Fall 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 features 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

CDER's Participation at 2019 FDA Science Forum

The 2019 FDA Science Forum, held on September 11-12, 2019, offered the public insights on the unique scientific research and collaborative efforts of FDA's 11,000 scientists. CDER scientists participated in the following topic areas:

- Precision Health
- Advanced Technology
- Product Accessibility, Integrity, & Security
- Predictive Tools
- Advancing Digital Health & Artificial Intelligence
- Outbreak
- Addiction
- Empowering Consumers, Patients, & Other Stakeholders

For the event brochure with informative poster session details click here.

FDA scientific Computing Day

On September 9-10, 2019, FDA hosted the7th Annual Scientific Computing Days symposium. The goals of this symposium were to 1) raise awareness about activities within FDA's centers in scientific computing, 2) help foster collaboration and improve networking, 3) promote the use of scientific computing for regulatory decision making, and 4) learn from one another about different approaches to scientific computing. Participants, including internal and external scientists, key industry contributors, and observers, gathered to help the FDA improve the application of technology, and scientific computing in support of our public health mission. The theme of this year's event was ***Scientific Computing and Health Data Flows: The Heart and Lifeblood of Public Health Innovation***, reflecting the need for improved flow of information within the Agency and to its external stakeholders.

To see the information on this event, including featured speakers click here. For information on the digital poster session click here.

OPQ's Emerging Technology Program

To address concerns about FDA's familiarity with industry's use of newer technology, CDER's Office of Pharmaceutical Quality (OPQ) created the Emerging Technology Program to promote the adoption of innovative approaches to pharmaceutical product design and manufacturing. Through the program, industry representatives can meet with Emerging Technology Team members to discuss, identify, and resolve potential technical and regulatory issues regarding the development and implementation of a novel technology prior to filing a regulatory submission.

For more information about this program, including contact information, click here.

CDER's Critical Path Innovation Meeting Program


CDER Critical Path Innovation Meeting Program

The Critical Path Innovation Meeting (CPIM) Program provides an opportunity for outside stakeholders to communicate directly with FDA subject matter experts to discuss potential scientific advancements in drug development. Within the CPIM setting, representatives from FDA and industry, academia, patient groups, scientific consortia and other organizations can have an open scientific discussion and exchange of ideas with a common goal of improving efficiency and success in drug development. CPIM discussions are non-binding on FDA and the requestor, and do not provide advice on a specific approval pathway, FDA policy, or guidance.

For more information, about this program please contact the CPIM Inquiries Mailbox or visit our website.

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 FDA Study Shines Light on Sunscreen Absorption.

In a study recently published in the *Journal of the American Medical Association* (JAMA), CDER scientists conducted a pilot study and learned that four active ingredients commonly found in sunscreen (avobenzone, oxybenzone, octocrylene, and ecamsule) were absorbed through the skin into the body.

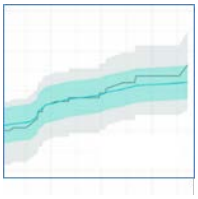
For more information, click here.

IN PRESS

Recent Publications by CDER Scientists

Predictive Analysis of First Abbreviated New Drug Application Submission for New Chemical Entities Based on Machine Learning Methodology

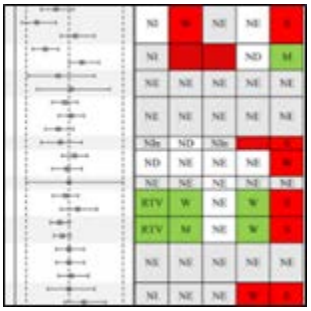
To better inform resource allocation and workload management for Abbreviated New Drug Application submissions, a machine learning algorithm was employed to predict the first submission. This model performed well in both internal and external validations and can serve as an effective planning tool for generic applications.



The potential role of the J-T_{peak} interval in proarrhythmic cardiac safety: current state of the science from the American college of clinical pharmacology and the cardiac safety research consortium

Drug-induced arrhythmia can lead to many complications, including death. Identifying drugs early in development that may cause arrhythmia is key, and an informative cardiac biomarker that can recognize these drugs has been of recent interest. The authors review the evidence supporting one potential ECG-based biomarker, the J-T_{peak} interval, which is a focus of the Comprehensive in Vitro Proarrhythmia Assay (CiPA) initiative and may be useful to gain additional insight into drugs associated with arrhythmias.

