



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Seventh Annual Predictive Safety Testing Consortium/Food and Drug Administration Scientific Workshop; 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 (CDER), in cosponsorship with the Critical Path Institute (C-Path), is announcing a public scientific workshop to discuss the impact of safety biomarkers on drug development. The purpose of the workshop is to discuss the following issues: Application of toxicometrics as a translational safety strategy that integrates nonclinical and clinical safety approaches; uses of rodent and non-rodent nonclinical species in biomarker qualification; and assay validation aspects during biomarker development and qualification.

DATES: The public workshop will be held on April 25, 2016, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg 31 Conference Center, the Great Room (rm. 1503 A/B), Silver Spring, MD 20993-0002.

The FDA Conference Center is a federal facility and is located on the White Oak campus and like all federal facilities employs security procedures. Entrance for scientific 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>.

FOR FURTHER INFORMATION CONTACT: Jacqueline Brooks-Leighton, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, rm. 4521, Silver Spring, MD 20993, 240-402-5292, FAX: 301-796-9907, email: jacqueline.brooks-leighton,@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA and C-Path have expressed a willingness to leverage their combined strengths to develop and apply predictive safety testing biomarkers in drug development. This annual public workshop is intended to bring together leading academic experts, interested pharmaceutical companies, regulatory agencies, patient advocacy groups, and non-profit organizations.

This meeting will offer the opportunity to provide updates on the progress made in various biomarker development areas by the Predictive Safety Testing Consortium, and to discuss issues related to the regulatory aspects of qualification and uptake of biomarkers in drug development, as well as roadblocks to the sharing of biomarker data by the scientific community.

II. Attendance, Registration, and Accommodations

There is no fee to attend the meeting, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Onsite registration on the day of the workshop is not guaranteed but may be possible if space is available. For questions regarding registration, please contact Stephanie Codd Anderson, 520-647-8376, email: scanderson@gmail.com, at the Critical Path Institute.

Persons interested in attending this meeting in person must register online by April 11, 2016 at <http://www.cvent.com/d/2fqz12/4W>.

FDA has verified the Web address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**. Interested persons without Internet access should contact Stephanie Codd Anderson at 520-647-8376 to register.

The public workshop will also be available to be viewed online via webcast at <https://collaboration.fda.gov/pstc0416/>.

Workshop attendees with special needs due to a disability should contact Stephanie Codd Anderson, 520-647-8376, email: scanderson@gmail.com, at the Critical Path Institute at least 7 days before the scientific workshop.

Attendees are responsible for their own hotel accommodations.

There will not be a transcript for this meeting.

Dated: March 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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