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

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**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