U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

November 6, 2019

Ebola survivor study expanded to include new technologies

MCMi regulatory science update

In addition to supporting ongoing response to Ebola outbreaks in the Democratic Republic of the Congo (DRC), FDA and government partners are conducting studies in West Africa to better understand how Ebola affects patients who have survived, and to learn how to more effectively treat these patients' chronic health problems.

In 2016, FDA awarded a contract to Stanford University to help the global scientific community better understand the course of Ebola virus infection—an important factor in finding new treatments. In 2017, research was expanded to include Zika virus infection.

In September 2019, the project was again expanded, to apply a new method to the study of Ebola and Zika tissue samples. The Stanford laboratory will use multiplexed ion beam imaging (MIBI) to identify viral reservoirs—cells or anatomical sites where viruses accumulate and persist—for both Ebola and Zika infection, ultimately facilitating the deployment of novel, effective analytical technologies into federal laboratory space.

Read more about this project

Related links:

- MCMi Extramural Research
- Multiplexed Ion Beam Imaging (Stanford)
- Ebola Preparedness and Response Updates from FDA

EUA updates

Third Zika diagnostic cleared

- **October 28, 2019:** FDA cleared the LIAISON XL Zika Capture IgM Assay II for the presumptive qualitative detection of Zika virus IgM antibodies in human sera collected from individuals meeting the CDC Zika virus clinical and/or epidemiological criteria. Previously, the test had been authorized only for emergency use under FDA's Emergency Use Authorization (EUA) authority. FDA revoked the EUA for the LIAISON XL Zika Capture IgM Assay II test, initially issued on April 5, 2017.

Related links:

- EUA Termination or Revocation
- Emergency Use Authorization--Archived Information
- Zika Virus Response Updates from FDA

Report | Drug Shortages: Root Causes and Potential Solutions

Drug Shortages: Root Causes and Potential Solutions (PDF, 3.8 MB) examines the underlying factors responsible for drug shortages and recommends enduring solutions. *Also see: Statement on FDA's new report regarding root causes and potential solutions to drug shortages (October 29, 2019)*

Events

- **November 8, 2019:** Vaccines and Related Biological Products Advisory Committee public meeting (Silver Spring, MD and webcast) - The committee will discuss and make recommendations on the development of chikungunya vaccines.
- **November 12-14, 2019:** Regulatory Education for Industry (REdI): Clinical Investigator Training Course (College Park, MD) This course provides an intermediate-level study of clinical trial principles with in-depth coverage of clinical trial design, issues in safety and efficacy, investigator responsibilities, understanding the investigator brochure, and FDA requirements across Centers. Upon completion, attendees should understand pre-clinical research, clinical trials, and FDA submissions for licensure of medical products.
- **November 18, 2019:** Development of Best Practices in Physiologically Based Pharmacokinetic Modeling To Support Clinical Pharmacology Regulatory Decision-Making Public Workshop (Silver Spring, MD and webcast) - To discuss best practices and evidentiary criteria in the use of physiologically based pharmacokinetic (PBPK) modeling approaches to support regulatory decision-making; share experiences and cases where applying PBPK modeling and simulation highlight the opportunities and limitations of this approach; obtain input from stakeholders on when, where, how, and with what limitations PBPK modeling and simulation may be applied in regulatory decision-making; and discuss the knowledge gaps and research needed to advance PBPK modeling sciences in drug development to support regulatory decisions. Register by **November 8, 2019**.
- **November 18-19, 2019:** Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development (Silver Spring, MD and webcast) - Co-sponsored by FDA, the Infectious Diseases Society of America (IDSA), the National Institute of Allergy and Infectious Diseases (NIAID), and Pew, this workshop will bring together a diverse array of subject matter experts in the fields of infectious diseases (ID), academics and industry and other government bodies to better understand the current state of U.S.-based ID trials and how to enhance enrollment and research in such trials. Register by **November 14, 2019**.
- **November 18-21, 2019:** Chemical and Biological Defense Science & Technology (CBD S&T) Conference (Cincinnati, OH) - Hosted by the Defense Threat Reduction Agency (DTRA). FDA will be presenting as part of a panel on Alternate and Innovative Mechanisms to Conduct Medical Countermeasure Discovery and Development with the Federal Government. Register by **November 1, 2019**.
- **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.

Information for industry

- Draft guidance - Providing Regulatory Submissions in Electronic Format: IND Safety Reports - Describes the electronic format sponsors will be required to use when they electronically submit to FDA investigational new drug application (IND) safety reports for serious and unexpected suspected adverse reactions that are required under 21 CFR 21 CFR 312.32(c)(1)(i). Comment by **December 30, 2019**. *Also see: FDA Adverse Event Reporting System (FAERS) Electronic Submissions (October 29, 2019)*

In case you missed it

- Janet Woodcock, MD, Director of the FDA Center for Drug Evaluation and Research (CDER), testified before the House Committee on Energy and Commerce, Subcommittee on Health, on Safeguarding Pharmaceutical Supply Chains in a Global Economy. Dr. Woodcock's statement includes information about advanced manufacturing, including medical countermeasure manufacturing, and implications for national security. *More about Advanced Manufacturing at FDA (October 30, 2019)*

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)