U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

August 15, 2018

Take our email survey (last chance!)

Regulatory science research tools

Helping researchers advance medical countermeasure (MCM) development

The FDA Medical Countermeasures Initiative (MCMi) funds research to further MCM development, including building tools to help MCM researchers advance their products and help FDA reviewers evaluate MCM products for approval.

MCM-related regulatory science tools funded (or partially funded) by FDA include:

- Cross-species immune system reference
- FDA-ARGOS (FDA dAtabase for Regulatory Grade micrObial Sequences)
- Zika virus reference materials for diagnostic developers
- FDA-CDC Antimicrobial Resistance Isolate Bank

Learn more about these tools, including how you can access them for your MCM-related research.

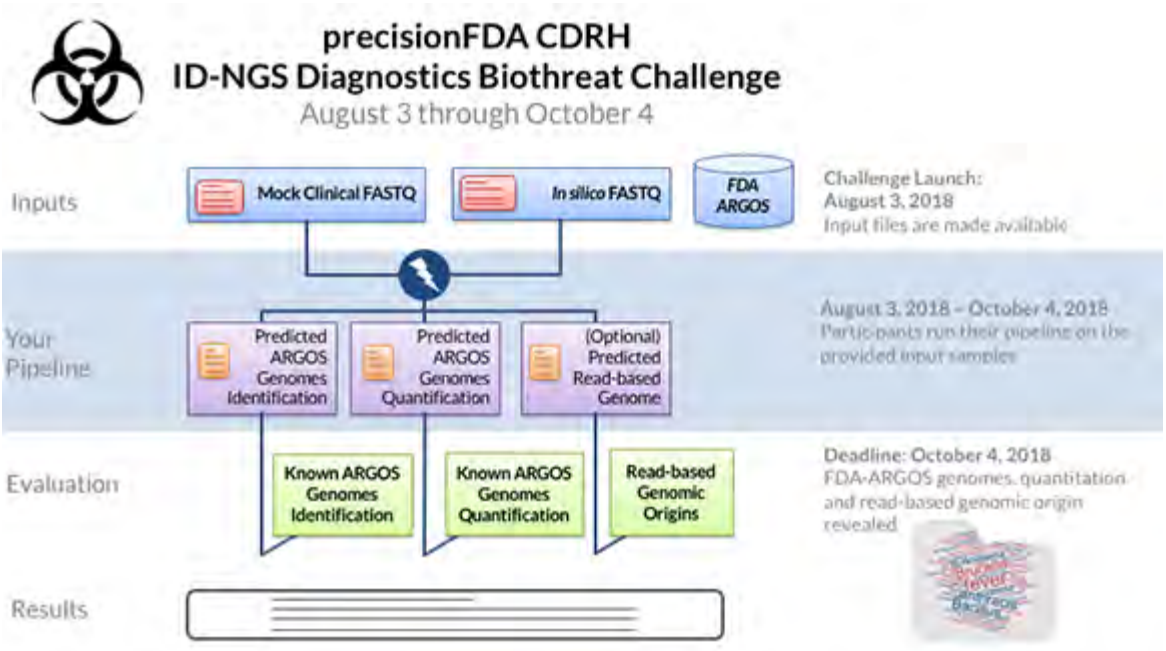
Image: An FDA scientist divides plasma from individuals recently infected with dengue or West Nile viruses into smaller volume samples for distribution. Qualified Zika test manufacturers can request an FDA reference panel to determine if their tests can differentiate flaviviridae antibodies (Zika, dengue, or West Nile). (FDA photo)

Related links:

- MCM-related extramural research funded by FDA
- MCM-related intramural research at FDA
- FDA Technology Transfer Program

Join the challenge to identify biothreat pathogens

Professional and citizen scientists: test your bioinformatics skills and software tools



Many infectious diseases have similar signs and symptoms, making it challenging for healthcare providers to identify the disease-causing agent. Infectious disease next-generation sequencing (ID-NGS) technology may enable the diagnosis of infections without prior knowledge of the disease's cause.

To encourage the development and improvement of ID-NGS analytical methods, precisionFDA – the community platform for NGS assay evaluation and regulatory science exploration – is launching the **precisionFDA CDRH Infectious Disease NGS Diagnostics Biothreat Challenge**.

Professional and citizen scientists are invited to test their bioinformatics skills and software tools in a challenge to identify pathogens from the FDA-ARGOS database within host samples using NGS short-read data. This challenge will enable the community to look at algorithm performance using a fixed reference genome standard.

The challenge is open now through **October 4, 2018**.

EUA updates

Emergency Use Authorization and related updates

August 3, 2018: EUA amendment - DPP Zika IgM Assay System (Chembio Diagnostic Systems, Inc.) - *more info*

August 7, 2018: Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines - The HHS Secretary is amending the August 1, 2016 Declaration to extend the effective time period of the declaration through December 31, 2022 and to clarify and add to the list of covered countermeasures to include all Zika virus vaccine types and technologies. *Also see PREP Act*

Reminder:
Laboratory personnel using Zika diagnostic assays under EUA are encouraged to report performance concerns directly to FDA at CDRH-EUA-Reporting@fda.hhs.gov, in addition to reporting concerns to the manufacturer.

Information about Zika EUAs and amendments is available on the FDA Zika virus response updates page. Also see the latest CDC Zika Laboratory Guidance, last updated July 24, 2017.

