FDA Science Forum 2015

FDA White Oak Building 31
Silver Spring, M.D.

May 27, 2015 – Day 1

8:30 – 8:40 AM Introduction
https://collaboration.fda.gov/fdascienceforum/

8:45 – 8:50 AM Welcome by *FDA Acting Chief Scientist*, Luciana Borio, M.D.

8:50 – 9:15 AM Remarks by *FDA Acting Commissioner*, Stephen M. Ostroff, M.D.

9:15 – 10:15 AM Poster Sessions 1 & 2 and Break

1. Ensure FDA Readiness to Evaluate Innovate Emerging Technologies
2. Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products

10:15 – 12:00 PM **Concurrent Sessions 1 & 2**

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

Great Room Section B, https://collaboration.fda.gov/fdascienceforum/

Session Chair: Steven K. Pollack, Ph.D., *Director, Office of Science and Engineering Laboratories, CDRH, FDA*

10:15 – 10:45 AM Breakthroughs in Imprint Lithography and 3D Additive Fabrication
Joseph M. DeSimone, Ph.D.
Chancellor's Eminent Professor of Chemistry and Chemical Engineering, University of North Carolina at Chapel Hill and North Carolina State University; Co-Founder and CEO, Carbon 3D

10:45 – 11:06 AM Single Cell Methods in Cell Product Characterization
Malcolm Moos, MD, Ph.D.
Medical Officer, CBER, FDA

11:06 – 11:28 AM Field Potable Devices – Taking the Laboratory to the Sample
Mark Witkowski, Ph.D.
Chemist, Trace Examination Section, Forensic Chemistry Center, ORA, FDA

11:28 – 11:50 AM The Intersection of Personalized Cardiac Therapies, Cell Based Diagnostics and Multi-Variate Physiological Monitoring
David G. Strauss, MD, Ph.D.
Medical Officer, CDRH, FDA

11:50 – 12:00 PM Q&A Session

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

Great Room Section C, https://collaboration.fda.gov/fdascienceforum3/

Session Chair: Lee Zwanziger, Ph.D., *Senior Science Policy Analyst, Risk Communication Staff, Office of Planning, Office of Policy, Planning, Legislation, and Analysis, Office of Policy, OC, FDA*

10:15 – 10:45 AM Lecture Title
Olivia Carter-Pokras, Ph.D.
Associate Professor, Epidemiology and Statistics, University of Maryland School of Public Health

10:45 – 11:01 AM E-Cigarette Use and Cigarette Smoking Behavior among U.S. Young Adults: A Mixed Methods Study
Blair N. Coleman, M.P.H.
Epidemiologist, CTP, FDA

11:01 – 11:17 AM Experimental Study of Patient Information Prototypes
LT. Oluwamurewa (Murewa) Oguntimein, M.H.S, CHES
Senior Regulatory Management Officer, Social Scientist, Office of Research and Standards, Division of Therapeutic Performance, CDER, FDA

11:17 – 11:33 AM Incorporating Patient Preferences into Regulatory Decision Making
Telba Irony, Ph.D.
Chief, General and Surgical Devices Branch, Division of Biostatistics and Office of Device Evaluation, CDRH, FDA

11:33 – 11:50 AM Recent Findings from Nonhuman Primates on the Long-Term Adverse Behavioral Effects of General Anesthesia When Given During Early Brain Development
Merle G. Paule, Ph.D., A.T.S.
Director, Division of Neurotoxicology, NCTR, FDA

11:50 – 12:00 PM Q&A Session

12:00 – 1:00 PM Lunch

1:00 – 2:45 PM **Concurrent Sessions 3 & 4**

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

Great Room Section B, https://collaboration.fda.gov/fdascienceforum/

Session Chair: Rakesh Raghuwanshi, MPH, *Scientific Program Manager, Office of Counterterrorism and Emerging Threats, OC, FDA*

1:00 – 1:30 PM Enhancing Preparedness Through Novel Partnerships for IT Innovation: USCIIT-PREP
J. Perren Cobb, M.D., F.C.C.M, F.A.C.S.
Medical Director, Surgical Intensive Care Unit, and Vice-chair, Department of Anesthesia, Critical Care, and Pain Medicine, Massachusetts General Hospital, Boston Massachusetts; Associate Professor of Anesthesiology and Associate Professor of Surgery, Harvard Medical School, Boston Massachusetts

1:30 – 1:51 PM Electrophysiological Biomarkers of Brain Injury
Cristin Welle, Ph.D.
Neurophysiologist, Office of Science and Engineering Labs, CDRH, FDA

