D., M.P.H., Medical Officer, Division of Molecular Genetics and Pathology, Molecular Genetics Branch, Center for Devices and Radiological Health, Food and Drug Administration (FDA)
- 2:15 p.m. – 2:45 p.m. CLIA and CAP Requirements for Biomarker Assays (LDT)
Daniel Chan, Ph.D., Johns Hopkins University
- 2:45 p.m. – 3:15 p.m. Break** (optional card collection for speed networking)
- 3:15 p.m. – 4:00 p.m. Panel Discussion: Statistical Considerations for Robust, Reproducible Biomarkers**
Chair: Ziding Feng, Ph.D., Fred Hutchinson Cancer Research Center
Panelists:
- Steven Skates, Ph.D., Massachusetts General Hospital
 - Zhen Zhang, Ph.D., Johns Hopkins University
 - Marina Kondratovich, Ph.D., Food and Drug Administration
 - Susan Gawel, M.S., Ph.D. Abbott Diagnostics
- 4:00 p.m. – 4:45 p.m. Panel Discussion: Technology and Licensing of Biomarkers from Research Lab to IVD Companies**
Chair: Carolina Livi, Ph.D., Agilent Technologies
Panelists:
- Eric Fung, M.D., Ph.D., GRAIL
 - Alan Wright, M.D., MPH, Roche Diagnostics
 - Ray Blanchard, Ph.D., QIAGEN
 - Jaime Greene, M.S., Technology Transfer Center, National Cancer Institute
 - Jeanine Pennington, Ph.D., Johns Hopkins University Tech Transfer Official

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Monday, September 9, 2019 Continued

4:45 p.m. – 5:30 p.m. **Industrial Benchmarks for Biomarkers in Commercialization**

Chair: Gerard J. Davis Ph.D., Abbott Laboratories

Panelists:

- Eric Fung, M.D., Ph.D., GRAIL
- Christoph Borchers, Ph.D., MRM Proteomics
- Christian Fermèr, Ph.D., Fujirebio Diagnostics AB
- Alan Wright, M.D., MPH, Roche Diagnostics
- Ray Blanchard, Ph.D., Qiagen

5:30 p.m. **Networking**

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Tuesday, September 10, 2019

- 7:00 a.m. – 8:00 a.m. Registration/Check-In**
- 8:00 a.m. – 8:15 a.m. Opening of the EDRN Scientific Workshop**
- Arul Chinnaiyan, M.D., Ph.D., University of Michigan Medical School
 - Joshua LaBaer, M.D., Ph.D., Arizona State University/The Biodesign Institute
- 8:15 a.m. – 8:25 a.m. Opening Remarks**
Douglas Lowy, M.D., Acting Director, National Cancer Institute
- 8:25 a.m. – 8:30 a.m. Welcome**
- Deborah Winn, Ph.D., Acting Director, Division of Cancer Prevention, National Cancer Institute
 - Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute
- 8:30 a.m. – 9:00 a.m. Special Lecture: Introduction by Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute**
Not All Genomes Falling Apart Lead to Cancer
Stephen Chanock, M.D., Director, Division of Cancer Epidemiology and Genetics, National Cancer Institute
- 9:00 a.m. – 11:50 a.m. Session 1: Multi-modal Testing: Markers, Analytes from Different Classes of Molecules-Integrative Analysis**
Moderator: James Herman, M.D., UPMC Hillman Cancer Center, University of Pittsburgh
- 9:00 a.m. – 9:30 a.m. Special Lecture: Introduction by Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute*
Development of The Multi-marker Assay and Algorithm
Graham Lidgard, Ph.D., Exact Sciences
- 9:30 a.m. – 10:00 a.m. Circular RNA in Cancer Detection*
Arul Chinnaiyan, M.D., Ph.D., University of Michigan Medical School
- 10:00 a.m. – 10:20 a.m. Break**
- 10:20 a.m. – 10:50 a.m. Lung Cancer Detection*
Marc Lenburg, Ph.D., Boston University
- 10:50 a.m. – 11:20 a.m. Serum Protein, Urine RNA and Tissue Metabolite Targets to Detect and Image Prostate Cancer*
Martin Sanda, M.D., Emory University
- 11:20 a.m. – 11:50 a.m. Multi-Modal Methods for Biomarker Discovery in Diseased Lung*
Charmion Cruickshank-Quinn, Ph.D., Agilent Technologies
- 11:50 a.m. – 12:00 p.m. Poster Presentations**
- 12:00 p.m. – 1:30 p.m. Lunch (on your own) and Poster Viewing**

