



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

Summer/Fall 2018

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](mailto:OTSCommunications@fda.hhs.gov).



**HIGHLIGHT**

**CDER's Modernization of the New Drugs Regulatory Program**

Janet Woodcock, M.D., CDER Director, has posted a blog about proposed changes to CDER's new drug regulatory program. This proposal focuses on the following areas:

- Recruiting the best and brightest individuals from many disciplines
- Enhancing our focus on multidisciplinary teams
- Prioritizing operational excellence
- Improving knowledge management
- Emphasizing the importance of safety across a drug's lifecycle
- Incorporating the patient voice

**Because people trust us, we're asked to do more and more.**

But we can't just work harder to keep up. To maintain and advance our global leadership – and better support our deeply committed staff –

**we need to modernize the New Drugs Regulatory Program.**

–Janet Woodcock, MD



To learn more, visit the [FDA Proposes Process Modernization to Support New Drug Development](#) blog. Also available is the [statement from FDA Commissioner Scott Gottlieb, M.D., on proposed modernization of FDA's drug review office](#).

In support of this modernization initiative, the CDER Research Governance Council (RGC) was established to set research goals, objectives and cross-cutting priorities, enhance systems for tracking research investments and spend, develop research outcome metrics, develop a process for reviewing CDER's research programs, and expand communication about CDER science program to stakeholders. More information on the RGC's efforts will be included in future newsletters.

### Recent CDER Impact Stories

CDER is continuing to highlight its regulatory science research in a series of [regulatory science impact stories](#). Three recent posts include:

- How CDER statisticians have helped to develop clinical trial designs with adaptive and statistical features suitable for a disease outbreak setting (click [here](#) to read story),
- How deep learning approaches are being developed to help drug reviewers to better understand patient experience (click [here](#) to read story), and
- How CDER researchers are learning which commonly prescribed sedative drugs may exacerbate the side effect of prescription opioids (click [here](#) to read 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, "[New Class of Drugs Fulfills Promise of RNA-based Medicine](#)" is now available. The approval of a small interfering RNA (siRNA) product to treat polyneuropathy caused by a rare and frequently fatal disease called hereditary transthyretin-mediated amyloidosis marks the arrival of a potentially game-changing class of therapeutics.

### Table of Surrogate Endpoints Now Available Online

A table of surrogate endpoints that were the basis of drug approval or licensure is now available on FDA's website. This table is intended to provide valuable information for drug developers on endpoints that may be considered and discussed with FDA for individual development programs.

For more information, visit the [surrogate endpoints webpage](#). To download the table, click [here](#) (XLS-38KB)

## Recent *CDER Conversations*

### CDER Conversations

Mitra Ahadpour, MD, DABAM, is the deputy director of CDER's Office of Translational Sciences (OTS) and an addiction medicine specialist. Dr. Ahadpour discusses how medication assisted treatment works and its importance in the fight against the opioid crisis that is currently affecting communities across the nation.

To read more about this *CDER Conversation*, click [here](#).



Raj Madabushi, Ph.D., is a team leader for the Guidance and Policy Team within OTS, Office of Clinical Pharmacology. Dr. Madabushi discusses the current status and promise of model-informed drug development approaches to help inform drug development and decision-making.

To read more about this *CDER Conversation*, click [here](#).

To see other past *CDER Conversations*, click [here](#).



## ONLINE RESOURCES

### CDER Collaboration with NCATS

We are working with the [Clinical and Translational Science Awards \(CTSA\) Program](#) team at National Center for Advancing Translational Sciences (NCATS) to enhance scientific interactions, including collaborations, sabbaticals and educational resources. The CTSA Program at NCATS supports a national

network of medical research institutions called hubs, that work together to improve the translational research process to get more treatments to more patients more quickly.

Through the OTS-NCATS collaborative efforts, educational resources at FDA, including publicly available trainings, course modules, case studies, and video lectures, have been added to two CTSA sites:

1. The [University of Rochester Regulatory Science](#) webpage, and
2. [Eagle-I](#), a resource discovery tool built to facilitate translational science research, that uses a Search engine named N-lighten, to query shared educational resources at NIH, FDA, Harvard Catalyst and Ohio State University.

### **FDA's Scientific Publications Online Database**

Are you looking for journal articles from FDA authors? Check out the [Scientific Publications by FDA Staff](#) online database which allows users to search for specific publication information by center and by date range.



## **UPCOMING EVENTS**

### **September**

Human Dermal (Skin) Safety Testing for Topical Drug Products: Regulatory Utility and Evaluation; Public Workshop; Request for Comments. FDA White Oak Campus, 10903 New Hampshire Avenue, Building 31 Conference Center, Rm. 1503, Section A, Silver Spring, MD 20993. September 10, 2018. [Meeting Information](#)

Patient Engagement in Real World Evidence (RWE): Lessons Learned and Best Practices (FDA CDRH and University of Maryland CERSI Collaborative Workshop). University of Maryland, School of Pharmacy, 20 N. Pine Street, Baltimore, MD 21201. September 12, 2018. [Meeting information.](#)

2018 PDA/FDA Joint Regulatory Conference, Putting Patients First: Ensuring Innovation, Quality, Compliance, and Supply in an Evolving Environment. September 24 – 26, 2018, Renaissance Hotel, 999 9th Street, NW, Washington, D.C. 20001. [Meeting Information](#)

### **October**

Predictive Immunogenicity for Better Clinical Outcomes. October 3-4, 2018. FDA White Oak Campus, 10903 New Hampshire Avenue, Building 31 Conference Center, Rm. 1503, Silver Spring, MD 20993-0002. [Meeting Information](#)

Patient-Focused Drug Development Guidance: Methods to Identify What is Important to Patients and Select, Develop or Modify Fit-for-Purpose Clinical Outcome Assessments, FDA White Oak Campus, 10903 New Hampshire Avenue Building 31, Rm. 1503, Silver Spring, MD 20993, October 15-16, 2018. [Meeting Information](#)

## November

Assessing and Communicating Heterogeneity of Treatment Effects for Patient Subpopulations: Challenges and Opportunities. November 28, 2018. FDA White Oak Campus, 10903 New Hampshire Avenue Building 31, Room 1503 (Great Room), Silver Spring, MD 20993. [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, 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](#).