1:51 – 2:13 PM Pandemic Influenza Preparedness: Development of Novel Technologies For In-Depth Evaluation Of Vaccine Efficacy And Long-Term Memory During H7 Clinical Trials
Surender Khurana, Ph.D.
Staff Scientist, Office of Vaccines Research and Review, CBER, FDA

2:13 – 2:35 PM Filovirus Detection and Threat Mitigation
Steven Wood, Ph.D.
Biologist, Office of Science and Engineering Laboratories, CDRH, FDA

2:35 – 2:45 PM Q&A Session

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

Great Room Section C, https://collaboration.fda.gov/fdascienceforum3/

Session Chair: Palmer A. Orlandi, Jr., Ph.D., *Acting Chief Science Officer and Research Director, OFVM, FDA*

1:00 – 1:30 PM Food Safety Systems in the Americas: A perspective from the Pan-American Health Organization (PAHO)
Enrique Pérez-Gutiérrez, D.V.M., M.Sc., M.P.V.M., Ph.D.

Senior Advisor, Foodborne Diseases and Zoonosis, Pan-American Health Organization

1:30 – 1:46 PM GenomeTrakr: A Pathogen Databases to Build a Global Genomic Network for Pathogen Traceback and Outbreak Detection
Peter Evans, Ph.D., M.P.H.
Supervisory Microbiologist and Chief, Molecular Methods and Subtyping Branch, CFSAN, FDA

1:46 – 2:02 PM The Nexus of Food Safety, Animal Health and Antimicrobial Resistance
Patrick McDermott, M.S., Ph.D.
Director, National Antimicrobial Resistance Monitoring System (NARMS), CVM, FDA

2:02 – 2:18 PM The Use of DNA Barcoding to Prevent Species-Specific Foodborne Illness and Detect Seafood Fraud
Jonathan Deeds, Ph.D.
Research Biologist, Office of Regulatory Science, CFSAN, FDA

2:18 – 2:35 PM Non-Targeted Screening Methods for Identification of Chemical Hazards of Public Health Concern
Tim Croley, Ph.D.
Supervisory Chemist, CFSAN, FDA

2:35 – 2:45 PM Q&A Session

2:45 – 3:45 PM Poster Sessions 3 & 4 and Break

3. Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security
4. Implement a New Prevention-Focused Food Safety System to Protect Public Health

3:45 PM End of Day 1

FDA Science Forum 2015

May 28, 2015 – Day 2

8:30 – 8:35 AM Keynote Introduction, Carol Linden, Ph.D., *Director, Office of Regulatory Science and Innovation*
https://collaboration.fda.gov/fdascienceforum2/

8:35 – 9:15 AM Cancer Genomes and the Wars Against Cancer
Bert Vogelstein, M.D.
Director, Ludwig Center at Johns Hopkins University
Investigator, Howard Hughes Medical Institute

9:15 – 10:15 AM Poster Sessions 5 & 6 and Break

5. Support New Approaches to Improve Product Manufacturing and Quality
6. Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes

10:15 – 12:00 PM **Concurrent Sessions 5 & 6**

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

Great Room Section B, https://collaboration.fda.gov/fdascienceforum2/

Session Chair: Sau (Larry) Lee, Ph.D., *Acting Associate Director for Science, Team Leader for OPQ Botanical Review Team, Office of Pharmaceutical Quality, CDER, FDA*, and Carolyn Wilson, Ph.D., *Associate Director for Research, CBER, FDA*

10:15 – 10:45 AM Framework for Chemical Characterization
Ram Sasisekharan, Ph.D.
Alfred H. Caspary Professor of Biological Engineering and Health Sciences & Technology, Koch Institute, Department of Biological Engineering, Massachusetts Institute of Technology

10:45 – 11:01 AM Screening for Counterfeit Pharmaceutical Products Using the CDx Device in Ultraviolet, Visible, and Infrared modes for Field and Laboratory Use
Nicola Ranieri
Research Biologist, Microscopy and Image Analysis, Trace Examination Section, ORA, FDA

11:01 – 11:17 AM Methods for Detection of Allergens in Food and in the Processing Environment: Approaches and Challenges
Lauren Jackson, Ph.D.
Chief, Process Engineering Branch, Division of Processing Science & Technology, Office of Food Safety, CFSAN, FDA

11:17 – 11:33 AM Advanced Analytics and Data Integration for Biomolecule Characterization

Sau (Larry) Lee, Ph.D.
Acting Associate Director for Science, Team Leader for OPQ Botanical Review Team, Office of Pharmaceutical Quality, CDER, FDA

11:33 – 11:50 AM Using NMR to Assess Structure and Comparability
Daron Freedberg, Ph.D.
Senior Scientist, CBER, FDA

11:50 – 12:00 PM Q&A Session

Concurrent Session 6: Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes
Great Room Section C, https://collaboration.fda.gov/fdascienceforum4/

