

2026 UMBC-Stanford Workshop on Clinical Trials and Regulatory Science

*From Statistical Rigor to AI-enabled
Decision-making*

University of Maryland Baltimore County (UMBC)
September 18-19, 2026

UMBC, (Sat at ITE Building, 104, and Fri at ILSB 223)
1000 Hilltop Circle, Baltimore, MD 21250

Saturday Sept. 19 Program
(ITE Building 104/ 102, Lecture Halls)

Poster Session

Poster: Lobby of ITE building, open: 9:00am – 5:00pm

(For poster presenters, please setup your poster during 8:00am – 9:00am at Sat, Sept. 19)
(We will try to provide poster stand and board.)

Saturday Sept. 19 Program

Registration: Lobby of ITE building, open after 8:00 am

8:00 am – 8:30 am: Continental Breakfast

8:30 am – 9:00 am: Opening and Welcome Remarks (ITE 104)

Chair: Dr. Yi Huang, UMBC

- Provost or President, UMBC (10min) – Karl stainer, or provost or president.
- Dr. Ying Lu (5min): Dr. T. L. Lai's lifetime achievement, Inaugural Lai Memorial Short Course series
- Dr. Jie Chen (5min): Dr. Joe Heyse's lifetime achievement, Inaugural Joe Heyse Memorial Short Course series
- Dr. Yi Huang: UMBC-Stanford Workshop history and traditions, conference notice and announcement, two memorial short course series in alternating years, and two student poster awards named after them.

9:00 am – 9:50 am: Keynote Speech (ITE 104)

Chair: Dr. Yi Huang (or someone from FDA), UMBC

Evolving Role of Statisticians in Drug Development in the Artificial Intelligence and Digital Health Era

Dr. Mark Levenson, Director, Office of Biostatistics, Center for Drug Evaluation and Research, FDA

9:50 am – 10:10 am: Coffee Break

10:10 am – 11:00 am: Keynote Speech (ITE 104)

Chair: Dr. Jie Chen, Taimei Intelligence Biopharma R&D

Topic/ title (TBD)

Dr. Lisa C. Lupinacci, SVP, Merck Research Laboratories

11:00 am – 12:00 pm: Panel discussion (ITE 104)

Chair: Drs. Jie Chen and Tian Lu, Taimei Intelligence Biopharma R&D and Stanford University

AI/ML: From Statistical Rigor to AI-enabled Decision-making

Panelists: (approximate 6 panelists)

Dr. Lisa C. Lupinacci, Merck Research Laboratories

Dr. Mark Levenson, FDA

Dr. Hongtu Zhu, UNC

Dr. Mike Baiocchi, Stanford University

One or two more panelists here

12:00 am – 12:20 am: Conference Group Photo

12:20 pm – 1:40 pm: Lunch Break
Catered lunch at the lobby of the ITE building

1:40 pm – 2:40 pm: Keynote Speech (ITE 104)

Chair: Dr. Ying Lu, Stanford University

Title: What are we doing with synthetic data?

Dr. Mike Baiocchi, Stanford University.

2:40 – 4:10 pm Invite Session

Session 1 – Room ITE 104

Title: AI Models and Tools for Clinical Trials

Organizer: Dr. Ying Lu, Stanford University

Chair: UMBC colleagues

**Title : Evidence-based Clinical Trial Design:
When the Power of AI Meets Statistical Rigor**

Dr. Will Ma, President and CEO, HopeAI

**Title : Navigating the AI Journey: Practical
Steps for Pharma's Clinical Research
Transformation**

Dr. Gary Ma, Taimei Technology

**Title : Unifying Clinical Trials, Literature, and
Real-World Data: An AI Platform for Clinical
Evidence Synthesis and Management**

Dr. Hui Wang, Founder of SageAI

**Title : The AI Revolution: Bubble or
Breakthrough for Drug Development (not
Discovery)?**

Yuan Ji, CSO & Co-founder of Bayesoft Inc

Session 2 -- Room 102

**Title: Advanced methods for Clinical Trial
design and Data synthesis**

Organizer: Dr. Yi Huang, UMBC

Chair: UMBC faculty

Title : TBD

Dr. Willam Wang, Merck Research Laboratories

**Title : Improving power and early decision-
making in clinical trial information-adaptive
design through integrated covariate and
auxiliary outcome information.**

Dr. Chixiang Chen, School of Medicine, UMB

Title : TBD

Dr. Martin Kline, CDER, FDA

**Title : One-class support vector machines
integrated Bayesian approaches for external
control borrowing in clinical trials**

Dr. Yi Huang, UMBC

4:10 – 4:30 pm Coffee Break

4:30 – 6:00 pm Invited Session

Session 3 – Room ITE 104

Memorial Session for Dr. Tze Lai

Organizers: Dr. Ying Lu, Stanford University

Chair: Dr. Zhaohai Li, George Washington U

**Title : Adaptive Design, Stochastic
Approximation, and Stochastic Optimization**

Professor Ying Kuen Cheung, Columbia University

**Title : Challenge in the analysis of large scale
data**

Professor Zhezhen Jin, Columbia University

Title : TBD

Professor Feifang Hu, George Washington University

Title : Matching Hearts, Improving Lives: Interpretable Modeling, Simulation-Based Heart Transplant Matching, and New Tools for Informative Missingness and Evolving Clinical Data with Shifts

Professor Jiayang Sun, George Mason University

Session 4 – Room 102

Innovative statistical methodologies to solve complex clinical problems

Organizers: Dr. Ling Shen, CareDx Inc.

Chair: Dr. Ling Shen, CareDx Inc

Title : Bias reduction in g-computation for covariate adjustment in randomized clinical trials

Dr. Haitao Chu, Pfizer

Title : Multi-state model framework to characterize patient journey and time-dependent covariates

Dr. Jing Shi, CareDx Inc

Title : Inverse probability weighting to adjust diagnostic performance from observational data

Ms. Sijia Wang, CareDx Inc

Title : Inverse Probability of Treatment Weighting: A Simple and Effective Approach to Covariate Adjustment for Survival Endpoints in Randomized Clinical Trials

Dr. Zhiwei Zhang, Gilead Sciences

Conference Reception Lobby of ITE building, 6:00 – 7:00 pm

Closing Remarks from Dr. Yi Huang and Special singer - Mrs. Letitia Lai. (10min)