

# 8th EDRN Steering Committee Meeting

## Agenda

Monday, June 23, 2003

### WORKSHOP ON MOVING BIOMARKERS FROM VALIDATION TO THE COMMERCIALIZATION PATHWAY *WORKSHOP AGENDA (Draft)*

- 12:00-1:45 p.m. Moving Biomarkers from Validation to a Commercialization Pathway: Regulatory Requirements and Programmatic Objectives
- Moderators: Mukesh Verma, Ph.D., NCI EDRN Program Director  
Wendy Patterson, Esq., NCI Technology Transfer Branch
- 12:00-12:10 p.m. *Overview:*  
Wendy Patterson, Esq., NCI Technology Transfer Branch
- 12:10-12:30 p.m. *Summary of FDA Requirements:*  
Steven J. Gutman, Ph.D., M.B.A., Director, FDA/CDRH Office of In Vitro Diagnostic Device Evaluation and Safety
- 12:30- 1:00 p.m. *MSA Validation Study:*  
Mark Schoenberg, M.D., Johns Hopkins Medical Institution  
Sigrid M. Volko, Ph.D., Assistant Director, Johns Hopkins University Office of Licensing and Technology Development  
Robert Kalik, Esq., Cangen International Corp.
- 1:00 - 1:30 p.m. *SELDI/Prostate Validation Study:*  
O. John Semmes, Ph.D., Eastern Virginia Medical School  
[*Senior Patent Counsel TBD*], Esq., CIPHERGEN Biosystems, Inc.  
William Grizzle, Ph.D., M.D., University of Alabama at Birmingham  
Ian Thompson, M.D., University of Texas Health Science Center at San Antonio
- 1:30 - 1:45 p.m. Discussion
- 1:45 - 2:00 p.m. Break
- 2:00 -3:45 p.m. Intellectual Property Strategies for Commercialization of EDRN-Validated Biomarkers: Government, Academic, and Industry Perspectives
- Moderators: Jacob Kagan, Ph.D., NCI EDRN Program Director  
Wendy Patterson, Esq., NCI Technology Transfer Branch

2:00 - 2:30 p.m.      *Government Perspective:*  
Wendy Patterson, Esq., Senior Advisor, NCI Technology Transfer Branch  
J. Terry Lynch, M.B.A., Licensing Officer, NIST Technology Partnerships Division

2:30 - 3:00 p.m.      *Academic Perspective:*  
  
Elaine Brock, Esq., Director, University of Michigan Medical School Office of Technology Transfer & Corporate Research  
  
Sigrid M. Volko, Ph.D., Assistant Director, Johns Hopkins University Office of Licensing and Technology Development  
  
Dean E. Brenner, M.D., University of Michigan Medical Center  
  
O. John Semmes, Ph.D., Eastern Virginia Medical School

3:00 - 3:30 p.m.      *Industry Perspective:*  
  
Bayer Corporation:  
[*Senior Patent Counsel TDB*], Esq.  
Peter J. Maimonis, Ph.D., Associate Director, Oncology Research  
  
Abbott Laboratories/Vysis:  
William E. Murray, Esq., Senior Counsel, Patents & Trademarks  
Steven Seelig, M.D., Ph.D., Divisional Vice President, Research & Development  
  
Cangen International Corporation:  
Robert Kalik, Esq., Chief Operating Officer

4:00-6:00 p.m.      Subcommittee Meetings (*By Invitation Only*)

4:00-6:00 p.m.      Discussion on Biorepository with Dr. Ann Barker, Deputy Director, NCI (*Closed Meeting, EC and all Chairs to Attend*)

6:00-7:00 p.m.      Dinner

7:00-8:00 p.m.      Subcommittee and Liaison Reports  
SPORE: Adi Gazdar  
PCPT: Ian Thompson  
AACR: William Bigbee  
ASCO: Austin Doyle  
CGN: Steven Skates  
MMHCC: Jeffrey Marks

