FDA and Gates Foundation collaborate to improve public health

U.S. Food & Drug Administration (FDA) sent this bulletin at 07/05/2017 09:05 AM EDT

FDA and the Bill & Melinda Gates Foundation share interests in scientific progress related to regulatory science and regulatory capacity-building to advance global public health.

FDA and the Gates Foundation signed a new Memorandum of Understanding (MOU) to establish a framework for collaboration.

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FDA and the Bill & Melinda Gates Foundation have launched a collaboration to improve global public health by fostering medical product innovation, and enabling medical product development, including medical countermeasures (MCMs).

FDA and the Gates Foundation signed a new Memorandum of Understanding (MOU) to establish a framework for collaboration. Activities will help facilitate regulatory science research and regulatory capacity-building, and develop solutions to address global public health challenges.

Related information

- MCM-related cooperative arrangements (including more MOUs)
- FDA is interested in scientific collaborations with stakeholders to further our public health mission. Who to contact
- For MCM-related partnering inquiries, please email AskMCMi@fda.hhs.gov

FDA Grand Rounds webcast

July 13, 2017, 12:00 - 1:00 p.m. ET

Join FDA research microbiologist Marc Allard, PhD, for FDA Grand Rounds to learn how his team used whole genome sequencing (WGS) to rapidly respond during a 2015 foodborne illness outbreak. CE credit is available.

Related information

- FDA’s Whole Genome Sequencing (WGS) Program
- Genome Trakr Network and video library
- About Dr. Allard
- Consumer Update: Whole Genome Sequencing: Cracking the Genetic Code for Foodborne Illness

Events

- July 6, 2017: Committee on Strategies for Identifying and Addressing Biodefense Vulnerabilities Posed by Synthetic Biology (Washington, DC), hosted by the National Academies of Sciences, Engineering, and Medicine (in-person only)
- July 10, 2017: Public workshop - Sentinel Training at FDA (Silver Spring, MD and webcast) - Early registration is recommended. Also see FDA’s Sentinel Initiative
• July 10-11, 2017: Bacteriophage Therapy: Scientific and Regulatory Issues Public Workshop (Rockville, MD), hosted by NIAID/NIH and FDA CBER - Registration is full, and this workshop will not be webcast. A transcript will be posted to the workshop web page when available.

• NEW! July 13, 2017: Webinar - Optimizing Your Study Data Submissions to FDA – Updates from CDER and CBER, 1:00 - 2:45 p.m. ET - FDA experts provide an overview of recent updates made to FDA’s Study Data Technical Conformance Guide (PDF, 486 KB) as well as important information and recommendations

• July 17, 2017: Public workshop - Developing Rabies Monoclonal Antibody Products as a Component of Rabies Post-Exposure Prophylaxis (Silver Spring, MD and webcast) - Register by July 12, 2017.

• NEW! July 19, 2017: Public workshop - Development of New Tuberculosis Drug Regimens - Scientific and Clinical Design Considerations (Silver Spring, MD and webcast) - Register by July 14, 2017

• NEW! August 14-15, 2017: NIST-DHS Standards for Pathogen Detection for Biosurveillance and Clinical Applications Workshop (Gaithersburg, MD) - The purpose of this workshop is to present state-of-the-art pathogen detection technologies, emphasizing the need for standards relevant to the clinical diagnostic and biothreat detection stakeholder communities. Abstracts are now being accepted, and registration is open. (fee)

• NEW! August 29, 2017: Regulatory/Scientific Challenges and Benefits of Repurposing Licensed Products for a Radiation Indication workshop (Rockville, MD and webcast), hosted by NIH/NIAID

• NEW! September 6-7, 2017: Crisis Leadership in Disasters Symposium and Disaster Health Symposium: Advancing the State of the Art (Bethesda, MD - submit abstracts by July 14, 2017), hosted by the Uniformed Services University of the Health Sciences (USUHS) and the National Center for Disaster Medicine & Public Health (NCDMPH). Registration for attendees who require pre-vetting (most non-DoD attendees) will close on August 30, 2017.

Information for industry

- FDA is requesting nominations for members to serve on the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) in the Center for Devices and Radiological Health. Members are selected from among authorities knowledgeable in the fields of science or engineering, applicable to electronic product radiation safety. Nominations received on or before August 14, 2017 will be given first consideration for membership on TEPRSSC.

- FDA is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee and device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health. Nominations received on or before August 22, 2017 will be given first consideration.

- In connection with promoting the use of innovative technologies, FDA is establishing a public docket to invite discussion of issues related to the adoption of continuous manufacturing by the pharmaceutical industry. Comment by September 21, 2017.
In case you missed it

- FDA unveils plan to eliminate orphan designation backlog - view FDA's Orphan Drug Modernization Plan (PDF, 108 KB) - about Orphan Drug designation (June 29, 2017)

- FDA Science: Working at the Speed of Emerging Technologies - also see webcast recordings from the 2017 FDA Science Forum (including MCM-related sessions) (June 16, 2017)

- FDA invites outstanding healthcare professionals, scientists, and engineers to apply to our two-year Commissioner's Fellowship Program. Apply by July 7, 2017, 5:00 p.m. ET.

- FDA is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Respond by July 17, 2017.

- CDC has released its 2018 Yellow Book, the definitive guide for healthy international travel. This edition features the latest information about infectious disease threats such as Zika, Ebola, and MERS as well as updated guidance for use of antibiotics to treat travelers' diarrhea. (June 29, 2017)