



October 23, 2019



FDA scientific meeting recordings available

FDA Science Forum

Held September 11-12, 2019

Transforming Health: Innovation in FDA Science

Don't miss the **Outbreak! session recording** (2 hours, 7 minutes), featuring 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, including use of the Animal Rule, emergency communication devices, and rapid diagnostic tests.

[All 2019 FDA Science Forum recordings](#)

7th Annual FDA Scientific Computing Days

Held September 9-10, 2019

Scientific Computing and Health Data Flows: The Heart and Lifeblood of Public Health Innovation

Presentations include information about FDA activities in scientific computing to help promote the use of

scientific computing for regulatory decision making. Don't miss the recordings on [digital biomarkers for real world evidence](#) (1 hour, 3 minutes), and [genomics data sharing](#) (1 hour, 31 minutes).

All 2019 FDA Scientific Computing Days recordings

Related links:

- [MCMi News and Events](#)
- [More FDA meetings, conferences, and workshops](#)

Did you know?



FDA has a **Cybercrime Investigations Unit**. This unit, within FDA's [Office of Criminal Investigations](#), in the Office of Regulatory Affairs, investigates the surface Internet as well as dark web marketplaces, where operators attempt to hide online illegal activity.

Read more in [FDA Voices](#)

Events

- **November 8, 2019:** [Vaccines and Related Biological Products Advisory Committee public meeting](#) (Silver Spring, MD and webcast) - The committee will discuss and make recommendations on the development of chikungunya vaccines.
- **November 12-14, 2019:** [Regulatory Education for Industry \(REI\): Clinical Investigator Training Course](#) (College Park, MD) This course provides an intermediate-level study of clinical trial principles with in-depth coverage of clinical trial design, issues in safety and efficacy, investigator

responsibilities, understanding the investigator brochure, and FDA requirements across Centers. Upon completion, attendees should understand pre-clinical research, clinical trials, and FDA submissions for licensure of medical products.

- **November 18, 2019:** [Development of Best Practices in Physiologically Based Pharmacokinetic Modeling To Support Clinical Pharmacology Regulatory Decision-Making Public Workshop](#) (Silver Spring, MD and webcast) - To discuss best practices and evidentiary criteria in the use of physiologically based pharmacokinetic (PBPK) modeling approaches to support regulatory decision-making; share experiences and cases where applying PBPK modeling and simulation highlight the opportunities and limitations of this approach; obtain input from stakeholders on when, where, how, and with what limitations PBPK modeling and simulation may be applied in regulatory decision-making; and discuss the knowledge gaps and research needed to advance PBPK modeling sciences in drug development to support regulatory decisions. [Register](#) by **November 8, 2019**.
- **November 18-19, 2019:** [Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development](#) (Silver Spring, MD and webcast) - Co-sponsored by FDA, the Infectious Diseases Society of America (IDSA), the National Institute of Allergy and Infectious Diseases (NIAID), and Pew, this workshop will bring together a diverse array of subject matter experts in the fields of infectious diseases (ID), academics and industry and other government bodies to better understand the current state of U.S.-based ID trials and how to enhance enrollment and research in such trials. Register by **November 14, 2019**.
- **November 18-21, 2019:** [Chemical and Biological Defense Science & Technology \(CBD S&T\) Conference](#) (Cincinnati, OH) - Hosted by the Defense Threat Reduction Agency (DTRA). FDA will be presenting as part of a panel on Alternate and Innovative Mechanisms to Conduct Medical Countermeasure Discovery and Development with the Federal Government. [Register](#) by **November 1, 2019**.
- **November 22, 2019:** [Blood Products Advisory Committee meeting](#) (Silver Spring, MD and webcast) - The committee will meet in open session to discuss scientific considerations for cold stored platelet products intended for transfusion, including product characterization, duration of storage and clinical indications for use. The committee will hear presentations on available characterization and functional studies of cold stored platelets, clinical studies, and the potential role of cold stored platelets in clinical care in military and civilian patient populations. The committee will also discuss the clinical studies needed to support the indications for use of cold stored platelet products stored beyond 3 days.

Information for industry

- FDA's Center for Drug Evaluation and Research (CDER) [invites pharmaceutical companies](#) interested in participating in the Fiscal Year 2020 CDER Office of Pharmaceutical Quality (OPQ) Staff Experiential Learning Site Visit Program to submit a site visit proposal. OPQ encourages companies engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to respond. Submit proposals by **November 18, 2019**.
- [Guidance - Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review](#) - This technical specifications document provides the sponsor/applicant detailed information and specifications for the content of datasets submitted to FDA's Center for Biologics Evaluation and Research (CBER) Office of Vaccines Research and Review (OVRR) and is designed to aid clinical and statistical reviewers in the review of vaccine applications, e.g., biologics license applications. FDA recommends submission of these datasets as part of the applicant's data tabulation datasets.

More News & Events

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