2023 FDA Science Forum:
Advancing Regulatory Science Through Innovation

AGENDA

Day 1

June 13, 2023

Time	Presentation	Speakers
9:00am - 9:05am	Introduction	*Sharron Watson* Office of Scientific Professional Development (OSPD), FDA
9:05am - 9:15am	Welcome	*Namandjé N. Bumpus, PhD* Chief Scientist, FDA
9:15am - 9:30am	Opening Remarks and Introduction of Keynote Speaker	*Robert M. Califf, MD* Commissioner, FDA
9:30am - 10:00am	Keynote Speaker	*Murray Lumpkin, MD* Deputy Director of Integrated Development, Bill & Melinda Gates Foundation
10:00am - 10:30am	Break	

Learning Objectives:

1. Discuss FDA contributions to the evolving science of clinical, non-clinical, and post-market evaluation.

2. Discuss how innovative approaches in evolving areas such as biomarkers, alternative methods for toxicity assessment, precision toxicology prediction, analytical chemistry, and advanced manufacturing may contribute to advances in regulatory decision-making and improve product quality and timeliness.

3. Discuss how FDA leverages social and behavioral sciences to empower patients and consumers.

4. Explain how AI and big data together can improve public health.

5. Discuss scientific advances using the One Health approach to innovative and continuous surveillance of food and cosmetic safety.

6. Discuss FDA's intramural and extramural regulatory science research to support Medical Countermeasure's (MCMs) and emerging technologies to reduce or eliminate pathogens

from medical products. The presentations will discuss the application of innovative tools and approaches to support pandemic response, development, and evaluation of MCMs and the detection of emerging agents.

7. Discuss how regenerative medicine and microbiome affect both individual and public health.

8. Describe methods that scientists at FDA are using to study and combat problems associated with substances of abuse.

Concurrent Session 1: Improving Clinical and Post-market Evaluation
Time: 10:30am - 12:30pm
Session Chairs/Moderators: Ruth Barratt, PhD, DVM
FDA Center for Drug Evaluation and Research (CDER)

Time	Presentation	Speakers
10:30am - 10:50am	Clinical Evidence and Medical Devices: Generating Actionable Evidence from the Real World	*Mary Beth Ritchey, PhD* FDA Center for Devices and Radiological Health (CDRH)
10:50am - 11:10am	CDER/CBER Real-world Evidence Program	*John Concato, MD* FDA Center for Drug Evaluation and Research (CDER)
11:10am - 11:30am	Real-world Evidence for Vaccine Effectiveness at FDA Center for Biologics Evaluation and Research	*Richard Forshee, PhD* FDA Center for Biologics Evaluation and Research (CBER)
11:30am - 12:00pm	Real-world Evidence to Provide Supportive Evidence for Evaluating the Safety and Effectiveness of Therapeutic Products	*Sebastian Schneeweiss, MD, ScD* Harvard University
12:00pm - 12:30pm	Panel Discussion and Q&A	*Sebastian Schneeweiss, MD, ScD* *Richard Forshee, PhD* *John Concato, MD* *Mary Beth Ritchey, PhD*

Concurrent Session 2: Product Development Tools and Manufacturing
Time: 10:30am - 12:30pm
Session Chair/Moderator: Suzanne Fitzpatrick, PhD
FDA Center for Food Safety and Applied Nutrition (CFSAN)

Time	Presentation	Speakers
10:30am - 11:00am	Advancing Drug Discovery with Biofabricated 3D Tissue Models	*Marc Ferrer, PhD* NIH National Center for Advancing Translational Sciences (NCATS)
11:00am - 11:15am	Advancing Translational Models and Tools into the Drug Review Process: Opportunities for Microphysiological Systems (MPS)	*Kevin Ford, PhD* FDA Center for Drug Evaluation and Research (CDER)
11:15am - 11:30am	Opportunities and Challenges in Using Liver Microphysiological Systems to Study Drug Metabolism and Hepatotoxicity	*Qiang Shi, PhD* FDA National Center for Toxicological Research (NCTR)
11:30am - 11:45am	Advanced Analytical Methods for Assessing the Efficacy of Regenerative Medicine Cellular Products	*Kyung Sung, PhD* FDA Center for Biologics Evaluation and Research (CBER)
11:45am - 12:00pm	Additive Manufacturing: A Case Study in Advanced Manufacturing of Medical Devices	*Matthew Di Prima, PhD* FDA Center for Devices and Radiological Health (CDRH)
12:00pm - 12:15pm	Enhancing Regulatory Toxicology Decision-making for Tobacco Products: The Role of Computational Toxicology Tools	*Luis Valerio Jr., PhD* FDA Center for Tobacco Products (CTP)
12:15pm - 12:30pm	Panel Discussion and Q&A	*Marc Ferrer, PhD* *Kevin Ford, PhD* *Qiang Shi, PhD* *Kyung, Sung, PhD* *Matthew Di Prima, PhD* *Luis Valerio Jr., PhD*
12:30pm - 1:30pm	Lunch	

