Activity Outline
2021 FDA Science Forum
May 26 - 27, 2021
Virtual

Activity Coordinator:
Rokhsareh Shahidzadeh (rokhsareh.shahidzadeh@fda.hhs.gov), Sharron Watson (Sharron.Watson@fda.hhs.gov),

Description

The FDA Science Forum is held biennially to inform the public about the cutting-edge science conducted at the Agency, and to show how scientific research is used in FDA's regulatory decisions to protect and promote public health. Open the public, industry, academia, patient advocates, government agencies, and current and potential collaborators, the two-day event offers an opportunity to hear FDA scientific experts and nationally renowned scientists speak on a range of topics associated with regulatory science. Sessions for the 2021 forum will highlight areas of FDA research such as: 1) improving clinical and post-market evaluation, 2) substance use, misuse, and addiction, 3) tools to effectively use big data, 4) product development and manufacturing, and 5) medical countermeasures (MCM), infectious disease and pathogen reduction technologies.

References

- FDA's Strategic Plan for Regulatory Science. Available: https://www.fda.gov/science-research/science-and-research-special-topics/advancing-regulatory-scienc e

Learning Objectives

- Discuss the potential utility and challenges of new technologies such as microphysiological systems, microbiome, or combination of both, in advancing product development and integrating this knowledge in scientific communications with regulatory and research work.
- Discuss the application of innovative tools and approaches to support pandemic response, development and evaluation of MCMs and the detection of adventitious agents.
- Describe several types of regulatory science related to substance use, misuse, and addiction, and how it can be used to inform FDA regulatory activities.

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, and physician assistants.

Agenda
Day 1 May 26, 2021

Time	Topic	Speaker
9:00 - 9:05 AM	Introduction- Sharron Watson, Office of Scientific Professional Development (OSPD)	*Not offered for CE*
9:05 - 9:15 AM	Welcome- RADM Denise Hinton, FDA Chief Scientist	*Not offered for CE*
9:15 - 9:45 AM	Opening Remarks and Introduction of Keynote Speaker- Janet Woodcock M.D., Acting FDA Commissioner	Janet Woodcock, MD
9:45 - 10:15 AM	Keynote Speech- Anthony S. Fauci, M.D., NIAID Director, NIH	Anthony Fauci, MD
10:15 - 10:30 AM	*Break*	
10:30 - 11:05 AM	**Concurrent Session 1: Improving Clinical and Post-market Evaluation (Session Chairs/Moderator: Julie Schneider, PHD, and Steven Berman, MPH)** Between Marketing Approval and Appropriate Use of Medical Products--Time to Transform the System	Robert Califf, MD *Not offered for CE*
11:05 - 11:20 AM	Applications for surveillance: Interrogating whole-genome sequence and CAERS data	James Pettengill, PhD
11:20 - 11:35 AM	Regulatory Science/Research needs related to Digital Health	Bakul Patel, MS, MBA

11:35 - 11:50 AM	Regulatory applications and research of model-informed drug development (MIDD)	Yaning Wang, PhD
11:50 - 12:05 PM	Including non-concurrent control data in Bayesian adaptive platform trials when temporal changes exist	Min (Annie) Lin, PhD *Not offered for CE*
12:05 - 12:30 PM	Q & A / Discussion	Robert Califf, MD James Pettengill, PhD Bakul Patel, MS, MBA Yaning Wang, PhD Min (Annie) Lin, PhD *Not offered for CE*
10:30 - 11:00 AM	**Concurrent Session 2: Tools to Effectively Use Big Data Moderator: Donna Mendrick, PhD** Democratizing Screening & Diagnostics with AI	Lily Peng, MD, PhD *Not offered for CE*
11:00 - 11:15 AM	Developing a Deep Learning MedDRA encoder (MedDRA-DeepCoder) for Patient Narratives	QAIS HATIM, PhD
11:15 - 11:30 AM	CBER BEST: Leveraging AI to build an automated adverse events reporting system	Hussein Ezzeldin, PhD
11:30 - 11:45 AM	BE ASSESSMENT MATE (BEAM) - A Data Analytics Tool to Enhance Efficiency, Quality, and Consistency of Bioequivalence Assessment	MENG HU, PhD
11:45 - 12:00 PM	Trade-off between explainability and predictivity in toxicity assessment with AI	Leihong Wu, PhD
12:00 - 12:15 PM	Use of machine learning to improve food safety quantitative microbial risk assessment	Hao Pang, PhD
12:15 - 12:30 PM	Role of AI in Medical Imaging	Berkman Sahiner, PhD
12:30 - 1:30 PM	*Lunch*	
1:30 - 1:40 PM	**Concurrent Session 3: Empowering Patients and Consumers Session Chairs/Moderator: Christine Lee, PharmD, PhD/Andrea Furia-Helms, MPH** Introduction- Andrea Furia Helms	Andrea Furia-Helms, MPH
1:40 - 1:55 PM	Listening Sessions to Uncover Patient Questions: The COVID-19 Vaccine Confidence Project	Susan Winckler, JD, R. Ph
1:55 - 2:05 PM	Understanding Perceptions and Attitudes about COVID-19 Testing in Underrepresented Populations	Jessica Weinberg, MPP
2:05 - 2:15 PM	COVID-19 and tobacco use: The latest from the Population Assessment of Tobacco and Health Study	Yu-Ching Cheng, PhD
2:15 - 2:25 PM	Impact of COVID-19 on FDA Orphan Products Grants	Christine Mueller
2:25 - 2:35 PM	COVID-19 Pandemic: Adjustments to Ongoing Clinical Trials	Wilson Bryan
2:35 - 2:45 PM	FDALabel – a FDA Product Labeling Tool Enabling Patients and Consumers Safety in Combating COVID-19	Hong Fang, PhD
2:45 - 2:55 PM	Patient Focus Groups to Enhance Communications Addressing Biosimilar Drug Products	Brian Lappin, MA
2:55 - 3:05 PM	2019 FDA Food Safety and Nutrition Survey – Making Food Safety and Nutrition Accessible to Public Health Professionals	Amy Lando, MPP