Events

- **August 21-22, 2018:** Public workshop - Development of Non-Traditional Therapies for Bacterial Infections (Silver Spring, MD and webcast) Discussions will focus on pre-clinical development, early stage clinical trials, and phase 3 clinical trial designs to evaluate safety and efficacy of non-traditional therapies intended to serve as primary or adjunctive therapy to existing antibacterial drugs. FDA is particularly interested in discussing pre-clinical and clinical development of several types of non-traditional therapies, including monoclonal antibodies, immunomodulators, lysins, and other non-traditional therapies.
- **August 22-23, 2018:** Workshop: Exploring Medical and Public Health Preparedness for a Nuclear Incident (Washington, DC), hosted by The National Academies of Sciences, Engineering, and Medicine - Participants will explore current assumptions behind and the status of medical and public health preparedness for a nuclear incident, examine potential changes in approach, and discuss challenges and opportunities for capacity building in the current threat environment.
- **September 4, 2018:** Facilitating Competition and Innovation in the Biological Products Marketplace (Silver Spring, MD) - FDA is announcing a public hearing on FDA's approach to enhancing competition and innovation in the biological products marketplace, including by facilitating greater availability of biosimilar and interchangeable products. Electronic or written comments will be accepted after the public hearing until **September 21, 2018.**
- **New! September 5, 2018:** N95 Day 2018 Webinar: Panel Discussion of Trending Topics on Respiratory Protection, 1:00 - 2:00 p.m. ET, hosted by CDC/NIOSH - NIOSH experts will share the science behind the established guidance and recommendations**.**
- **New! September 5-6, 2018:** Medical Product Shortages during Disasters: Opportunities to Predict, Prevent, and Respond - A Workshop (Washington, DC), hosted by the National Academies of Sciences, Engineering, and Medicine, and sponsored by the HHS Office of the Assistant Secretary of Preparedness and Response. To attend in-person, register in advance.
- **September 12, 2018:** Public hearing on FDA's Predictive Toxicology Roadmap - FDA is seeking comments on how to foster the development and evaluation of emerging toxicological methods and new technologies and incorporate them into regulatory review, as applicable. To attend, register by **August 29, 2018**. *Also see: FDA's Predictive Toxicology Roadmap (PDF, 2.2 MB)*
- **New! September 14, 2018:** Public workshop - Advancing the Development of Pediatric Therapeutics 5: Advancing Pediatric Pharmacovigilance (Silver Spring, MD and webcast) - To provide a forum to gather information on the latest developments in pediatric pharmacovigilance from the perspective of various stakeholders and to expand the conversation to include the utility and challenges of emerging pharmacovigilance tools, including specific challenges associated with pediatric data tools. To attend in-person or by webcast, register by **September 6, 2018.**
- **New! October 29-30, 2018:** Save the date for BARDA Industry Day (Washington, DC) - Engage and network with members of BARDA, ASPR and other government and industry stakeholders. Registration coming soon. BARDA invites pharmaceutical companies, biotech and other innovators to present a Lightning Talk. Apply by **September 7, 2018.**

Information for industry

- FDA released the Biosimilars Action Plan (PDF, 383 KB) to provide information about the key actions the agency is taking to encourage innovation and competition among biologics and the development of biosimilars. *(July 18, 2018)*
- Reminder: Comments are due on the draft guidance for industry, Smallpox (Variola Virus) Infection:

Developing Drugs for Treatment or Prevention (PDF, 120 KB) by **September 10, 2018**.

More: MCM-Related Guidance by Date

In case you missed it

- FDA supports critical research to spur innovation for continuous manufacturing technology to support and advance drug and biologics development - FDA awarded three grants, using its authority under the 21st Century Cures Act, to institutions of higher education and non-profit organizations to study and recommend improvements for the continuous manufacturing of drugs and biological products, as well as similar innovative monitoring and control techniques. *Also see: FDA's Emerging Technology Program (August 1, 2018)*
- FDA approves first generic drug under new pathway aimed at enhancing market competition for sole source drugs - FDA approved several strengths of potassium chloride oral solution as the first generic drugs to receive a Competitive Generic Therapy (CGT) designation. This new approval pathway was created to expedite the development and review of a generic drug for products that lack competition. *(August 8, 2018)*
- FDA has launched a new Medication Guide database to replace the current Medication Guide web page. Medication guides are provided with many prescription medicines. A Medication Guide is a form of patient labeling that is part of the FDA-approved prescription drug labeling. Medication Guides address issues that are specific to particular prescription drugs or biologic products and can help patients avoid serious adverse events. *(August 8, 2018)*
- Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's new efforts to advance antimicrobial stewardship in veterinary settings - Combating antimicrobial resistance continues to be a top priority for FDA. To further these efforts, FDA will soon implement a new, five-year blueprint for how the FDA plans to build on its current programs to advance antimicrobial stewardship in veterinary settings. *(July 31, 2018)*
- 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. Send a letter or email stating interest by **August 29, 2018**.
- From HHS - HHS, DoD, Spero co-sponsor novel oral antibiotic development to treat deadly infections - First-of-its-kind public-private partnership takes aim at biothreats, drug-resistant bacteria. *(July 16, 2018)*
- From the National Institute of Standards and Technology (NIST) - New Cell Lines Produce NIST Monoclonal Antibody for Improved Manufacturing of Biologic Drugs - "Researchers will be able to look at the broad issues currently facing manufacturers of mAb therapeutics with a system that is not proprietary; the NIST cell lines will encourage innovation and exploration that isn't related to specific product development." *(July 31, 2018)*
- You want to make a difference. FDA wants to hire you. Follow @FDAJobs on Twitter, or visit www.fda.gov/jobs.

Did someone forward you this email? ***Subscribe***

(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)