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, PhD — 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 — *Introduction of AI/ML*
Alan Edelman, PhD — Professor of Applied Mathematics, Computer Science & AI Laboratory, MIT, Chief Scientist, JuliaHub Inc.

10:45 AM – 11:00 AM — *Case Study 1A Presentation*
James Lu, PhD — Distinguished AI Scientist, Clinical Pharmacology, Genentech

11:00 AM – 11:15 AM — *Case Study 1B Presentation*
Nadia Terranova, PhD — Head of Advanced Data Analytics, Quantitative Pharmacology, Merck KGaA, Darmstadt

11:15 AM – 11:30 AM — *Case Study 1C Presentation*
Niklas Korsbo, PhD — Lead Developer and Scientist, DeepPumas

11:30 AM – 11:45 AM — *Case Study 1D Presentation*
Rahul Goyal, MS — Pharmaceutical Sciences PhD Student, Center for Translational Medicine, University of Maryland School of Pharmacy

11:45 AM – 12:10 PM — *FDA Landscape Analysis*
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	*AI/ML Challenges: Bias, Generalizability, Opacity*	
	Luca Foschini, PhD	President and CEO, Sage Bionetworks
2:15 PM – 2:35 PM	*Trustworthy AI*	
	Elham Tabassi, PhD	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 Application of AI/ML*	
	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, PhD	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