4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0331]

International Consortium of Cardiovascular Registries

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

Summary: The Food and Drug Administration (FDA) is announcing a public meeting entitled "International Consortium of Cardiovascular Registries." The purpose of this meeting is to discuss the development of an international consortium of cardiovascular registries with a broad array of interested stakeholders. The initial pilot phase of this effort will be developing relationships and analysis strategies for transcatheter cardiac valve registries, with the understanding that these efforts would be expanded to additional cardiovascular devices in the future.

Date and Time: The meeting will be held on April 22, 2013, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non- FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Persons: Benjamin Eloff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4210, Silver Spring, MD 20993, 301-796-8528, Benjamin.eloff@fda.hhs.gov; or Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4110, Silver Spring, MD 20993, 301-796-6689, Danica.marinac-dabic@fda.hhs.gov.

Registration: Registration is free and will be on a first-come, first-served basis. Persons interested in attending this public meeting must register online by 5 p.m. on April 11, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 7 a.m.

To register for the public meeting, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. Select this public meeting from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, mailing address, email address, and telephone number. Those without Internet access should contact Susan Monahan to register (Susan.Monahan@fda.hhs.gov or 301-796-5661). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (Susan.Monahan@fda.hhs.gov or 301-796-5661) no later than April 11, 2013.

Streaming Webcast of the Public Meeting: This meeting will also be available via Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on April 11, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after April 16, 2013. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Comments: FDA is holding this public meeting to obtain information on the topics identified in section II. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. The deadline for submitting comments related to this public meeting is May 22, 2013. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

Regardless of attendance at the public meeting, interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading

of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Transcripts: Transcripts will not be provided.

SUPPLEMENTARY INFORMATION:

I. Background

Cardiovascular procedures are performed in hundreds of thousands of patients every year to treat all manner of cardiovascular disease from coronary artery disease to peripheral vascular disease, intracardiac ablation to surgical interventions, implant of stents to implants of pacemakers, defibrillators, and their associated leads. Information obtained from clinical trials is often limited due to small size, short followup, and lack of generalizability. Observational studies and registries have become increasingly important data sources for assessing the performance of cardiovascular therapeutic medical devices in the real-world setting. However, these registries are often limited in scope and size to a specific country, region, or health care provider system.

Developing a comprehensive understanding of the performance of these devices requires not only an indepth analysis across data sources to link device use to clinical outcomes, but also to incorporate data from international experience with these devices and procedures. FDA is holding this workshop to discuss the development of an international consortium of cardiovascular registries that would allow for broad-based analysis and surveillance of medical device exposure and related clinical outcomes. This effort follows on the successful model of the International Consortium of Orthopedic Registries (ICOR), which has developed a

framework for distributed analysis across their member registries around the world. The development of a similar consortium of cardiovascular registries will begin with a narrowed scope incorporating transcatheter valve therapy devices and procedures.

At the end of this workshop, FDA intends that the participants and stakeholders will develop a comprehensive plan for the development of an operational international consortium of cardiovascular registries. This plan will identify specific issues that must be addressed and provide a "roadmap" for full implementation.

II. Topics

Topics to be discussed at this meeting include:

- The role of registry consortia in postmarket surveillance,
- Goals of the International Consortium of Cardiovascular Registries,
- Lessons learned from the development of the ICOR,
- Development of an international consortium of transcatheter valve registries as a pilot phase,
- Analysis of near- and long-term outcomes reported through registries, and
- Discussion of capabilities, challenges, and limitations of existing transcatheter valve registries.

Dated: March 27, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

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