Public Workshop - Study Methodologies for Diagnostics in the Postmarket Setting, May 12, 2011

U.S. Food & Drug Administration

The Food and Drug Administration (FDA) is announcing a public workshop of Study Methodologies for Diagnostics in the Postmarket Setting.

The purpose of the workshop is to provide a forum for discussion among FDA, governmental agencies, academia, physicians and various stakeholders with expertise in epidemiology, statistics, diagnostics and biomedical research to advance the methodologies for diagnostics in the postmarket setting.

- Date, Time and Location [1]
- Federal Register Notice [2]
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Date, Time and Location

This meeting will be held May 12, 2011, beginning at 8.30 a.m. at the following location:

FDA White Oak Campus
10903 New Hampshire Ave
The Great Room (Room 1503), White Oak Conference Center, Bldg 31
Silver Spring, MD, 20903

This meeting will be webcast and registration will be required.

- White Oak Campus Driving Directions and Parking Information [6]

Food and drinks will be available for purchase by participants during the meeting breaks.

Draft Agenda

8:30-8:40AM	**Study Methodology for Diagnostics in the Postmarket Setting**

8:30-8:35AM	**Welcome and Announcements** - *Hui-Lee Wong, PhD, Epidemiologist, Division of Epidemiology, FDA/CDRH/OSB*
8:35-8:40AM	**Opening Remarks** - *William Maisel, MD,MPH, Deputy Director for Science, FDA/CDRH*
8:40-9:30AM	**Session 1: Evaluation of Diagnostic Devices through Total Product Life Cycle** *Moderator: Hesha Duggirala, PhD, Epidemiologist, Division of Epidemiology, FDA/CDRH/OSB*
8:40- 9:00AM	**Premarket Evaluation of Diagnostics** *Robert L. Kramm, MD, Medical Officer, FDA/CDRH/ODE* *Robert L. Becker Jr, MD, Chief Medical Officer, FDA/CDRH/OIVD*
9:00-9:20AM	**Postmarket Surveillance of Diagnostics** *Jill Marion, Team Leader, Division of Patient Safety Partnerships, FDA/CDRH/OSB* *Jean M. Cooper, DVM, Associate Director, Surveillance and Outreach Programs/FDA/CDRH/OIVD*
9:20-9:30 AM	**Unique Opportunities for Advancing the Methods and Infrastructure for Postmarket Studies of Medical Devices** *Danica Marinac-Dabic , MD , PhD, Director, Division of Epidemiology, FDA/CDRH/OSB*
9:30-9:40AM	**BREAK**
9:40-11:45AM	**Session 2: Potential Gaps in the Postmarket Studies and Surveillance of Diagnostic Devices** *Moderator: Ellen Pinnow, MS, Branch Chief, Division of Epidemiology, FDA/CDRH/OSB*
9:40-9:55AM	**Current Methodological Challenges of In Vitro Diagnostics at the Postmarket Setting** *Steve Gutman, MD, MBA, BlueCross Blue Shield Evidence Based Practice Center*
9:55-10:10AM	**Point-of-care Diagnostics in Post-Approval Settings**

	Elliot Cowan, PhD, Chief, Product Review Branch, Division of Emerging and Transfusion Transmitted Diseases, FDA/CBER/OBRR
10:10-10:25AM	**Postmarket Surveillance of Medical X-ray Imaging** *CAPT Sean M. Boyd, MPH, Deputy Director, Division of Mammography Quality and Radiation Programs, FDA/CDRH/OCER*
10:25-10:40AM	**Gaps and Challenges of Diagnostics for Glaucoma** *Gadi Wollstein, MD, Associate Professor and Director, Ophthalmic Imaging Research Laboratories University of Pittsburgh School of Medicine*
10:40-10.55AM	**Framework for Postmarket Study Design for Diagnostics in Primary Care** *Matthew Thompson, MD, MPH, DPhil, Associate Professor, Oregon Health and Science University*
10.55-11.10AM	**Cardiac Monitoring Devices: Clinical Alarm Fatigue** *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*
11:10-11:45PM	**PANEL: Potential Gaps and How We Can Address Them** *Moderator:* Kristen Meier, PhD, Mathematical Statistician, FDA/CDRH/OSB 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** *Moderator: XueYing Sharon Liang, MD, PhD, Epidemiologist, Division of*

