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Medical Countermeasures Initiative Update



June 12, 2019

Got pathogens?

Share your samples with FDA to help support MCM development

Many infectious diseases have similar signs and symptoms, making it challenging for healthcare providers to quickly identify the disease-causing agent. Doctors must often use multiple test methods to reveal the particular microbe causing illness, and ultimately determine the best treatment for patients.

Today, next-generation sequencing (NGS) technology could accomplish in a single test what might have required several different tests in the past. In other words, labs would be able to run diagnostic tests without knowing what disease(s) to test for.

However, before labs can conduct this type of test, the infrastructure to support NGS must be developed, including reference databases of microbial genomes. Both industry and FDA need these databases to help advance new medical countermeasures (MCMs)—diagnostics in particular—for emerging biothreats, including Ebola and Zika.

The FDA Database for Reference Grade Microbial Sequences ([FDA-ARGOS](#)) generates quality-controlled microbial reference genomes for diagnostic use, and makes them freely available in a public database.

Community stakeholders: We need your samples.

The FDA-ARGOS team and [collaborators](#) are specifically searching for unique, hard-to-source microbes such as biothreat organisms, emerging pathogens, and clinically significant bacterial, viral, fungal, and parasitic genomes. We aim to collect sequence information for a minimum of 5 isolates per species. [Most-wanted organism list](#) (PDF, 93 KB)



Related information

- [Access the FDA-ARGOS Database @ NCBI](#)
 - [Facts about FDA-ARGOS](#)
 - [Decoding Ebola: Next-Generation Sequencing of the Ebola Genome for the FDA-ARGOS Database](#) (MCMi regulatory science profile)
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Events

- **June 26-28, 2019: NIIMBL 2019 National Meeting** (Washington, DC) - The program will feature perspectives from industry and government leaders and showcase the work of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) community as it develops the cutting-edge technologies and training programs designed to enhance patient access to life-saving medicines. FDA's Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER), and Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER), are two of the featured speakers on June 27. *(fee)*
 - **New! July 11-12, 2019: Leveraging Randomized Clinical Trials to Generate Real-World Evidence for Regulatory Purposes public workshop** (Washington, DC and webcast) - To explore key considerations for utilizing randomized designs, such as large simple trials or those that incorporate pragmatic elements, and real-world data (RWD) to generate real-world evidence (RWE). Discussion will focus on key components of trial design including intervention selection, outcome measurement, blinding, and study population characteristics as well as important regulatory considerations. Register by **July 10, 2019**.
 - **July 12, 2019: Public meeting: Limited Population Pathway for Antibacterial and Antifungal Drugs** (Silver Spring, MD and webcast). The purpose of the meeting is to provide a public forum for FDA to listen to comments on the draft guidance for industry, [Limited Population Pathway for Antibacterial and Antifungal Drugs](#) that was published in the Federal Register on June 13, 2018. FDA is also reopening the comment period on this draft guidance for comments to be submitted for consideration before we finish work on the final version of the guidance. Register by **July 1, 2019**. Submit comments by **August 12, 2019**.
 - **New! July 17, 2019: Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations public workshop** (Washington, DC and webcast) - To capture stakeholder experiences with risk-based approaches to monitoring of clinical investigations and gather stakeholder input on opportunities to further the implementation of risk-based approaches to monitoring. Register by **5:00 p.m. ET July 16, 2019**. Also see draft guidance [A Risk-Based Approach to Monitoring of Clinical Investigations: Questions and Answers](#), issued in March 2019.
 - **New! September 11-12, 2019: 2019 FDA Science Forum** (Silver Spring, MD) - Save the date!
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Information for industry

- Draft guidance: [Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment](#)

[Practices, and Trial Designs](#) - Provides recommendations for more inclusive trial practices, trial designs, and methodological approaches sponsors can take to broaden eligibility criteria and increase enrollment of more diverse populations in clinical trials. Broadening eligibility criteria, when appropriate, maximizes the generalizability of trial results and the ability to understand the therapy's benefit-risk profile across the patient population likely to use the drug in clinical practice, without jeopardizing patient safety. Comment by **August 6, 2019**. (June 6, 2019)

In case you missed it

- [FDA approves new treatment for hospital-acquired and ventilator-associated bacterial pneumonia](#) - FDA approved a new indication for the previously FDA-approved drug, Zerbaxa (ceftolozane and tazobactam) for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in patients 18 years and older. The FDA initially approved Zerbaxa in 2014 to treat complicated intra-abdominal infections and for complicated urinary tract infections. (June 3, 2019)
- From HHS - [BARDA-supported Zika Virus Test Receives FDA Clearance; Ready for Clinical Laboratory Use](#) - The first commercially available Zika virus diagnostic, a product BARDA supported through its advanced research and development program, [received authorization for marketing](#) from FDA on May 23, 2019. The test provides results from a blood sample in about four hours. Called the ZIKV Detect 2.0 IgM Capture ELISA, the test exemplifies the progress that is possible with public-private partnerships. (June 6, 2019)
- From HHS - [HHS Seeks to Expand its Network Innovation Accelerators into More States](#) - Funding is available from the U.S. Department of Health and Human Services for organizations to provide specific biotechnology innovators with the technical and entrepreneurial support needed to accelerate development of their products. Applications are due by **11:59 p.m. ET July 23, 2019**.
- **Last chance!** From HHS - The National Biodefense Science Board is [accepting applications](#) for new members. Apply by **June 15, 2019**.
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.



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