

**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**

**University of California-San Francisco/Stanford University CERSI**

CERSI	<b>University of California-San Francisco (UCSF)-Stanford University</b>
Speaker	<b>Russ B. Altman, MD, PhD</b>
Title and Location	<b>Professor and Co-Director UCSF-Stanford CERSI Departments of Bioengineering, Genetics, Medicine and Computer Science Stanford University, Stanford, CA</b>
Biography	<b>Russ Biagio Altman is a professor of bioengineering, genetics, &amp; medicine (and of computer science, by courtesy) and past chairman of the Bioengineering Department at Stanford University. His primary research interests are in the application of computing and informatics technologies to problems relevant to medicine. He is particularly interested in methods for understanding drug action at molecular, cellular, organism and population levels. His lab studies how human genetic variation impacts drug response (e.g. <a href="http://www.pharmgkb.org/">http://www.pharmgkb.org/</a>). Other work focuses on the analysis of biological molecules to understand the action, interaction and adverse events of drugs (<a href="http://features.stanford.edu/">http://features.stanford.edu/</a>). He has chaired the Science Board advising the FDA Commissioner. He currently serves on the Advisory Committee to the NIH Director.</b>
Presentation Title	<b>UCSF-Stanford Innovative Regulatory Science on the West Coast</b>
Presentation Abstract	<p><b>Research Projects Overview:</b> 5 research projects have been funded so far this year which involve teams of FDA and UCSF/Stanford scientists working on areas of research that are critical for approval of medical products. These include projects focused on:</p> <ul style="list-style-type: none"> <li>• <b>Improving Pharmacovigilance (two projects)</b> Nigam Shah will present the initial progress on: “Improving ADR Signal Detection by Combining Signals from Spontaneous Reports and Electronic Health Records”.</li> <li>• <b>Developing In Vitro Methods to Inform the Conduct of Clinical Studies in Patients with Drug-induced Renal Impairment.</b> Kathy Giacomini will present initial progress on: “Renal Impairment in New Drug Development” and in the afternoon of the Science Symposium UCSF postdoc; Chia-Hsiang Hseuh will give a poster presentation.</li> <li>• <b>Developing Standards for Spinal Devices</b></li> <li>• <b>Developing Standardized Data Formats for the Electronic Health Record to Enhance the Conduct of Clinical Trials</b></li> </ul> <p><b>Educational Programs Overview:</b> the CERSI educational team is in the process of designing and implementing CERSI educational programs in Regulatory Sciences, which will focus especially on regulatory sciences of special interest to west coast industries. We plan to roll out an exciting curriculum at UCSF and Stanford that will be available not only to students, postdocs and faculty at UCSF and Stanford, but to industry and FDA scientists as well. Professional Certificate Programs on Fundamentals and Frontiers in Regulatory Science in development.</p>