3:05 - 3:15 PM	Addressing Demographic Subgroup Underrepresentation in Oncology	Lola Fashoyin-Aje, MD, MPH
3:15 - 3:25 PM	Advancing Health Equity through Outreach and Communications	Jovonni Spinner
3:25 - 3:30 PM	Closing Remarks / Discussion- Christine Lee	Christine Lee, PhD, PharmD
1:30 - 2:00 PM	**Concurrent Session 4: Product Development and Manufacturing Session Chairs/Moderator: Suzanne Fitzpatrick, PhD** 21st Century Solutions for 21st Century Problems	Geoffrey Ling *Not offered for CE*
2:00 - 2:15 PM	MALDI Imaging Mass Spectrometry: A New Imaging Modality for Use in Toxicological Studies	Elizabeth Jones, PhD
2:15 - 2:30 PM	Advancing New Alternative Methodologies at FDA: The Expanded Decision Tree	Szabina Stice, PhD
2:30 - 2:45 PM	ISTAND: A pilot program to address novel technologies as Drug Development Tools (DDTs)"	Christopher Leptak, MD, PhD
2:45 - 3:00 PM	Medical Device Cybersecurity	Kevin Fu, PhD
3:00 - 3:15 PM	FDA's Advanced Manufacturing Journey	Sau Lee, PhD
3:15 - 3:30 PM	Understanding Ex vivo manufacturing of HSC-based therapeutics	pankaj mandal, PhD

Day 2 May 27, 2021

Time	Topic	Speaker
8:55 - 9:00 AM	Opening Remarks- Rokhsareh Shahidzadeh, Office of Scientific Professional Development (OSPD)	*Not offered for CE*
9:00 - 9:05 AM	**Concurrent Session 5: Advancing Products Based on Novel Technologies Session Chair / Moderator: Beverly Lyn-Cook, PhD/Silvia Pineiro, PhD** Introduction- Silvia Pineiro, PhD	Silvia Pineiro, PhD
9:05 - 9:30 AM	Overcoming challenges in co-culture of super strict anaerobes with a healthy human colon mucosal barrier	Linda Griffith, PhD
9:30 - 9:40 AM	Advancing Regulatory Science Through Organ on a Chip	Daniel Tadesse, PhD, DVM
9:40 - 9:50 AM	Microbiome as an additional criterion for safety assessment	Sangeeta Khare, PhD
9:50 - 10:05 AM	Emergence of nosocomial associated opportunistic pathogens in the gut microbiome after antibiotic treatment revealed by a mouse model metagenome analysis	Zhihua Li, PhD
10:05 - 10:15 AM	Safety and Effectiveness of Fecal Microbiota Transplantation Products	Paul Carlson, PhD
10:15 - 10:30 AM	Microphysiological Systems Regulatory Research Considerations: Evaluation of a model system	Kirsten Eckstrum, PhD
10:30 - 10:40 AM	Evaluation of endothelial cell responses to nanomaterials using a dynamic flow model	Shelby Skoog
10:40 - 10:50 AM	Microphysiological Systems to assess the functional capacity of regenerative medicine cellular products	Kyung Sung
10:50 - 11:00 AM	Closing Remarks/ Discussion- Beverly Lyn-Cook	Beverly Lyn-Cook, PhD

