

**The Food and Drug Administration's (FDA's)
2015 ORSI Science Symposium
April 27, 2015
SPEAKER ABSTRACTS AND BIOGRAPHIES**

Session 1: Centers for Excellence in Regulatory Science and Innovation (CERSIs) Presentations – 8:35-11:30 AM

Johns Hopkins University CERSI

CERSI	Johns Hopkins University
Speaker	G Caleb Alexander, MD, MS
Title and Location	Co-Director, Johns Hopkins Center for Drug Safety and Effectiveness Associate Professor, Epidemiology and Medicine Johns Hopkins Bloomberg School of Public Health Department of Epidemiology Baltimore, MD
Biography	G. Caleb Alexander, MD, MS is an Associate Professor of Epidemiology and Medicine at Johns Hopkins Bloomberg School of Public Health, where he serves as a founding co-Director of the Center for Drug Safety and Effectiveness. He is a practicing general internist and pharmacoepidemiologist and is internationally recognized for his research examining prescription drug utilization. Dr. Alexander is the author of over 170 scientific articles and book chapters, and he has published regularly in leading scientific journals including JAMA, Health Affairs and the Annals of Internal Medicine. He is a frequent speaker on health care issues and has served on numerous editorial and advisory boards, including Drug Safety, Journal of General Internal Medicine, American Journal of Health System Pharmacy, Medical Decision Making and Medical Care. Due to its impact and relevance to a broad sector of the general public, his work has been widely featured in a media including the Economist, Scientific American, the New York Times, the Wall Street Journal, Washington Post, National Public Radio and other media. Dr. Alexander’s research focuses on population-based patterns and determinants of pharmaceutical use, clinical decision-making regarding prescription drugs, and the impact of changes in regulatory and payment policy on pharmaceutical utilization. In addition to expertise conducting survey-based investigations, he has also extensive experience with the analysis of secondary data sources including administrative claims and large national surveys. Dr. Alexander received his B.A. cum laude from the University of Pennsylvania, an MD from Case Western Reserve University, and a Master of Science from the University of Chicago.
Presentation Title	Regulatory Science and Innovation: Optimizing the Evidentiary Basis for Decision-Making at the FDA
Presentation Abstract	The Johns Hopkins University (JHU) Center of Excellence in Regulatory Science and Innovation (CERSI) builds on the enormous strengths of Johns Hopkins University in quantitative sciences and pharmacology to provide novel education, exchange and collaborative research programs that are focused on three specific areas of FDA’s regulatory science and innovation strategy which include: (i) Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development; (ii) Ensure FDA Readiness to Evaluate Innovative Emerging Technologies; and (iii) Harness Diverse Data through Information Sciences to Improve Health Outcomes. In his brief remarks, Dr. Alexander will describe the key features of the JHU CERSI and highlight the research projects and educational programs underway during its first year of collaboration with the FDA.