U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research Spring/Summer 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.

HIGHLIGHT

Refreshed Web Pages on Science and Research at CDER

FDA has refreshed its Web pages on science and research at the Center for Drug Evaluation and Research to better provide dynamic examples of regulatory science projects underway and describe how our research advances public health. We will continue to add new information, resources, and videos in the months to come, so stay tuned!

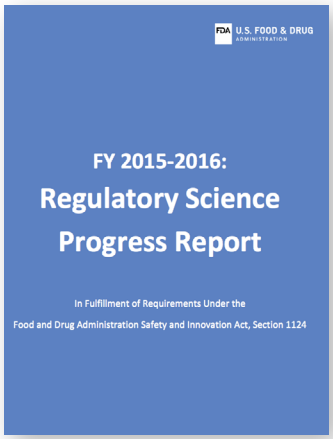
NEWS

FDA Releases FY 2015-2016: Regulatory Science Progress Report

FDA recently released a Regulatory Science Progress Report for fiscal years 2015 and 2016, in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA) requirements. Developed by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH), the report provides a comprehensive overview of FDA's scientific efforts to advance medical product

development. This report is a valuable resource for people seeking a better understanding of what we at FDA mean by "regulatory science" and how our research benefits the public.
The report features:

- Examples of how our work supports the development of innovative tools, methods, and guidance;
- Scientific insights that spur medical product development;
- Recent enhancements to FDA's scientific infrastructure and organization; and
- Accomplishments from FDA's engagement with numerous scientific consortia.



2017 *America's Got Regulatory Science Talent Competition* Winners Present Their Work at FDA

Winners of the 2017 *America's Got Regulatory Science Talent Competition* presented their innovative ideas at FDA on April 12, 2017. The competition fosters students' interest in the pioneering field of regulatory science, requiring student teams to invent innovative solutions to regulatory science challenges in the eight scientific priority areas identified in FDA's Strategic Plan for Regulatory Science. This year's panel of judges evaluated each presentation for the quality, novelty, potential significance, and feasibility of the students' proposed solutions.

The ideas covered a broad range of topics with important public health potential, including risk communication through labeling, transparency of biomarker integration in accelerated approval pathways, accessibility and functionality of clinical trial results, and testing of 3D-printed personalized implants.

Creation of the Office of New Drugs Regulatory Science Program

The Regulatory Science Program (RSP) in CDER's Office of New Drugs (OND) consists of the Biomarker Development and Regulatory Science Team in the Immediate Office as well as Associate Directors for Regulatory Science, located across OND's six Offices of Drug Evaluation.

RSP's mission is to develop, implement, and communicate policies and programs to enhance the regulatory review process by:

- Identifying knowledge gaps and areas of need for prioritization of resources for research, guidances, Manuals of Policies and Procedures (MAPPs), and Standard Operating Procedures (SOPs) and providing leadership for those areas;
- Developing a shared learning culture to enhance scientific understanding and consistent, data-driven decision making across review divisions;
- Promoting consistent adoption and implementation of drug development tools, technologies, and innovative clinical trial designs across review divisions;
- Facilitating OND internal and external stakeholder outreach with review divisions to inform regulatory decisions, identify regulatory barriers, and develop strategies to mitigate challenges.

Together, these activities will help OND achieve its goal in supporting the development and monitoring of new drugs and biologics that are safe, effective, and available to the public.

For example, in June 2016, RSP supported the Office of Antimicrobial Products (OAP) public workshop, Clinical Trial Design Considerations for Malaria Drug Development. Global stakeholders and multiple FDA centers representing devices and biologics participated in the workshop. Dr. Edward Cox, OAP director, noted at the conclusion of the workshop, "This is an area of drug development that's important. I think the workshops provide an opportunity for a broad group of experts to get together and understand the current state of the field regarding clinical trials and drug development and also areas for additional development and questions for the future."

Online Resources and Presentations

New Web Page: Meet the Faces behind FDA Science

The FDA scientists highlighted in Meet the Faces behind FDA Science talk about their passion for the work they do, FDA's pioneering regulatory science culture and opportunities for professional growth, and why they love working at FDA.

