A Deep Dive: FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence

March 14th, 2023 | 10:00 AM – 12:00 PM (ET)

AGENDA

SBIA Introduction	**Forest "Ray" Ford, PharmD, BCPS** *Captain*, *USPHS* Small Business and Industry Assistance (SBIA) Division of Drug Information (DDI) Office of Communications (OCOMM)
Introduction	**Liang Zhao, PhD** *Director* Division of Quantitative Methods and Modeling (DQMM) Office of Research and Standards (ORS) Office of Generic Drugs (OGD)
Overview **(contents of the guidance)**	**Stella C. Grosser, PhD** *Director* Division of Biometrics VIII (DB VIII) Office of Biostatistics (OB) Office of Translational Sciences (OTS)
Statistical Test for Population Bioequivalence	**Sungwoo Choi, PhD** *Mathematical Statistician* DB VIII | OB | OTS
Statistical Approaches to Establishing Bioequivalence – Specific Situations: An Overview of In Vitro Release Test (IVRT), In Vitro Permeation Test (IVPT), and Earth Mover's Distance (EMD) comparative studies	**Kimberly Raines, PhD** *Branch Chief* Division of Biopharmaceutics (DB) Office of New Drug Products (ONDP) Office of Pharmaceutical Quality (OPQ)
Statistical Methods for Narrow Therapeutic Index and Highly Variable Drug Products	**Donald Schuirmann, MS** *Expert Mathematical Statistician* DB VIII | OB | OTS
Comparative Clinical Endpoint Bioequivalence Studies	**Fairouz Makhlouf, PhD** *Deputy Director* DB VIII | OB | OTS

Bioequivalence Studies in Multiple Groups	**Wanjie Sun, PhD** *Lead Mathematical Statistician* DB VIII | OB | OTS
Adaptive Design for Bioequivalence Studies	**Wanjie Sun, PhD** *Lead Mathematical Statistician* DB VIII | OB | OTS
Bioequivalence Statistics for Adhesion and Irritation Studies	**Somesh Chattopadhyay, PhD** *Lead Mathematical Statistician* DB VIII | OB | OTS
Dose Scale Analysis to Support Bioequivalence Assessment	**Meng Hu, PhD** *Lead Chemical Engineer* DQMM | ORS | OGD
Recommendations in the 2022 Revised Bioequivalence Statistical Guidance and Bioequivalence Assessments	**Zhen Zhang, PhD** *Senior Pharmacologist* Division of Bioequivalence I (DB I) Office of Bioequivalence (OBI) OGD
Panel Discussions	**All Presenters and** **Lanyan (Lucy) Fang, PhD** *Deputy Director* DQMM | ORS | OGD **Ying Fan, PhD** *Lead Pharmacologist* Division of Clinical Review (DCR) Office of Safety and Clinical Evaluation (OSCE) OGD **David Coppersmith, JD** Regulatory Counsel Office of Generic Drug Policy (OGDP) OGD
Closing	