4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Weighing the Evidence: Variant Classification and Interpretation in Precision Oncology; 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 "Weighing the Evidence: Variant Classification and Interpretation in Precision Oncology." The purpose of the public workshop is to engage stakeholders and solicit input from experts in oncology precision medicine on how to best weigh and evaluate evidence for classification and interpretation of sequencing results for precision oncology.

DATES: The public workshop will be held on January 29, 2018, from 8:30 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), 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 https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Hisani Madison, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5547, Silver Spring, MD 20993, 240-402-6581, hisani.madison@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The goal of precision oncology is to use a cancer patient's genetic data to help determine which therapeutic(s) might be most effective in treating their disease. Next generation sequencing is increasingly employed in oncology because the technology can be used to screen a large number of mutations simultaneously to optimize and personalize patient care. The increasing number of reported mutations may lead to uncertainty for clinicians in the interpretation and prioritization of the variants with respect to the clinical significance and optimal course of action, respectively.

In January 2017, the Association for Molecular Pathology, the American Society of Clinical Oncology, and the College of American Pathologists published a joint consensus recommendation for standards and guidelines for the interpretation and reporting of sequence variants in cancer. However, the implementation of these recommendations is not consistently applied across all stakeholders. FDA is holding this public workshop to engage stakeholders and solicit input from internal and external experts in precision oncology to discuss how genetic sequencing data is best implemented in patient management so that innovative regulatory strategies can be advanced to support the development of safe and effective precision-based drugs and devices for marketing.

II. Topics for Discussion

Topics for discussion at the public workshop include:

- An overview of the state of the science for sequence variant classification in oncology and its practical use in treating patients;
- The level of evidence required for reporting variants and/or guiding patient treatment;
- Best practices for the use of public/private databases for variant classification and interpretation in oncology; and
- Future directions for data sharing, standardization, and establishing consistency in precision oncology.

The workshop will include a series of brief presentations to provide information to frame the main topics and interactive discussions via several panel sessions. Following the presentations, there will be a moderated discussion where speakers and additional panelists may be asked to provide their individual perspectives.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by January 19, 2018, by 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration

on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Peggy Roney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993-0002, 301-796-5671, email: Peggy.Roney@fda.hhs.gov no later than January 10, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration web page after January 10, 2018. Organizations are requested to view using one connection per location.

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 https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.).

Dated: November 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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