# 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

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### Organizing Committee

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| 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 |

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## 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** | |
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| *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 |
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| 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 |