U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research | Winter 2017

WHAT'S NEW IN REGULATORY SCIENCE

Welcome to our first quarterly update! Four times a year the Center for Drug Evaluation and Research will be sending out an update to share information on 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.

HIGHLIGHTS

Dr. Woodcock Discusses CDER's Biomarker Qualification Program

In our new video, Dr. Janet Woodcock, Director of CDER, describes the purpose of CDER's Biomarker Qualification Program and how it can help support the development of new biomarkers to make decisions that affect patient health. This is the first in a four video series. The rest of the videos will be released in early 2017.

Opportunities at CDER

ORISE Fellowships

Apply for ORISE fellowships at CDER through the Oak Ridge Institute for Science and Education Research Participation Programs. The ORISE programs at FDA are educational 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 ORAU for the U.S. Department of Energy.

NEWS

Framework for Biomarker Evidentiary Criteria for Biomarker Qualification Released

In December 2016, the Foundation for the National Institutes of Health released the Framework for Defining Evidentiary Criteria for Biomarker Qualification (PDF, 45 pages). The Framework defines the level of evidence needed to support qualification of biomarkers. It was developed in partnership with FDA, the National Institutes of Health, Critical Path Institute, the Pharmaceutical Research and Manufacturers of America, and multiple pharmaceutical companies and incorporates input from nearly 200 scientific leaders in the field. Download the document (PDF, 45 pages).

Biomarkers Used as Outcomes in Development of FDA-Approved Therapeutics (October 2007-December 2015)

This table provides examples of some biomarkers that have been accepted and used as endpoints in clinical trials for drug and biologic approvals across 12 therapeutic areas. Specifically, these biomarkers were used as outcomes in the development of FDA-approved new molecular entities and new biological therapeutics in different disease areas from fiscal year 2007 to fiscal year 2015. Access the table.

BEST Resource—New Content Added December 2016

Language confusion can delay medical product development and even cause failure in late-phase trials. To help with this problem, the FDA-NIH Biomarker Working Group developed the Biomarkers, EndpointS, and other Tools (BEST) Resource for scientific and medical communities to use consistent terminology throughout all stages of medical product development. The BEST Resource is a living document that is updated periodically with additional definitions and examples. Stakeholders are encouraged to provide feedback by email to biomarkers@ncbi.nlm.nih.gov.

New Biomarker Qualification Program Web Pages

CDER has launched a new suite of Web pages to inform stakeholders about biomarkers and the Biomarker Qualification Program. The pages have been organized for easier navigation and include expanded information on how to submit a biomarker for qualification and a new education and training section.

ENGAGE WITH US

Critical Path Innovation Meetings

CDER's Critical Path Innovation Meetings (CPIM) provide opportunities for investigators from industry, academia, patient advocacy groups, and government to (1) engage in discussions with CDER about what can support innovations, (2) identify and address gaps in existing knowledge, and (3) improve efficiency and success in drug development. CPIM is broad in scope, and topics have included potential biomarkers in early phases of development and not ready for submission to the qualification program, natural history studies, emerging technologies or new uses of existing technologies, and novel clinical trial designs and methods.