9:00 - 9:05 AM	**Concurrent Session 6: MCM, Infectious Disease and Pathogen Reduction Technologies Session Chairs/Moderator: Monica Young, PhD, CAPT Tracy MacGill, PhD Moderator: Carol Weiss, MD, PhD**Introduction- Carol Weiss, MD, PhD	Carol Weiss, M.D., Ph.D.
9:05 - 9:30 AM	Outbreak Preemption and Response in the Genomic and Information Age	Pardis Sabeti *Not offered for CE*
9:30 - 9:45 AM	Evaluation of Pathogenesis of SARS-CoV-2 Variants	Tony Wang, PhD
9:45 - 10:00 AM	Artificial Intelligence-powered Drug Repurposing against COVID-19	Zhichao Liu, PhD
10:00 - 10:15 AM	Device Medical Countermeasure Activities During the COVID-19 Pandemic	Heather Agler, PhD
10:15 - 10:30 AM	Emerging technologies for adventitious agent detection and their application to CDER products	Kathryn King, PhD
10:30 - 10:45 AM	ORA's work in support of Medical Countermeasures	ELIZABETH MILLER, PharmD
10:45 - 10:55 AM	Panel Discussion/Q&A	Pardis Sabeti Tony Wang, PhD Zhichao Liu, PhD Heather Agler, PhD Kathryn King, PhD ELIZABETH MILLER, PharmD *Not offered for CE*
10:55 - 11:00 AM	Closing Remarks	Carol Weiss, M.D., Ph.D.
11:00 - 12:00 PM	*Lunch*	
12:00 - 12:05 PM	**Concurrent Session 7: Food and Cosmetic Safety: The Role of Innovation and Technology Session Chairs/Moderators: Chad Nelson, MSPH, PhD, Jeffrey Ward, DVM, Zhichao Lin, PhD**Introduction- Chad Nelson, M.S.P.H., PhD	Chad Nelson, PhD
12:05 - 12:35 PM	One Health as a Collaborative Response to Food Safety Risks	Kali Kniel, PhD
12:35 - 12:50 PM	CFSAN's Use of Innovative Science to Address Current and Emerging Public Health Priorities	Susan Mayne, PhD, F.A.C.E.
12:50 - 1:05 PM	FDA Support of Recent Foodborne Illness Outbreak Investigations	Daniel Rice, DrPH
1:05 - 1:20 PM	What Won't an Animal Eat? Innovation in Animal Diets	David Edwards, PhD
1:20 - 1:35 PM	Mind the [Data] Gap: Contributions of FDA's NCTR to Evaluate Cosmetics Safety	Luisa Camacho, PhD
1:35 - 2:00 PM	Panel Discussion/ Q&A- Moderator: Jeffrey Ward, et al.	Kali Kniel, PhD Susan Mayne, PhD, F.A.C.E. Daniel Rice, DrPH Luisa Camacho, PhD Chad Nelson, PhD Jeffrey Ward, DVM, MS, PhD
12:00 - 12:05 PM	**Concurrent Session 8: Substance Use, Misuse, and Addiction Session Chair/Moderator: Marta Sokolowska, PhD** Introduction- Marta Sokolowska, PhD	Marta Sokolowska, PhD

12:05 - 12:35 PM	Substance use disorders linked to COVID-19 susceptibility	Nora Volkow, MD
12:35 - 12:50 PM	COVID-19 and the Opioid Crisis: A Social Media Perspective	Jill Settle, PhD
12:50 - 1:05 PM	And the Kids Vaped on: Teens, Tobacco, and the National Youth Tobacco Survey	Karen Cullen, PhD, MPH
1:05 - 1:20 PM	Investigation of Opioid Exposure and Neural Tube Defects – In Vivo and In Vitro Approaches	Amy Inselman, PhD
1:20 - 1:35 PM	Tobacco and Cannabis – Did EVALI teach us anything?	Priscilla Callahan-Lyon, MD
1:35 - 2:00 PM	Panel Discussion/Q&A - Moderator: Marta Sokolowska, PhD, et al.	Nora Volkow, MD Jill Settle, PhD Karen Cullen, PhD, MPH Amy Inselman, PhD Priscilla Callahan-Lyon, MD Marta Sokolowska, PhD

