Dr. Yi Tsong, Deputy Division Director,

Division of Biometrics VI, Office of Biostatistics, Office of Translational Sciences
Center for Drug Evaluation and Research, FDA
10903 New Hampshire Ave, Silver Spring, MD 20993
e-mail: yi.tsong@fda.hhs.gov

Yi Tsong received his Ph.D. in math. Statistics from the University of North Carolina at Chapel Hill in 1979. He did his post-doctoral training in cardiovascular prevention and biostatics at Northwestern Medical School (1978-1980). He worked as senior statistician in pattern recognition at Lockheed Engineering and Management Company (1981-1983) and biostatistical consultant at The University of Texas Medical Branch at Galveston (1984-1987) before joining FDA. He served as team leader of postmarketing risk assessment, statistical reviewer of NDA submission of critical care and pain relief products. He is currently the Deputy Division Director and Acting Team Leader for statistical team of Chemistry and Manufacturing Control. He specializes in postmarketing risk assessment, drug manufacturing process control and quality assurance, active control noninferiority/equivalence tests, adaptive designs and QTc trials. He received 8 CDER and 12 FDA level awards for contributions in postmarketing drug risk assessment, for advisory on CDER postmarketing risk assessment external contracts, medication errors, quality control evaluation, drug compliance, in vitro bioequivalence, drug compliance, drug abuse potential studies, setting quota of scheduled substances, adaptive design and non-inferiority tests, et al. He publishes frequently in numerous professional journals. He served as Treasurer, Board Director and President of International Chinese Statistical Association. He serves also as the Associate Editor of Statistics in Medicine and J. of Biopharmaceutical Statistics