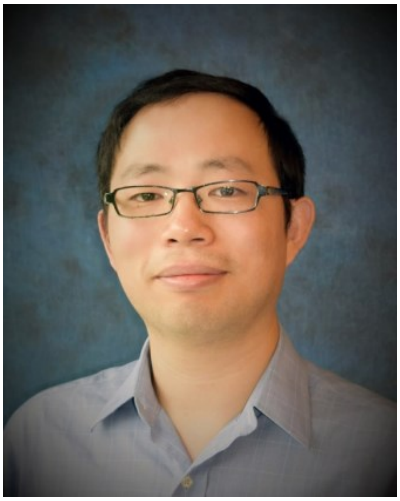
Academic Webinar Series



Jincheng Shen, Ph.D.

Assistant Professor,
Dept. of Population Health Sciences,
University of Utah
USA

October 17th, Tuesday
9-10 am EST

For more information regarding upcoming webinar schedule, please contact: ecc@boehringer-ingelheim.com

Title

Phase I Trials Design with Dose Expansion Cohort

Abstract

Phase I oncology trials is an essential step towards successful translation from laboratory and animal test to human studies in drug development, which commonly focus on assessment of the drug safety. The primary goal of such studies is to find the maximum-tolerated dose (MTD) so that severe side effects could be controlled during future efficacy studies, such as the following phase II trials. Recently, there has been an increasing trend of including dose-expansion cohorts (DECs) in phase I trial designs in the hope of collecting more information from the additional samples. However, in general, several challenges in the design and analysis of DECs have not been statistically addressed. It is still not quite clear what would be the best practice of conducting DECs to characterize the toxicity profile and/or identify early signs of efficacy. Here, Dr. Shen will discuss the role of simulation based studies in assessing various DEC proposals after traditional 3+3 dose escalation and de-escalation processes, as well as their comparison with other phase I, phase I/II and phase II studies. The practice of simulations would provide us better ideas on the implementation of DEC in phase I trial designs, and the usefulness of allowing the flexibility of continuous monitoring of toxicity and efficacy. Guidelines could thus be established for making efficient designs of DEC incorporated phase I trials based on the primary aim of the investigators.

Professional Biography

Dr. Jincheng Shen is an Assistant Professor in the Department of Population Health Sciences at the University of Utah. Dr. Shen received his PhD in Biostatistics from the University of Michigan. He then worked at the Harvard T.H. Chan School of Public Health as a postdoctoral fellow. Dr. Shen's current research work involves statistical methodology development for clinical and genetics related questions, with a focus on causal inference and statistical machine learning.

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