Continuing Education Accreditation

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In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 9 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 9.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-21-062-L04-P, and ACPE Universal Activity Number JA0002895-0000-21-062-L04-T for 9.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 9.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Agler, Heather, PhD, Senior Program Manager, Center for Devices and Radiological Health *nothing to disclose*
- Bryan, Wilson *nothing to disclose*
- Califf, Robert, MD, Head of Clinical Policy and Strategy, Verily / Google Health *I received Salary from Verily Life Sciences / Google Health for a role as Employee. I received Stocks from Cytokinetics for a role as Board Member.*
- Callahan-Lyon, Priscilla, MD, Senior Science Advisor, Office of the Center Director, CTP, FDA Center for Tobacco Products*nothing to disclose*
- Camacho, Luisa, PhD, Senior Staff Fellow, FDA/NCTR *nothing to disclose*
- Carlson, Paul, PhD, Biologist/Principal Investigator, FDA/CBER *nothing to disclose*
- Cheng, Yu-Ching, PhD, Lead Health Scientist, FDA Center for Tobacco Products *nothing to disclose*
- Cullen, Karen, PhD, MPH, Supervisory Epidemiologist, FDA/CTP *nothing to disclose*
- Eckstrum, Kirsten, PhD, Research Biologist, Food and Drug Administration *nothing to disclose*
- Edwards, David, PhD, Director, FDA CVM OSC DAF *nothing to disclose*
- Ezzeldin, Hussein, PhD, Senior Staff Fellow, U.S. Food and Drug Administration *nothing to disclose*
- Fang, Hong, PhD, Health Informatics Scientist, FDA/NCTR *nothing to disclose*
- Fashoyin-Aje, Lola, MD, MPH, Deputy Division Director, FDA/CDER/OND/OOD/DOIII *nothing to disclose*
- Fauci, Anthony, MD, Director, NIH *nothing to disclose*
- Fu, Kevin, PhD, Acting Director, Medical Device Cybersecurity, FDA CDRH, FDA CDRH *I received Salary from 626 Holdings, LLC for a role as Consultant. I received Stocks from Virta Labs, Inc for a role as Stockholder. I received Salary from Univ. Michigan for a role as Employee. I received Salary from Robins Kaplan LLC for a role as Consultant. I received Research grant paid to employer/institution from National Science Foundation for a role as Other - Grant PI at Univ. Michigan.*
- Furia-Helms, Andrea, MPH, Director, Office of Patient Affairs, FDA *nothing to disclose*
- Griffith, Linda, PhD, Professor of Biological and Mechanical Engineering, Massachusetts Institute of Technology *I received Stocks from Lumicell, Inc for a role as Board Member.*
- HATIM, QAIS, PhD, Computer Scientist/Statistician, FDA *nothing to disclose*
- HU, MENG, PhD, Staff Fellow, CDER\OGD\ORS\DQMM *nothing to disclose*
- Inselman, Amy, PhD, Research Biologist, National Center for Toxicological Research *nothing to disclose*
- Jones, Elizabeth, PhD, Staff Fellow, National Center For Toxicological Research *nothing to disclose*
- Khare, Sangeeta, PhD, Research Microbiologist, US FDA *nothing to disclose*
- King, Kathryn, PhD, Staff Scientist/Product Quality Reviewer, FDA CDER OPQ Office of Biotechnology Products*nothing to disclose*
- Kniel, Kali, PhD, Professor, University of Delaware *nothing to disclose*
- Lando, Amy, MPP, Social Scientist, CFSAN/FDA *nothing to disclose*
- Lappin, Brian, MA, Social Science Analyst, CDER/OCOMM *nothing to disclose*
- Lee, Christine, PhD, PharmD, General Health Scientist, FDA *nothing to disclose*
- Lee, Sau, PhD, Deputy Director of Science, OPQ/CDER *nothing to disclose*
- Leptak, Christopher, MD, PhD, Director, CDER Biomarker Qualification Program, FDA/CDER/OND/OND IO *nothing to disclose*
- Li, Zhihua, PhD, Biologist, FDA *nothing to disclose*
- Lin, Min (Annie), PhD, Statistical Science Director, AstraZeneca *I received Salary from AstraZeneca for a role as Employee.*
- Ling, Geoffrey *I received Salary from CEO, On Demand Pharmaceuticals for a role as Employee. I received Stocks from Predigen for a role as Board Member. I received Stocks from NED Biosystems for a role as Board Member. I received Stocks from Catalyst Biosciences for a role as Board Member. I received Stocks from AutoMedx for a role as Other - Shareholder.*
- Liu, Zhichao, PhD, principal investigator, NCTR *nothing to disclose May reference off-label use.*
- Lyn-Cook, Beverly, PhD, Research Biologist, National Center for Toxicological Research *nothing to disclose*
- MILLER, ELIZABETH, PharmD, Assistant Commissioner Medical Products & Tobacco Operations, Office of Regulatory Affairs*nothing to disclose*
- Mayne, Susan, PhD, F.A.C.E., Director, Center for Food Safety and Applied Nutrition, FDA *nothing to disclose*
- Mueller, Christine, Medical Officer, FDA Office of Orphan Products Development *nothing to disclose*
- Nelson, Chad, PhD, Toxicologist, FDA/CFSAN *nothing to disclose*
- Pang, Hao, PhD, Biologist, Food and Drug Administration *nothing to disclose*
- Patel, Bakul, MS, MBA, Director, Digital Health, Center for Devices and Radiological health *nothing to disclose*

