Some Statistical Issues in Drug Development

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Abstract:
Drug development within the pharmaceutical industry has been undergoing rapid change, and this includes the statistician’s role in that process. In particular, innovative statistical design and analysis approaches have greatly improved the efficiency of drug development. This seminar will cover several important statistical issues in drug development including adaptive design, platform design, and structured benefit-risk evaluation. In addition, state of some statistical challenges in pharm in 10 years will be shared as well.

Biography:
Qi Jiang, PhD, is an Executive Director of Global Biostatistical Science at Amgen. In this role, she is biostatistical therapeutic area head for oncology and hematology and also the lead of Center of Excellence for Safety and Benefit:Risk. In addition, Dr. Jiang provides oversight to Amgen’s biostatistical efforts in Asia. Before joining Amgen, she worked at the Harvard School of Public Health, Merck, and Novartis.

Dr. Jiang has many years of clinical trial experience in early and late clinical development phases across a broad spectrum of therapeutic areas. She has published more than 80 peer-reviewed statistical and medical papers and book chapters on statistical method development, study design, and data analysis and reporting. She has been frequently invited to give presentations at national and international professional conferences. In addition, Dr. Jiang is an editor of two books: “Quantitative Evaluation of Safety in Drug Development” published in 2014, and “Benefit-Risk Assessment Methods in Medical Product Development” published in 2016.

Dr. Jiang was a co-lead of American Statistical Association Biopharmaceutical Section Safety Working Group and is a co-lead of the Quantitative Sciences in the Pharmaceutical Industry (QSPI) Benefit:Risk working group. She is an Associate Editor for Statistics in Biopharmaceutical Research and is a Fellow of the American Statistical Association. In 2013, she received a Healthcare Businesswomen’s Association (HBA) Rising Star award.