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

Co-Organizers:
- Carolina Livi, Ph.D. Agilent
- Daniel W. Chan, Ph.D., Johns Hopkins University

Monday, September 9, 2019

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, FDA

1:45 p.m. – 2:15 p.m. **FDA Regulatory Requirements for Successful Biomarkers Application**
Douglas Jeffery, Ph.D. Deputy Director, Division of Immunology and Hematology Devices, CDRH, 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., John Hopkins University
- Marina Kondratovich, Ph.D., Food and Drug Administration
- Susan Gawel, 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, MD, Ph.D., GRAIL
- Alan Wright, M.D., MPH, Roche Diagnostics
- Lisa Finkelstein, Ph.D., Technology Transfer Center, National Cancer Institute
- Jeanine Pennington, Ph.D. Johns Hopkins University Tech Transfer Official

4:45 p.m. – 5:30 p.m. **Industrial Benchmarks for Biomarkers in Commercialization**
*Chair:* Gerard J. Davis Ph.D., CDx Lead, R&D Abbott Diagnostics Division, Abbott Laboratories
*Panelists:*
- Eric Fung, MD, Ph.D., GRAIL
- Chris Borchers, Ph.D., MRM Proteomics
- Christian Fermer, Ph.D., Fujirebio Diagnostics AB
- Alan Wright, M.D., MPH, Roche Diagnostics

5:30 p.m. **Networking**
11th Early Detection Research Network (EDRN) Scientific Workshop
Next Generation of Biomarkers
September 10-12, 2019
Bethesda North Marriott Hotel & Conference Center
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Tuesday, September 10, 2019

8:00 a.m. – 8:15 a.m.  Opening of the EDRN Scientific Workshop
  - Arul Chinnaiyan, M.D., Ph.D., University of Michigan
  - 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)
  TBD
  - 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 across
Moderator: James Herman, M.D., University of Pittsburg

9:00 a.m. – 9:30 a.m.  Special Lecture: (Introduction by Sudhir Srivastava, Ph.D., M.P.H, National Cancer Institute)
  TBD
  - Graham Lidgard, Ph.D., Exact Sciences

9:30 a.m. – 10:00 a.m.  TBD
  - Arul Chinnaiyan, M.D., Ph.D., University of Michigan

10:00 a.m. – 10:20 a.m.  Break

10:00 a.m. – 10:20 a.m.  TBD
  Presenter TBD

10:20 a.m. – 10:50 a.m.  TBD
  - Martin Sanda, M.D., Emory University

10:50 a.m. – 11:20 a.m.  Multi-Modal Methods for Biomarker Discovery in Diseased Lung
  Charmion Cruickshank-Quinn, Ph.D., Agilent Technologies

11:20 a.m. – 12:00 p.m.  Poster Presentations – 5 presentation 2 minutes each

12:00 p.m. – 1:30 p.m.  Lunch and Poster Viewing (on your own)

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.  TBD
  - Robert Gillies, Ph.D., H. Lee Moffitt Cancer Center and Research Institute, Inc.
Tuesday, September 10, 2019 (continued)

Session 2: Imaging and Radiomics (continued)

2:00 p.m. – 2:30 p.m.  TBD
Julie Sutcliffe, Ph.D., University of California Davis

2:30 p.m. – 3:00 p.m.  TBD
Eugene Koay, M.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)
TBD
Elliot Fishman, M.D., Johns Hopkins University

3:50 p.m. – 4:20 p.m.  TBD
Janis Taube, M.D., M.Sc., Johns Hopkins University

4:20 p.m. – 4:50 p.m.  TBD
Paul Boutros, Ph.D., University of California Los Angeles

4:50 p.m. – 5:00 p.m.  Poster Presentations – 5 presentation 2 minutes each

5:00 p.m. – 6:30 p.m.  International Forum

C-EDRN
Wanqing Chen, M.D., Ph.D., Director Office of Cancer Screening, Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

Cancer Research UK
David Crosby, Ph.D., Head of Early Detection Research at Cancer Research UK