Session Chair: Lisa M. LaVange, Ph.D., *Director, Office of Biostatistics, Office of Translational Sciences, CDER, FDA*

10:15 – 10:45 AM Individualized Therapy as a Practical Aspect of Patient Care
Howard L. McLeod, Pharm.D.
Medical Director, DeBartolo Family Personalized Medicine Institute and Senior Member, Department of Cancer Epidemiology, Moffitt Cancer Center

10:45 – 11:06 AM Not in Our Stars but in Ourselves: The Pharmacogenetic Determinants of Immunogenicity of Therapeutic Proteins
Zuben E. Sauna, Ph.D.
Senior Staff Fellow, CBER, FDA

11:06 – 11:28 AM Pharmacogenomics and Biomarker-Based Drug Development
Michael Pacanowski, Pharm.D., M.P.H.
Associate Director for Genomics and Targeted Therapy, Office of Clinical Pharmacology, CDER, FDA

11:28 – 11:50 AM Statistical Evaluation of “Me-Too" Companion Diagnostic Tests for Selecting Therapies
Gene Pennello, Ph.D.
Team Leader and Mathematical Statistician (Biomedical), Division of Biostatistics, CDRH, FDA

11:50 – 12:00 PM Q&A Session

12:00 – 1:00 PM Lunch

1:00 – 2:00 PM Poster Sessions 7 & 8 and Break
7. Modernize Toxicology to Enhance Product Safety
8. Harness Diverse Data through Information Sciences to Improve Health

Outcomes

2:00 – 3:45 PM **Concurrent Sessions 7 & 8**

Concurrent Session 7: Modernize Toxicology to Enhance Product Safety

Great Room Section B, https://collaboration.fda.gov/fdascienceforum2/

Session Chairs: Donna Mendrick, Ph.D., *Associate Director for Regulatory Activities, NCTR, FDA*, and James Weaver, Ph.D., *Research Pharmacologist, Office of Applied Regulatory Science, CDER, FDA*

2:00 – 2:30 PM Human Microlivers for Disease Modeling
Sangeeta Bhatia, M.D., Ph.D.
John J. and Dorothy Wilson Professor of Health Sciences and Technology and Electrical Engineering and Computer Science, Massachusetts Institute of Technology

2:30 – 2:46 PM Discovery and Analytical Validation of System Biology Translation Biomakers of Toxicity
Richard D. Beger, Ph.D.
Branch Chief, Biomarkers and Alternative Models Branch, NCTR, FDA

2:46 – 3:02 PM Nonclinical Development of Neurotoxicity Biomarkers Using In Vivo MRI
Serguei Liachenko, M.D., Ph.D.
Director of Bioimaging, NCTR, FDA

3:02 – 3:18 PM Replacing the Clinical Thorough QT Study with a Panel of In Vitro Assays and Computational Integration
Norman Stockbridge, M.D., Ph.D.
Division Director, Division of Cardiovascular and Renal Products, Office of New Drugs, CDER, FDA

3:18 – 3:35 PM Humanized Hepatic Mice: In Vivo Model to Predict Human-Specific Immunotoxicity, Drug Metabolism and Hepatotoxicity
Kristina E. Howard, D.V.M., Ph.D.
Research Veterinary Medical Officer, Division of Applied Regulatory Science, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA

3:35 – 3:45 PM Q&A Session

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

Great Room Section C, https://collaboration.fda.gov/fdascienceforum4/

Session Chairs: Eric Donaldson, Ph.D., *Clinical Virology Reviewer, Division of Antiviral Products, CDER,*

FDA, and Roger G. Perkins, MS, *Senior Advisor, Division of Bioinformatics and Biostatistics, NCTR, FDA*

2:00 – 2:30 PM Transforming Trillions of Points of Data into Diagnostics, Therapeutics, and New Insights into Disease
Atul Butte, MD, Ph.D.
Director, Institute for Computational Health Sciences and Professor of Pediatrics, University of California, San Francisco

2:30 – 3:45 PM Panel Discussion: Next Generation Sequencing Technology at FDA
Carolyn Wilson, Ph.D., *Associate Director for Research, CBER, FDA*
Hugh A. Rand, Ph.D., *Bioinformatics Team Lead, CFSAN, FDA*
Heike Sichtig, Ph.D., *Principal Investigator/Regulatory Scientist, CDRH, FDA*
Weida Tong, Ph.D., *Director, Division of Bioinformatics and Biostatistics, NCTR, FDA*

3:45 – 4:00 PM Break

4:00 – 4:15 PM Closing Remarks and Adjourn, Carol Linden, Ph.D., *Director, Office of Regulatory Science and Innovation*
https://collaboration.fda.gov/fdascienceforum2/