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Medical Countermeasures Initiative Update

January 22, 2020

A large blue graphic with white and orange text. The text reads 'WHITE PAPERS DUE BY MARCH 2, 2020 5:00 P.M., ET'. The date and time are in larger, bold fonts. The graphic is decorated with several icons: a syringe, test tubes, a microscope, a pill, a flask, a bar chart, a document, a pie chart, and the FDA logo.

## Call for white papers

### FDA BAA: Advanced Research and Development of Regulatory Science

The FDA Medical Countermeasures Initiative (MCMi) [Regulatory Science Program](#) develops tools, standards, and approaches to assess medical countermeasure (MCM) safety, efficacy, quality, and performance.

In addition to funding FDA research, MCMi also funds external research partners to forward our goal of translating cutting-edge science and technology into innovative, safe, and effective MCMs.

Extramural MCM regulatory science is primarily funded through a Broad Agency Announcement (BAA), which has been updated for the current fiscal year, FY 2020. MCM-related areas of interest include:

- **Research Area 3: Support new approaches to improve product manufacturing and quality** (for example, proposals to support [advanced manufacturing](#) for pandemic preparedness and response, or

rapidly scale MCM manufacturing capabilities)

- **Research Area 7: Facilitate development and availability of MCMs to protect against threats to U.S. and global health and security**

In FY 2020, FDA is encouraging the submission of chemical defense-related topics under Area 7. Proposers are encouraged to submit white papers by **5:00 p.m. ET, March 2, 2020**, for consideration in FY 2020.

**Questions?** Contact us before you submit. Email [AskMCMi@fda.hhs.gov](mailto:AskMCMi@fda.hhs.gov) to ask questions about MCM-related research areas or request an informal discussion prior to white paper submission.

[View the BAA](#)

#### Related links:

- [MCM extramural research](#), including current and previous projects, and more about the BAA
- [Full BAA PDF](#) (669 KB)
- [What are MCMs?](#)
- [Previous BAA awards in other research areas](#)

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## Events

- **January 28-30, 2020:** [ASM Biothreats](#) (Arlington, VA) - Hosted by the American Society for Microbiology (*fee*)
- **January 28-29, 2020:** [HHS Tick-Borne Disease Working Group public meeting](#) (Washington, DC and webcast) - [Register](#) in advance.
- **February 3, 2020:** [Advancing EUA IVD Products Toward Full Marketing Status workshop](#) (Silver Spring, MD) - Hosted by FDA and the Medical Device Innovation Consortium (MDIC)
- **New! February 13-14, 2020:** [FDA and MHRA Good Clinical Practice Symposium: Data Integrity in Global Clinical Trials - Tackling Challenging Topics in 2020](#) (London, UK) - Day one will be available through a livestream. Register in advance.
- **February 25-26, 2020:** Public Workshop - [Evolving Role of Artificial Intelligence in Radiological Imaging](#) (Bethesda, MD and webcast) - Register by **4:00 p.m. ET February 12, 2020**.
- **February 25-26, 2020:** [Developing Medical Countermeasures To Treat the Acute and Chronic Effects of Ocular Chemical Toxicity](#) (Rockville, MD) - Register by **January 31, 2020**.
- **March 3, 2020:** Public workshop - [Facilitating End-to-End Development of Individualized Therapeutics](#) (Silver Spring, MD and webcast) - To attend in person, register by **February 18, 2020**.
- **New! March 5, 2020:** Public workshop - [Medical Extended Reality: Toward Best Evaluation Practices for Virtual and Augmented Reality in Medicine](#) (Silver Spring, MD and webcast) - Register by **February 28, 2020, 4:00 p.m. ET**.
- **March 18-19, 2020:** [Joint Civil & DoD CBRN Symposium](#) (Alexandria, VA) - Hosted by the Defense

Strategies Institute (*fee*)

- **March 31 - April 3, 2020: Preparedness Summit** (Dallas, TX) - Hosted by the National Association of County & City Health Officials (NACCHO) (*fee*)
- **April 20-24, 2020: Training Course: Achieving Data Quality and Integrity in Maximum Containment Laboratories** (Bethesda, MD) - Apply to attend by **February 28, 2020**.

*Note: To reduce the length of this newsletter, descriptions for events have been shortened. You can find more information about these and other events on the [MCMi News and Events](#) page.*

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## Information for industry

- **Expiration date extension update** - FDA is alerting civilian health care professionals and emergency responders of two additional DuoDote lots that are no longer useable and should be properly disposed of. Please refer to the table on this page for such updates: [FDA alerts health care providers and emergency responders of expiration date extension updates for certain auto-injectors manufactured by Meridian Medical Technologies](#). (*January 10, 2020*)
  - **Reminder:** comment by **February 12, 2020** on the draft guidance [Qualification Process for Drug Development Tools Guidance for Industry and FDA Staff](#).
  - [Device Advice](#) from the FDA Center for Devices and Radiological Health (CDRH) includes [How to Study and Market Your Device](#), and [How to Determine if Your Product is a Medical Device](#). Learn more with [CDRH Learn training modules](#).
  - **More funding alerts:**
    - The FDA [Office of Infectious Diseases](#) is accepting proposals focused on updating susceptibility test interpretive criteria (breakpoints). Specifically, research proposals focused on evaluating microbiologic and pharmacokinetic data that could be utilized by standards development organizations and the FDA to update breakpoints will be prioritized. Proposals should be submitted to the FDA Broad Agency Announcement, priority area 2.4.4. Quad charts and white papers are due by **February 28, 2020**. [Additional information about applying](#) (PDF, 99 KB)
    - From NASA - The [Translational Research Institute for Space Health](#) (TRISH) released a [new funding initiative](#) supporting research advances in the study of effects of space radiation on human physiology and seeking countermeasures to be used in deep space exploration. This new initiative seeks effective human-based complex *in vitro* and *ex vivo* models to study a variety of novel countermeasures against space relevant ionizing radiation exposure, which future deep space explorers must endure. Proposals are due **February 14, 2020**.
    - From NIAID - The [2020 NIAID Omnibus Broad Agency Announcement No. HHS-NIH-NIAID-BAA2020-1](#) contains five distinct research areas, including Research Area 001 - Development of Radiation/Nuclear Medical Countermeasures (MCMs). The objective of this Research Area is to advance the development of candidate MCMs to reduce mortality and/or major morbidities associated with exposure to radiation from a radiological or nuclear incident. Proposals are due by **3:00 p.m. ET, April 9, 2020**.
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## In case you missed it

- The FDA Center for Biologics Evaluation and Research (CBER) is recruiting to fill a [Physician, GP-0602-14 position](#) to serve in the Division of Epidemiology (DE), Office of Biostatistics and Epidemiology (OBE). The Division of Epidemiology in CBER/OBE studies and monitors the safety of a diverse portfolio of important and innovative biological products, including vaccines, blood products, gene therapies, human tissues, and cellular therapies. Applications will be accepted through **January 31, 2020**.
- [Mind the Gap: Bridging the 'Valley of Death' for U.S. Biomanufacturing](#), a blog post from the National Institute of Standards and Technology (NIST), includes information about FDA collaborations to help innovate U.S. biomanufacturing. (January 14, 2020) *More from FDA: [Advanced Manufacturing](#)*
- From HHS/ASPR - [The skyrocketing need for speed: partnering to develop rapid diagnostic tests that protect patients from antibiotic resistant infections during disasters and every day](#) (January 8, 2020)



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