

**20th EDRN Steering Committee Meeting**  
**March 1 – March 3, 2010**  
**Tempe Mission Palms Hotel and Conference Center**  
**Tempe, Arizona**

**Agenda**

**Monday March 1, 2010**

**7:30 – 8:30 a.m.**

**Sign-In and Continental Breakfast**

8:30 – 8:35 a.m.  
*Palm Ballroom DEF*

Opening of Steering Committee Meeting  
David Sidransky, M.D., Johns Hopkins University  
School of Medicine

8:35 – 8:40 a.m.  
*Palm Ballroom DEF*

Welcome & Introduction  
Joshua LaBaer, M.D., Ph.D., Arizona State University

8:40 – 8:50 a.m.  
*Palm Ballroom DEF*

Approval of September, 2009 EDRN Steering Committee Minutes  
David Sidransky, M.D., Johns Hopkins University  
School of Medicine

8:50 – 9:20 a.m.  
*Palm Ballroom DEF*

State of the EDRN  
Sudhir Srivastava, Ph.D., M.P.H., National Cancer  
Institute

9:20 – 10:00 a.m.  
*Palm Ballroom DEF*

FDA Recognition of Biomarkers: The New “Qualification for Use” Process  
Ray Woosley, M.D., Ph.D., Critical Path Institute

**10:00 – 10:20 a.m.**

**Break**

**10:20 a.m. – 12:20 p.m.**  
*Palm Ballroom DEF*

**Session 1: Aggressive, Chemoresistant Tumors across All Organ Sites May Have Common Cause**  
*Organizers:*

- Laura Esserman, M.D., M.B.A. University of California, San Francisco
- Dean Brenner, M.D., University of Michigan

*10:20 – 10:30 a.m.*

Introduction/Statement of Problem and Opportunity  
Laura Esserman, M.D., M.B.A., University of California, San Francisco

*10:30 – 10:45 a.m.*

Pooling Open Source Datasets for Discovery and Analysis of Gene Signatures  
Christopher Benz, M.D., University of California, San Francisco

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**Monday March 1, 2010 Continued**

**Session 1: Aggressive, Chemoresistant Tumors across All Organ Sites May Have Common Cause Continued**

*10:45 – 11:00 a.m.*  
*Palm Ballroom DEF*

Immune Function as a Potential Common Determinant of Poor vs. Good Outcome

- o Martin “Mac” Cheever, M.D., University of Washington
- o Michael Campbell, Ph.D., University of California, San Francisco

*11:00 – 11:15 a.m.*

WNT Pathway as a Paradigm for the Pathobiology of Aggressive Chemoresistant Tumors

David Jablons, M.D., University of California, San Francisco

*11:15 – 11:30 a.m.*

Comparison of Molecular Profiles across Cancers

John Park, M.D., University of California, San Francisco

*11:30 – 12:20 p.m.*

Questions, Discussion, and Action Items

Discussion Topics:

1. Are there prognostic signatures, common across tumor types, which separate indolent from aggressive disease?
2. Is the mechanism of progression of chemoresistant cancers likely to be common across cancers or specific to the organ site of cancer origin?
3. What are the potential host & tumor (pathway) mechanisms that might dictate response & progression?
4. Is there a collaborative pilot across EDRN organ sites to help investigate hypotheses?

**12:20 – 2:00 p.m.**

**Lunch (On Your Own)**

**2:00 – 6:00 p.m.**

**Collaborative Group Meetings**

*Joshua Tree Room*

Breast/Gynecological Cancers

*Xavier Room*

Gastrointestinal Cancers

*Cloister East Room*

Lung/Upper Aerodigestive Cancers

*Palm Ballroom DEF*

Prostate/Urologic Cancer

**6:00 – 8:00 p.m.**

**Dinner (On Your Own)**

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**Monday March 1, 2010 Continued**

**8:00 – 9:00 p.m.**                      **Data Sharing and Informatics Subcommittee Meeting**  
*Palm Ballroom DEF*

**8:00 – 9:00 p.m.**                      **Collaborative Group Chairs Meeting**  
*Joshua Tree Room*

**Tuesday March 2, 2010**

**7:00 – 8:00 a.m.**                      **Sign-In and Continental Breakfast**

8:00 – 8:15 a.m.                      Paradigm Change from Curative to Predictive, Preventive and Personalized Medicine: Novel Strategic Trends in Europe  
*Palm Ballroom DEF*  
Vincenzo Costigliola, M.D., President of European Medical Association

