



Center for Drug Evaluation and Research

FALL | 2017

# WHAT'S NEW IN REGULATORY SCIENCE

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).

## Highlights

### New on FDA.gov

#### CDER Scientists – In Their Own Words

To highlight the scope, diversity, and impact of CDER's regulatory science initiatives, we developed a new series of videos. Hear our scientists and physicians discuss their efforts to advance new science, as members of FDA's research community. Each video illustrates how CDER works to protect and promote public health by enabling the development of new therapeutics and ensuring the safety and efficacy of drugs for the American public.

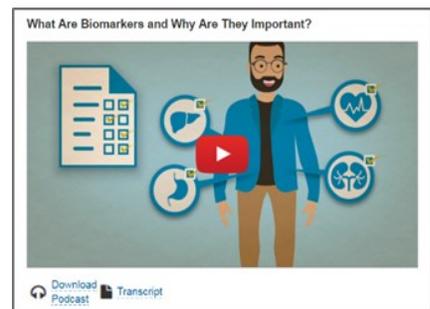
Visit our [video web page](#) to watch.



Dr. Lynne P. Yao  
Director  
Division of Pediatric and Maternal Health  
Office of New Drugs, CDER

#### Biomarker Videos and Podcasts

Have you seen the [updated "Biomarker Videos and Podcasts" web page](#)? Now you can watch videos or download podcasts that describe the role of biomarkers and the CDER Biomarker Qualification Program. The videos feature Dr. Janet Woodcock, Director of CDER, and other CDER staff. [Two educational case study modules](#) are also available.



## Regulatory Science in Action

The refreshed [web section on science and research at CDER](#) features [stories describing how CDER research advances public health](#), including:

- [Finding a Better Test for Predicting the Risk Drugs Pose to the Heart](#)
- [Strengthening U.S. Drug Product Manufacturing](#)
- [Overcoming Challenges to Evaluating Equivalence in Complex Drugs](#)
- [Developing New Ways to Evaluate Bioequivalence for Topical Drugs](#)
- [Addressing Concerns About the Quality of Generic Drugs for Treating Epilepsy](#)
- [Helping to Better Communicate the Risks and Benefits in Prescription Drug Advertising](#)

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## Other Online Resources

### Dr. David Strauss Featured in DIA Global Forum Podcast

Dr. David Strauss, Director of the Division of Applied Regulatory Science, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, describes the role his division plays in helping to close the gap between scientific innovation and drug review.

[Download the podcast](#)

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### Looking for Research Consortia or Partnerships?

Consortia-pedia, created by Faster Cures ([www.fastercures.org](http://www.fastercures.org)), is a searchable catalogue that contains searchable information on hundreds of research consortia. The catalog is updated periodically, and the most recent update has over 500 consortia and partnerships listed. This is a comprehensive public resource for researchers seeking partners with similar interests and objectives.

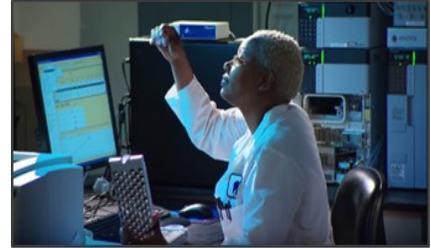
Visit the [Consortia-pedia website](#) to learn more about this resource.

## Opportunities at FDA

### Interested in Jobs and Fellowships at CDER?

CDER seeks highly-qualified and diverse candidates to help it meet scientific and regulatory challenges. This video series explores career opportunities available at CDER.

- [Looking for the best and the brightest to join CDER!](#)
- [Looking for an opportunity? Learn about the various fellowship programs at CDER.](#)
- [Why it's cool to be a statistician at FDA](#)
- [Learn about the frontiers of clinical pharmacology and drug development.](#)
- [Inspector Reviewers: Bridging the past and future](#)



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### Office of the Commissioner Jobs

- [Associate Director for Scientific Staffing](#)

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### ORISE Fellowships

[Apply for Oak Ridge Institute for Science and Education \(ORISE\) fellowships at CDER](#) through the ORISE Research Participation Programs. The ORISE programs at FDA are education and training programs designed to provide opportunities for students, recent graduates, and university faculty to participate in project-specific FDA research and developmental activities. ORISE is managed by Oak Ridge Associated Universities (ORAU) for the U.S. Department of Energy.

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