Concurrent Session 3: Empowering Patients and Consumers
Time: 1:30pm - 3:30pm
Session Chair/Moderator: Kathryn LaRosa, MPH
FDA Center for Tobacco Products (CTP)

Time	Presentation	Speakers
1:30pm - 2:00pm	Discussion on Increasing the Diversity of Patient and Caregiver Engagement with the Center for Biologics Evaluation and Research on Food Allergy Drug Development	*Joey Mattingly, PharmD, PhD* University of Utah, College of Pharmacy
2:00pm - 2:15pm	Providing Information Needed to Make Decisions about COVID-19 Vaccines: Qualitative Testing of Educational Materials	*Alexandria Smith, MSPH* FDA Center for Drug Evaluation and Research (CDER)
2:15pm - 2:30pm	Amplifying Equity of Voices: Empowering Patients and Consumers	*Julie Hsieh, PhD* FDA Office of the Commissioner (OC), Office of Minority Health and Health Equity (OMHHE)
2:30pm - 2:45pm	FDA's Closer to Zero Initiative: What Parents Can Do to Help Protect Children from Environmental Contaminants	*Kellie Casavale, PhD* FDA Center for Food Safety and Applied Nutrition (CFSAN)
2:45pm - 3:00pm	Promoting Antimicrobial Stewardship in the Next Generation: Educational Projects Funded by the FDA's Veterinary Laboratory Investigation and Response Network	*Sarah Peloquin, DVM* FDA Center for Veterinary Medicine (CVM)
3:00pm - 3:15pm	A Patient-centered Approach Toward the Development of a Patient-reported Outcome Measure	*Fraser Bocell, PhD* FDA Center for Devices and Radiological Health (CDRH)
3:15pm - 3:30pm	Panel Discussion and Q&A	*Joey Mattingly, PharmD, PhD* *Alexandria Smith, MSPH* *Kellie Casavale, PhD* *Sarah Peloquin, DVM* *Fraser Bocell, PhD* *Kathryn LaRosa, MPH* *Christine Lee, PharmD, PhD* (OC/OMHHE)

Concurrent Session 4: Tools to Effectively Use Big Data
Time: 1:30pm - 3:30pm
Session Chair/Moderator: Hesha Duggirala, PhD (CVM)

Time	Presentation	Speakers
1:30pm - 2:00 pm	Securing Machine Endpoints in a Post-Quantum Operating Environment	**Jose L. Arrieta** **Imagineer**
2:00pm - 2:10 pm	Reimagining Regulatory Data Submissions through Fast Healthcare Interoperability Resources (FHIR)	*Jose Galvez, MD* FDA Center for Drug Evaluation and Research (CDER)
2:10pm - 2:20pm	Leveraging Large Datasets for the Development and Evaluation of New Artificial Intelligence (AI)-Enabled Medical Imaging Devices	*Frank Samuelson, PhD* FDA Center for Devices and Radiological Health (CDRH)
2:20pm - 2:30pm	Using Genomic Data and Machine Learning to Study Antimicrobial Resistance in Foodborne Pathogens	*Amy Merrill, MS* *Chih-Hao Hsu, PhD* FDA Center for Veterinary Medicine (CVM)
2:30pm - 2:40pm	Machine Learning and Case Identification in Claims Data	*Ravi Goud, MD* FDA Center for Biologics Evaluation and Research (CBER)
2:40pm - 2:50pm	Using Machine Learning to Predict Non-compliance in the Global Food Supply: Improving Risk-informed Resource Allocation and Public Health Protection	*Jeffrey Chou, MSPH* FDA Center for Food Safety and Applied Nutrition (CFSAN)
2:50pm - 3:30pm	Panel Discussion	*Steve Condrey, MPS* *Office of Regulatory Affairs (ORA)* *Joshua Xu, PhD* *FDA National Center for Toxicological Research (NCTR)* *Yu Mei, PhD* FDA Center for Tobacco Products (CTP)

