

April 30: Lilliam Rosario, Ph.D., Modernizing the Review Process Through Innovation



SYNOPSIS:

This presentation will provide an overview of how CDER's Computational Science Center (CSC) is integrating bioinformatics and analytics into the regulatory review environment. There are a number of components that work together to enable reviewers to utilize analytical tools to assist them in answering regulatory review questions and making decisions. These components include guidance and rule development, submission and use of standardized data, data validation, analytical tools that support data exploration from the reviewer perspective, and repositories to allow data integration. The CSC is a program that provides services to CDER, and review divisions to implement the components and facilitate analytical tool skill development.

[Session details...](#)

BIO:

Dr. Lilliam Rosario is the Director of the Office of Computational Science (OCS) in the Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). The OCS leads and directly supports the modernization of CDER's scientific computing capabilities by providing services across the spectrum of innovation, supporting the submission and use of high-quality data, and providing access to high-end analytical tools and training, enabling the overall regulatory review process. Dr. Rosario has served as associate director in the FDA's Office of Science and Innovation, Office of the Chief Scientist. She has also worked in the Office of New Drugs in FDA's CDER. Dr. Rosario holds a Ph.D. in neuroscience from Rutgers University and a B.A. in chemistry from the University of Puerto Rico.

SUMMARY:

Topic: Modernizing the Review Process Through Innovation

Speaker: Lilliam Rosario, Ph.D.

Date: Wednesday, April 30, 11 a.m.-12 p.m. EDT

You are invited to listen to Dr. Rosario's presentation in Room 2W908 in the NCI Shady Grove Building on Medical Center Drive or via WebEx.

Presentation: A screen cast of the presentation will be available for viewing after the event here on our [Speaker Series Videos page](#) and on the [NCI's CBIIT Speaker Series YouTube Playlist](#) . The presentation slides are also attached.

About the NCI CBIIT Speaker Series:

The National Cancer Institute (NCI) Center for Biomedical Informatics and Information Technology (CBIIT) Speaker Series is a bi-weekly knowledge-sharing forum featuring both internal and external speakers on topics of interest to the biomedical informatics and research communities. For additional information, including past speaker series presentations, visit the [CBIIT Speaker Series page](#).

Questions? Please email us at NCICBIITcomms@mail.nih.gov.

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