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June 26, 2019

Helping translate new technologies into safe, effective medical countermeasures

Part 2 of an occasional series on the ways FDA helps prepare for and respond to public health emergencies

FDA's Medical Countermeasures Initiative (MCMi) Regulatory Science Program is developing tools, standards, and approaches to help assess medical countermeasure (MCM) safety, efficacy, quality, and performance. Examples of our research—conducted [by FDA](#), and with [extramural](#) partners—includes:

- Drug development tools, such as nonclinical models and immune biomarkers
- *In silico* predictive models, such as [organs-on-chips](#)
- Next-generation sequencing-based *in vitro* diagnostic platforms
- Reference materials to support development of MCMs for threats such as Ebola and [Zika](#)

[MCM Regulatory Science](#)

Related information

- [Regulatory science research tools](#) (MCM-related regulatory science tools funded or partially funded by FDA)

- [MCMi FY 2018 program update](#) (PDF, 4 MB – see page 34 for regulatory science updates)
 - [FDA's MCM roles, part 1: How FDA helps make MCMs available in emergencies](#) (PDF, 106 KB)
 - [What are medical countermeasures?](#)
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Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA)



On June 24, 2019, the President signed into law S.1379, the [Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019](#) (PDF, 320 KB), which reauthorizes and modifies programs related to public health emergency preparedness and response.

Related information:

- [MCM-Related Counterterrorism Legislation](#) (FDA page, including new PAHPAIA section)
 - [New law strengthens U.S. efforts to prepare, respond and recover from disasters](#) (statement by Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services [HHS ASPR])
 - [Pandemic and All-Hazards Preparedness and Advancing Innovation Act 2019: What Does It Mean for Me and My Organization?](#) (from the HHS ASPR Blog)
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Events

- **New! June 26, 2019:** [Strategic National Stockpile \(SNS\) Temperature Considerations for Medical Countermeasures Webinar](#), 1:30 p.m. ET, hosted by CDC - The purpose of this webinar is to provide public health partners with an overview of the [Strategic National Stockpile's](#) responsibilities for maintaining and distributing cold chain products. It will also explain what the state planning considerations should be for receiving and transporting medical countermeasures (MCM) from the stockpile to local vaccination points. Free CDC TRAIN account required to register.
- **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**.

- **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*.
- **September 11-12, 2019:** [2019 FDA Science Forum](#) (Silver Spring, MD) - Agenda coming soon. Topic areas include: Outbreak! FDA's approach to prevention and response, including prevention through cybersecurity and promoting medical product and food security, and rapid response to infectious disease and foodborne pathogen outbreaks, e.g. the use of the Animal Rule, emergency communication devices, rapid diagnostic tests, antimicrobial resistance.

Information for industry

- **Reminder:** Comment by **July 8, 2019** on the draft guidance: [Submitting Documents Utilizing Real-World Data \(RWD\) and Real-World Evidence \(RWE\) to the FDA for Drugs and Biologics](#). This draft guidance encourages sponsors and applicants who are using RWD to generate RWE as part of a submission to provide information on their use of RWE to the FDA in a simple, uniform format. FDA will use this information for internal tracking purposes only. Also see: *[FDA In Brief: FDA issues draft guidance to industry on submitting real-world evidence in new drug and biologic applications](#) (May 8, 2019)*

In case you missed it

- FDA supports the development of next-generation sequencing (NGS)-based diagnostics to help healthcare providers identify and treat the right pathogen. To help build NGS infrastructure, our [FDA-ARGOS](#) database makes publicly available quality-controlled microbial reference genomes for diagnostic use. The FDA team is looking for unique, hard-to-source microbes like biothreat organisms, emerging pathogens, and AMR-related pathogens to help improve the database. We encourage the community to [share microbe samples](#). (*June 12, 2019*)
- [FDA poliovirus assay is faster and more versatile than current assays used in vaccine development and environmental surveillance](#) - FDA scientists have developed a poliovirus assay that is faster and more versatile than those now used to monitor polio vaccine production, assess patient responses to polio vaccines during clinical trials, and do environmental surveillance of vaccine poliovirus. The assay is also the first to measure the amount of several different strains simultaneously in a mixture of polioviruses. (*June 17, 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 CDC - [Dengue and Zika Virus Diagnostic Testing for Patients with a Clinically Compatible Illness and Risk for Infection with Both Viruses](#) - This report summarizes existing and new guidance on dengue and Zika virus diagnostic testing for patients with a clinically compatible illness who live in or recently traveled to an area where there is risk for infection with both viruses. (June 14, 2019)
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