



Center for Drug Evaluation and Research
**WHAT'S NEW IN
REGULATORY SCIENCE**

Summer 2019

Brought to you by the [Office of Translational Sciences \(OTS\)](#) in collaboration with the [Office of Communications \(OCOMM\)](#) in the [Center for Drug Evaluation and Research \(CDER\)](#).

What's New in Regulatory Science is a quarterly newsletter from the Food and Drug Administration's Center for Drug Evaluation and Research. It includes new developments, opportunities, and initiatives in regulatory science, with the goal of advancing medical product development.

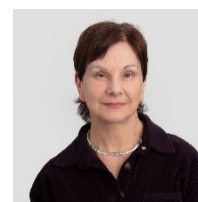
Please share this message and the [sign-up link](#) with colleagues, and if you have comments or questions, contact us at OTSCommunications@fda.hhs.gov.



HIGHLIGHT

SHEDDING NEW LIGHT ON SUNSCREEN ABSORPTION

In a [recent installment](#) of the series [FDA Voices](#), CDER Director Dr. Janet Woodcock, and Dr. Teresa Michele, Director of CDER's Division of Nonprescription Drug Products in the Office of New Drugs, comment on the results of an exploratory maximal usage trial (MUSt) evaluating the systemic absorption (through the skin and into the body) of sunscreen active ingredients using four commercially available sunscreen products applied under maximal use conditions. Results from the trial, which was led by researchers at the Division of Applied Regulatory Science in the Office of Translational Sciences' Office of Clinical Pharmacology, are available in a [preliminary communication](#) in the May 6, issue of the *Journal of the American Medical Association*. Drs. Woodcock and Michele also discuss a [proposed rule](#) to update regulatory requirements for sunscreen products according to the latest scientific standards.



Dr Janet Woodcock



Dr. Teresa Michele

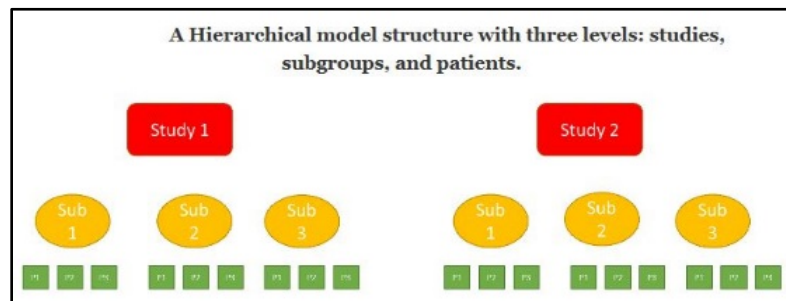
RECENT CDER IMPACT STORIES



CDER is continuing to highlight its regulatory science research in a series of [regulatory science impact stories](#). The most recent post focused on obtaining better estimates for patient subgroups in clinical trials:

Using innovative statistical approaches to provide the most reliable treatment outcomes information to patients and clinicians

CDER statisticians are improving our understanding of how drugs affect different patients by using Bayesian hierarchical models to analyze clinical trial results for patient subgroups. The estimates obtained in these analyses will be included in the [Drug Trials Snapshots](#), which help to convey information obtained in clinical trials supporting drug development to the public. Click [here](#) to read the story.



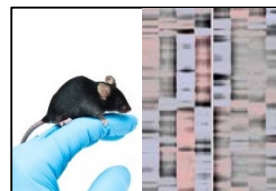
RECENT SPOTLIGHT ON CDER SCIENCE



CDER continues with its [Spotlight on CDER Science](#) series featuring the Center's noteworthy scientific and research-oriented activities. The latest spotlight articles include:

A Novel Mouse Model Offers Insights About Hypersensitivity to an HIV Drug

A novel mouse model carrying a human gene variant is now able to show us how certain cells of the immune system play key roles in helping some patients tolerate the HIV drug abacavir while other patients experience hypersensitivity to it.



For more information, [click here](#).



IN PRESS

[Generating Model Integrated Evidence for Generic Drug Development and Assessment](#)

Liang Zhao, Myong-Jin Kim, Lei Zhang, and Robert Lionberger

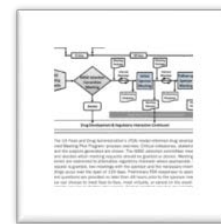
Quantitative methods and modeling (QMM) covers a spectrum of tools and many of them—particularly physiologically based models and quantitative clinical pharmacology—are critical to generic drug development. In this paper, the authors delve more deeply into the use of QMM in the modernization of generic drug development, bioequivalence assessment and regulatory decision making.