End of Day 1

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Day 2

June 14, 2023

Concurrent Session 5: Food and Cosmetic Safety
Time: 9:00am - 11:00am
Session Chair/Moderator: Rajesh Nayak, PhD (NCTR)

Time	Presentation	Speakers
8:55am-9:00 am	Opening Remarks	*Rokhsareh Shahidzadeh* Office of Scientific Professional Development (OSPD), FDA
9:00am - 9:30am	International Liaison Group for Methods on Risk Assessment of Chemicals (ILMERAC): Sharing Scientific Expertise in the Area of Methodologies for Chemicals in Food with National and International Risk Assessment Agencies across the Globe	*Djien Liem, PhD* European Food Safety Authority (EFSA), Parma, Italy
9:30am - 9:45am	Progress and Needs for New Alternative Methods in CFSAN's Regulatory Mission	*Steven M. Musser, PhD* FDA Center for Food Safety and Applied Nutrition (CFSAN)
9:45am - 10:00am	Studies to Assess the Virulence of Enteric Foodborne Pathogens	*Steven Foley, PhD* FDA National Center for Toxicological Research (NCTR)
10:00am - 10:15am	An Update on NCTR and Office of Cosmetics and Colors' (OCAC) Collaborative Efforts to Support Cosmetics Safety Evaluation	*Luísa Camacho, PhD* FDA National Center for Toxicological Research (NCTR)
10:15am - 10:30am	The US National Antimicrobial Resistance Monitoring System: Helping Ensure the Efficacy of Antibiotics	*Patrick McDermott, PhD* FDA Center for Veterinary Medicine (CVM)

10:30am - 11:00am	Panel Discussion and Q&A	*Djien Liem, PhD* *Steven M. Musser, PhD* *Steven Foley, PhD* *Luísa Camacho, PhD* *Patrick McDermott, PhD*

Concurrent Session 6: Medical Countermeasures, Infectious Disease, and Pathogen Reduction Technologies
Time: 9:00am - 11:00am
Session Chairs/Moderators: Jenna Osborn, PhD (CDRH);
Monica (Burts) Young, PhD (CBER); and
Mugimane Manjanatha, PhD (NCTR)

Time	Presentation	Speakers
9:00am - 9:05am	Introduction	*Mugimane Manjanatha, PhD* FDA National Center for Toxicological Research (NCTR)
9:05am - 9:25am	Investing in the Future of Health Security	*Sandeep Patel, PhD* Biomedical Advanced Research and Development Authority (BARDA)
9:25am - 9:45am	FDA ARGOS: Where Trusted Sequence Data Meets Quality by Design Approach	*Vahan Simonyan, PhD, DSc* Embleema and George Washington University
9:45am - 10:00am	Assessing the Role of T-cell Responses in SARS-CoV-2 Protection	*Marian Major, PhD* FDA Center for Biologics Evaluation and Research (CBER)
10:00am - 10:15am	Development of Regulatory Science Tools to Accelerate Development of Medical Devices in Public Health Emergencies	*Jenna Osborn, PhD* FDA Center for Devices and Radiological Health (CDRH)
10:15am - 10:30am	Development of a Platform Approach to Model Neurotropic Viral Infections and Characterize the Therapeutics that Target Them	*Daniela Verthelyi, MD, PhD* FDA Center for Drug Evaluation and Research (CDER)
10:30am - 10:45am	Evaluation of Testicular Organoids as a Model for Zika Virus Infection	*Dayton Petibone, PhD* FDA National Center for Toxicological Research (NCTR)
10:45am - 11:00am	Panel Discussion and Q&A	*Mugimane Manjanatha, PhD* *Sandeep Patel, PhD* *Vahan Simonyan, PhD, DSc* *Marian Major, PhD* *Jenna Osborn, PhD*