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

	Health Zivan 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**

Biosketches

TIME	SPEAKER NAME	BIOSKETCH
8:40-9:00AM	*Robert L. Kramm, MD*	Dr. Lee Kramm is a board certified Ophthalmologist with a Masters' degree in Biomedical Engineering. He earned his graduate degree from the Tulane University School of Engineering and his medical degree is from the University of Miami School of Medicine. Following medical school he received general and surgical training in Ophthalmology from the Rocky Mountain Lions Eye Institute at the University of Colorado in Denver. He is currently a medical officer and scientific reviewer in the Division of Ophthalmic, Neurological and ENT Devices in the Office of Device Evaluation where he has served for four years.
8:40-9:00AM	*Robert L. Becker Jr, MD*	Robert Becker is Chief Medical Officer for the Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH), FDA, with special attention to inter-office coordination on regulation of newly emerging genetic/genomic IVD's. Dr. Becker previously

		served as Director, Division of Hematology and Immunology Devices, in OIVD. He is experienced in regulation of IVD's aimed at cell- and tissue-based specimens (e.g. classical hematology, flow cytometry, cytology, histopathology), plus blood coagulation tests, and immunoserologic tests. Dr. Becker earned his MD and PhD in Immunology at Duke University, and he is board certified in anatomic and clinical pathology. He served in the United States Air Force as a pathologist at the Armed Forces Institute of Pathology, Washington, DC from 1983 to 2004, specializing in urologic pathology and with research and clinical service applying image analysis and flow cytometry to diagnostic pathology.
9:00-9:20AM	*Jill Marion*	
9:00-9:20AM	*Jean M. Cooper*	
9:20-9:30AM	*Danica Marinac-Dabic, MD, PhD*	Danica Marinac-Dabic, MD, PhD is a Director of the Division of Epidemiology at the Center for Devices and Radiological Health, Food and Drug Administration. She is a physician and epidemiologist with the background in obstetrics, gynecology and perinatal epidemiology. Dr. Marinac-Dabic leads three postmarket programs at CDRH: (1) Post-Approval Studies Program, that encompasses the design, review, monitoring and oversight of the post-approval studies

		mandated as a condition of approval; (2) Postmarket Surveillance Studies Program, in charge of postmarket studies mandated under Section 522 of the Act; and (3) Epidemiologic Research Program, designed to build medical device regulatory research infrastructure and conduct independent epidemiologic research studies to ensure CDRH science-based regulatory decision making. Dr. Marinac-Dabic serves as the Chair of the CDRH Human Subject Research Review Committee, the Chair of the CDRH Epidemiologic Research Council and the Member of the FDA Research Quality Assurance Board. Dr. Marinac-Dabic earned her M.D., Master of Science Degree in Human Reproduction and Ph.D. in Epidemiology from the University of Belgrade Medical School, Belgrade, Yugoslavia. Dr. Marinac-Dabic is the author of several book chapters, manuscripts and presentations on various topics in the field of medical device epidemiology and surveillance.
9:40-9:55AM	*Steve Gutman, MD, MBA,*	Dr. Gutman is an Associate Director of Technical Evaluation Center at BlueCross BlueShield; he joined the program in January 2010. He was previously professor of pathology and a founding member of the University of

		Central Florida's new medical school. Prior to that, he was with the FDA for 17 years as a regulatory scientist, where he was a founding member and director of the Office of In Vitro Diagnostic Evaluation and Safety (OIVD) within the Center for Devices and Radiological Health. OIVD regulates in-home and laboratory diagnostic tests; as a result of his experience, Dr. Gutman has broad clinical knowledge as well as extensive expertise in evaluating evidence supporting diagnostic test utility. Earlier, he served as chief of the Clinical Laboratory at the Buffalo Veteran's Administration Center. He has been a prolific speaker at many different types of meetings throughout his career, and has recently been invited to serve on panels convened by the Institute of Medicine and the College of American Pathologists.
9:55-10:10AM	*Elliot Cowan, PhD,*	
10:10-10:25AM	*CAPT Sean M. Boyd,*	CAPT Sean M. Boyd serves as a Director Regulatory Operations Officer and Acting Deputy Director of the Division of Mammography Quality and Radiation Programs in the Office of Communication, Education and Radiation Programs at FDA's Center for Devices and Radiological Health (CDRH). In this capacity he is responsible for CDRH enforcement programs that ensure the safe

