Hybrid Public Workshop 2025:
Artificial Intelligence in Drug & Biological Product Development

Be a part of a dynamic conversation as leading experts dive into the rapidly evolving role of AI in transforming drug and biological product development — spotlighting the evolving role of AI in advancing the safety, efficacy, and quality of drug and biological product development.

Workshop Agenda
October 7, 2025
9:00 AM – 5:00 PM (EDT)

9:00 a.m.	**Welcome and Opening Remarks**
9:00 a.m.	Welcome and Opening Remarks **Morgan Hanger**, *Executive Director, Clinical Trials Transformation Initiative (CTTI)*
9:05 a.m.	Keynote Speakers **Shantanu Nundy,** *Advisor on Artificial Intelligence (contractor), Office of the Commissioner, FDA* AND **M. Khair ElZarrad,** *Director, Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), FDA*
9:15 a.m.	*Update: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products* Presenter: **Gabriel Innes,** *Assistant Director for Data Science and AI Policy, OMP, CDER, FDA*
9:30 a.m.	**Session 1: Where Are We Now?**

	Session Objective: Delve into recent accomplishments in AI and explore the integration of multi-disciplinary expertise in AI model development for drug and biological product programs moving forward. **Moderator:** **M. Khair ElZarrad,** *Director, OMP, CDER, FDA* **Presenters**: **Greg Meyers**, *Executive vice president and chief digital and technology officer, BMS* **Thomas Osborne,** *Chief Medical Officer, Microsoft Federal* **Dana Lewis,** *Independent researcher, Developer, and Founder of OpenAPS*
10:40 a.m.	**BREAK**
10:55 a.m.	**Session 2: Data Quality, Reliability, Representativeness, and Access in AI-Driven Drug Development**
	Session Objective: Explore use cases and strategies related to data reliability, quality, representativeness, and access within the drug development life cycle. **Moderators**: **Hussein Ezzeldin,** *Associate Director for Advanced Technologies, OBPV, CBER, FDA* **Lanyan (Lucy) Fang,** *Supervisory Pharmacologist, OGD, FDA* **Presenters**: **Wesley Anderson**, *Quantitative Medicine Scientist, The Critical Path Institute* **Michelle Longmire**, *Co-Founder and Chief Executive Officer, Medable, Inc.* **Sheraz Khan,** *Senior Director, Generative AI, Pfizer*
12:05 p.m.	**LUNCH**
1:35 p.m.	**Session 3: Model Performance, Explainability, Transparency, and Interpretability in AI-Driven Drug Development**
	Session Objective: An overview of illustrative use cases that highlight topics including AI model performance, explainability, transparency, and interpretability across the drug development life cycles. **Moderators**: **Hao Zhu,** *Director, Division of Pharmacometrics, OTS/OCP/DPM* **Nicole Mahoney**, *Executive Director, Regulatory Policy, and Global Regulatory Policy Lead, Data and Digital Technologies, Novartis* **Presenters**: **Prasanna Rao**, *Chief Products and Innovation Officer, Saama* **Andrea Downing,** *President and Co-Founder, The Light Collective* **Oanh Dang,** *Office of Surveillance and Epidemiology, CDER, FDA*

2:45 p.m.	**BREAK**
3:00 p.m.	**Session 4: Navigating the Future of AI in Drug Development**
	Session Objective: Potential strategies, collaborations, and considerable next steps for academia, industry, patient advocacy groups, regulatory agencies, and other interested parties. **Moderators**: **Gabriel Innes,** *Assistant Director for Data Science and AI Policy, OMP, CDER, FDA* **Rebecca Nebel,** *Senior Director of Science and Regulatory Advocacy, PhRMA* **Presenters**: **Jon Walsh**, *Founder & Chief Scientific Officer, Unlearn.AI* **Jessilyn Dunn**, *Assistant Professor of Biomedical Engineering, Duke University* **Ryan Hoshi,** *Director of Regulatory Policy and Intelligence, AbbVie*
4:15 p.m.	**Discussion**
	Moderator: **Anindita Saha,** *Associate Director for Data Science and Artificial Intelligence Policy (acting), OMP, CDER, FDA* **Discussants:** **Qi Liu**, *Associate Director for Innovation & Partnership in the Office of Clinical Pharmacology (OCP)/ Office of Translational Sciences, CDER, FDA* **Shantanu Nundy,** *Advisor on Artificial Intelligence (contractor), Office of the Commissioner, FDA*
4:45 p.m.	**Concluding Remarks**
	Qi Liu, *Associate Director for Innovation and Partnership, OCP, FDA*
5:00 p.m.	**Adjourn Workshop**