U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

November 20, 2019

Characterizing immunity to Ebola and Marburg to support medical countermeasure development

MCMi regulatory science update

The breadth and durability of the human immune response to infection with Ebola virus and Marburg virus—as well as the vaccine-induced immune response in individuals vaccinated with investigational vaccines against those viruses—is not well understood. This lack of understanding can create challenges for the development of medical countermeasures (MCMs) to combat these threats.

To help address these challenges, FDA is supporting a study of the immune response in Ebola Virus disease and Marburg Virus disease survivors as well as in individuals vaccinated with investigational Ebola vaccines. This study will help the evaluation of the performance of existing MCMs while also supporting the development of next-generation MCMs.

FDA awarded this contract in September 2019 to the University of California, Los Angeles (UCLA) School of

Public Health, who—in collaboration with the Congolese Institut National de la Recherche Biomédicale (National Institute for Biomedical Research)—will expand a biobank of plasma and peripheral blood mononuclear cell (PBMC) samples to help support the development of MCMs against Ebola and Marburg viruses.

Read more about this project

Related links:

- MCMi Extramural Research
- Ebola Preparedness and Response Updates from FDA

FDA issues final guidance for development of smallpox treatments as part of preparedness efforts

“While the World Health Organization declared smallpox eradicated in 1980, concerns have persisted that smallpox could be used as a biological weapon. The FDA plays a pivotal role preparing our nation to be able to protect the American people from biological threats, including by providing guidance and support for the development of medical countermeasures that can be used safely, effectively and reliably during public health emergencies,” said Anna Abram, FDA Deputy Commissioner for Policy, Legislation, and International Affairs.

“We work with government partners as well as non-government organizations, universities and research centers, and industry to further the development of medical countermeasures as part of our vital public health mission. Despite recent advances in developing an effective treatment for smallpox, drug developers still face challenges in bringing forward these medical countermeasures, which are critical should smallpox ever be used as a biological weapon. The agency’s work to advance safe and effective medical countermeasures is a high priority, and today’s final guidance on the development of drugs to treat or prevent smallpox builds upon currently available guidance, further advancing the agency’s long-standing commitment to the development of robust medical countermeasure preparedness efforts."

On November 15, 2019, FDA issued final guidance, Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention, which is designed to assist drug manufacturers designing studies to appropriately establish the safety and efficacy of drugs to treat or prevent smallpox infection.

Read the full FDA statement

Related links:

- Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention - Guidance for Industry (PDF, 127 KB)
- Smallpox Preparedness and Response Updates from FDA

EUA updates

EUA amendment:

- **November 12, 2019:** In response to BioFire Defense LLC's request, FDA concurred (PDF, 151 KB) with modifications to the authorized Instructions for Use of the FilmArray Biothreat-E test to include new data on analytical exclusivity wet-testing and associated limitations. FDA also concurred with modifications to the (1) Instructions for Use, including wording in the intended use, to improve the overall clarity and accuracy of the document, and (2) Healthcare Provider and Patient Fact Sheets, that were requested by FDA. *For more information, including links to the revised documents, see Emergency Use Authorizations (Devices)*

Events

- **November 22, 2019:** Blood Products Advisory Committee meeting (Silver Spring, MD and webcast) - The committee will meet in open session to discuss scientific considerations for cold stored platelet products intended for transfusion, including product characterization, duration of storage and clinical indications for use. The committee will hear presentations on available characterization and functional studies of cold stored platelets, clinical studies, and the potential role of cold stored platelets in clinical care in military and civilian patient populations. The committee will also discuss the clinical studies needed to support the indications for use of cold stored platelet products stored beyond 3 days.
- **New! December 4, 2019:** Informational Meeting: The Importation of Infectious Biological Agents, Infectious Substances and Vectors (webcast), hosted by CDC - This webcast is an opportunity for all interested parties (e.g., academic institutions; biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities; and educational facilities) to obtain specific guidance and information regarding import permit regulations for the importation of infectious biological agents, infectious substances and vectors. The webcast will also provide assistance to those interested in applying for an import permit from federal agencies within the United States. Register by **November 22, 2019**. *Also see Import Permit Program (IPP), from CDC*
- **New! December 5-6, 2019:** Repurposing Off-Patent Drugs: Research & Regulatory Challenges (Rockville, MD) - Hosted by FDA, the U.S. National Institutes of Health (NIH), and the Reagan-Udall Foundation for the FDA, this workshop will explore opportunities and challenges in assessing the safety and efficacy of repurposed drugs; patient experiences; and potential strategies to prioritize certain drugs and diseases for repurposing.

Information for industry

- Draft guidance - Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff (PDF, 470 KB) - The 21st Century Cures Act (Cures Act), enacted on December 13, 2016, requires that FDA make publicly available on its website best practices for drug safety surveillance activities. The draft document sets forth risk-based principles by which FDA conducts ongoing postmarketing safety surveillance for drug and biological products to address the Cures Act requirements. Comment by **January 6, 2020**. *Also see: Statement on the agency's efforts to protect patients through postmarket drug safety surveillance practices (November 6, 2019)*

In case you missed it

- FDA approves new antibacterial drug to treat complicated urinary tract infections as part of ongoing efforts to address antimicrobial resistance - FDA approved Fetroja (cefiderocol), an antibacterial drug for treatment of patients 18 years of age or older with complicated urinary tract infections (cUTI), including kidney infections caused by susceptible Gram-negative microorganisms, who have limited or no alternative treatment options. *Also see: Antimicrobial Resistance Information from FDA (November 14, 2019)*
- Data standards for Animal Rule studies – FDA has been working with the Critical Path Institute and the Clinical Data Interchange Standards Consortium (CDISC) to develop electronic data standards for the natural history and efficacy studies conducted in animals that support Animal Rule applications. The Standard for Exchange Nonclinical Data (SEND) Implementation Guide for Animal Rule studies (SENDIG Animal Rule) and the last part of the associated controlled terminology were published by CDISC in September.
- MedWatch is FDA's program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics. With recent updates, you can now attach images of the product or fill out the form in Spanish. *(November 8, 2019)*

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