

NAME: Yang Song

PHOTO



[PRESENT POSITIONS]

Senior Director, Biostatistics at Vertex Pharmaceuticals Inc. 2016-present.

[FORMER POSITIONS]

From Senior Biometrician to Director, Merck & Co., Inc., 2007-2016, including 3 years (2012-2015) in Merck's R&D Center in Beijing China.

Senior Biostatistician, Johnson & Johnson, 2005-2007.

[DEGREES]

Ph.D. in Statistics, University of Wisconsin – Madison, USA, 2005

B.S. in Probability & Statistics, Peking University, China, 1999.

[FIELDS OF MAJOR STATISTICAL ACTIVITIES]

Biopharmaceutical statistics, especially in the areas of subgroup analysis, biomarker, efficient drug development strategies, rare disease clinical trials, real world data and evidence, and data integration. Statistical applications in global drug development in multiple disease areas, including rare diseases, oncology, and vaccines, in the US and in China.

[SELECTED PUBLICATIONS]

- **Xihao Li, Yang Song. Target population statistical inference with data integration across multiple sources – an approach to mitigate information shortage in rare disease clinical trials. Statistics in Biopharmaceutical Research, 2019.**
- **Zhiwei Jiang, Yang Song, Qiong Shou, Jielai Xia, William Wang. A Bayesian prediction model between a biomarker and the clinical endpoint for dichotomous variables. Trials, 2014.**

- Xing Sun, Xiaoyun Li, Cong Chen, Yang Song. A Review of Statistical Issues with Progression-Free Survival as an Interval-Censored Time-To-Event Endpoint. *Journal of Biopharmaceutical Statistics*, 2012.
- Jerald S. Schindler, Yang Song. Statisticians Supporting Late-stage Clinical Development at Merck. *International Chinese Statistical Association Bulletin*, July 2012.
- Yang Song, Cong Chen. Optimal Strategies for Developing a Late-stage Clinical Program with a Possible Subset Effect. *Statistics in Biopharmaceutical Research*, 2012.
- Yang Song, George Y.H. Chi. A Method for Testing a Prespecified Subgroup in Clinical Trials. *Statistics in Medicine*, 2007.

[ICSA ACTIVITIES]

Scientific Program Committee & Student Paper Committee, ICSA Applied Statistical Symposium, 2019

Session organizer and speaker in multiple ICSA Applied Statistical Symposiums.

[PROFESSIONAL COMMITTEES]

ASA Biopharmaceutical Section Real World Evidence Scientific Working Group

Steering Committee, ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, 2019, 2020

Co-chair, Organizing Committee, New England Rare Disease Statistics (NERDS) Workshop by New England Statistical Society, 2019

Co-chair, Organizing Committee, Boston Area Rare Disease Statistics Workshop, 2018

Co-chair, Organizing Committee, DIA China Quantitative Science Forum, 2013, 2014, 2015.

[HONORS AND AWARDS]

MSD China CEO Award, MSD R&D (China), 2013, 2012.

Merck Research Labs Key R&D Award, Merck Research Labs, 2012.

Special Achievement Award, Merck Research Labs, 2011, 2009.

Johnson & Johnson Innovation Standards of Leadership Award, 2006.

[STATEMENT]

I am grateful to be nominated by the ICSA Nomination and Election Committee as a candidate to serve in the Board of Directors of the ICSA. My experience with the ICSA began with the 2008 applied statistical symposium in Piscataway, NJ, when I organized a session on Innovative Design in Oncology Clinical Trials. I was immediately impressed by the strength of the ICSA to promote our profession

through a diverse community across academia, industry and government, not to mention the fantastic food and entertainment at the banquet. Since then, ICSA applied statistical symposium has always been one of my favorite conferences to participate in, as a speaker or session organizer, until 2019 when I was fortunate to serve in the Scientific Program Committee & Student Paper Committee in last year's symposium. Between 2012 and 2015, I was assigned by Merck to build a local biostatistics team for its R&D center in Beijing. From my experience with ICSA, I saw a great need to promote the biostatistics profession across academia, industry, and government in the fast-evolving drug development community in China. To that end, I led the efforts to organize the first 3 DIA China Quantitative Science Forums since 2013.

With the experience to serve the diverse community to promote our profession, and with my 15-year biopharmaceutical industry experience, I plan to have the following contribution areas of my focus if I am given opportunity to serve in the ICSA Board of Directors.

- (1) **Promote statistical innovation to meet emerging drug development needs.** Statistics has always been a driving force in innovations for clinical trial methodology. We have seen the great influence of adaptive design and precision medicine methodology. In the last a few years, unique aspects of immune-oncology drug development generated another wave of innovation. More recently, the drug development community is now facing with clinical trial challenges posed by rare diseases and gene therapies and new data generated by RWD/RWE. The role of our profession in the problem solving to bring innovative therapies to patients expeditiously need to be a focus of ours.
- (2) **Engage communities of fast-growing areas.** The last decade has seen an explosion of data sciences. While we continue ICSA's focus in these areas, we also need to engage communities of other emerging areas. For example, many biotech companies are working on rare disease therapies with some common statistical challenges. I worked with others to lead the efforts to organize a forum, now known as New England Rare Disease Statistics (NERDS) workshop, in 2018 and 2019. We should monitor and engage these fast-growing communities.
- (3) **Continue ICSA's global reach.** ICSA leadership has had the vision to grow it to be a leading statistical society in Asia. To this goal, I would like to contribute my experience of not only working in China and working with Japan but also engaging the local drug development community across academia, industry, and government.
- (4) **Help career development of ICSA members.** One of ICSA's main functions is to serve its members. It would be a tremendous value added if we can create more opportunities under the ICSA umbrella for member career

development. In addition to increase recruiting activities at ICOSA conferences, we could also consider mentorship possibilities.

I am grateful and excited about the opportunity to serve our profession through serving the community.