4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Clinical Outcomes Assessment Development and Implementation: Opportunities and Challenges; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Clinical Outcomes Assessment Development and Implementation: Opportunities and Challenges." The purpose of the public workshop is to provide updates on accomplishments, challenges, and ongoing efforts in the use of clinical outcome assessments (COAs), and plan for the future of COA development and utilization in drug development programs, including how to incorporate the patient voice in drug development using well-defined and reliable patient-centered outcome measures. The public workshop will also discuss standards for COA use and collaborative processes for COA development and dissemination.

Date and Time: The public workshop will be held on April 1, 2015, from 8:30 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and routine security checks before the workshop.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD

20993-0002. Entrance for the public workshop 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. Attendees are responsible for their own accommodations.

The public workshop will also be available to be viewed online via Webcast at https://collaboration.fda.gov/COApublicworkshop2015. Persons interested in participating by Webcast must register online by March 27, 2015.

Contact Person: Michelle Campbell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6471, Silver Spring, MD 20993-0002, 240-402-6019, email: COApublicworkshop@fda.hhs.gov.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited to 150 attendees. Workshop space will be filled in order of receipt of registration. Those accepted in to the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. If registration is filled, attendance to the workshop will be available only through the Webcast.

To register, visit http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm. For those without Internet access, please call Michelle Campbell (See Contact Person) to register.

If you need special accommodations due to a disability, please contact Michelle Campbell (See Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The Center for Drug Evaluation and Research (CDER) reviews COAs, including patient-reported outcome measures, clinician-reported outcome measures, and observer-reported outcome measures, when submitted with an investigational new drug application, a new drug application, or a biologics licensing application. CDER also reviews a COA when submitted for qualification as a drug development tool. Qualification of a COA is a regulatory determination that the COA is well-suited for a specific context of use in drug development. Following a public announcement of the qualification decision by FDA, the COA will be publicly available for use in any appropriate drug development program.

This workshop will focus on current challenges and opportunities in COA development and use, including establishing appropriate standards for use; current efforts to encourage inclusion of well-defined and reliable patient-centered outcome measures in drug development; use of collaborative efforts in developing and utilizing COAs through various partnerships; and future efforts to address challenges and gaps of COA development and use for patient-centered drug development and medical product labeling.

For more information on this public workshop, visit http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm.

The Agency encourages patient advocates, health care providers, researchers, regulators, individuals from academia, industry, and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to

Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm approximately 45 days after the workshop.

Dated: February 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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