INTERNATIONAL CHINESE STATISTICAL ASSOCIATION

泛華統計協會

Preclinical Safety Statistics: Introduction, Perspectives, and New Developments

Host: Xin Huang **Speaker:** Dingzhou Li

Date: April 24th, 2026, 3:00-4:00 pm EST

Registration link:
https://us06web.zoom.us/webinar/register/WN_XAFPyggERh-zkECcgyzABA

About the webinar:

Preclinical safety studies are central to pharmaceutical development, informing decisions from first-in-human dosing through late-stage clinical trials. These studies—including general toxicology, safety pharmacology, and reproductive and developmental toxicology—pose statistical challenges driven by complex designs, heterogeneous endpoints, limited sample sizes, and regulatory and animal-welfare constraints.

This webinar reviews core statistical design and analysis principles for preclinical safety assessment, including dose-response evaluation, trend-based testing, handling monotonic and non-monotonic responses, baseline adjustment, sex and time effects, and the use of historical control data. Emphasis is placed on how these choices affect power, Type I error control, and interpretability in highly automated analysis environments.

The session then focuses on emerging developments that reshape study efficiency and decision-making. Virtual Control Groups (VCG) are discussed as a design and analysis strategy that leverages external and historical data to reduce reliance on concurrent controls while preserving operating characteristics. Bayesian methods are presented as a complementary framework for uncertainty quantification and information borrowing, enabling transparent evaluation of trade-offs through operating-characteristic assessment. Examples illustrate how these approaches can be integrated to support robust, ethical, and future-ready preclinical safety studies.

About Speaker

Dr. Dean (Dingzhou) Li has a doctorate degree in Physics and a master's in Biostatistics from the University of Michigan. He is currently a Senior Director and Group Lead of Drug Safety Statistics of the Nonclinical Statistics organization at Pfizer. Dean has extensive experience in supporting preclinical/non-clinical safety assessments in various disciplines, as well as in drug discovery, metabolism, and pharmacokinetics. Apart from portfolio work, he is the leading statistician of several cross-pharm safety consortia/working groups in collaboration with pharma and regulatory agencies. He has also been active in providing continuing education in statistics to scientists. Dean has co-authored one book chapter, two white papers, and over 50 peer-reviewed journal articles on preclinical safety work.

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