Medical countermeasure monitoring and assessment update | Advancing new TBI treatments and blood pathogen reduction technologies

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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

March 27, 2019

MCM monitoring and assessment update

Monitoring and assessing medical countermeasures (MCMs) after they are dispensed or administered in response to a chemical, biological, radiological, or nuclear threat or an emerging infectious disease is vital to protecting public health, particularly in the case of MCMs that may have limited human efficacy data prior to use. FDA is a key partner—with other U.S. government agencies—in developing MCM monitoring and assessment capabilities, such as this new project.

New project: Examining the Ability to Conduct Influenza Antiviral Effectiveness Studies in Sentinel by Improving Confounding Control

This activity is the second project sponsored by the FDA Office of the Chief Scientist (OCS), Office of Counterterrorism and Emerging Threats (OCET) to explore how the Sentinel System may inform study protocols for medical countermeasure safety and effectiveness and to provide a valuable baseline for comparison during a public health emergency. The objective of this methods activity is to determine whether there is evidence of residual confounding in the association between influenza antiviral(s) and influenza complications in observational studies. *(March 21, 2019)*

Read more, on the Sentinel Initiative Website – OCET Activity 2 Project Page

Related information

- Descriptive Analyses in the Sentinel System for the FDA Office of Counterterrorism and Emerging Threats – first project sponsored by FDA/OCET using the Sentinel System *(July 18, 2018)*
- Monitoring and Assessment of Medical Countermeasures as Part of a Public Health Emergency Response – article in special supplement to the *American Journal of Public Health*, September 2018

- MCM Monitoring and Assessment – MCM Issues webpage with additional information and resources
- MCM-Related Legal and Policy Presentations, Publications and Q&As, including monitoring and assessment presentations

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Advancing development of new TBI treatments

On March 12, 2019, FDA qualified the OsiriX CDE Software Module, from the TBI Endpoints Development Initiative. This is the third qualification of a medical device development tool (MDDT) by the FDA, and the first of a biomarker test tool type.

A biomarker test is a lab test or instrument used to detect or measure an indicator of biologic processes or pharmacologic responses to a treatment (biomarker). This qualification provides a tool for more efficient development of devices in a critical area of medicine – traumatic brain injury (TBI) treatment.

Also see: Biomarkers for Brain Injury Monitoring, an MCMi intramural research project

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FDA efforts to promote and foster blood pathogen reduction technologies

Ensuring the safety of blood products is one of our highest priorities. This owes not only to the important role that they play in medical care, but also to their unique risks. Blood products can be susceptible to contamination by both existing and emerging pathogens. In cases where the pathogens aren't readily identified, there's a risk that many people receiving blood products could be exposed to an emerging pathogen even before the danger is identified.

For these and other reasons, there's a need for better safety measures to mitigate the potential risks to blood products. The good news is that the technology exists to potentially transform our assurance of safety of these blood products, while potentially reducing their cost.

The FDA Center for Biologics Evaluation and Research (CBER) is working with a variety of different partners to pursue multiple avenues of research to advance pathogen reduction technology. We believe perfecting these approaches is a critical priority.

Read the full statement from FDA Commissioner Scott Gottlieb, M.D., and Director of FDA's Center for Biologics Evaluation and Research Peter Marks, M.D., Ph.D.

Events

- **April 3-5, 2019:** Eleventh Annual Sentinel Initiative Public Workshop (Bethesda, MD) - Experts will share recent developments within the Sentinel Initiative, provide training on Sentinel System's tools and data infrastructure, and promote engagement and collaboration with patients, industry and

consumers. *Also see the Sentinel System Five-Year Strategy: 2019-2023 (PDF, 1.7 MB)*