[The US Food and Drug Administration's Model-informed Drug Development Paired Meeting Pilot Program: Early Experience and Impact](#)

Rajanikanth Madabushi, Jessica M. Benjamin, Renmeet Grewal, Michael A. Pacanowski, David G. Strauss, Yaning Wang, Hao Zhu, Issam Zineh

In this commentary, the authors describe the motivation for FDA's Model-informed Drug Development Paired Meeting Pilot Program, review its progress in its first year, and discuss lessons learned.



[Purification and Analytics of a Monoclonal Antibody from Chinese Hamster Ovary Cells Using an Automated Microbioreactor System](#)

Sai Rashmika Velugula-Yellela, David N. Powers, Phillip Angart, Anneliese Faustino, Talia Faison, Casey Kohnhorst, Erica J. Fratz-Berilla, Cyrus D. Agarabi

A detailed protocol for the purification monoclonal antibody therapeutics from cell culture fluid from microbioreactors and useful analytics to determine critical quality attributes are described.



[Commentary on "Statistics at FDA: reflections on the past six years"](#)

Aloka G. Chakravarty

The Acting Director of CDER's Office of Biostatistics provides an update on recently initiated efforts under the 21st Century Cures Act to advance complex innovative trial designs, including adaptive clinical trial designs; the use of real-world evidence in regulatory submissions; and some key milestones in guidance development.





RESOURCES

Regulatory Science Research and Education

The public can access CDER's Regulatory science and educational activities at [FDA.gov](https://www.fda.gov). These activities are aimed at speeding the development of new drugs while ensuring that they are safe and effective.



Science & Research (Drugs)

Science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.



CDERLearn Training and Education

Learning opportunities for healthcare professionals, industry, consumers, and academia.

For more information, [click here](#).



UPCOMING EVENTS

The following are meetings, conferences, and workshops sponsored or co-sponsored by the Center for Drug Evaluation and Research (CDER):

July 2019

- Public Workshop: Leveraging Randomized Clinical Trials to Generate Real-World Evidence for Regulatory Purposes, July 11 - 12, 2019. The Westin City Center, 1400 M St NW, Washington, DC 20005. [Meeting Information](#)
- FDA-ASCO Public Workshop: 2019 Clinical Outcome Assessments in Cancer Clinical Trials, July 12, 2019, FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. [Meeting Information](#)
- FDA Public Meeting: Limited Population Pathway for Antibacterial and Antifungal Drugs, July 12, 2019, FDA White Oak Campus, 10993 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. [Meeting Information](#)
- FDA Public Meeting: Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) using International Council for Harmonisation (ICH) E2B(R3) Standards,

July 17, 2019, FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. [Meeting Information](#)

August 2019

- Public Workshop: Development of Antiviral Drugs for the Treatment of Adenoviral Infection in Immunocompromised Patients, August 8, 2019, FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. [Meeting Information](#)
- Public Workshop: Precision Dosing: Defining the Need and Approaches to Deliver Individualized Drug Dosing in the Real-World Setting Meeting Information, August 12, 2019, FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. [Meeting Information](#)

September 2019

- Regulatory Education for Industry (RedI): 2019 Complex Generic Drug Product Development Workshop – September 25-26, 2019, The Hotel, 7777 Baltimore Ave, College Park, Maryland 20740. [Meeting Information](#)



CAREER OPPORTUNITIES



FDA has a new campaign to advance ongoing efforts to recruit and retain a world-class workforce dedicated to protecting and promoting the public health. Information on job vacancies, employment events, and hiring programs are available by following [@FDAJobs](#) on Twitter and by visiting the [FDA's LinkedIn page](#), the [Jobs at CDER webpage](#) and [Career Opportunities at CDER webpage](#) (videos). Help us spread the news through your social media networks!

For more information, please visit the [FDA In Brief webpage](#).

Scientific Internships and Fellowships / Trainees and Non-U.S. Citizens

Whether you're an undergraduate looking to pursue a career in science, a graduate science student seeking experience in regulatory science, a postgraduate looking for fellowship opportunities, or a senior scientist pursuing research experience in your field of expertise, FDA offers you many paths to learning about the exciting field of regulatory science. Click [here](#) for more information.