## Tuesday, June 24, 2003

- 7:00-8:00 a.m. Registration and Continental Breakfast
- 8:00-8:30 a.m. Introduction  
William Bigbee and University of Pittsburgh Officials
- 8:30-8:40 a.m. Welcome & Approval of January 2003 SC minutes:  
David Sidransky
- 8:40-8:50 a.m. Welcome  
Peter Greenwald
- 8:50-9:10 a.m. NCI Update  
Sudhir Srivastava
- 9:10-9:30 a.m. NCI Strategic Initiative  
Anna Barker  
Deputy Director of the National Cancer Institute
- 9:30-9:40 a.m. A Critique of the EDRN: Successes and Failures  
Bernard Levin  
Chair, EDRN Network Consulting Committee
- 9:40-10:15 a.m. Guest Lecture  
Cancer: What have we learned and how can we apply it?  
Lee Hartwell  
President and Director, Fred Hutchinson Cancer Research Center
- 10:15-10:30 a.m. Break
- 10:30 a.m.-Noon EDRN High Risk Cohorts: Resource for Validation Studies

*Moderators:* Wendy Wang, Jacob Kagan

*Speakers:* Patrice Watson  
Xifeng Wu (Margaret Spitz's laboratory)  
William Rom  
Ian Thompson  
Sandra Hoffman (Kathy Helzlsouer's lab)  
Daniel Cramer/ Ian Jacobs

- 12:00-1:00 p.m. Lunch  
EC Meeting (Working Lunch) *by Invitation Only*

- 1:00-1:30 p.m. Antibody Arrays

*Moderators:* Jeffrey Marks, Jacob Kagan

*Speaker:* Brian Haab  
Van Andel Research Institute

1:30-1:45 p.m.	Update: EDRN Antibody Array Project Jacob Kagan
1:45-2:15 p.m.	MALDI-TOF and Biomarker Discovery Yingming Zhao
2:15-5:00 p.m.	Collaborative Group Meeting ( <i>by Invitation Only</i> )
5:00 7:00 p.m.	Dinner (On Your Own)
7:00-7:15 p.m.	Collaborative Group Reports
7:15-9:00 p.m.	Collaborative Showcase: Prostate and Urologic Cancers Group

## Wednesday, June 25, 2003

- 7:00-8:00 a.m. Continental Breakfast
- 8:00-8:30 a.m. Guest Speaker  
The proteome of DNA replication in cancer  
Linda H. Malkas
- 8:30-9:00 a.m. MALDI/SELDI-TOF-MS proteomic profiling for cancer early  
detection and molecular diagnosis - summary of latest studies  
  
William L. Bigbee
- 9:00-10:30 a.m. Highlights of the Associate Membership Program  
  
*Moderators:* Mukesh Verma, Wendy Wang  
*Speakers:* Ying-Hsiu Su/Timothy Block, Thomas Jefferson  
University  
Detection of tumor-related genetic and epigenetic  
modifications in urine  
  
Edward Patz/Jeffrey Marks, Duke University  
Expression Profiling with a MALDI-TOF Platform  
Identifies Serum Markers for Lung Cancer  
  
Eleftherios Diamandis/Sudhir Srivastava,  
University of Toronto  
  
Carolyn Muller, University of Texas, Dallas  
  
David Bowtell/ Stephen Meltzer  
Strategies for the development of biomarkers of  
gastric cancer  
  
Mai Brooks/ David Chia  
Angiogenesis and breast cancer detection and  
prevention  
  
Panel Discussion: EDRN Associate Membership Program (AM)  
and its Accomplishments  
*Panelists:* EDRN Sponsoring PIs

9:00-10:30 a.m. Highlights of the Associate Membership Program (Continued)

Suggested topics for discussion:

1. Sponsor's interactions with AM, collaboration and benefits to EDRN
2. Specific examples in terms of resource sharing and or technology transfer
3. Suggestions to integrate AM in additional EDRN activities
4. How does AM benefit EDRN goals and vise versa

10:30-10:45 a.m. Break

10:45-11:00 a.m. Administrative Issues

11:00 a.m.-Noon Update: EDRN Bioinformatics Infrastructure and Tools

*Moderators:* Sudhir Srivastava, Donald Johnsey

*Speakers:* Daniel Crichton  
Mark Thornquist  
Heather Kincaid

12:00-1:00 p.m. Lunch

1:00-3:00 p.m. EDRN Computational Tools for Biomarker Discovery and Validation

*Moderator:* Sudhir Srivastava

*Speakers:* Steven Skates, Brigham and Women's Hospital  
Ziding Feng, Fred Hutchinson Cancer Center  
Zhen Zhang/Dan Chan, Johns Hopkins (Alan Partin's Group)  
UCLA (David Chia's Group)  
Florin Selaru/Stephen Meltzer, University of Maryland

3:00-3:15 p.m. New Business

3:15 p.m. Adjourn