



FDA Public Workshop on Study Methodology for Diagnostics in the Postmarket Setting

**FDA White Oak Building 31, Silver Spring, MD
May 12, 2011**

DRAFT AGENDA

8:30-8:40AM	Study Methodology for Diagnostics in the Postmarket Setting
8:30-8:35AM	Welcome and Announcements – <i>Hui-Lee Wong, PhD, Epidemiologist, Division of Epidemiology, FDA/CDRH/OSB</i>
8:35-8:40AM	Opening Remarks – <i>William Maisel, MD, MPH, Deputy Director for Science, FDA/CDRH</i>
8:40-9:30AM	Session 1: Evaluation of Diagnostic Devices through Total Product Life Cycle
	<i>Moderator: Hesha Duggirala, PhD, Epidemiologist, Division of Epidemiology, FDA/CDRH/OSB</i>
8:40- 9:00AM	Premarket Evaluation of Diagnostics <i>Robert L. Kramm, MD, Medical Officer, FDA/CDRH/ODE</i> <i>Robert L. Becker Jr, MD, Chief Medical Officer, FDA/CDRH/OIVD</i>
9:00-9:20AM	Postmarket Surveillance of Diagnostics <i>Jill Marion, Team Leader, Division of Patient Safety Partnerships, FDA/CDRH/OSB</i> <i>Jean M. Cooper, DVM, Associate Director, Surveillance and Outreach Programs/FDA/CDRH/OIVD</i>
9:20-9:30 AM	Unique Opportunities for Advancing the Methods and Infrastructure for Postmarket Studies of Medical Devices <i>Danica Marinac-Dabic, MD, PhD, Director, Division of Epidemiology, FDA/CDRH/OSB</i>
9:30-9:40AM	BREAK
9:40-11:45AM	Session 2: Potential Gaps in the Postmarket Studies and Surveillance of Diagnostic Devices
	<i>Moderator: Ellen Pinnow, MS, Branch Chief, Division of Epidemiology, FDA/CDRH/OSB</i>
9:40-9:55AM	Current Methodological Challenges of In Vitro Diagnostics at the Post-market Setting <i>Steve Gutman, MD, MBA, BlueCross BlueShield Evidence Based Practice Center</i>
9:55-10:10AM	Point-of-care Diagnostics in Post-Approval Settings <i>Elliot Cowan, PhD, Chief, Product Review Branch, Division of Emerging and Transfusion Transmitted Diseases, FDA/CBER/OBRR</i>
10:10-10:25AM	Postmarket Surveillance of Medical X-ray Imaging <i>CAPT Sean M. Boyd, MPH, Deputy Director, Division of Mammography Quality and Radiation Programs, FDA/CDRH/OCER</i>
10:25-10:40AM	Gaps and Challenges of Diagnostics for Glaucoma <i>Gadi Wollstein, MD, Associate Professor and Director, Ophthalmic Imaging Research Laboratories University of Pittsburgh School of Medicine</i>
10:40-10:55AM	Framework for Postmarket Study Design for Diagnostics in Primary Care <i>Matthew Thompson, MD, MPH, DPhil, Associate Professor, Oregon Health and Science University</i>
10.55-11.10AM	Cardiac Monitoring Devices: Clinical Alarm Fatigue <i>Barbara J. Drew, RN, PhD, FAAN, FAHA, Lillian and Dudley Aldous Professor of Nursing Science, Clinical Professor of Medicine, Cardiology University of California, San Francisco</i>
11:10-11:45PM	PANEL: Potential Gaps and How We Can Address Them <i>Moderator: Kristen Meier, PhD, Mathematical Statistician, FDA/CDRH/OSB</i> Felipe Aguel, PhD, FDA/CDRH/ODE Steve Gutman, MD, MBA Elliot Cowan, PhD CAPT Sean M. Boyd, MPH Gadi Wollstein, MD Matthew Thompson, MD, MPH, DPhil