		manufacture of x-ray systems used for medical diagnostic imaging. These programs also ensure quality of mammographic procedures performed by facilities in the U.S., which aid in the early detection of breast cancer. CAPT Boyd joined CDRH in 1999, and since that time has managed several aspects of FDA's electronic radiation control program impacting a variety of medical, consumer and commercial electronic products. Previously in CDRH, he worked in the areas of device electromagnetic compatibility and radiation therapy medical devices. CAPT Boyd began his career as a regulatory researcher and engineering analyst with FDA's Winchester Engineering and Analytical Center in Winchester, MA. He received his undergraduate degree in Biomedical Engineering from Boston University and his Masters in Public Health from the Uniformed Services University of the Health Sciences.
10:25-10:40AM	*Gadi Wollstein, MD,*	
10:40-10:55AM	*Matthew Thompson, MD, MPH, DPhil.,*	Dr Thompson is Associate Professor in the Department of Family Medicine at Oregon Health & Science University, and Senior Clinical Scientist at the University of Oxford Department of Primary Health Care. He has extensive experience in primary care research, particularly in the areas of

		infectious disease, paediatrics, and diagnostics. He is Co-Director of the Oxford Centre for Monitoring and Diagnosis (www.madox.org [7]), a research center funded by the UK National Institute for Health Research which is dedicated to improving diagnostic and monitoring strategies used for acute and chronic conditions in primary care. This initiative also includes a horizon scanning system for new and emerging diagnostic technologies. Other ongoing research studies include primary research and systematic reviews of diagnostics in primary care, particularly the use of new diagnostic and point of care technologies. Dr Thompson has over 60 peer reviewed publications, and has been awarded major grant funding from the UK's National Institute of Health Research, and Health Technology Assessment (HTA) Programmes. Dr Thompson's clinical background is in Family Medicine. He is a member of the HTA Programme Diagnostics and Screening Panel in the UK, and is Editorial Advisor to several medical journals including the British Medical Journal.
10:55-11:10AM	*Barbara J. Drew, RN, PhD, FAAN, FAHA,*	
12:45-1:00PM	*Frank E. Harrell Jr*	
1:00-1:15PM	*Jersey Chen, MD, MPH*	
1:15-1:30PM	*Ilana Gareen, PhD*	Dr. Ilana Gareen is an epidemiologist in the

		Department of Community Health at Brown University. Dr. Gareen's research focuses on evaluating new and existing medical technologies. Her work concentrates on the comparative effectiveness of diagnostic imaging tests, including the downstream consequences of medical interventions, in particular the impact that these new technologies have on the medical system, patient health, and patient quality of life. Dr. Gareen has been with the American College of Radiology Imaging Network (ACRIN) since its inception. She has worked on multiple studies evaluating diagnostic imaging technologies and their impact on patient health, including the National Lung Screening Trial, The National CT Colonography Trial, and the National Oncologic PET Registry. In addition, she is a co-investigator in the Center for Comparative Effectiveness Research in Cancer Imaging, where she is working with collaborators to merge data from the NLST and NOPR with data from the Centers for Medicare Services to evaluate post-imaging health outcomes and health care utilization. Dr. Gareen has been interested in the issue of Postmarketing surveillance of medical technologies since early in her research career when she examined the

		association of intrauterine devices and pelvic inflammatory disease.
1:40-1:55PM	*Laura G. Wesolowski*	
1:55-2:10PM	*Robert F. DeFraites*	
2:10-2:25PM	*Marina Kondratovich*	
3:10-3:25PM	*Thomas A. Trikalinos, MD, PhD*	Dr Thompson is Associate Professor in the Department of Family Medicine at Oregon Health & Science University, and Senior Clinical Scientist at the University of Oxford Department of Primary Health Care. He has extensive experience in primary care research, particularly in the areas of infectious disease, paediatrics, and diagnostics. He is Co-Director of the Oxford Centre for Monitoring and Diagnosis (www.madox.org [7]), a research center funded by the UK National Institute for Health Research which is dedicated to improving diagnostic and monitoring strategies used for acute and chronic conditions in primary care. This initiative also includes a horizon scanning system for new and emerging diagnostic technologies. Other ongoing research studies include primary research and systematic reviews of diagnostics in primary care, particularly the use of new diagnostic and point of care technologies. Dr Thompson has over 60 peer reviewed publications, and has been awarded major grant funding from the UK's National Institute of Health

