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Medical Countermeasures Initiative Update

February 5, 2020



## Novel coronavirus (2019-nCoV)

FDA is working with U.S. Government partners, including the U.S. Centers for Disease Control and Prevention (CDC), and international partners to closely monitor an outbreak caused by a novel (new) coronavirus first identified in Wuhan City, Hubei Province, China.

On January 27, 2020, FDA [announced critical actions](#) to advance development of novel coronavirus medical countermeasures.

As with any emerging public health threat, FDA is collaborating with interagency partners, product developers, international partners, and global regulators to expedite the development and availability of medical products needed to diagnose, treat, mitigate and prevent such outbreaks.

[Learn more: 2019-nCoV updates from FDA](#)

### Related links:

- [Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](#), from the FDA Center for Biologics Evaluation and Research (CBER) (*February 4, 2020*)
  - For more updates from FDA, follow [@SteveFDA](#), [@US\\_FDA](#), [@FDA\\_Global](#), and [@FDA\\_MCMi](#) on Twitter
  - [2019 Novel Coronavirus](#) (CDC)
  - [Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus](#) (HHS) (*January 31, 2020*)
  - *Also see [EUA updates and Information for industry below](#)*
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## Emergency Use Authorization (EUA) updates

- **February 4, 2020:** FDA [authorized emergency use](#) of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, a real-time RT-PCR test for the presumptive qualitative detection of nucleic acid from the 2019-nCoV in upper and lower respiratory specimens collected from individuals who meet [CDC criteria for 2019-nCoV testing](#). Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), to perform high-complexity tests. To date, this test has been limited to use at CDC laboratories; this authorization allows the use of the test at any CDC-qualified lab across the country. [Additional technical information and fact sheets](#) - Also see, from CDC: [Information for Laboratories](#)



**Diagnostic test developers interested in potential EUA for tests to detect 2019-nCoV should contact [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov) for further information and templates.**

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## Events

- **New! February 13, 2020:** [FDA Grand Rounds: Detection of Transmissible Spongiform Encephalopathy Agents in Biological Products Using Protein Aggregation Assays](#) webcast, 12:00 - 1:00 p.m. ET - register in advance
- **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**.
- **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**.

- **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**.
- **New! March 5, 2020:** [Advancing Animal Models for Antibacterial Drug Development](#) (Silver Spring, MD and webcast) - Hosted by FDA, the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA) to discuss progress and challenges in the development and advancement of various animal models for serious infection. [Register](#) by **11:59 p.m. ET, March 2, 2020**.
- **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**.

You can find more information about these and other events on the [MCMi News and Events](#) page.

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## Information for industry

- BARDA, a component of the HHS Assistant Secretary of Preparedness and Response (ASPR), is supporting U.S. government market research to identify medical countermeasures with the potential to help address the 2019-nCoV outbreak. **If your company is developing 2019-nCoV diagnostics, therapeutics, vaccines, or other products, submit your ideas to BARDA's online portal.**
  - FDA is [requesting](#) that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Blood Products Advisory Committee (BPAC) for CBER notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the BPAC. Submit materials by **February 24, 2020**.
  - FDA invites medical device companies, health care facilities, and academia to submit proposals as part of the [CDRH Experiential Learning Program](#) (ELP) for regulatory review staff. Submit proposals by **12:00 p.m. ET, February 24, 2020**.
  - **Funding reminder:** Proposers are encouraged to submit white papers to the FDA [Broad Agency Announcement](#) (BAA) by **5:00 p.m. ET, March 2, 2020**, for FY 2020 awards. [MCM-related areas](#) include research and development to support regulatory science and innovation, under 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), and Research Area 7: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security. In fiscal year (FY) 2020, FDA is encouraging the submission of chemical defense-related topics under Area 7.
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## In case you missed it

- FDA approved [AUDENZ](#), (Influenza A (H5N1) Monovalent Vaccine, Adjuvanted) for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. AUDENZ is approved for use in persons 6 months of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine. This vaccine will be produced and distributed under contract to the U.S. Government as part of national pandemic preparedness initiatives. (January 31, 2020) Also see, from HHS/ASPR: [New Pandemic Influenza Vaccine Uses Next Generation Technology to Strengthen Health Security](#)
- [FDA In Brief: FDA Updates Prioritization Policy for Original Abbreviated New Drug Applications, Amendments and Supplements to Maximize Impact on Public Health](#) (January 30, 2020)
- From HHS/ASPR - The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) [Multiyear Budget Report for fiscal years \(FY\) 2018–2022](#) has been posted. This report includes the multiyear budgets for the following Department of Health and Human Services (HHS) entities involved in MCM development and stockpiling: the National Institutes of Health (NIH), ASPR's Biomedical Advanced Research and Development Authority (BARDA) and Strategic National Stockpile (SNS), and FDA. (January 29, 2020)



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