Statistical Issues in the Evaluation of Biologics Products

Henry S. Hsu
US Food and Drug Administration, Rockville, MD, USA

Biologics License Application (BLA) for biologics products are submitted to the Center for Biologics Evaluation and Research (CBER) of the US Food and Drug Administration (FDA) for review. There are three Offices within CBER that review efficacy and safety of (i) vaccines, (ii) blood and blood products, and (iii) cellular, tissue and gene therapies in submissions to support product licensure. An overview of the function of Division of Biostatistics in CBER will be presented. Statistical issues in the evaluation of biologics products w ill be discussed. More specifically, three issues will be discussed: (i) potency measurement in bioassay, (ii) post-hoc analysis in licensing submission, (iii) adaptive approach in clinical trials under 21 CFR 50.24 exception from informed consent.

[Henry S. Hsu, 1401 Rockville, 200S, HFM-215, Rockville, MD 20852-1448, USA; henry.hsu@fda.hhs.gov]