

If your email program has trouble displaying this email, [view it as a web page](#).



Medical Countermeasures Initiative Update



July 17, 2019

How FDA uses science to speed medical device innovation

The MDDT program streamlines the medical device development and review process

The [Medical Device Development Tools \(MDDT\)](#) program streamlines the medical device development and review process by advancing the development and use of scientifically validated and qualified methods, materials, and measurements for assessing how devices work. FDA has developed and qualified the first nonclinical assessment model tool as part of the MDDT program.

[Read more in FDA Voices](#)

Image: Scientists in FDA's Center for Devices and Radiological Health (CDRH) Office of Science and Engineering Labs (OSEL) demonstrate a novel material that they have developed for assessing the safety of High Intensity Therapeutic Ultrasound (HITU) devices.

Events

- **July 17, 2019:** [Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations public workshop](#) (Washington, DC and webcast) - To capture stakeholder experiences with risk-based approaches to monitoring of clinical investigations and gather stakeholder input on opportunities to further the implementation of risk-based approaches to monitoring. *Also see draft guidance [A Risk-Based Approach to Monitoring of Clinical Investigations: Questions and Answers](#), issued in March 2019.*
- **New! July 23, 2019:** The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) will host a [Project Call 3.1 Concept Phase Webinar](#) at 2:30 p.m. ET. [Project Call 3.1](#) seeks proposals addressing technology, workforce development, and global health priority areas identified by NIIMBL members. Register in advance.
- **New! August 13, 2019:** [Webinar - FDA Innovation Challenges: Identify Sterilization Alternatives and Reduce Ethylene Oxide Emissions](#), 3:00 - 4:30 p.m. ET - FDA will host a webinar on two FDA Innovation Challenges to spur the development of new approaches to device sterilization. FDA's Center for Devices and Radiological Health will accept applications for this challenge through October 15, 2019. *Also see: [Preventing Medical Device Shortages by Ensuring Safe and Effective Sterilization in Manufacturing](#)*
- **September 11-12, 2019:** [2019 FDA Science Forum](#) (Silver Spring, MD) - [Agenda](#) and registration now available. Topic areas include: Outbreak! FDA's approach to prevention and response, including prevention through cybersecurity and promoting medical product and food security, and rapid response to infectious disease and foodborne pathogen outbreaks, e.g. the use of the Animal Rule, emergency communication devices, rapid diagnostic tests, antimicrobial resistance.

Information for industry

- FDA has [published a series of presentations](#) to educate and inform stakeholders on Complex Innovative Trial Designs (CID) and the CID Pilot Meeting Program and application process. The CID Pilot program is designed to advance the use of complex adaptive, Bayesian, and other novel clinical trial designs. The program offers sponsors an opportunity for increased interaction with the FDA to discuss their proposed CID. (*June 26, 2019*)
- [FDA In Brief: FDA seeks public feedback on new drug approval transparency efforts](#) - FDA issued a [Federal Register notice](#) to open a docket for public comment as part of the agency's continuous assessment of the efficiency and transparency of the clinical data used in the regulatory decision-making process for drug and biological products assessed by the FDA's Center for Drug Evaluation and Research (CDER). The notice specifically asks for feedback on the [Clinical Data Summary Report \(CSR\) Pilot Program](#) and the new integrated review of marketing applications process and documentation template. Comment by **August 26, 2019**. (*June 26, 2019*)
- FDA [issued a proposed rule](#) to amend its regulations concerning the use of master files for biological products. Comment by **August 27, 2019**. *Also see: ["Deemed to be a License" Provision of the BPCI Act](#) and [FDA In Brief: FDA takes new step to help advance the transition of certain biological products](#) (*June 28, 2019*)*
- FDA announced the availability of a draft guidance for industry, [M10 Bioanalytical Method Validation](#), that was developed by the International Council for Harmonisation. The draft guidance describes the

various elements and expectations to validate specific tests used to measure the parent and active metabolites of drugs administered in nonclinical and clinical studies submitted in regulatory applications for biological matrices such as plasma, blood, or serum. Comment by **August 26, 2019**.
(June 28, 2019)

- The CDRH 2020 [Experiential Learning Program](#) site visit proposal solicitation period is open until **12:00 p.m. August 8, 2019**. CDRH is inviting medical device companies, academia, and health care facilities to participate in this formal training program. (July 8, 2019)
- [Risk Evaluation and Mitigation Strategies: Modifications and Revisions Guidance for Industry](#) - This guidance provides information on how the FDA defines the types of changes to approved risk evaluation and mitigation strategies (REMS), how application holders should submit changes to an approved REMS, and how the FDA will process submissions from application holders for changes to REMS. (July 9, 2019)

In case you missed it

- Consumer update: [Plan, Prepare and Protect Your Pet Before, During and After an Emergency](#)
- FDA Voices: [Ensuring Patient Safety and Drug Manufacturing Quality Through Partnership with European Union Regulators](#) - The Mutual Recognition Agreement (MRA) with the European Union (EU), allows FDA to more effectively deploy our inspectional resources across the globe. After five years of close FDA-EU cooperation, FDA has completed capability assessments of 28 EU member states. (July 11, 2019)
- From HHS - [ASPR Next Innovation Day](#) - ASPR Next is a new program to spur innovation in the development of new technologies and products that can be used to provide lifesaving care in austere circumstances. To kick off this initiative, ASPR is bringing together partners to discuss ways to develop cutting-edge technologies to save lives when disaster strikes. ASPR is looking for partners to us address issues in nine areas of interest to disaster response stakeholders, including medical countermeasure dispensing. ASPR Next Innovation Day will be held on **August 7-8, 2019** in Washington, DC and online. Register by **July 26, 2019**.
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.



Did someone forward you this email? [Subscribe](#)
(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)



Twitter: @FDA_MCMi
www.fda.gov/medicalcountermeasures

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
[Privacy Policy](#) | www.fda.gov