	Barbara J. Drew, RN, PhD, FAAN, FAHA
11:45-12:45PM	LUNCH (on your own)
12:45–3:10PM	Session 3: Methodologies for Postmarket Studies for Diagnostic Devices <i>Moderator: XueYing Sharon Liang, MD, PhD, Epidemiologist, Division of Epidemiology, FDA/CDRH/OSB</i>
12:45-1:00PM	Direct Measures of Diagnostic Utility Based on Diagnostic Risk Models <i>Frank E. Harrell Jr, PhD, Professor, Vanderbilt University School of Medicine</i>
1:00-1:15PM	Examining Cardiovascular Imaging with Instrumental Variable Techniques in Medicare Enrollment and Claims Databases <i>Jersey Chen, MD, MPH, Assistant Professor of Medicine, Yale School of Medicine</i>
1:15-1:30PM	Methodological Issues in Postmarketing Surveillance of Diagnostic Imaging Modalities <i>Ilana Gareen, PhD, Assistant Professor, Brown University</i>
1:30-1:40PM	BREAK
1:40-1:55PM	Postmarket Surveillance of Rapid Human Immunodeficiency Virus Assays <i>Laura G. Wesolowski, PhD, Epidemiologist, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, Centers for Disease Control and Prevention</i>
1:55-2:10PM	Epidemiological Resources in the US Armed Forces for Surveillance of Diagnostic Devices <i>Robert F. DeFraites, MD MPH, COL MC, Director, Armed Forces Health Surveillance Center</i>
2:10-2:25PM	Evaluation of Semi-automated Liquid-based Cytology Tests Using the Centers for Medicare and Medicaid Databases <i>Marina Kondratovich, PhD, Associate Director for Clinical Studies, FDA/CDRH/OIVD</i>
2:25-3:00PM	PANEL: Next Steps for Study Methodologies <i>Moderator: Estelle Russek-Cohen, PhD, Deputy Director, FDA/CBER/OBE</i> Alicia Toledano, ScD, Statistics Collaborative, Inc. Gene Pennello, PhD, FDA/CDRH/OSB Frank E. Harrell Jr. PhD Jersey Chen, MD, MPH Ilana Gareen, PhD Laura G. Wesolowski, PhD, CDC Robert F. DeFraites, MD MPH Marina Kondratovich, PhD
3:00-3:10PM	BREAK
3:10–5:00PM	Session 4: Evidence Synthesis and Knowledge Management for Diagnostic Devices <i>Moderator: Michelle Tarver-Carr, MD, PhD, Epidemiologist, Division of Epidemiology, FDA/CDRH/OSB</i>
3:10-3:25PM	Meta-analyses for Evaluating Performance of Medical Tests <i>Thomas A. Trikalinos, MD, PhD, Co-Director Tufts Evidence-based Practice Center, Associate Director, Center for Clinical Evidence Synthesis, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center</i>
3:25-3:40PM	Bringing Together Evidence Generation and Evidence Synthesis to Improve Colon Cancer Genetic Testing and Treatment Decisions <i>Katrina A.B. Goddard, PhD, Senior Investigator, Kaiser Permanente Northwest, Center for Health Research Northwest</i>
3:40-3:55PM	Comparative-Effectiveness of Imaging Tools <i>Gregory Klein, PhD, Senior Researcher, University of Washington</i>
3:55-4:10AM	Electronic Health Records for the Postmarket Assessment of Diagnostics: Patient Community <i>Kenneth Mandl, MD, MPH, Co-Director, Centers of Disease and Control Center of Excellence in Public Health Informatics; Associate Professor, Harvard-MIT Division of Health Sciences and Technology</i>
4:10-4:25PM	Exploration and Visualization of Postmarket Data <i>Jian Ying Hu, PhD, Thomas J. Watson Research Center, International Business Machine (IBM) Corp.</i>
4:25-5:00PM	PANEL: Future Directions Danica Marinac-Dabic, MD, PhD

	Steve Gutman, MD, MBA Wendy Nilsen, PhD, National Institutes of Health Zivana Tezak, FDA/CDRH/OIVD Thomas A. Trikalinos, MD Katrina A.B. Goddard, PhD Gregory Klein, PhD Kenneth Mandl, MD, MPH Jian Ying Hu, PhD
5:00-5:15 PM	WRAP-UP and SUMMARY

Acronyms

FDA	Food and Drug Administration
CDRH	Center for Devices and Radiological Health
CBER	Center for Biologics Evaluation and Research
ODE	Office of Device Evaluation
OIVD	Office of In Vitro Diagnostics
OSB	Office of Surveillance and Biostatistics
OCER	Office of Communication, Education and Radiological Programs
OSEL	Office of Science and Engineering Laboratories
OBRR	Office of Blood Research and Review
OBE	Office of Biostatistics and Epidemiology