		Research, and Health Technology Assessment (HTA) Programmes. Dr Thompson's clinical background is in Family Medicine. He is a member of the HTA Programme Diagnostics and Screening Panel in the UK, and is Editorial Advisor to several medical journals including the British Medical Journal.
3:25-3:40PM	*Katrina A.B. Goddard, PhD*	Dr. Goddard is a genetic epidemiologist and biostatistician who focuses on identifying genetic risk factors for various diseases and population-level genetic surveillance. She has been active in genetic research for complex diseases, including prostate cancer, esophageal cancer, Alzheimer's disease, diabetic nephropathy, cystic fibrosis, severity of symptoms from dengue infection, and genetic risk factors for obstetrical conditions. She is a Co-PI for the ARRA-funded CERGEN study to conduct comparative effectiveness research on genomic applications for colon cancer. She is also a Co-PI for a Knowledge Synthesis Center to synthesize evidence on current and emerging genetic tests and support translation of evidence into clinical and policy recommendations. Dr. Goddard is the director of the NW Biobank, a resource developed to promote genomic research that includes biological samples linked to electronic

		medical record data from Kaiser Permanente members. She serves on the Board of Directors for the International Genetic Epidemiology Society, and she has been the chair of the Ethical, Social, and Legal Issues Committee for this organization.
3:40-3:55PM	*Gregory Klein, PhD*	Gregory Klein is a Senior Researcher in the Health Services Department at the University of Washington. He is currently serving as Director of the ADVancing Innovative Comparative Effectiveness Research in Cancer Diagnostics (ADVICE) project, an ARRA-funded CER joint effort with investigators from the University of Washington, the Fred Hutchinson Cancer Research Center, and the Group Health Research Institute in Seattle. Dr. Klein has a multi-faceted background in medical imaging in the academic and commercial worlds, with an emphasis towards quantitative analysis of PET and MRI data. Prior to his appointment at the University of Washington, he was President and CEO of QuantifiCare, Inc., a core lab that developed imaging devices and managed image-based endpoints for drug and device clinical trials. In previous academic positions at the Lawrence Berkeley National Laboratory and the Johns Hopkins University, Dr. Klein developed imaging reconstruction and

		quantification methodologies for advanced imaging techniques with applications to oncology, cardiology and neurology. Dr. Klein’s current research focus is comparative effectiveness and cost analyses of imaging diagnostics.
3:55-4:10AM	*Kenneth Mandl, MD*	Dr. Mandl has innovated and published extensively in the areas of personally controlled health records, disease outbreak detection, public health surveillance, and national health information infrastructure. Recognized for his teaching and research, he has received the Barger Award for Excellence in Mentoring at Harvard Medical School and the Presidential Early Career Award for Scientists and Engineers, the highest honor bestowed by the United States government to outstanding scientists and engineers. Mandl co-directs a CDC Center of Excellence in Public Health Informatics. He is a leader of the SMArtPlatforms project—part of a major federal initiative seeking to create an “app store” for health. Mandl is a member of the Advisory Committee to the Director of the CDC and of Lister Hill Center Board of Scientific Counselors at the National Library of Medicine. He is an attending physician in pediatric emergency medicine, a faculty member in the Harvard Medical

		School Center for Biomedical Informatics and affiliated faculty at the Harvard-MIT Division of Health Sciences and Technology.
4:10-4:25PM	*Jian Ying Hu, PhD*	Jianying Hu is a research staff member at IBM T. J. Watson Research Center, NY. She received the Ph.D. degree in Computer Science from SUNY Stony Brook in 1993. Prior to joining IBM she was with Bell Labs from 1993 to 2000, and Avaya Labs Research from 2001 to 2003. Her main research interests include statistical pattern recognition, machine learning and data mining, with applications to healthcare informatics, business analytics, document analysis, and multimedia content analysis and retrieval. She served as associate editor of the IEEE Transactions on Image Processing from 2001 to 2005, associate editor of the IEEE Transactions on Pattern Analysis and Machine Intelligence from 2006 to 2010, and Chair of Technical Committee on Reading Systems of the International Association for Pattern Recognition from 2004 to 2008. She is currently on the editorial board of the journals Pattern Recognition, and International Journal on Document Analysis and Recognition. Dr. Hu is a fellow of the International Association of Pattern

		Recognition and a senior member of IEEE.

Registration

The deadline for online registration will be Thursday, May 5, 2011.

If you need special accommodations due to a disability, please contact Susan Monahan at 301-796-5661, at susan.monahan@fda.hhs.gov [8] at least 7 days in advance of the meeting.

Registration is free and registration will be on a first-come, first-served basis for this Workshop. Early registration is recommended because seating and webcast ports are limited.

Please use either the **In-Person Workshop Attendance** registration form, or the **Online Webcast Viewing** registration form.

Registration for In-Person Workshop Attendance

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Phone Number * (No dashes or spaces in phone numbers please)
Affiliation *
Submit Clear Form

Contact Us

For information regarding registration and special accommodations, contact:

- Susan Monahan
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[3] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/#agenda

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