

FDA-MCERSI Workshop on Application of Artificial Intelligence and Machine Learning for Precision Medicine

Virtual Public Workshop

February 17, 2023

10:00 AM-4:15 PM Eastern Time

Organizing Committee

Qi Liu, PhD	OCP, OTS, CDER, FDA
Kunal Naik, PharmD	OCP, OTS, CDER, FDA
Neha Mehta, MS	OCP, OTS, CDER, FDA
Joga Gobburu, PhD, MBA	University of Maryland, School of Pharmacy

WORKSHOP AGENDA:

10:00 AM – 10:05 AM	Welcome Session (Meeting Logistics and Housekeeping) Qi Liu, PhD, MStat, FCP Associate Director for Innovation and Partnership, OCP, OTS, CDER, FDA Joga Gobburu, PhD Professor, School of Pharmacy and School of Medicine, Director of Center for Translation Medicine, University of Maryland Kunal Naik, PharmD Pharmacist, OCP, OTS, CDER, FDA
10:05 AM – 10:30 AM	Keynote Speaker Interview Eric Topol, MD Founder and Director, Scripps Research Translational Institute, Professor Molecular Medicine, Executive Vice-President, Scripps Research

SESSION 1: Background and Current Landscape

Moderator: Joga Gobburu, PhD Professor, School of Pharmacy and School of Medicine, Director of Center for Translation Medicine, University of Maryland

10:30 AM – 10:45 AM	Advancements of Differentiable Simulation for Scientific Machine Learning & AI Alan Edelman, PhD Professor of Applied Mathematics, Computer Science & AI Laboratory, MIT, Chief Scientist, JuliaHub Inc.
10:45 AM – 11:00 AM	AI-Partnered Dynamical Model Discovery for Precision Medicine James Lu, PhD Distinguished AI Scientist, Clinical Pharmacology, Genentech
11:00 AM – 11:15 AM	AI/ML-Enabled Drug-Disease Modeling Nadia Terranova, PhD Head of Advanced Data Analytics, Quantitative Pharmacology, Merck KGaA, Darmstadt
11:15 AM – 11:30 AM	Accelerated Drug Development and Precision Pharmacotherapy using DeepPumas Niklas Korsbo, PhD Lead Developer and Scientist, DeepPumas
11:30 AM – 11:45 AM	ScreenMCM: A Machine Learning Based-Product Screening Tool to Accelerate Medical Countermeasure Development Rahul Goyal, MS Pharmaceutical Sciences PhD Student, Center for Translational Medicine, University of Maryland School of Pharmacy
11:45 AM – 12:10 PM	Application of Artificial Intelligence and Machine Learning in Drug Development and Precision Medicine Hao Zhu, PhD, MStat Director, Pharmacometrics Division, OCP, OTS, CDER, FDA
12:10 PM – 1:00 PM	Lunch Break

1:00 PM – 1:35 PM	Session 1 Panel Discussion	
Moderator:	Joga Gobburu, PhD	Professor, School of Pharmacy and School of Medicine, Director, Center for Translational Medicine, University of Maryland
Panelists:	Alan Edelman, PhD	Professor of Applied Mathematics, Computer Science & AI Laboratory, MIT, Chief Scientist, JuliaHub Inc.
	James Lu, PhD	Distinguished AI Scientist, Clinical Pharmacology, Genentech
	Nadia Terranova, PhD	Head of Advanced Data Analytics, Quantitative Pharmacology, Merck KGaA, Darmstadt
	Niklas Korsbo, PhD	Lead Developer and Scientist, DeepPumas
	Rahul Goyal, MS	Pharmaceutical Sciences PhD Student, Center for Translational Medicine, University of Maryland School of Pharmacy
	Hao Zhu, PhD, MStat	Director of the Pharmacometrics Division, OCP, OTS, CDER, FDA

SESSION 2: Challenges and Future Direction

	Moderator: Qi Liu, PhD, MStat, FCP	Associate Director for Innovation and Partnership, OCP, OTS, CDER, FDA
1:35 PM – 1:55 PM	Precision Medicine 2030	
	Mike Pacanowski, PharmD, MPH	Director, Translational and Precision Medicine Division, OCP, OTS, CDER, FDA
1:55 PM – 2:15 PM	Challenges in AI/ML for Health: Bias, Generalizability, Privacy	
	Luca Foschini, PhD	President and CEO, Sage Bionetworks
2:15 PM – 2:35 PM	NIST AI Risk Management Framework	
	Elham Tabassi	Senior Research Scientist, NIST
2:35 PM – 2:55 PM	Federated Learning	
	Joseph Lehar, PhD	Senior Vice President of Strategy, Owkin
2:55 PM – 3:15 PM	Regulatory Considerations for the Use of AI in Drug Development	
	Tala Fakhouri, BSc, PhD, MPH	Associate Director for Policy Analysis, OMP, CDER, FDA
3:15 PM – 3:30 PM	Coffee Break	
3:30 PM – 4:05 PM	Session 2 Panel Discussion	
Moderator:	Qi Liu, PhD, MStat, FCP	Associate Director for Innovation and Partnership, OCP, OTS, CDER, FDA
Panelists:	Paul Schuette, PhD	Scientific Computing Coordinator, OB, CDER, FDA
	Matthew Diamond, MD, PhD	Chief Medical Officer for Digital Health Center of Excellence, CDRH, CDER, FDA
	Mike Pacanowski, PharmD, MPH	Director, Translational and Precision Medicine Division, OCP, OTS, CDER, FDA
	Luca Foschini, PhD	President and CEO, Sage Bionetworks
	Elham Tabassi	Senior Research Scientist, NIST
	Joseph Lehar, PhD	Senior Vice President of Strategy, Owkin
	Tala Fakhouri, BSc, PhD, MPH	Associate Director for Policy Analysis, OMP, CDER, FDA
4:05 PM – 4:15 PM	Closing Remarks	
	Joga Gobburu, PhD	Professor, School of Pharmacy and School of Medicine, Director of Center for Translation Medicine, University of Maryland