Spotlight on CDER Science

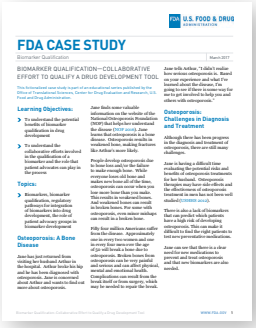
Spotlight on CDER Science is a new take on the From Our Perspective series, featuring articles written by FDA scientists about their research. Read our newest stories:

- Novel Approach Allows Expansion of Indication for Cystic Fibrosis Drug, by Dr. Tony Durmowicz and Dr. Mike Pacanowski
- Modernizing the Way Drugs Are Made: A Transition to Continuous Manufacturing, by Dr. Sau Lee
- Tuberculosis Biorepository Aims To Bolster TB Drug Development by Facilitating Research on Biomarkers, by Dr. Leonard Sacks

New Biomarker Resources

Videos: New CDER Biomarker Qualification Program videos are available, including videos featuring Dr. Janet Woodcock, director of CDER, discussing biomarker development, the importance of biomarkers, and the role of FDA and stakeholders in biomarker qualification. A series of modules by FDA experts helps stakeholders interested in biomarker research better understand various aspects of FDA's Biomarker Qualification Program, such as biomarker terminology, pathways for using biomarkers in drug development, context of use, and the implications of biomarker qualification. More modules on biomarker topics are in development.

Case studies: CDER is developing a series of fictionalized case studies illustrating scenarios relevant to the biomarker qualification process or the drug development and review process. This case study includes learning objectives, a description of the drug development challenge, biomarker development and qualification processes, and FDA-related information and resources on the topic.


FDA CASE STUDY

Biomarker Qualification

BIOMARKER QUALIFICATION—COLLABORATIVE EFFORT TO QUALIFY A DRUG DEVELOPMENT TOOL

Learning Objectives:

Topics:

Osteoporosis: A Bone Disease

Osteoporosis: Challenges in Diagnosis and Treatment

- FDA Case Study: Biomarker Qualification—Collaborative Effort to Qualify a Drug Development Tool (PDF - 186 KB)

NIH 2016-2017 Sumner J. Yaffee Memorial Lecture Series in Pediatric Clinical Pharmacology

Watch archived webinars from NIH's 2016-2017 Sumner J. Yaffe Memorial Lecture Series in Pediatric Clinical Pharmacology, including presentations by FDA's Dr. Susan McCune and Dr. Lynne Yao.

GDUFA Regulatory Science Initiatives: Generic Drug Research Public Workshop May 3, 2017

On May 3, 2017, FDA held a public workshop about its generic drug regulatory science initiatives. The workshop covered the current status of the initiatives and offered an opportunity for the public to provide input on research priorities. See the agenda, download PowerPoint files, and watch presentations from the workshop.

FDA Drug Information Soundcast in Clinical Oncology (D.I.S.C.O.)

FDA Drug Information Soundcast in Clinical Oncology (DISCO) is an FDA podcast series that provides information about new product approvals, emerging safety information for cancer treatments, and other current topics in cancer drug development.

Opportunities at CDER

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 students, recent graduates, and university faculty opportunities 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.

FDA Commissioner's Fellowship Program—Applications Due Soon!

The FDA Commissioner's Fellowship Program (CFP) is accepting applications for the Class of 2017 through July 7, 2017. This two year fellowship provides outstanding health care professionals, scientists, and engineers an opportunity to conduct cutting-edge research on targeted scientific, policy, or regulatory issues under the mentorship of an FDA senior scientist. Learn more about how to apply for the CFP.

Upcoming Events Related to Regulatory Science Sponsored or Co-sponsored by the Center for Drug Evaluation and Research (CDER)

FDA provides a constantly updated list of upcoming meetings, conferences, and workshops, a number of which are about regulatory science issues important to CDER. For example, a scientific workshop to discuss opioid formulations with abuse-deterrent properties is being held on July 10 and 11, 2017. The web page also includes a list of past events.

Check out previous copies of this newsletter on our web page.