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Tuesday, September 10, 2019 (Continued)

- 1:30 p.m. – 3:00 p.m.** **Session 2: Imaging and Radiomics**
Moderator: Matthew Schabath, Ph.D., H. Lee Moffitt Cancer Center and Research Institute Inc.
- 1:30 p.m. – 2:00 p.m.* Radiomics of Screening: Hope or Hype?
Robert Gillies, Ph.D., H. Lee Moffitt Cancer Center and Research Institute, Inc.
- 2:00 p.m. – 2:30 p.m.* The integrin $\alpha\beta6$ is a promising molecular target for early detection, diagnosis and therapeutic intervention
Julie Sutcliffe, Ph.D. University of California Davis
- 2:30 p.m. – 3:00 p.m.* Imaging-related Considerations for Early Detection of Pancreatic Cancer
Eugene Koay, M.D., Ph.D., The University of Texas MD Anderson Cancer Center
- 3:00 p.m. – 3:20 p.m.** **Break**
- 3:20 p.m. – 4:50 p.m.** **Big Data and AI/Machine Learning**
Moderator: Marc Lenburg, Ph.D., Boston University
- 3:20 p.m. – 3:50 p.m.* **Special Lecture** Introduction by Sudhir Srivastava, Ph.D., M.P.H, National Cancer Institute

The Potential for Early Detection of Pancreatic Cancer: The Role of Deep Learning and Radiomics
Elliot Fishman, M.D., Johns Hopkins University
- 3:50 p.m. – 4:20 p.m.* Illuminating the Tumor Microenvironment: Astronomy Informs Pathology
Janis Taube, M.D., M.Sc., Johns Hopkins University
- 4:20 p.m. – 4:50 p.m.* Variability in Tumour Presentation: The Influence of the Germline on Somatic Evolution
Paul Boutros, Ph.D., M.B.A. University of California Los Angeles
- 4:50 p.m. – 5:00 p.m.** **Poster Presentations**
- 5:00 p.m. – 6:30 p.m.** **International Forum**
Cancer Research UK
David Crosby, Ph.D., Head of Early Detection Research at Cancer Research UK

Panelists:
 - Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute
 - Joshua LaBaer, M.D., Ph.D., Arizona State University/The Biodesign Institute
 - Arul Chinnaiyan M.D., Ph.D., University of Michigan Medical School
- 6:30 p.m.** **Adjourn for the Day**

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Wednesday, September 11, 2019

