4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1075]

Minimum Clinically Important Difference: An Outcome Metric in Orthopaedic Device Science and Regulation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Minimum Clinically Important Difference: An Outcome Metric in Orthopaedic Device Science and Regulation." FDA is co-sponsoring this public workshop together with the Board of Regents of the University System of Georgia by and on behalf of the Georgia Institute of Technology's Translational Research Institute for Biomedical Engineering and Science (TRIBES). The purpose of this public workshop is to bring together a wide variety of stakeholders to discuss key topics relating to minimum clinically important difference (MCID) for patient-reported outcome (PRO) instruments used in orthopaedic extremity device-related procedures in order to streamline evidence-based scientific rationales for regulatory guidance of clinical trials and device study design.

Date and Time: The public workshop will be held on November 27, 2012, from 7:45 a.m. to 5:30 p.m., and on November 28, 2012, from 7:45 a.m. to 1 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993, on November 27, 2012 (Day 1), and Building 66, Atrium, on November 28, 2012 (Day

2). Entrance for the public workshop participants (non-FDA employees) is through Building 1 on Day 1 and Building 66 on Day 2, 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 Person: Faisal Mirza, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 1558, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6910 or 6311, FAX: 301-847-8117, email: faisal.mirza@fda.hhs.gov.

Registration: TRIBES will charge a registration fee for non-federal employees to cover its share of the expenses associated with the workshop. The registration fee is $230 for non-federal employees. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by November 13, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on Day 1 of the public workshop will be provided beginning at 6:45 a.m. The onsite registration fee is $275.

If you need special accommodations due to a disability, please contact Joyce Raines at 301-796-5709, email: joyce.raines@fda.hhs.gov no later than November 13, 2012.

To register for the public workshop, please visit the Georgia Institute of Technology's TRIBES Web site at http://www.tribes.gatech.edu/mcid-conf-2012. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

For more information on the public workshop, please see FDA's Medical Devices News & Events--Workshops and Conferences calendar at

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.)

Streaming Webcast of the Public Workshop: This public workshop will also be available as a Webcast for registrants only. Persons interested in viewing the Webcast must register online by November 13, 2012. 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 will be sent connection access information after November 13, 2012. 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, please 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.)

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, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Evidence-based medicine guidelines advise the use of PRO instruments for assessing the successes of clinical treatment in practice and clinical investigations. However, the selection of a valid instrument and accurate estimation of its respective clinically meaningful differences remain challenging particularly with orthopaedic device-related procedures. The MCID approach has been proposed to overcome this problem for PRO instruments. There have been various methodological approaches to determine MCID for particular PRO instruments but consistency in the literature remains elusive in orthopaedics and, thus, is the focus of this workshop.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

1. Current high-quality validated PRO instruments used in orthopaedic extremity device-related procedures and published MCID values, if any, for the various PRO instruments.
2. The impact of variables such as gender, racial/ethnic diversity, age, body mass index, timeliness, patient expectations, and patient satisfaction on PRO response and how this affects MCID calculation within these diverse populations and particular target subgroups of interest.
3. Methodology for determining the MCID for validated PRO instruments in a consistent, reliable, and reproducible manner that is least cumbersome.

4. Current evidence on how the MCID, pertaining to a particular PRO instrument that is used in device-related orthopaedic extremity surgery, may affect patient outcomes and device regulation.
5. Potential standard metric by which to gauge patient outcomes across the spectrum of devices, target populations, and variables of interest, in order to streamline evidence-based scientific rationales for regulatory guidance of clinical trials and device study design.

Approximately 45 days after the workshop, presentation slides will be available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.)

Dated: November 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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