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February 27, 2019



April 8-12, 2019
Achieving Data Quality and Integrity in
Maximum Containment Laboratories

April 8-10, 2019
Achieving Data Quality and Integrity in Clinical
Trials Involving High-Consequence Pathogens

**Register by
March 7, 2019**

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Two courses on data quality to support MCM development for high-consequence pathogens

April 8-12, 2019 (Bethesda, MD)

[Achieving Data Quality and Integrity in Maximum Containment Laboratories](#)

This popular [course](#) offers a unique opportunity for the regulatory and scientific communities to discuss complex issues in an interactive environment and identify and share best practices for ensuring **nonclinical** data quality and integrity in BSL-4 facilities. [Register](#)

April 8-10, 2019 (Bethesda, MD)

New course! [Achieving Data Quality and Integrity in Clinical Trials Involving High-Consequence Pathogens](#)

New [course](#) focusing on the preparation and execution of research **clinical trials** to facilitate the approval of medical countermeasures for high-consequence pathogens. [Register](#)

Both courses are hosted by FDA's Medical Countermeasures Initiative (MCMi) and the University of Texas

Medical Branch at Galveston (UTMB).

Related information:

- [MCMi Professional Development Activities](#)



Emergency diagnostics news

FDA, CDC, and CMS launch task force to help facilitate rapid availability of diagnostic tests during public health emergencies

On February 26, 2019, FDA, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) [announced the launch of the Tri-Agency Task Force for Emergency Diagnostics](#). This task force has been created to help leverage the expertise of each agency to advance rapid development and deployment of diagnostic tests in clinical and public health laboratories during public health emergencies. Also see: [Charter: Tri-Agency Task Force for Emergency Diagnostics](#) (PDF, 196 KB)

New web pages

[Information for Laboratories Implementing IVD Tests Under EUA](#)

This page is intended for laboratories that are implementing *in vitro* diagnostic (IVD) assays (tests) under an Emergency Use Authorization ([EUA](#)) and will help laboratories using tests available under EUA learn more about the benefits and limitations of EUA tests, and answer frequently asked questions, including how to report problems with a EUA test to FDA during an emergency.

[How to Submit a Pre-EUA for *In vitro* Diagnostics to FDA](#)

To help prepare for potential and current emergencies, FDA works with medical countermeasure developers to prepare Pre-EUA packages, when appropriate. A Pre-EUA package contains data and information about the safety, quality, and efficacy of the product, its intended use under a future or current EUA, and information about the emergency or potential emergency situation. This page is intended for manufacturers of IVD tests.

Funding deadline reminder

Submit BAA white papers for FY19 by March 29, 2019

Extramural MCM regulatory science is primarily funded through a [Broad Agency Announcement](#) (BAA) for research and development to support regulatory science and innovation, under area 7: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security. [View current MCMi BAA projects](#)

The current BAA announcement will remain open until further notice, but proposers are encouraged to submit white papers by **March 29, 2019** for current fiscal year (FY19) awards.

Events

- **March 5, 2019:** [CDISC SENDIG-AR public webinar](#), 11:00 a.m. – 12:30 p.m. ET - Free webinar providing an overview of the draft Standard for Exchange Nonclinical Data (SEND) Implementation Guide for Animal Rule studies (SENDIG-AR), hosted by the Clinical Data Interchange Standards Consortium (CDISC). Register by **March 5, 2019**. See [Electronic data standards for Animal Rule studies for more information](#)
- **March 6-7, 2019:** [Vaccines and Related Biological Products Advisory Committee \(VRBPAC\) meeting](#) (Silver Spring, MD and [webcast](#)) - Topics include discussion and recommendations on the selection of strains to be included in the influenza virus vaccines for the 2019 to 2020 influenza season.
- **March 14, 2019:** Webinar - [The Least Burdensome Provisions: Concept and Principles Final Guidance](#), 1:00 - 2:30 p.m. ET. This final guidance describes the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to the regulation of medical devices.
- **New! March 18, 2019:** [Enhancing the Incorporation of Patient Perspectives in Clinical Trials public workshop](#) (Silver Spring, MD and webcast) - The workshop, convened by the Clinical Trials Transformation Initiative (CTTI), will discuss stakeholders' perspectives on challenges and barriers to patients participating in clinical trials and best practices and key considerations for enhancing the incorporation of patient perspectives on clinical trial access, design, conduct, and post-trial follow-up. [Register](#) by **March 11, 2019**.
- **New! March 19, 2019:** [Webinar - Implementation of Final Rule on Human Subject Protection: Acceptance of Data from Clinical Investigations for Medical Devices](#), 3:00 - 4:30 p.m. ET
- **New! March 20-21, 2019:** [Blood Products Advisory Committee meeting](#) (Silver Spring, MD and [webcast](#)) - Matters considered at the meeting will include testing of the blood supply for Zika virus.
- **March 26-29, 2019:** [Preparedness Summit](#) (St. Louis, MO) - Hosted by NACCHO; FDA is a sponsor. This year's theme is "Preparedness Summit 2019: The Evolving Threat Environment." (*fee*)

Information for industry

- **February 26, 2019:** [Draft guidance - Quality Considerations for Continuous Manufacturing](#) (PDF, 197 KB), to clarify the FDA's current thinking regarding innovative CM approaches and can help resolve potential issues some companies have as they consider implementation. [Comment](#) by **May 28, 2019**. Also see: [Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on FDA's modern approach to advanced pharmaceutical manufacturing](#) (February 26, 2019)
- FDA is reminding stakeholders that February 21, 2019 is the effective date for compliance with the

[final rule on Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices](#) (Federal Register notice, February 21, 2018). The rule updates the standards for accepting clinical data from clinical investigations conducted inside and outside the United States to protect human participants, and to help ensure the quality and integrity of data obtained through such investigations. On **March 19, 2019**, FDA will host a [webinar for stakeholders](#) who want to learn more about the implementation of this final rule. Also see: [Acceptance of Data from Clinical Investigations for Medical Devices](#)

- FDA is reopening the comment period for the proposed rule entitled “Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations” that appeared in the [Federal Register of November 15, 2018](#). FDA is taking this action due to technical difficulties at the Federal eRulemaking portal. Comments on the proposed rule may be submitted at <https://www.regulations.gov> (Docket No. FDA-2018-N-2727) and are now due by **March 7, 2019**.

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

In case you missed it

- FDA’s Center for Biologics Evaluation and Research (CBER) is looking for a [post-doctoral research fellow](#) to develop vaccines against Ebola, influenza & respiratory syncytial virus (RSV). (February 14, 2019)
- From HHS - [New HHS-Sponsored Research Provides New Tool and Updated Guidance on Mass Chemical Decontamination](#) - More than a million first responders and emergency managers in the United States now have a science-based chemical decontamination decision tool and updated guidance on how best to decontaminate a massive number of people after chemical exposure. (February 21, 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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