

September 26, 2018

MCM regulatory science news

U.S. Department of Defense (DoD) and FDA collaborate to help speed potential countermeasures for Ebola and other viruses

Understanding microbial pathogenesis—the mechanism by which microbes cause disease—is essential for developing medical products to prevent, diagnose, and treat microbial infections. This requires not only an understanding of the pathogenic microbes, but also the cellular and immune responses those microbes stimulate in infected people.

However, obtaining samples from people who have been infected to study their cellular and immune responses can be difficult, particularly for rare viruses such as Ebola, Marburg, Rift Valley fever, and Crimean Congo hemorrhagic fever due to logistical, regulatory, and ethical considerations.



FDA awarded a three-year interagency agreement to the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to establish a better understanding of the microbial pathogenesis of several viruses: Ebola, Marburg, Rift Valley fever, Crimean Congo hemorrhagic fever, Chikungunya virus, and Zika. This work will help advance the understanding of the microbial pathogenesis of viral hemorrhagic fevers and Zika virus in humans—a key step toward enabling the development of medical countermeasures (MCMs).

[Read more about this project](#)

Image: U.S. Navy Lt. Andrea McCoy tests a patient sample for the Ebola virus at a Naval Medical Research Center mobile laboratory in Liberia. (Photo by U.S. Army Africa/CDC)

Related links:

- [MCM extramural research](#) - information about funding and projects, including additional Ebola-related research
- [Ebola preparedness and response updates from FDA](#)

September is National Preparedness Month

National Preparedness Month

It's important to have a plan for emergency medication and medical supplies for both people and animals

While FDA and other agencies work hard every day to help prepare the nation for potential threats, everyone can be involved in disaster readiness. Learn [what you can do now](#), including precautions for storing water and ensuring the safety of food and medical supplies for your family and pets during and after hurricanes and heavy rain, possible flooding and power outages.

Events

- **New! September 26, 2018:** [How to get FDA Secure Email](#) - CBER Webinar for industry, 10:00 a.m. ET - CBER's secure email policy takes effect October 1, 2018. This webinar will provide information about how to set up secure email with FDA. Topics covered include methods for setting up secure email and how to request assistance.
- **October 3, 2018:** [Vaccines and Related Biological Products Advisory Committee \(VRBPAC\) public meeting](#) (Silver Spring, MD and [webcast](#)) - The VRBPAC will meet in an open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2019 southern hemisphere influenza season.
- **October 22, 2018:** [Science Board to the FDA public meeting](#) (Silver Spring, MD and [webcast](#)) - The [Science Board](#) will hear a response from the Center for Veterinary Medicine (CVM) to the recommendations made by the Science Board's 2017 review of CVM's [National Antimicrobial Resistance Monitoring System](#) program. The Science Board will also discuss potential hazards and nutritional considerations in the production of food derived from animal cell culture technologies.
- **October 29-30, 2018:** [BARDA Industry Day](#) (Washington, DC) - Engage and network with members of BARDA, ASPR and other government and industry stakeholders. [Registration](#) is open.
- **November 13-15, 2018:** [Clinical Investigator Training Course](#) (Silver Spring, MD) - Experts from FDA, the University of Maryland, and the University of Pennsylvania will provide training in all aspects of clinical studies: preclinical and clinical science, statistical structure of trials, ethical requirements, and regulatory considerations. Registration closes on **November 6, 2018**, or when registration is full.
- **November 27, 2018:** [Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions public meeting](#) (Washington, DC and [webcast](#)) - This meeting will give stakeholders the opportunity to provide input on the underlying systemic causes of drug shortages, and make recommendations for actions to prevent or mitigate drug shortages. To attend in-person, [register](#) by **November 21, 2018**.

Information for industry

- **RFI (reminder):** [Development of New Antibacterial Drugs Active Against Multi-Drug Resistant Bacteria](#) - The FDA Center for Drug Evaluation and Research (CDER) [Office of Antimicrobial Products](#) issued a Request for Information (RFI) on September 11, 2018, to solicit informal input from the public and private sectors to obtain external input into developing an annual list of regulatory science initiatives specific for antimicrobial products. Respond by **October 31, 2018**.
- FDA [announced the fee rate](#) for using a material threat medical countermeasure priority review voucher (MCM PRV) for fiscal year (FY) 2019. *(September 26, 2018)*
- Draft guidance - [Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers](#) (PDF, 363 KB) - to clarify questions relating to product identifiers that are required by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA) for packages and homogenous cases of certain drug products. Submit [comments](#) by **November 19, 2018**. Also see: [FDA advances policies related to bolstering security of drug products in the U.S. supply chain](#) *(September 19, 2018)*
- Guidance for industry - [Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications \(510\(k\)\) with Different Technological Characteristics](#) (PDF, 538 KB) Also see: [FDA In Brief: FDA takes new steps to enable innovators to more efficiently advance technological characteristics of certain medical devices while ensuring safety of products](#) *(September 24, 2018)*

More: [MCM-Related Guidance by Date](#)

In case you missed it

- From the White House - [Statement from the President on the National Biodefense Strategy and National Security Presidential Memorandum](#) - "Today, I have taken action to better protect the American people by releasing a [National Biodefense Strategy](#) (PDF, 919 KB) and signing a [National Security Presidential Memorandum \(NSPM\)](#) that will strengthen our Nation's defenses against biological threats to health and safety. The implementation of these actions will promote a more efficient, coordinated, and accountable biodefense enterprise. Taken together, they represent a new direction in the Nation's defense against biological threats." *(September 18, 2018)*
- FDA has released the latest edition of the (CDER) [Director's Corner Podcast](#) - Dr. Woodcock discusses what FDA is doing to address drug shortages, and how FDA is working with industry to help lessen their impact (audio and transcript files available). *(September 20, 2018)*
- [FDA awards grants to foster innovation for advanced manufacturing technology as part of the agency's efforts to ensure a robust and reliable supply of biological products](#) - FDA awarded five grants to institutions of higher education and non-profit organizations to study and recommend improvements for the continuous manufacturing of biological products, as well as similar innovative monitoring and control techniques. *(September 20, 2018)*
- Visit our new web page, [Antimicrobial Resistance Information from FDA](#), for the latest on AMR from across FDA.
- 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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