Research Strategies, Study Designs and Statistical Approaches to Biomarkers Validation for Cancer Diagnosis and Detection

Agenda

Wednesday, July 28, 2004

8:00 a.m.	**Welcome** *Dr. Peter Greenwald, Director, DCP*
8:10 a.m.	**Institute / Agency Perspectives** *NCI (Dr. Anna Barker) and FDA (Dr. Theresa Mullin)*
8:45 a.m.	**Workshop Goals and Objectives** *Dr. Sudhir Srivastava*
9:00 a.m.	**Biomarkers in the clinical trial design for diagnosis and early detection** *Dr. Don Berry*
9:30 a.m.	**Biomarkers of Early Detection: Statistical Perspectives** *Dr. Stuart Baker*
10:00 a.m.	**Some aspects of the use of high dimensional data for cancer risk determination** *Dr. Ross Prentice*
10:30 a.m.	Break
10:50 a.m.	**Panel Discussion:** Review and Weaknesses of Observational Data on Biomarkers Utility in Cancer Detection and Diagnosis **Moderators:** - Drs. Susan Ellenberg and Ross Prentice Strengths and Weaknesses of Observational Validation Designs for High Dimensional Data: - Dr. Richard Simon Proteomics: - Dr. Ziding Feng Genomics: - Dr. Yudong He
12:00 noon	Lunch Break

1:30 p.m.	**Panel Discussion:** Strengths and Weaknesses of Longitudinal and Cohort-based Designs; Piggy-Backing Approach through Treatment and/or Prevention Trials **Moderators**: Drs. Bob O'Neil and Richard Schilsky Dr. Donna (Pauler) Ankerst Dr. Garnet Anderson Dr. Sylvan Green
3:00 p.m.	Break
3:15 p.m.	Experimental Designs and Analytical Methods To Support Validation of Biomarkers for Detection and Diagnosis: **Moderators:** Drs. Lance Liotta and Sylvan Green • Definitions of risk, early detection, diagnosis and prognosis for biomarkers and algorithms in statistical and clinical contexts: -Dr. Steven Skates • Flexible study designs for ongoing and future trials to accommodate emerging biomarkers and technology: -Dr. Sue-Jane Wang • Acceptable data reduction approach for high dimensional data derived from high throughput assays:- Dr. Yu Shyr • Non-traditional methods, including modeling for biomarker validation: - Dr. Robert Boer • Algorithms to combine multiple markers deriving from high throughput discovery: -Dr. Martin McIntosh
5:30 p.m.	Adjourn Day I

Thursday, July 29, 2004

8:00 a.m.	**FDA Guidelines for Technology and Biomarker Evaluation** Dr. Steven Gutman
9:00 - 12:00 P.M.	**Breakout Group I** Analytical and Performance Characteristics **Co Chairs**: Drs. Stuart Baker, Martin McIntosh, Steven Skates and Yu Shyr **Breakout Group II** Considerations for Biomarker validation regulatory requirements for Commercialization **Co-Chairs**: *Drs. Emmanuel Petricoin, Sudhir Srivastava, and Lakshmi Vishnuvajjala*

	Breakout Group III Development of Alternative, Non-Traditional Approaches to Biomarker Validation **Co-Chairs**: *Drs. Ziding Feng, Sue-Jane Wang, Ralph Kodell* **Breakout Group IV** Clinical and biological challenges: Biological perspective **Co-Chairs**: *Drs. William Grizzle, Dean Brenner, and Jose Costa* **Breakout Group V** Biological specimen from large Institutional Trials In Support of Biomarker Validation **Co-Chairs**: *Drs. Steven Hirschfeld, Ross Prentice, and Padma Maruvada*
10:00 a.m.	Break
12:00 noon	Lunch Break
1:30 p.m.	**Report Presentation of Breakout Sessions** Discussants:
3:00 p.m.	**Development of a Position Paper on Biomarker Validation** **Assignment of Report Writers** **Non-NCI and Non-FDA Chairs:** Chairs of Breakout Groups **NCI and FDA:** Drs. Lance Liotta, Greg Downing, Greg Campbell, Ziding Feng, Sudhir Srivastava, and Padma Maruvada
4:00 p.m.	**Adjourn at Day II**