



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1989]

Second Annual Workshop on Clinical Outcome Assessments in Cancer Clinical Trials; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research, in co-sponsorship with the Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium, is announcing a public workshop entitled "Second Annual Workshop on Clinical Outcome Assessments in Cancer Clinical Trials." The purpose of the public workshop is to provide a forum for collaborative multidisciplinary discussion to identify opportunities and address challenges for clinical outcome assessments, particularly patient-reported outcome (PRO) assessments, in oncology drug development. In this public workshop, a broad array of international stakeholders involved in oncology drug development and PRO measurement will provide perspectives on the role of PRO measures to provide complementary clinical data on the symptomatic side effects of anti-cancer agents. Speakers and panelists will explore the utility of information derived from existing and emerging PRO measures and discuss potential ways to improve the collection, analysis, and presentation of the data to support drug development and better inform treatment decisions. In addition, workshop participants will discuss possible approaches to the patient-reported assessment of an investigational drug's overall side effect

burden as a clinical trial endpoint. This public workshop will include speakers and panelists from regulatory agencies, academia, patient advocacy groups, and the medical product industry.

DATES: The public workshop will be held on April 25, 2017, from 8 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Ave., Bethesda, MD 20814, 301- 657-1234.

FOR FURTHER INFORMATION CONTACT: Theresa Hall, Patient-Reported Outcome Consortium, Critical Path Institute, 1730 East River Road, Tucson, AZ 85718, 520-777-2875, FAX: 525-547-3456, email: thall@c-path.org; and Valerie Vashio, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796- 3710, FAX: 301-796-9909, email: valerie.vashio@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical outcome assessment (COA) tools are intended to capture how patients experience a disease and its treatment by assessing symptoms, function, and other aspects of a patient's health-related quality of life (HRQL). PRO measures are one important type of COA tool. There is growing interest in optimizing the use of PRO measures to better incorporate the patient perspective into oncology drug development. While PRO measures can be used to evaluate the efficacy of cancer treatments, there is increasing interest in the use of PRO tools to assess symptomatic side effects of treatment. New PRO item banks and libraries are becoming available that can provide needed flexibility to tailor the PRO assessment to the wide range of side effects seen with the various mechanistic classes utilized in contemporary drug development. FDA is interested in gaining feedback on methods to integrate the patient into the

assessment of safety and tolerability of cancer drugs through systematic patient-reporting of side effects during clinical trials. This public workshop will discuss standard clinician reporting of adverse events, the development and implementation of the PRO-Common Terminology Criteria for Adverse Events (CTCAE) assessment tool, and explore different analysis and presentation methods for longitudinal patient-reported adverse event data.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this public workshop. The registration fee is charged to help defray the costs of the public workshop facility, speaker and panelist expenses, audiovisual equipment, materials, and food. Persons interested in attending this public workshop must register by April 21, 2017. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. Seats are limited, and registration will be on a first-come, first-served basis.

To register for the public workshop, please complete registration online at <https://www.cvent.com/events/second-annual-workshop-on-clinical-outcome-assessments-coas-in-cancer-clinical-trials/registration-270d8a5ee3ae4a108938851e2a7d0ea7.aspx>.

(FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	\$400
Charitable Nonprofit/Academic	\$100 (Contact C-Path)

Government	\$100 (Contact C-Path)
------------	------------------------

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814, are eligible for a reduced rate of \$249 per night, not including applicable taxes. To receive the reduced rate, please contact the hotel directly at 301-657-1234 and reference the Critical Path Institute April 2017 workshop or book online at:

<https://aws.passkey.com/event/15624700/owner/14877/landing?gtid=8d00149fbdf860c0e824aee45de33531>.

If you need special accommodations due to a disability, please contact the Hyatt Regency Bethesda at least 7 days in advance.

III. Transcripts

Transcripts will not be available. Presentations and associated audio files will be available on the C-Path Web site approximately 30 days after the public workshop at <https://c-path.org/category/events/>.

Dated: April 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-07766 Filed: 4/17/2017 8:45 am; Publication Date: 4/18/2017]