

# 2015 FDA Science Forum



Day 1: May 27, 2015

[Welcome](#) by Acting Chief Scientist Luciana Borio, M.D.

[Remarks](#) by Acting Commissioner, Stephen M. Ostroff, M.D.

## Session 1: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

1. [Breakthroughs in Imprint Lithography and 3D Additive Fabrication](#)  
by Joseph M. DeSimone, Ph.D.
2. [Single Cell Methods in Cell Product Characterization](#)  
by Malcolm Moos, MD, Ph.D.
3. [Field Portable Devices – Taking the Laboratory to the Sample](#)  
by Mark Witkowski, Ph.D.
4. [The Intersection of Personalized Cardiac Therapies, Cell Based Diagnostics and Multi-Variate Physiological Monitoring](#)  
by David G. Strauss, MD, Ph.D.

## Session 2: Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products

1. [E-Cigarette Use and Cigarette Smoking Behavior among U.S. Young Adults: A Mixed Methods Study](#)  
by Blair N. Coleman, Ph.D., MPH (Starts at 00:00)
2. [Experimental Study of Patient Information Prototypes](#)  
by LT. Oluwamurewa Oguntimein, M.H.S, CHES (Starts at 00:12)

3. [Incorporating Patient Preferences into Regulatory Decision Making](#)  
by Telba Irony, Ph.D. (Starts at 00:22)
4. [Recent Findings from Nonhuman Primates on the Long-Term Adverse Behavioral Effects of General Anesthesia When Given During Early Brain Development](#)  
by Merle G. Paule, Ph.D., A.T.S. (Starts at 00:38 )

### **Session 3: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security**

1. [Enhancing Preparedness through Novel Partnerships for IT Innovation: USCIIT-PREP](#)  
by J. Perren Cobb, M.D., F.C.C.M, F.A.C.S.
2. [Electrophysiological Biomarkers of Brain Injury](#)  
by Cristin Welle, Ph.D.
3. [Pandemic Influenza Preparedness: Development of Novel Technologies for In-Depth Evaluation of Vaccine Efficacy and Long-Term Memory During H7 Clinical Trials](#)  
by Surender Khurana, Ph.D.
4. [Filovirus Detection and Threat Mitigation](#)  
by Steven Wood, Ph.D.

### **Session 4: Implement a New Prevention-Focused Food Safety System to Protect Public Health**

1. [Food Safety Systems in the Americas: A perspective from the Pan-American Health Organization \(PAHO\)](#)  
by Enrique Pérez-Gutiérrez, D.V.M., M.Sc., M.P.V.M., Ph.D. (Starts at 00:00)
2. [GenomeTrakr: A Pathogen Databases to Build a Global Genomic Network for Pathogen Traceback and Outbreak Detection](#)  
by Ruth E. Timme, Ph.D. (Starts at 00:28 )
3. [The Nexus of Food Safety, Animal Health and Antimicrobial Resistance](#)  
by Patrick McDermott, M.S., Ph.D. (Starts at 0:42)
4. [The Use of DNA Barcoding to Prevent Species-Specific Foodborne Illness and Detect Seafood Fraud](#)  
by Jonathan Deeds, Ph.D. (Starts at 01:00)

5. [Non-Targeted Screening Methods for Identification of Chemical Hazards of Public Health Concern](#)  
by Tim Croley, Ph.D. (Starts at 01:16)

## Day 2: May 28, 2015

### Keynote

#### [Cancer Genomes and the Wars against Cancer](#)

by Bert Vogelstein, M.D.

### Session 5: Support New Approaches to Improve Product Manufacturing and Quality

1. [Screening for Counterfeit Pharmaceutical Products Using the CDx Device in Ultraviolet, Visible, and Infrared Modes for Field and Laboratory Use](#)  
by Nicola Ranieri
2. [Methods for Detection of Allergens in Food and in the Processing Environment: Approaches and Challenges](#)  
by Lauren Jackson, Ph.D.
3. [Advanced Analytics and Data Integration for Biomolecule Characterization](#)  
by Sau Lee, Ph.D.
4. [Using NMR to Assess Structure and Comparability](#)  
by Daron Freedberg, Ph.D.

### Session 6: Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes

1. [Individualized Therapy as a Practical Aspect of Patient Care](#)  
by Howard L. McLeod, Pharm.D. (Starts at 00:00)
2. [Not in Our Stars but in Ourselves: The Pharmacogenetic Determinants of Immunogenicity of Therapeutic Proteins](#)  
by Zuben E. Sauna, Ph.D. (Starts at 00:31) )
3. [Pharmacogenomics and Biomarker-Based Drug Development](#)  
by Michael Pacanowski, Pharm.D., M.P.H. (Starts at 00:51)

4. [Statistical Evaluation of “Me-Too” Companion Diagnostic Tests for Selecting Therapies](#)  
by Gene Pennello, Ph.D. (Starts at 01:11)

## Session 7: Modernize Toxicology to Enhance Product Safety

1. [Human Microlivers for Disease Modeling](#)  
by Sangeeta Bhatia, M.D., Ph.D.
2. [Discovery and Analytical Validation of System Biology Translation Biomarkers of Toxicity](#)  
by Richard D. Beger, Ph.D.
3. [Nonclinical Development of Neurotoxicity Biomarkers Using In Vivo MRI](#)  
by Serguei Liachenko, M.D., Ph.D.
4. [Replacing the Clinical Thorough QT Study with a Panel of In Vitro Assays and Computational Integration](#)  
by Norman Stockbridge, M.D., Ph.D.
5. [Humanized Hepatic Mice: In Vivo Model to Predict Human-Specific Immunotoxicity, Drug Metabolism and Hepatotoxicity](#)  
by Kristina E. Howard, D.V.M., Ph.D.

## Session 8: Harness Diverse Data through Information Sciences to Improve Health Outcomes

1. [Transforming Trillions of Points of Data into Diagnostics, Therapeutics, and New Insights into Disease](#)  
by Atul Butte, MD, Ph.D. (Starts at 00:00)
2. [Panel Discussion: Next Generation Sequencing Technology at FDA with Atul Butte MD, Ph.D., Carolyn Wilson, Ph.D., Hugh A. Rand, Ph.D., Zivana Tezek, Ph.D., and Weida Tong, Ph.D.](#)  
Moderated by Eric Donaldson, Ph.D. (Starts at 00:35)