Winter 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

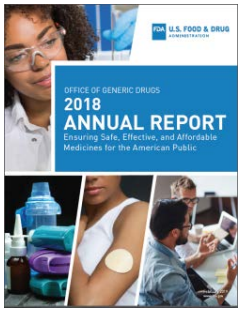
STATE OF CDER 2019

Janet Woodcock, MD, CDER's Center Director, delivered the State of CDER 2019 podcast, reflecting the accomplishments of the past year and priorities for 2019, including:

- New Drug/Biologic Regulatory Program Modernization
- Drug Shortages
- Compounding
- OTC Monograph User Fee Program
- Opioid Crisis

Download Podcast https://www.fda.gov/downloads/Drugs/NewsEvents/UCM630836.mp3
View Transcript: https://www.fda.gov/Drugs/NewsEvents/ucm630838.htm

2018 ANNUAL REPORT FROM CDER'S OFFICE OF GENERIC DRUGS



Office of Generic Drugs Annual Report, click here

RECENT CDER IMPACT STORIES

CDER is continuing to highlight its regulatory science research in a series of regulatory science impact stories. Four recent posts include:

Determining the Clinical Benefit of Treatment Beyond Progression with Immune Checkpoint Inhibitors

Anti-cancer drugs called checkpoint inhibitors have led to dramatic responses in several advanced cancers, including metastatic melanoma, lung cancer, kidney cancer, bladder cancer, and head and neck cancers. CDER researchers are evaluating whether it is clinically beneficial to treat cancer patients with checkpoint inhibitors if their tumors do not immediately shrink in response to these drugs. (Click here to read full story.)

Supporting Drug Development Through Physiologically Based Pharmacokinetic Modeling

CDER clinical pharmacologists are helping the drug development community use computational models to achieve safe and effective dosing recommendations for patients who are taking more than one drug. (Click here to read full story.)

Transitioning a Powerful Analytical Tool to Manufacturing to Improve the Quality of Complex Therapeutics

Mass spectrometry is a technology that can give manufacturers and regulators more detailed information about the critical quality attributes of complex products. CDER's evaluation of this approach is intended to help manufacturers apply this tool toward improved quality control of protein products, including therapeutics for cancer. (Click here to read full story.)

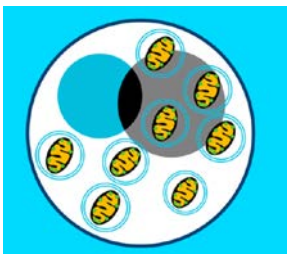
Evaluating the Potential of Microengineered Human Cellular Systems to Predict Drug Effects in the Clinic

CDER researchers are developing microengineered systems that will allow replication of human physiology, better prediction of drug effects, and, potentially, a reduction in clinical trial failures. These research platforms will be also useful in situations where clinical trials are limited or unfeasible, such as in efforts to develop medical countermeasures to public health emergencies and to evaluate therapies for rare diseases. (Click here to read full 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:

New Drug Class Employs Novel Mechanism for Migraine Treatment and Prevention (click here)



CDER Scientists Investigate Critical Cellular Functions That Can Be Targeted to Kill Cancer Cells (click here)

RECENT CDER CONVERSATIONS

CDERConversations

Paula Rausch, Ph.D., RN, who is the Associate Director for Research and Risk Communications in CDER's Office of Communications, describes how we use online and social media data to inform our pharmacovigilance efforts, and what it can and cannot tell us. To read more about this *CDER Conversation*, click here.

Dionne Price, Ph.D., who is the Director of the Division of Biometrics IV in CDER's Office of Biostatistics, describes the latest developments in the rapidly advancing area of complex innovative trial designs– including the use of adaptive, Bayesian, and other novel statistical approaches and how these may help streamline and advance drug development and inform regulatory decision-making. To access this *CDER Conversation*, click here.

To see more *CDER Conversations*, click here.

RESOURCES

Biomarkers

- Recent FDA co-authored publication related to biomarkers, entitled: *Translational Safety Biomarkers of Kidney Injury.*" To read full article, click here.
    - **To search for other scientific publications by FDA staff, click here.**

- FDA has issued a draft guidance to facilitate the efficient qualification of novel biomarkers that can help advance drug development. This draft guidance describes an evidentiary framework to support qualification of a biomarker that consists of several components: describing the drug development need, defining the context of use for the biomarker, considering potential benefits if the biomarker is qualified for use, and considering potential risks associated with the proposed use of the biomarker in a drug development program. For more information, click here.

- The Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium and Critical Path Institute have achieved the first ever qualification of a clinical safety biomarker by the U.S. Food and Drug Administration to help with the d*etection of drug-Induced acute kidney injury in clinical trials.* For more information, click here.

UPCOMING EVENTS

March 2019

- FDA-NBTS Public Workshop: Product Development for Central Nervous System (CNS) Metastases, March 22, 2019, Building 31 Conference Center, Great Room. Meeting Information

April 2019

- Regulatory Education for Industry (REdI): Generic Drug Forum April 3-4, 2019 Meeting Information
- Development of Antibacterial Drugs for the Treatment of Nontuberculous Mycobacterial Infection, April 8, 2019. FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room, Silver Spring, MD 20993.
- Health Canada and United States Food and Drug Administration Joint Public Consultation on International Council for Harmonization of Technical Requirements for Human Use (ICH). April 29, 2019. FDA's White Oak Campus, 10903 New Hampshire Ave. Bldg 31 Conference Center, Great Room, Silver Spring, MD 20993. Meeting Information

May 2019

- FY 2019 Generic Drug Regulatory Science Initiatives Public Workshop, Wednesday, May 1, 2019, FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Great Room, Silver Spring, MD 20993. Meeting Information
- DILI Conference, Marriott Inn & Conference Center, University of Maryland University College, 3501 University Blvd. East Hyattsville, MD 20783. May 7-8, 2019. Meeting Information
- Public Meeting: Drugs Compounded for Office Stock by Outsourcing Facilities. May 21, 2019. FDA White Oak Campus, 10993 New Hampshire Avenue, Building 31 Conference Center, Great Room, Silver Spring, MD 20993-0002. 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 and the Jobs at FDA webpage. Help us spread the news through your social media networks!

For more information, please visit FDA In Brief webpage.

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