- **April 8, 2019:** Public workshop: Development of Antibacterial Drugs for the Treatment of Nontuberculous Mycobacterial Infection (Silver Spring, MD and webcast) - to discuss the clinical trial design considerations, including endpoints, related to the development of antibacterial drug products for treatment of nontuberculous mycobacterial (NTM) disease. Register by **April 4, 2019**.
- **New! April 9-11, 2019:** 4th FDA/PQRI Conference on Advancing Product Quality (Rockville, MD) - Hosted by FDA and the Product Quality Research Institute (PQRI), the conference brings together regulatory, industry and academic leaders to discuss critical topics in drug product delivery design, development, and manufacture. Online registration closes **April 3, 2019**. *(fee)*
- **New! April 17, 2019:** Public Meeting on the Draft Guidance to Support Compliance with the Intentional Adulteration Rule (College Park, MD and webcast) - To discuss the draft guidance for compliance and implementation of the "Mitigation Strategies to Protect Food Against Intentional Adulteration" rule, which was issued under the FDA Food Safety Modernization Act. Register by **April 10, 2019**.
- **April 18, 2019:** NIIMBL Global Health Fund Workshop: Replacing Animal-based Release Testing for Vaccines (Washington, DC area) - Hosted by the National Institute for Innovation in Manufacturing Biopharmaceuticals, this workshop will explore the current state of animal-based release testing and discuss alternative approaches. Organizers encourage those with in-depth knowledge of *in vitro* vaccine potency and toxicity tests to consider attending.
- **New! May 1, 2019:** FY 2019 Generic Drug Regulatory Science Initiatives public workshop (Silver Spring, MD and webcast) - To provide an overview of the status of regulatory science initiatives for generic drugs and an opportunity for public input on these initiatives. To attend in-person or via webcast, register by April 1, 2019 by emailing complete contact information for each attendee (including the attendee's name, title, affiliation, address, email, and telephone number) to GDUFARegulatoryScience@fda.hhs.gov. Also submit any requests to make oral presentations as part of your registration email. Submit comments by **June 1, 2019**.
- **New! May 14, 2019:** Public workshop: BioCompute Objects: Tools for Communicating NGS Data and Analysis (Silver Spring, MD and webcast), co-sponsored by FDA, the George Washington University and the BioCompute Partnership to engage more stakeholders in creating and using BioCompute for NGS and other bioinformatics data analysis communications with the FDA. Specifically, the workshop will have two components: use case examples, and hands on & demonstrations of new tools that leverage BioCompute. A new Precision FDA-BioCompute Challenge will also be launched at the event. Space limited; please register in advance.

Information for industry

- Statement by FDA Commissioner Scott Gottlieb, M.D., on new strategies to modernize clinical trials to advance precision medicine, patient protections and more efficient product development - FDA is releasing guidance for industry on strategies that can support the development of precision medicines, and guidance on risk-based monitoring that can be accomplished through the incorporation of more computerized systems for effective oversight. These guidances, Enrichment Strategies for Clinical Trials to Support Determinations of Effectiveness of Human Drugs and Biological Products (PDF, 576 KB), and A Risk Based Approach to Monitoring of Clinical Investigations: Questions and Answers (PDF, 118 KB - submit comments by **May 14, 2019**), can help

facilitate efficient development of novel innovations, while also generating the robust evidence needed to better assess product safety and efficacy. *(March 14, 2019)*

- Draft guidance - Rare Diseases: Natural History Studies for Drug Development (PDF, 355 KB) - To help inform the design and implementation of natural history studies that can be used to support the development of safe and effective drugs and biological products for rare diseases. Comment by **May 24, 2019**. *(March 25, 2019) Also see: FDA In Brief: FDA takes new steps to advance natural history studies for accelerating novel treatments for rare diseases*
- Guidance - Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research (PDF, 133 KB) - Provides CBER recommendations on the use of standards in product development and control as well as the use of such standards in CBER's managed review process. The guidance announced in this notice finalizes the draft guidance of the same title dated December 2017. *(March 26, 2019)*
- **Reminder:** Broad Agency Announcement (BAA) white papers for FY 2019 funding consideration are due **March 29, 2019**. *Learn more and view current MCMi BAA projects*
- *More: MCM-Related Guidance by Date*

In case you missed it

- From HHS - BARDA is looking for research fellows to help advance innovations in clinical trial design for medical countermeasures for health security threats. Applications due **May 31, 2019**.
- From NIH - NIAID is seeking proposals to carry out research in one of three areas: radiation countermeasures, therapeutics for antibiotic-resistant (AR) bacteria, and vaccine candidates for AR bacteria. Submit proposals by **May 20, 2019**.
- From HHS - New on the ASPR Blog: Combating and Containing the Ebola Outbreak *(March 14, 2019)* and Preparing for a Potential Domestic Ebola Outbreak *(March 15, 2019)*
- 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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