BsUFA Regulatory Research Pilot Program
FY23 External Research Awards

Under the commitments outlined in the third Biosimilar User Fee Act (BSUFA) commitment letter, FDA is exploring ways to enhance biosimilar and interchangeable biosimilar product development and regulatory science, specifically in the areas of **1) improving the efficiency of biosimilar product development** and **2) advancing the development of interchangeable products**. To this end, the following research grant was awarded from the funding opportunity - https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-23-026.html

Bridging the Gap: Using Foreign Real-World Data to Inform Interchangeable Biosimilar Approvals

Principal Investigator: Catherine Marie Lockhart

Institute: Academy of Managed Care Pharmacy, Inc

Abstract from Grant Application: This study will use real-world data (RWD) from the U.S., Italy, and Denmark to evaluate alternative approaches to meet the standard for interchangeable products (Area 2.ii.). The long-term objective is to develop recommendations for the FDA on using foreign RWD to improve regulatory processes. The study will determine the potential of RWD from outside the U.S. to improve the power and generalizability of U.S. regulatory studies. Researchers will use an observational/non-interventional retrospective cohort design to address two specific aims with the following methods:

Aim 1: Evaluate the feasibility and validity of a biosimilar interchangeability (e.g. switching) study using real-world data from the U.S. and sources from outside the U.S. The study will evaluate the quality of RWD from two foreign sources and develop a common data model to harmonize the data. The Principal Investigator (PI) will design a shared protocol. Co-Investigators will conduct emulations of a switching study of a biosimilar product at U.S., Italian, and Danish sites. The PI will compare the results at each site and compare the results with an existing study to validate our findings.

Aim 2: Develop recommendations for the FDA on how to address the challenges of using real-world data from outside the United States in its regulatory decision-making processes. Based on learnings from Aim 1, the PI will propose guidance for the FDA to consider. The guidance will recommend strategies to address the unique challenges associated with collecting, standardizing, and validating RWD from international sources.

This study will show how using foreign RWD can significantly improve the efficiency of the FDA regulatory process, leading to increased adoption of safe and effective biosimilar products. This innovative approach could also serve as a model for using RWD from outside the U.S. in regulatory decision-making across different therapeutic areas. This study will help the FDA advance its mission of making safe and effective drugs available to patients