- 7:00 a.m. – 8:00 a.m. Registration/Check-In**
- 8:00 a.m. – 8:30 a.m. Special Lecture** Introduction by Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute
Genomic Testing for Population Risk Stratification in Breast Cancer
Fummi Olopade, M.D., University of Chicago
- 8:30 a.m. – 12:00 p.m. Session 3: Organ-Specific Research Conducted by the EDRN Collaborative Groups**
- 8:30 a.m. – 9:25 a.m. Breast and Gynecological Cancers**
- 8:30 a.m. – 8:45 a.m. Overview of the Collaborative Group Activities
Steven Skates, Ph.D., Massachusetts General Hospital
- 8:45 a.m. – 9:05 a.m. A 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
- 9:05 a.m. – 9:25 a.m. Collaborative Project: Circulating Autoantibody Biomarkers for Early Detection of Ovarian Cancer
Robert Bast, M.D., The University of Texas MD Anderson Cancer Center
- 9:25 a.m. – 10:20 a.m. Gastrointestinal Cancers**
- 9:25 a.m. – 9:40 a.m. Overview of the Collaborative Group Activities
Robert Schoen, M.D., M.P.H., University of Pittsburgh
- 9:40 a.m. – 10:00 a.m. Early Detection of Pancreatic Cancer: Collaborative Studies Under the EDRN Umbrella
Anirban Maitra, M.B.B.S., The University of Texas MD Anderson Cancer
- 10:00 a.m. – 10:20 a.m. Identifying DNA Methylation Biomarkers for Non-Endoscopic Detection of Barrett's Esophagus
Sanford Markowitz, M.D., Ph.D., Case Western Reserve University
- 10:20 a.m. – 10:40 a.m. Break**
- 10:40 a.m. – 11:35 a.m. Prostate and Urological Cancers**
- 10:40 a.m. – 10:55 a.m. Overview of the Collaborative Group Activities
O. John Semmes, Ph.D., Eastern Virginia Medical School
- 10:55 a.m. – 11:15 a.m. Proteomic Tissue Classifier for Early Prediction of Prostate Cancer Progression
Tao Liu, Ph.D., Pacific North West National Laboratory
- 11:15 a.m. – 11:35 a.m. Identification of Aggressive Prostate Cancers: In-depth Proteomics of Tissues and Urines
Thomas Kislinger, Ph.D., University of Toronto

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Wednesday, September 11, 2019 (Continued)

Organ-Specific Research Conducted by the EDRN Collaborative Groups

11:35 a.m. – 12:00 p.m. Lung and Upper Aerodigestive Cancers

11:35 a.m. – 11:40 a.m. Overview of the Collaborative Group Activities
Pierre Massion, M.D., Vanderbilt-Ingram Cancer Center

11:40 a.m. – 12:00 p.m. Optimizing DNA Methylation Detection for Early Lung Cancer
James Herman, M.D., UPMC Hillman Cancer Center University of Pittsburgh

12:00 p.m. – 1:00 p.m. Lunch (on your own)

1:00 p.m. – 1:30 p.m. Associate Member Special Presentation: Introduction by Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute

Automated Molecular Diagnosis of Suspicious Breast Lesions in Underdeveloped Countries
Saraswati Sukumar, Ph.D., Barbara B. Rubenstein Professor of Oncology, Professor of Pathology, Johns Hopkins University School of Medicine

1:30 p.m. – 3:10 p.m. Allied Consortia (Interaction with and support by the EDRN Overview of consortia and presentation of one research project; not just stating goals of the consortium)

1:30 p.m. – 1:50 p.m. BloodPAC: Establishing Standards to Accelerate Development and Approval of Liquid Biopsy Technology
Lauren Leiman, M.B.A., Executive Director, Blood Profiling Atlas in Cancer

1:50 p.m. – 2:10 p.m. Consortium for Molecular and Cellular Characterization of Screen Detected Lesions: Overview of Collaborative Projects including Pathology Working Group
Angelo DeMarzo, M.D., Ph.D., Johns Hopkins University School of Medicine

2:10 p.m. – 2:30 p.m. Pancreatic Cancer Detection Consortium (PCDC)
Brian Wolpin, M.D., M.P.H., Dana-Farber Cancer Institute

2:30 p.m. – 2:50 p.m. Chronic Pancreatitis Diabetes and Pancreatic Cancer Consortium (CPDPC)
Stephen Pandol, M.D., Cedars-Sinai Medical Center

2:50 p.m. – 3:10 p.m. Translational Liver Cancer Consortium (TLC)
Anna Lok, M.D., University of Michigan Medical School

3:10 p.m. – 3:30 p.m. Break

3:30 p.m. – 5:00 p.m. Advances in Liquid Biopsies

3:30 p.m. – 4:00 p.m. Liquid Biopsies: Beyond Blood
Kenneth Kinzler, Ph.D., Johns Hopkins University School of Medicine

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Wednesday, September 11th Continued