		Daniela Verthelyi, MD, PhD *Dayton Petibone, PhD*
11:00am - 12:00pm	Lunch	

Concurrent Session 7: Advancing Products Based on Novel Technologies
Time: 12:00pm - 2:00pm
Session Chairs/Moderators: Julie Schneider, PhD
FDA Oncology Center of Excellence (OCE); and
Mugimane Manjanatha, PhD (NCTR)

Time	Presentation	Speakers
12:00pm - 12:30pm	Update on Personalized Cancer Vaccines	*Catherine J. Wu, MD* Dana-Farber Cancer Institute and Harvard Medical School
12:30pm - 12:45pm	Use of Next Generation Sequencing (NGS) technologies in B-cell Receptor-Based Immunome Profiling and Minimal Residual Disease (MRD) Biomarker Discovery	*Wenming Xiao, PhD* FDA Center for Drug Evaluation and Research (CDER)
12:45pm - 1:00pm	Host-Microbiome Crosstalk: Disruption of Gastrointestinal Barrier as Toxicity Assessment Tool	*Sangeeta Khare, PhD* FDA National Center for Toxicological Research (NCTR)
1:00pm - 1:15pm	Regulatory Perspectives on Advancing Regenerative Medicine Products and Emerging Technologies	*Carolyn Yong, PhD* FDA Center for Biologics Evaluation and Research (CBER)
1:15pm - 1:30pm	Dermal Drug Delivery via Dissolvable Microneedles: Formulation Variables Affecting Critical Quality Attributes (CQAs)	*Nahid Kamal, PhD* FDA Center for Drug Evaluation and Research (CDER)
1:30pm - 1:45pm	Assessment of Trabecular Bone Stiffness Using Radiomics and Deep-learning Features	*Qian Cao, PhD* FDA Center for Devices and Radiological Health (CDRH)
1:45pm - 2:00pm	Panel Discussion and Q&A	*Catherine J. Wu, MD* *Wenming Xiao, PhD* *Sangeeta Khare, PhD* *Carolyn Yong, PhD* *Nahid Kamal, PhD* *Qian Cao, PhD*

Concurrent Session 8: Substance Use, Misuse, and Addiction
Time: 12:00pm - 2:00pm
Session Chair/Moderator: Arit Harvanko, PhD
FDA Center for Tobacco Products (CTP)

Time	Presentation	Speakers
12:00pm - 12:05pm	Introduction	*Marta Sokolowska, PhD* FDA Center for Drug Evaluation and Research (CDER)
12:05pm - 12:35pm	Abuse Liability Testing with Humans: Review of Standard Methods and Recent Innovations Using Cigarettes Varying in Nicotine Content as an Exemplar	*Stephen T. Higgins, PhD* University of Vermont
12:35pm - 12:45pm	Field Deployable Analytical Toolkit for Rapid Analysis of FDA-Regulated Products at International Ports of Entry	*LT Martin M. Kimani, PhD* Office of Regulatory Affairs (ORA)
12:45pm - 12:55pm	Blunt and Non-Blunt Cannabis Use Associated with Cigarette, E-Cigarette, and Cigar Initiation: Findings from the Population Assessment of Tobacco and Health Study	*Heather L. Kimmel, PhD* NIH National Institute on Drug Abuse (NIDA)
12:55pm - 1:05pm	Leveraging Systems Modeling to Inform Policies on Opioids	*Sara Eggers, PhD* FDA Center for Drug Evaluation and Research (CDER)
1:05pm - 1:15pm	Public Health Harms from Prescription Stimulant Diversion and Nonmedical Use	*Rose Radin, PhD* FDA Center for Drug Evaluation and Research (CDER)
1:15pm - 1:25pm	Barriers to Prescribing Buprenorphine as a Medication for Opioid Use Disorder: Healthcare Providers' Practices, Perspective, and Experiences	*Matthew Walker, DrPH* FDA Center for Drug Evaluation and Research (CDER)
1:25pm - 1:35pm	Neonatal Opioid Withdrawal Syndrome: A Scientific and Regulatory Update	*An Massaro, MD* FDA Office of the Commissioner (OC)
1:35pm - 2:00pm	Panel Discussion	*Marta Sokolowska, PhD* *Stephen T. Higgins, PhD* *LT Martin M. Kimani, PhD* *Heather L. Kimmel, PhD* *Sara Eggers, PhD*

		Rose Radin, PhD *Matthew Walker, DrPH* *An Massaro, MD*

End of Day 2