



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

**Winter 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 Videos providing insight on CDER regulatory science**

CDER has launched a new series of videos in which Center Director Janet Woodcock, M.D., describes major challenges in drug evaluation and development and how FDA and its collaborators are addressing them. The following videos are now available:

- [Improving Drug Review with Data Standards](#)  
Learn how data standards can support the integration of real world evidence into the drug development process and patient-centric decisions.
- [Patient-Focused Drug Development](#) Explore how the voice of the patient critically impacts drug development.



Dr. Woodcock discusses how data standards can integrate real world evidence into the drug development process in the [Improving Drug Review with Data Standards](#) video.

- [Real World Evidence](#) Learn how FDA is collaborating with external stakeholders to identify and evaluate previously unreported adverse reactions and support early detection of safety signals.
- [The Importance of Partnerships and Consortia](#) Explore how partnerships and consortia can enable us to address challenging regulatory science questions.

CDER has also added new videos and podcasts to its collection of interviews with some of its leading investigators. In "[CDER Scientists – In Their Own Words](#)," these investigators describe their roles in FDA's regulatory science program, and how their research advances drug development and the public health. Click the investigator's name below to view their video:

- [Kathryn Aikin, Ph.D.](#), describes how social scientists at CDER evaluate prescription drug advertisements and analyze how they are interpreted by patients to ensure they convey information that is truthful, balanced, and not misleading.
- [Celia Cruz, Ph.D.](#), provides an update on how the Office of Pharmaceutical Quality is investigating innovative approaches to drug manufacturing like 3D printing, and developing advanced analytic approaches to ensure the quality of a new generation of drug products.
- [Lisa LaVange, Ph.D.](#), provides an overview of how CDER's statisticians assess evidence in pre- and post-market settings to ensure that drugs are safe and effective while helping to improve the design of the clinical trials used to evaluate new personalized treatments for cancer.
- [Raj Madabushi, Ph.D.](#), explains how computational approaches like Model-Informed Drug Development are being used to improve drug dosing in children and other populations and help to provide better guidance to developers.
- [Karen Mahoney, M.D.](#), describes a logical drug label language approach developed and championed by her division to facilitate the over-the-counter availability of Naloxone, an opioid blocking drug.
- [Michael Nguyen, M.D.](#), provides a brief introduction to Sentinel, FDA's active surveillance program, and describes how it engages with multiple data partners to help monitor medical products and provides epidemiologists with new opportunities to address urgent questions of drug safety and efficacy.
- [Ashutosh Rao, Ph.D.](#), describes how research on protein oxidation provides critical information on the stability of protein therapeutics and supports development of safer and more effective versions of these products.
- [Amy Rosenberg, M.D.](#), discusses cutting edge research examining alterations in protein therapeutics and treatment modalities that may improve patient outcomes.
- [Connie Ruzicka, Ph.D.](#), gives an overview on how new kinds of portable instrumentation can be used to screen dietary supplements for harmful additives.
- [David Strauss, M.D., Ph.D.](#), uses several examples of multi-disciplinary projects from CDER's Division of Applied Regulatory Science to illustrate how clinical, laboratory, and computational approaches are being used to predict how a patient may respond to a new drug.

- [Daniela Verthelyi, M.D., Ph.D.](#), describes development of methods to evaluate biologic products submitted via the abbreviated licensure pathway (biosimilars), and CDER's efforts to develop new treatments for a parasitic disease that affects millions of individuals worldwide.
- [Kimberly Witzmann, M.D.](#), explores the challenges of evaluating equivalence of generic and brand name drugs, describing how the Office of Generic Drugs is developing new ways to evaluate complex products such as drugs delivered with inhalers.
- [Lynne Yao, M.D.](#), highlights the need to develop safe and effective drugs for children and pregnant women, and describes how CDER is helping to ensure that specific labeling is available to guide prescribing for these patients.



## OTHER ONLINE RESOURCES AND PRESENTATIONS

### The State of CDER 2018 podcast

Dr. Woodcock reflects on the accomplishments and highlights of 2017, and previews what is planned for 2018 in such areas as patient-focused drug development, drug compounding, modernizing FDA's IT platform, and addressing the opioid crisis.



Click [here](#) to download the podcast and to obtain transcript information.