- Peng, Lily, MD, PhD, Product Manager, Google *I received Salary from Google for a role as Employee. I received Stocks from Google for a role as Employee.*
- Pettengill, James, PhD, Geneticist, US FDA *nothing to disclose*
- Pineiro, Silvia, PhD, Senior Scientist, FDA *nothing to disclose*
- Rice, Daniel, DrPH, Associate Director, FDA ORA Office of Regulatory Science *nothing to disclose*
- Sabeti, Pardis, Professor, Harvard University *I received Stocks from Danaher Corporation for a role as Board Member. I received Stocks from NextGenJane for a role as Other - Former SAB member, investor. I received Stocks from Sherlock Biosciences for a role as Other - Co-founder and consultant. I received Stocks from TruGenomix for a role as Other - Investor.*
- Sahiner, Berkman, PhD, Senior Biomedical Research Scientist, FDA/CDRH/OSEL/DIDSR *nothing to disclose*
- Settle, Jill, PhD, Social Scientist, FDA *nothing to disclose*
- Skoog, Shelby, Staff Fellow, US FDA *nothing to disclose*
- Sokolowska, Marta, PhD, Associate Director for Controlled Substances, FDA *nothing to disclose*
- Spinner, Jovonni, Senior Public Health Advisor, FDA/OC/OMH *nothing to disclose*
- Stice, Szabina, PhD, Toxicologist, FDA *nothing to disclose*
- Sung, Kyung, Principal Investigator, Division of Cellular and Gene Therapies, Office of Tissues and Advanced Therapies*nothing to disclose*
- Tadesse, Daniel, PhD, DVM, Research Microbiologist, FDA *nothing to disclose*
- Volkow, Nora, MD, Director, National Institute on Drug Abuse *nothing to disclose*
- Wang, Tony, PhD, Principal Investigator, CBER/FDA *nothing to disclose*
- Wang, Yaning, PhD, Director, Division of Pharmacometrics, OCP/OTS/CDER/FDA *nothing to disclose*
- Ward, Jeffrey, DVM, MS, PhD, Senior Science Advisor, FDA/CVM/OCD *nothing to disclose*
- Weinberg, Jessica, MPP, Social Science Analyst, FDA/CDRH/PSE *nothing to disclose*
- Weiss, Carol, M.D., Ph.D. *nothing to disclose*
- Winckler, Susan, JD, R. Ph, CEO, Reagan-Udall Foundation for the FDA *I received Salary from Clients of Leavitt Partners for a role as Consultant. I received Salary from Supporters of the Reagan-Udall Foundation for the FDA for a role as Employee. I received Honorarium from Leavitt Equity Partners Management for a role as Other - Board observer for SCA Pharmaceuticals (a 503B outsourcing facility). I received Honorarium from Leavitt Equity Partners Management for a role as Other - Board Observer for PAI Pharmaceuticals.*
- Woodcock, Janet, MD, Acting Commissioner of Food and Drugs, FDA *nothing to disclose*
- Wu, Leihong, PhD, Visiting Scientist, FDA/NCTR *nothing to disclose*
- mandal, pankaj, PhD, Senior Staff Fellow, FDA *My spouse received Salary from Hansoh Bio for a role as Employee. My spouse received Stocks from Sanofi for a role as Employee.*

Planning Committee

- Shahidzadeh, Rokhsareh, RN, MSN, Senior Regulatory Health Education Specialist, FDA *nothing to disclose*
- South, Erin, PharmD, Pharmacist, FDA *My spouse and I received Salary from CVS Health for a role as Employee. My spouse received Stocks from CVS Health for a role as Employee. My spouse received Salary from CVS Health for a role as Employee.*
- Watkins-Bryant, Theresa, MD, Medical Officer, FDA/CTP/OS/DIHS/MEDICAL *nothing to disclose*

CE Consultation and Accreditation Team

- Bryant, Traci, M.A.T., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
There are no imposed requirements.