Panelists:
  o Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute
  o Joshua LaBaer, M.D., Ph.D., Arizona State University/The Biodesign Institute
  o Arul Chinnaian M.D., Ph.D., University of Michigan

6:30 p.m.  Adjourn for the day
Wednesday, September 11, 2019

8:00 a.m. – 8:30 a.m. Special Lecture (Introduction by Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute)

TBD
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. TBD
Amanda Paulovich, M.D., Ph.D., Fred Hutchinson Cancer Research Center

9:05 a.m. – 9:25 a.m. TBD
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. TBD
Anirban Maitra, M.B.B.S., The University of Texas MD Anderson Cancer Center

10:00 a.m. – 10:20 a.m. TBD
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. TBD
Tao Liu, Ph.D., Pacific North West National Laboratory

11:15 a.m. – 11:35 a.m. TBD
Thomas Kislinger, Ph.D., University of Toronto

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 University

11:40 a.m. – 12:00 p.m. TBD
James Herman, M.D., University of Pittsburgh

12:00 p.m. – 1:00 p.m. Lunch (on your own)
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**Wednesday, September 11, 2019 (continued)**

**1:00 p.m. – 1:30 p.m.**  
**Associate Member Special Presentation:** (Introduction by Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute)  
TBD
Saraswati Sukumar, Ph.D. Barbara B. Rubenstein Professor of Oncology, Professor of Pathology, Johns Hopkins University

**1:30 p.m. – 3:10 p.m.**  
**Allied Consortia** (their 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**  
Lauren Leiman, M.B.A., Executive Director, Blood Profiling Atlas in Cancer

**1:50 p.m. – 2:10 p.m.**  
**Molecular Characterization of Screen Detected Lesions (MCL)**  
Angelo DeMarzo, M.D., Ph.D., Johns Hopkins University

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

**2:30 p.m. – 2:50 p.m.**  
**Chronic Pancreatitis Diabetes and Pancreatic Cancer Consortium (CPDPC)**  
Stephen Pandol, M.D., University of California Los Angeles

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

**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.**  
**TBD**  
Kenneth Kinzler, Ph.D., Johns Hopkins University

**4:00 p.m. – 4:30 p.m.**  
**TBD**  
David Wong, D.M.D., D.M.Sc., University of California Los Angeles

**4:30 p.m. – 5:00 p.m.**  
**TBD**  
David Lyden, M.D., Ph.D., Weill Cornell Medicine

**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

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., MD Anderson Cancer Research Center

8:15 a.m. – 9:00 a.m.   Panel Discussion: Biology of Liquid Biopsy
Panelists:
  o  Kenneth Kinzler, Ph.D., Johns Hopkins University
  o  Jasmine Zhou, Ph.D., University of California Los Angeles

Discussion Topics:
  o  Does biology support PanCancer (multiple or all cancers) detection?
  o  How would tumor heterogeneity and population risk heterogeneity affect this (PanCancer) effort? What is needed to address this challenge?
  o  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:
  o  Mark Thornquist Ph.D., Fred Hutchinson Cancer Research Center
  o  Zhen Zhang, Ph.D., Johns Hopkins University
  o  Robert Bresalier, The University of Texas MD Anderson Cancer Center

Discussion Topics:
  o  What factors should be taken into considerations when deciding on the performance of biomarkers for cancer early detection?
  o  When locking down the performance characteristics for assay validation, how much consideration should be given to cost-benefit analysis?
  o  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?

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
Thursday, September 12, 2019 Continued

Session 3: Overdiagnosis Continued

10:35 a.m. – 11:20 a.m.  Panel Discussion: Cost-benefit analysis of overdiagnosis? Harm versus Benefit?
Panelists:
  o Robert Bast, M.D. The University of Texas MD Anderson Cancer Center
  o Anirban Maitra, M.D., The University of Texas MD Anderson Cancer Center
  o Karen Anderson, M.D., Arizona State University/The Biodesign Institute
  o Matthew Schabath Ph.D., Moffit Cancer Center

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

11:20 a.m.  Adjourn

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

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

12:00 p.m.  Adjourn