## **Keynote Speaker**



Josh Chen, Ph.D., Head of Global Biostatistical Sciences at Sanofi Pasteur. His team provides quantitative leadership through life cycle of vaccines, including discovery research, toxicology, CMC, biomarker strategy, translational sciences, clinical development strategy, study design, medical affairs, and value generation for payers. Josh promotes value and impact of quantitative scientists in the biopharmaceutical industry, and drives research and application of innovative statistical methods. His research interest includes clinical trial group sequential methods, adaptive designs and multiregional clinical trials (MRCTs). Josh's research collaboration has led to publication of a book on the best practices for simultaneous

global development and 50+ papers in peer-reviewed journals. Josh was a co-lead of the acrossindustry MRCT Consistency Working Group. He is a life time member of ICSA, was a member of the ICSA Board of Directors, and served as a program co-chair for the 2008 ICSA Applied Symposium. Josh received his PhD in Statistics from the University of Wisconsin-Madison, and Master and Bachelor degrees in Probability and Statistics from Peking University. He is a Fellow of the American Statistical Association.

## Time: December 15 (Tuesday): 9:00-10:00AM (Central Time)

Host: Gang Li, Ph.D., Director, Statistics and Decision Science, Janssen Research & Development

**Title:** Use of Real World Healthcare Data to Accelerate Vaccine Development in the Post COVID Era

**Abstract:** Human vaccine research and development is a lengthy, risky and expensive process which typically takes 10-15 years from discovery to approval. Lessons learned from the current collaborative efforts to develop safe and effective COVID-19 vaccines within 12-18 months support the aspiration that it is possible to accelerate vaccine development using innovative approaches. Before the COVID pandemic, there had been strong interest in the potential use of real-world evidence for regulatory purposes. The COVID pandemic will further catalyzes digital transformation and advancement of information technology infrastructure and as a result, vast increase in high quality real world data pertaining to patient health and healthcare delivery. In this talk, we will advocate use of real world data from healthcare systems, including electronic health records (EHRs), medical claims and billing data, and patient registries, to generate fit-for-purpose real world evidence in support of the safety and effectiveness of an experimental vaccine for regulatory decisions.