

# ASA-NJ Webinar Series



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## The Next Chapter of Biometrics: AI and Regulatory Readiness

 Friday, March 20, 2026

 11:00 AM – 1:00 PM ET

 Live Zoom Webinar - Free to register

ASA NJ × HopeAI

🕒 11:00am - 11:30am ET

Keynote 1

## The Application of AI in Drug Development and Regulation



**Ruihao Huang**  
AI Review Lead, FDA

🕒 11:30am - 12:00pm ET

Keynote 2

## The Role of Statisticians in the Era of AI



**Will Ma**  
Founder & CEO, HopeAI

🕒 12:00pm - 1:00pm ET

Panel

## What to Expect in 2026 for AI in Clinical Development

👥 PANELISTS



**Ram Tiwari**  
Former Biostat Director  
FDA



**Ellie Xiong**  
Founder, TorchMedtech  
Former Reviewer, FDA



**Hiroshi Tamada**  
Chief Medical Officer  
Remiges Ventures



**Ruihao Huang**  
AI Review Lead, FDA



**Will Ma**  
Founder & CEO, HopeAI

👥 FACILITATOR



**Xiaomai Zhang**  
Chief Marketing Officer, HopeAI

## Speakers Bio



### Ruihao Huang

AI Review Lead, FDA

Dr. Ruihao Huang serves as the AI Review Lead in the Innovation and Partnership Program at the U.S. FDA's Center for Drug Evaluation and Research (CDER), Office of Clinical Pharmacology. He is also a member of the CDER AI Review Rapid Response (R3) Team, providing technical expertise on the use of AI across the drug development lifecycle.

Dr. Huang has extensive experience reviewing AI/ML applications in regulatory submissions, including Investigational New Drugs (INDs), Drug Development Tools (DDTs), and Emergency Use Authorizations (EUAs). He notably developed an AI/ML algorithm during the Anakinra review to identify the appropriate treatment population—marking the first FDA regulatory decision supported by AI/ML for patient selection.

He has also contributed to FDA guidance on AI in drug development and received the 2024 FDA Scientific Achievement Award for Excellence in Data and Computational Science.



### Will Ma

Founder & CEO, HopeAI

Will Ma is the founder and CEO of HopeAI, a Mayo Clinic Platform\_Accelerate company on a mission to bring hope to patients through AI-accelerated clinical development. HopeAI has developed AI teammates that combine clinical insights with statistical innovations, enabling faster and more precise clinical trials.

Prior to founding HopeAI, Will had over 10 years of experience in clinical development, including working as a statistician at Sanofi and BMS, and serving as a faculty member at Moffitt Cancer Center. Will is also a serial entrepreneur who co-founded Learnta, an AI learning company, and grew it to over 1,600 learning centers.

## Speakers Bio



### Ram Tiwari

Former Biostat Director, FDA

Dr. Ram C. Tiwari, PhD, FASA, is a globally recognized leader in biostatistics and regulatory science with decades of experience shaping statistical methodologies used in drug development and regulatory decision-making. He previously served as Director of the Division of Biostatistics at the U.S. Food and Drug Administration (FDA), where he led statistical review and methodological innovation across numerous drug and biologics submissions.

Dr. Tiwari later served as head of statistical methods at Bristol Myers Squibb, where he advanced cutting-edge statistical approaches for clinical development and benefit-risk evaluation.

An expert in Bayesian methods and adaptive trial designs, his research has significantly influenced modern frameworks for benefit-risk assessment and clinical evidence evaluation. Dr. Tiwari is a Fellow of the American Statistical Association (FASA) and has received multiple awards from the FDA, NIH, and NCI for his contributions to statistical science and public health research.



### Ellie Xiong

Founder, TorchMedtech | Former Reviewer, FDA

Ellie Xiong is a former FDA reviewer who contributed to regulatory guidance and regulatory science tools for AI-based Software as a Medical Device (SaMD) in FDA. She founded TorchMedtech, a regulatory consulting firm that helps global medical technology companies navigate FDA pathways and bring innovative devices to the U.S. market.

Ellie graduated from Columbia University and Harvard Medical School.

## Speakers Bio



### Hiroshi Tamada

Chief Medical Officer, Remiges Ventures

Hiroshi Tamada, M.D., Ph.D., MPH is a physician-scientist and biotechnology executive with deep expertise in translational drug development and clinical strategy. He currently serves as Chief Medical Officer at Remiges Ventures / RDiscovery, supporting early- and mid-stage biotech companies across oncology, immunology, and advanced therapeutic platforms.

Previously, Dr. Tamada held roles at Pfizer, Merck, and Bristol Myers Squibb, contributing to clinical development and medical affairs across multiple therapeutic areas. Trained as a cardiologist, he has worked across academia and industry on innovative therapeutic approaches, including precision medicine and cell-based therapies.

Dr. Tamada holds an M.D. and Ph.D. from Jichi Medical University and an MPH from Johns Hopkins University.



### Xiaomai Zhang

Chief Marketing Officer, HopeAI

Xiaomai Zhang is the Chief Marketing Officer at HopeAI. At HopeAI, Xiaomai leads brand strategy, industry partnerships, and ecosystem development across the AI and life sciences communities.

Prior to joining HopeAI, Xiaomai began her career in media as an award-winning journalist and documentary director. She later built and monetized a digital platform with over 100,000 followers and scaled a 200+ creator network, operating at the forefront of the early creator economy and social commerce landscape.

Her career has since spanned consumer platforms, cross-border digital commerce, and public-sector research strategy, giving her hands-on experience across 2C, 2B, and 2G markets.