Drug-drug interaction studies of methadone and antiviral drugs: lessons learned

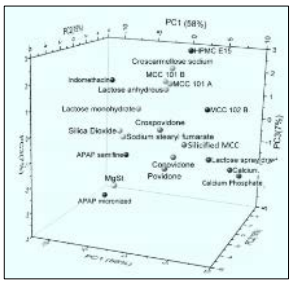


Many individuals being treated for human immunodeficiency virus (HIV) or hepatitis C infection are drug users, and antiviral medications may have important interactions with methadone, which is commonly used to treat addiction. Drug-drug interaction studies between all FDA-approved HIV and hepatitis C virus medications and methadone were collected and deposited into a database. Analysis of this database determined that one enzyme, CYP2B6, plays a significant role in methadone metabolism. The authors suggest that genotyping for this enzyme should be considered in methadone drug-drug interaction studies and that predictive models to determine the influence of various medications on methadone metabolism should be developed.

Multimodal analysis of FDA drug safety communications: lessons from zolpidem

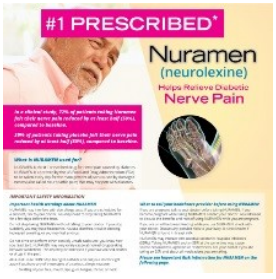
With investigators at Brigham and Women's Hospital in Boston, CDER researchers studied the content, dissemination (via traditional and social media), and uptake (by physicians and patients) of drug safety communications about the sleeping aid zolpidem (Ambien). They found incomplete dissemination of key safety-related information. Furthermore, patient and physician interviews revealed important gaps in patient-provider communication.

Development and applications of a material library for pharmaceutical continuous manufacturing of solid dosage forms



Continuous manufacturing (CM), by which the ingredients of a drug product are fed through an assembly line of fully integrated components, promises to revolutionize drug manufacturing. To advance CM, CDER researchers described the creation of a material library, i.e., a database of material attributes such as compressibility, permeability, and flow properties, and the correlations between them. This library can be continually expanded, refined, and used to develop CM processes for various drug products.

Market claims and efficacy information in direct-to-consumer prescription drug print advertisements



CDER researchers conducted a randomized study in patients with diabetes to determine the influences of "market claims" (for example, "# 1 prescribed") and quantitative efficacy information about a drug. They found that market claims affected perceptions of the drug's benefits, while quantitative information about product efficacy did not show a large influence on perceptions. The authors suggest

that these findings can help inform stakeholders and policy makers as they work to ensure direct-to-consumer prescription drug promotion does not mislead patients.

Suboptimal UVA attenuation by broad spectrum sunscreens under outdoor solar conditions contributes to lifetime UVA burden

FDA has recently proposed 1) to require that all sunscreens with SPF values of 15 and above satisfy broad spectrum requirements and 2) to add a requirement to the current broad-spectrum test to ensure that as SPF increases broad spectrum protection also increases, and that broad-spectrum products provide adequate protection against UVA. A study by CDER researchers of 32 commercial broad-spectrum sunscreen drug products found that six of them failed broad spectrum testing and about 40% had suboptimal UVA protection when tested under conditions of sun exposure.

UPCOMING EVENTS

Below are upcoming meetings, conferences, and workshops sponsored or co-sponsored by CDER. For details on each event, click here.

Date	Event	Event Type
11/06/2019	FDA-MRA Approaches to Neoadjuvant Treatment in Melanoma: A Public Workshop	Workshop
11/07/2019	Promoting Effective Drug Development Programs: Opportunities and Priorities for FDA's Office of New Drugs	Workshop
11/14/2019	Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee Meeting Announcement	Advisory Committee
11/18/2019	Development of Best Practices in Physiologically Based Pharmacokinetic Modeling to Support Clinical Pharmacology Regulatory Decision-Making	Meeting
12/04/2019	Regulatory Education for Industry (REdI): 2019 CDER Prescription Drug Labeling Conference – Dec. 4-5, 2019	Conference
12/06/2019	Public Workshop on Patient-Focused Drug Development: Guidance 4 – Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making	Workshop
12/12/2019	Fourth International Workshop on Global Bioequivalence Harmonization Initiative (GBHI) FDA/AAPS/EUFEPS CO-SPONSORSHIP AGREEMENT	Workshop

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 can be found by following @FDAJobs on Twitter and by visiting FDA's LinkedIn page and the Jobs at CDER and the Career Opportunities at CDER webpages. In addition, you can contact OTS directly at CDEROTSHires@fda.hhs.gov. 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 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.