8:15 – 8:45 a.m.                      From (Too) Late Stage Intervention to Early Detection: Making the Policy Case to Decision Makers Here, There and Everywhere  
*Palm Ballroom DEF*  
Michael Birt, Ph.D., Center for Sustainable Health, Biodesign, Arizona State University

**8:45 – 11:40 a.m.**                      **Session 2: Working with Cohorts**  
*Palm Ballroom DEF*  
*Organizers:*

- o Samir Hanash, M.D., Ph.D., Fred Hutchinson Cancer Research Center
- o Wendy Wang, Ph.D., National Cancer Institute

8:45 – 8:55 a.m.                      Introduction  
Samir Hanash, M.D., Ph.D., Fred Hutchinson Cancer Research Center

8:55 – 9:10 a.m.                      Large Breast Cancer Primary Prevention Trial Cohort  
Paola Muti, M.D., Scientific Director, Regina Elena National Cancer Institute, Italy

9:10 – 9:25 a.m.                      NCI's Cohort Consortium Program  
Britt Reid, Ph.D., National Cancer Institute

9:25 – 9:40 a.m.                      Harvard Cohort Studies  
Rulla Tamimi, Sc.D., Harvard Medical School

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**Tuesday March 2, 2010 Continued**

**Session 2: Working with Cohorts Continued**

9:40 – 9:55 a.m.                      The CARET Biorepository: A Cohort of 18,314 Cigarette Smokers  
*Palm Ballroom DEF*                      Gary Goodman, M.D., Swedish Cancer Institute

**9:55 – 10:15 a.m.                      Break**

10:15 – 10:30 a.m.                      SPORE/EDRN Lung Cancer Reference Set  
*Palm Ballroom DEF*                      William Bigbee, Ph.D., University of Pittsburgh

10:30 – 11:40 a.m.                      Discussion  
*Discussants: Organizers and Speakers*

Topics to be covered:

1. Use of cohorts for biomarker discovery vs. validation
2. Use of cohorts for risk biomarkers vs. early detection biomarkers studies
3. Use of cohorts vs. use of reference sets like the SPORE-EDRN Lung reference set
4. Study design issues:
  - Pooling vs. no pooling of samples for efficiency and to reduce sample consumption
  - Impact of variation in sample collection protocols on study design
  - Impact of long term sample storage on study design and findings
  - Importance of Multi-investigator, multi-platform based study designs
  - Review actual some prior studies of the use of cohorts for biomarker discovery and validation
  - Challenges of data integration, storage and mining across studies

**11:40 – 1:00 p.m.                      Lunch (On Your Own)**

**11:40 – 1:00 p.m.                      EDRN Executive Committee Meeting (Closed Session)**  
*Xavier Room*

**1:00 – 1:30 p.m.                      Karyometric Analysis: An Integrating Biomarker for Risk Stratification and Chemoprevention Efficacy**  
*Palm Ballroom DEF*                      David Alberts, M.D., Arizona Cancer Center, University of Arizona

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**Tuesday March 2, 2010 Continued**

**1:30 – 4:15 p.m.**  
*Palm Ballroom DEF*

**Session 3: Imaging as Companion Diagnostics in Biomarkers-aided Diagnosis**

*Organizers:*

- Ian Thompson, M.D., University of Texas at San Antonio
- Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute

*1:30 – 1:55 p.m.*

Integrating Biomarkers with Imaging for Early Detection of Lung Cancer

Claudia Henschke, M.D., Ph.D., & David Yankelevitz, M.D., Arizona Biodesign Institute and Mount Sinai School of Medicine

*1:55 – 2:20 p.m.*

Imaging: Biomarkers for Cancer Risk Stratification

Hemant Roy, M.D., Northwestern University

*2:20 – 2:45 p.m.*

Imaging: The Challenge of Turning Art into Quantifiable Science

Eliot Siegel, M.D., VA Maryland Health Care System

*2:45 – 3:10 p.m.*

Radiotracer Techniques with PET Imaging

Terence Z. Wong M.D., Ph.D., Duke University Medical Center

**3:10 – 3:30 p.m.**

**Break**

*3:30 – 4:15 p.m.*  
*Palm Ballroom DEF*

Discussion

*Discussants: Organizer and Speakers*

Statistical Considerations in Studies of Imaging as Companion Diagnostics

Mark Thornquist, Ph.D., EDRN Data Management and Coordinating Center

Richard Mazurchuk, Ph.D., Trocaire College

**4:15 – 5:30 p.m.**  
*Palm Ballroom DEF*

**Session 4: EDRN Prostate and Urologic Cancers Collaborative Group Projects**

*Organizer:* Jacob Kagan, M.Sc., Ph.D., National Cancer Institute

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**Tuesday March 2, 2010 Continued**