### The Role of Consortia in Biomarker Development and Qualification

The FDA's Biomarker Qualification Program Educational Module Series describes CDER's scientific public-private partnerships (consortia), how CDER engages with them, and how they can advance biomarker development. Click [here](#) to view the module.



## Spotlight on CDER Science



### **CDER Researchers Explore the Promise and Potential of 3D Printed Pharmaceuticals**

Using state of the art laboratory platforms, CDER researchers are studying several advanced manufacturing technologies, including 3-dimensional (3D) printing. Recent advances in 3D printing (often referred to as additive manufacturing) highlight its tremendous potential to produce drug products that are exquisitely tailored (for example in their dosage and delivery forms) to the needs of an individual patient. Click [here](#) for more information on how CDER is advancing our basic understanding of 3D printing processes, and developing evaluative methods that can foster development of drug products manufactured with this technology.

### **Developing a Regulatory Framework to Evaluate Real World Evidence in Drug Development**

Real world evidence (RWE) is clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real world data obtained outside the clinical study setting. Under the [21st Century Cures Act](#), FDA is directed to develop a regulatory framework to evaluate how RWE can be used to support approval of new indications for approved drugs or help fulfill post-approval study requirements.

FDA currently accepts RWE to support regulatory decision-making about drug safety and is seeking stakeholder input in identifying promising areas for pilot demonstrations and innovative methods for deriving RWE. FDA continues to engage industry, patients, patient advocacy organizations, and others stakeholders to address key issues such as standardizing nomenclature, and methodological considerations for data collection, reporting, and analysis.

The National Academies of Science Engineering Medicine (NASEM) has coordinated a series of workshops titled “Examining the Impact of Real World Evidence on Medical Product Development.” Material from workshop I in this series, “Incentives,” is available on the NASEM [website](#). Workshop III, focusing on operationalizing the collection and use of real-world evidence, is scheduled for July 2018.

## Generic Drugs Science and Research

The Office of Research and Standards, a sub-office of the [Office of Generic Drugs](#), supports the regulatory science program established under the [Generic Drug User Fee Amendments](#) (GDUFA). As part of their ongoing work to make FDA's Generic Drugs program efforts more accessible to the public, OGD has expanded its Science & Research web presence to provide more intuitive navigation and easily digestible content. Information includes priorities and projects, research publications and resources, guidances and reports, collaboration opportunities, and generic drugs science and research news. Click [here](#) to view the new web pages.

### Priorities & Projects

Learn more about FDA generic drug research priorities, public workshops, and awarded projects

### Research Publications & Resources

Browse FDA generic drug research published in scholarly journal articles, presentations, and posters

### Guidances & Reports

View FDA generic drug research publications, including product-specific guidances and annual reports

### Collaboration Opportunities

See a listing of available grant and fellowship opportunities

The revised [Generic Drugs webpage](#) launched in September 2017. These changes offer site visitors easy access to information, whether they are patients, industry, reporters, researchers, or healthcare providers.



## UPCOMING EVENTS

### March 2018

- Public Meeting: Utilizing Innovative Statistical Methods and Trial Designs in Rare Disease Drug Development, March 19, 2018. [Meeting Information](#)
- Promoting the Use of Complex Innovative Designs in Clinical Trials, March 20, 2018. [Meeting Information](#)

### April 2018

- Public Workshop: CDER and You: Keys to Effective Engagement, April 3, 2018. [Meeting information](#)
- Public Meeting: Patient-Focused Drug Development for Opioid Use Disorder, April 17, 2018. [Meeting information](#)

## May 2018

- FY 2018 Generic Drug Research Public Workshop, Thursday, May 24, 2018. [Meeting Information](#)

## OPPORTUNITIES AT CDER

### CDER Summer Research Participation Program 2018 (Paid Internship Opportunity)

This summer program, administered under the auspices of the Oak Ridge Institute for Science and Education (ORISE), is an opportunity for participants to engage with mentors, and examine questions on topics relevant to the CDER's needs, gaining hands-on experience on regulatory research projects under expert mentors. Interns will work at CDER's White Oak Campus, Silver Spring, MD.

Application deadlines vary by placement office. For more information on CDER opportunities, click [here](#) and search "CDER summer."