4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Sequencing Quality Control II; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Sequencing Quality Control II." The purpose of the public workshop is to define the scope of project and study designs, and solicit participation of DNA sequencing community and stakeholders for data generation, management, analysis, and interpretation.

DATES: The public workshop will be held on September 13 and 14, 2016, 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 Wilson Hall, Bldg. 1, National Institutes of Health (NIH), 31 Center Dr., Bethesda, MD 20892. Entrance for the public workshop participants (non-NIH employees) is through the NIH Gateway Center where routine security check procedures will be performed. For parking and security information, please refer to https://www.nih.gov/about-nih/visitor-information/campus-access-security.

FOR FURTHER INFORMATION CONTACT: Weida Tong, National Center for Toxicological Research (NCTR), Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870-543-7142, FAX: 870-543-7854, weida.tong@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA's Critical Path Initiative (http://www.fda.gov/oc/initiatives/criticalpath/) identifies pharmacogenomics as a key

opportunity in advancing medical product development and personalized medicine. FDA has issued the "Guidance for Industry: Pharmacogenomic Data Submissions" (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079849.pdf) to facilitate scientific progress in the field of pharmacogenomic data integration in drug development and medical diagnostics. Microarrays represent a core technology in pharmacogenomics and toxicogenomics; however, next-generation sequencing technologies promise to provide some unique advantages in DNA and RNA analyses and are expected to be adopted by the pharmaceutical and medical industries for advancing personalized nutrition and medicine.

Starting in 2005, FDA initiated an open project, MicroArray Quality Control (MAQC), which has gone through three phases. MAQC-I focused on the technical aspects of microarray-based gene expression measurements, the MAQC-II focused on validation of microarray-based predictive models, and MAQC-III, which is also called the Sequencing Quality Control (SEQC), focused on assessing the performance of whole transcriptome sequencing (RNA-seq).

The Sequencing Quality Control Phase 2 (SEQC-II) is a natural extension of the SEQC project with emphasis on DNA-Seq for various applications. The SEQC-II project, with broad participation from scientists and reviewers within FDA and collaborators across the public, academic, and private sectors, is expected to help prepare FDA for the next wave of submission of genomic data generated from the next-generation sequencing technologies.

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by August 31, 2016. FDA will email a confirmation to those who have registered. There is no registration fee for the public

workshop. Early registration is recommended because seating is limited. No registration on the day of the public workshop will be provided.

If you need special accommodations due to a disability, please contact Weida Tong (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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