**Session 4: EDRN Prostate and Urologic Cancers Collaborative Group Projects Continued**

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| <i>4:15 – 4:30 p.m.</i><br><i>Palm Ballroom DEF</i> | <u>Introduction to the GU Collaborative Studies</u> <ul style="list-style-type: none"><li>○ Jacob Kagan, M.Sc., Ph.D., National Cancer Institute</li><li>○ Martin Sanda, M.D., Beth Israel Deaconess Medical Center</li></ul>  |
| <i>4:30 – 4:50 p.m.</i>                             | <u>Update on MSA Validation Trial for Detection of Superficial Bladder Cancer</u> <ul style="list-style-type: none"><li>○ Mark Schoenberg, M.D., Johns Hopkins Medical Institutions</li><li>○ Mark Thornquist, Ph.D., Fred Hutchinson Cancer Research Center</li></ul>   |
| <i>4:50 – 5:10 p.m.</i>                             | <u>Update on Urinary PCA3 Validation Trial for Prostate Cancer</u><br>John Wei, M.D., University of Michigan   |
| <i>5:10 – 5:30 p.m.</i>                             | <u>EDRN ProPSA Validation Trial for Prostate Cancer</u><br>Daniel Chan, Ph.D., Johns Hopkins Medical Institutions  |
| <b>5:30 – 7:00 p.m.</b>                             | <b>Dinner (On Your Own)</b>  |
| <b>7:00 – 9:00 p.m.</b><br><i>Palm Ballroom DEF</i> | <b>Industry Forum</b><br><i>Organizer:</i> Lynn Sorbara, Ph.D., National Cancer Institute<br><br><u>EDRN Investigator Perspective</u><br>Timothy Block, Ph.D., Drexel University<br><br><u>Industrial Perspective</u><br>Edward Brody, Ph.D., SomaLogic, Inc.<br><br><u>Panel Discussion</u><br><i>Discussants: Organizer and Speakers</i> |

Discussion Topics:

1. How will the **Forum** be structured/conducted as an ongoing entity?
2. How can the EDRN help/support/encourage collaboration among industry partners and academic investigators?
3. What projects might be ready or “off the shelf” for such collaboration?
4. How can we better streamline the issues of IP, etc.? What role will the **Forum** play in this?

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**Wednesday March 3, 2010**

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| <b>7:00 – 8:00 a.m.</b>                                    | <b>Sign-In and Continental Breakfast</b>   |
| 8:00 – 8:30 a.m.<br><i>Palm Ballroom DEF</i>               | <u>Credentialing DNA Methylation Biomarkers for use in the TAPG Prostate Cancer and the UK/ANZ DCIS Cohort Studies</u><br>Attila Tibor Lorincz, Ph.D., Wolfson Institute of Preventive Medicine, Queen Mary University of London |
| <b>8:30 – 9:40 a.m.</b><br><i>Palm Ballroom DEF</i>        | <b>EDRN Bioinformatics Update</b><br><i>Organizer:</i> Christos Patriotis, Ph.D., National Cancer Institute  |
| 8:30 – 8:50 a.m.   | <u>Facilitating Biomarkers Research through an Integrated Informatics System for the EDRN</u><br>Daniel Crichton, M.S., Jet Propulsion Laboratory  |
| 8:50 – 9:10 a.m.   | <u>Using Cloud Computing to Share Multi-Platform Data: Example from the EDRN-Canary Collaboration</u><br>Mark Thornquist, Ph.D., Fred Hutchinson Cancer Research Center  |
| 9:10 – 9:30 a.m.   | <u>Capturing Comprehensive Results of Biomarkers Research from EDRN Validation Studies</u><br>Kristen Anton, M.S., Dartmouth Medical School  |
| 9:30 – 9:40 a.m.   | <u>NCI Translational Research Interaction Network (NTRIN) –Overview</u><br>Annalisa Gnoleba, B.S., National Cancer Institute   |
| <b>9:40 – 10:00 a.m.</b>                                   | <b>Break</b>   |
| <b>10:00 a.m. – 12:00 p.m.</b><br><i>Palm Ballroom DEF</i> | <b>EDRN Principal Investigator Meeting (Closed Session)</b><br>Discuss and Synthesize Collaborative Group Recommendations  |
| <b>12:00 p.m.</b>  | <b>Adjourn</b>   |