Public Workshop - Post Approval Studies 2012 Workshop: Design, Methodology, and Role in Evidence Appraisal throughout the Total Product Life Cycle, August 30, 2012

U.S. Food & Drug Administration

The Food and Drug Administration (FDA) is announcing the following public workshop entitled Post Approval Studies 2012 Workshop: “Design, Methodology, and Role in Evidence Appraisal throughout the Total Product Life Cycle.” The topics of discussion will include the following: post-approval studies in the Total Product Life Cycle, best practices and improvement of implementation strategies for post-approval studies, public health impact and innovative methodologies for evidence appraisal. FDA is holding this public workshop to provide update and obtain stakeholders input on Post-Approval Studies ordered at the time of device approval.

- Date, Time and Location [1]
- Federal Register Notice [2]
- Agenda [3]
- Registration [4]
- Contact Us [5]

Date, Time and Location

This workshop will be held August 30, 2012, beginning at **8:00 am** at the following location:

FDA White Oak Campus
10903 New Hampshire Avenue
Building 31 Conference Center (Great Room, Room 1503)
Silver Spring, MD 20993

- Link for FDA Campus Information [6]

The workshop will be webcasted.

Agenda

Time	Subject
8:00-8:05	Call for Order and Introductions
8:05-8:15	Welcome and Goals for the Day
8:15-8:30	Welcoming Remarks and Postmarket

	Surveillance
Session I: PAS in the Total Product Lifecycle	
8:30-8:40	PAS Program Overview
8:40-8:50	Premarket Factors Leading to PAS Questions
8:50-9:00	Use of PAS Data Throughout Device Life-Cycle
9:00-9:30	New Postmarket Initiatives and the PAS Program
9:30-10:00	Panel Discussion
10:00-10:10	**Break**
Session II: Best Practices and Improvement of PAS Implementation Strategies	
10:10-10:20	FDA Perspective on Opportunities for PAS Studies Implementation
10:20-10:30	Industry Perspective on Opportunities for PAS Studies Implementation
10:30-10:40	Innovative Methodologies, Data Sources and Leveraging Existing Infrastructure
10:40-10:50	Use of International Infrastructure and Data
10:50-11:00	Best Practices and the Role of Partnerships
11:00-11:45	Panel Discussion
11:45-12:00	Background for Small Group Discussions
12:00-1:00	**Lunch**
Session III: PAS Impact on Public Health and Medical Device Innovation	
1:00-2:05	Small Group Discussion: PAS Program and Medical Device Innovation
2:05-2:15	**Break**
2:15-2:45	Small Groups Summary Reports (5 minutes /each)
Session IV: Opportunities for Innovative use of PAS Data	
2:45-3:00	Improving Trial Design: FDA Perspective on using PAS Data for Bayesian Priors, historical controls, OPC, etc.
3:00-3:15	Innovative Approaches to Evaluate Rare Outcomes in PAS
3:15-3:30	Academia, Research, MDEpiNet

	Perspective: PAS as Part of Larger Study
3:30-3:45	Patient Advocate Perspective: PAS Data to Support Health Care Decision Making
3:45-4:00	CMS Perspective: Reimbursement Decisions and Collaborative Review
4:00-4:45	Panel Discussion
Wrap-up: Moving Forward and Next Steps	
4:45-5:00	Vision for the Future of PAS Program
5:00	Adjourn

Registration

If you wish to attend this workshop (in person or via webcast) you must register by close of business on August 28.

There is no fee to register for the workshop and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you require special accommodations due to a disability, or need additional information regarding registration, please contact Cindy Garris, Office of Communications, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Silver Spring, MD 20993, 301-796-5861, FAX: 301-847-8142, Cynthia.garris@fda.hhs.gov [7].

Attendance ❍ In-Person
❍ Webcast
Title ❍ Mr. ❍ Mrs. ❍ Ms. ❍ None
First Name *
Last Name * M.D.❑ Ph.D.❑
Email*
Please enter Email again for verification :

Phone Number* (No dashes or spaces in phone numbers please)
Company or Organization *
Small Group Discussion If you'd like to join a small group discussion, please select:
(none)
Submit Clear Form

Contact Us

For questions regarding workshop content please contact:

Nilsa Loyo-Berrios, PhD, MSc

Center for Devices and Radiological Health
Food and Drug Administration,
10903 New Hampshire Ave., WO-66 Rm. 3214
Silver Spring, MD 20993
Phone: (301)796-8528
email: Nilsa.Loyo-Berrios@fda.hhs.gov [8]

or

Danica Marinac-Dabic, MD, PhD
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., WO-66 Rm. 4110
Silver Spring, MD 20993
phone: (301)796-6689
email: Danica.Marinac-Dabic@fda.hhs.gov [9]

Source URL (retrieved on *10/22/2014 - 10:02pm*):
http://www.mdtmag.com/news/2012/08/public-workshop-post-approval-studies-2012-workshop-design-methodology-and-role-evidence-appraisal-throughout-total-product-life-cycle-august-30-2012?qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#date
[2] http://www.gpo.gov/fdsys/pkg/FR-2012-08-21/html/2012-20469.htm
[3] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#agenda
[4] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#registration
[5] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#contact
[6] http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm
[7] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:Cynthia.garris@fda.hhs.gov
[8] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:Nilsa.Loyo-Berrios@fda.hhs.gov
[9] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:Danica.Marinac-Dabic@fda.hhs.gov