Agenda: EDRN FDA Education Workshop

The purpose of this workshop was to open dialogue between FDA staff that provide oversight for review of in vitro diagnostic applications and EDRN scientists currently performing clinical validation studies on cancer biomarkers. Issues related to FDA review of diagnostic tests were presented by FDA personnel. Representatives from EDRN provided details on supporting data of their validation studies and the resources developed within EDRN to facilitate such research for FDA compliance. The agenda provided here provides links to the presentations by each speaker.

EDRN FDA Education Workshop

Natcher Conference Center

National Institutes of Health

Bethesda, MD

February 15, 2007

9:00 - 9:05 am Welcome
Paul Wagner, Ph.D., National Cancer Institute
Francis Kalush, Ph.D., Food and Drug Administration
9:05 - 9:30 am
Sudhir Srivastava, Ph.D., M.P.H., National Cancer Institute
Overview of NCI's Early Detection Research Network
9:30 - 9:40 am Questions
9:40 - 10:10 am
Steve Gutman, M.D., Food and Drug Administration
FDA Overview of Molecular Diagnostics and Critical Path Initiative
10:10 - 10:20 am Questions
10:20 - 10:35 am Coffee Break
10:35 - 11:05 am
Margaret Pepe, Ph.D, Fred Hutchinson Cancer Research Center
EDRN Approach to Biomarker Validation: Statistical Approaches, Designs, and Parameters for Evaluation Early Detection Biomarkers
11:05 - 11:15 am Questions
11:15 - 11:55 am
Robert Becker, M.D, Ph.D., Food and Drug Administration
Establishment of an In Vitro Diagnostic (IVD) Claim
Greg Campbell, Ph.D., Food and Drug Administration
Statistical Approaches, Clinical Study Designs, and Parameters for Evaluation of IVD Biomarkers: FDA Regulatory Requirements
11:55 - 12:05 pm Questions
12:05 - 12:25 pm
Jackie Dahlgren, Fred Hutchinson Cancer Research Center

Validation Study Management System: A Category 5 Software System for Managing EDRN Validation Studies

12:25 - 12:35 pm Questions

12:35 - 1:30 pm Lunch

1:30 - 2:00 pm

Jorge Marrero, M.D., University of Michigan

DCP for Hepatocellular Carcinoma Validation Trial

2:00 - 2:30 pm

Mark Schoenberg, M. D., Johns Hopkins University

MSA for Bladder Cancer Validation Trial (Part 1)

Mark Thornquist, Ph.D., Fred Hutchinson Cancer Research Center

MSA for Bladder Cancer Validation Trial (Part 2)

2:30 - 3:00 pm Questions and discussion

Jorge Marrero, M.D., Ziding Feng, Ph.D., Mark Schoenberg, M.D., Mark Thornquist Ph.D., Maria Chan, Ph.D., and Gene Penello, Ph.D

Moderator: Paul Wagner, Ph.D., NCI

3:00 - 3:10 pm Break

3:10 - 3:40 pm

Daniel Cramer, M.D., Brigham and Women's Hospital

Panel of Protein Markers for Ovarian Cancer

3:40 - 4:10

Alla Ivanova, M.D., New York University School of Medicine

Protein Markers for Mesothelioma

Mark Thornquist, Ph.D., Fred Hutchinson Cancer Research Center

Statistical Considerations for Mesothelioma

4:10 - 4:40 pm Questions and discussion

Daniel Cramer, M.D., Mark Thornquist, Ph.D., Alla Ivanova, M.D., Dave Li, M.D., and Estelle Russek-Cohen, Ph.D.

Moderator: Francis Kalush, Ph.D., FDA

4:40 - 5:00 pm General Discussion

Lead by: Sudhir Srivastava, Ph.D., M.P.H., NCI and Larry Kessler, Sc.D., FDA