A research opportunity is available in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. The candidate will train in CDER/Office of Translational Sciences/Office of Biostatistics. Any interested candidates should apply directly at [www.zintellect.com](http://www.zintellect.com) under the advertisement number FDA-CDER-2020-0487 and also send their CV to Mahboob Sobhan.

**Project description:**

This project will evaluate if there are more distal endpoints than clinical pregnancy that could reliably predict live births in studies including women undergoing Assisted Reproductive Technology (ART) procedures.

Under the direction and guidance of a mentor, the participant will have the opportunity to learn how to access the Center for Disease Control (CDC) database; evaluate the database structure; write code for consolidating the relevant data for the project objective; create analysis data files, and write statistical analysis plans to handle potential statistical issues related to such health-related databases.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

**Desired candidate:**

A Doctoral degree in biostatistics, statistics, applied mathematics, or related fields with a strong emphasis on programming, data science, and modeling. Qualified candidates with a Master’s degree may also be considered provided that the candidate demonstrates familiarity in modeling using survey data or related to the development of surrogate endpoints. Degree must have been received within five years of the appointment start date.

Familiarity with use of large survey data stored in relational databases; written and oral communication with clinicians, epidemiologists, and biostatisticians; R and SAS programming. Basic knowledge of clinical research and human reproduction.
Familiarity with data management, longitudinal survey data, and statistical approaches to model building, calibration and validation to evaluate and develop biomarkers or algorithms for use as surrogate endpoints; familiarity with joint modeling techniques using large longitudinal databases, including modeling of longitudinal intermediate outcomes.

Regards,

Celene

Celene Moorer, MS
Science Policy Analyst, OND Research Program

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