Advances in Liquid Biopsies Continued

- 4:00 p.m. – 4:30 p.m.* NCI-Liquid Biopsy Consortium (NLBC)
David Wong, D.M.D., D.M.Sc., University of California Los Angeles
- 4:30 p.m. – 5:00 p.m.* Exosome Protein Signatures as Biomarkers for Cancer Detection
David Lyden, M.D., Ph.D., Weill Cornell Medical College
- 5:00 p.m. – 6:30 p.m.** **Poster Viewing**
- 6:30 p.m.** **Adjourn for the Day**

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Thursday, September 12, 2019

7:00 a.m. – 8:00 a.m. Registration and Check-In

8:00 a.m. – 11:20 a.m. Contemporary Topics and Panel Discussions

8:00 a.m. – 9:00 a.m. Session 1: Liquid Biopsy

8:00 a.m. – 8:15 a.m. The Wide World of Circulating Biomarkers; The Opportunities and The Challenges

Samir Hanash, M.D., Ph.D., The University of Texas MD Anderson Cancer Research Center

8:15 a.m. – 9:00 a.m. Panel Discussion: Biology of Liquid Biopsy

Panelists:

- Kenneth Kinzler, Ph.D., Johns Hopkins University School of Medicine
- Jasmine Zhou, Ph.D., University of California Los Angeles

Discussion Topics:

- Does biology support PanCancer (multiple or all cancers) detection?
- How would tumor heterogeneity and population risk heterogeneity affect this (PanCancer) effort? What is needed to address this challenge?
- How do mutations in benign tissues affect liquid biopsy analysis?

9:00 a.m. – 10:00 a.m. Session 2: Diagnostic Performance

9:00 a.m. – 9:15 a.m. Setting up the Bar of Diagnostic Performance: Sensitivity, Specificity and Predictive Values for Biomarkers

David Ransohoff, M.D., University of North Carolina at Chapel Hill

9:15 a.m. – 9:30 a.m. Substantial Reduction in Validation Sample Size with the Opportunity for Second-chance Discovery

Stuart Baker, Sc.D., National Cancer Institute

9:30 a.m. – 10:00 a.m. Panel Discussion:

Panelists:

- Mark Thornquist Ph.D., Fred Hutchinson Cancer Research Center
- Zhen Zhang, Ph.D., Johns Hopkins Medical Institutions
- Robert Bresalier, M.D., The University of Texas MD Anderson Cancer Center

Discussion Topics:

- What factors should be taken into considerations when deciding on the performance of biomarkers for cancer early detection?
- When locking down the performance characteristics for assay validation, how much consideration should be given to cost-benefit analysis?
- There are a number of biomarkers tests that are commonly used to compare with the new tests, e.g. CA19-9 for pancreatic cancer. What is the basis for using these values?

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10:00 a.m. – 10:20 a.m. Break

10:20 a.m. – 11:20 a.m. Session 3: Overdiagnosis

10:20 a.m. – 10:35 a.m. Cancer Overdiagnosis: A Biological Challenge and a Clinical Dilemma
Barnett Kramer, M.D., National Cancer Institute

10:35 a.m. – 11:20 a.m. Panel Discussion: Cost-benefit analysis of overdiagnosis? Harm versus Benefit?

Panelists:

- Robert Bast, M.D., The University of Texas MD Anderson Cancer Center
- Anirban Maitra, M.B.B.S., The University of Texas MD Anderson Cancer Center
- Karen Anderson, M.D., Ph.D., Arizona State University/The Biodesign Institute
- Matthew Schabath Ph.D., H. Lee Moffitt Cancer Center and Research Institute Inc.

Discussion Topics:

- How one should balance overdiagnosis issues when dealing with rare, lethal cancer? Pancreatic? Ovarian?
- With newer diagnostic assays with high sensitivity how should one deal with false positives and overdiagnosis? Clinical dilemma?

11:20 a.m. Adjourn EDRN Scientific Workshop

8:00 a.m. – 12:50 p.m. EDRN Network Consulting Team Meeting (Closed Session)

(White Oak A)

- NCT Team Members
- EDRN Chair and Co-Chair
- Chairs of EDRN Collaborative Groups
- NCI Program Staff

12:50 p.m. Adjourn