Opportunity Title: Evaluation of the Uptake of Qualified Biomarkers Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2018-0290

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2018-0290

How to Apply A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional references

All documents must be in English or include an official English translation.

If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Description A research opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Translational Sciences/Immediate Office (OTS/IO)

This project is related to the qualification of biomarkers (which is a broad subcategory of medical signs which can be measured and are reproducible). Biomarkers are distinct from disease or illness symptoms. Instead, biomarkers give an indication of the probable effect of treatment (risk indicators/predictors), whether a disease is already present (diagnostic), or how the disease may progress/develop (prognostic). Biomarkers in regulatory science are utilized in order to identify increases or decreases in certain Pharmacokinetic/Pharmacodynamic response, substantiate dosing decisions, identify safety risks, etc. FDA's Biomarker Qualification Program (BQP) works with stakeholders to develop and qualify measurable and reliable biomarkers for a specific use in drug development. The BQP offers a formal process to guide requestors as they develop a biomarker so that the biomarker is: suited to a particular well defined COU ("context of use"); to ensure that biomarker measurement is feasible and reliable; and that the analytical performance adequately supports the COU.

The goal of this project is to examine the impact of biomarker qualification on drug development and on regulatory review Till to date, six biomarker qualification (BQ) submissions have been successful and 13 biomarkers have been qualified. Ten biomarkers out of the 13 are safety biomarkers to be used in non-clinical safety studies. One is a diagnostic biomarker to be used in patient selection and two are prognostic enrichment biomarkers. We propose a pilot project that will be aimed at evaluating whether the qualifications have resulted in the uptake of the newly qualified biomarkers in drug development and in regulatory review.

Under the guidance of a mentor the participant will be analyzing the data submitted on various types of drug applications which is already stored in several databases (DARRTS, EDR, Global Submit) and will be involved in a project which helps identify data mining key words for automated extraction related to key biomarkers. The participant will be examining the use of the qualified biomarker for "proposed use" (e.g. protocols), "recommended use" and "use" in both nonclinical and clinical submissions and contextualizing the use of the biomarker for a specific COU. Via doing so, the participant will be learning how to develop an analysis plan, carry out an analysis, and develop appropriate metrics for specific biomarkers. The participant may also use

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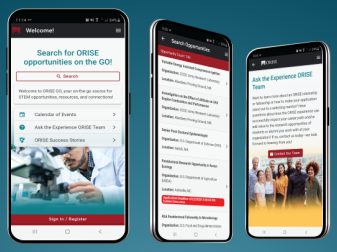

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excel, develop graphs, tables, and put together a presentation from their findings.

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 12 months, 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, MD area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least (3) of the past five (5) years in order for FDA to be able to complete a background check.

Qualifications

Eligible applicants must have received a Master's, Medical or Doctoral degree in biology, toxicology, or a related field, from an accredited U.S. College or University within the last five years. Knowledge in biomarkers, computational biology, bioinformatics and knowledge management is desired. Familiarity with graphics and other visualization tools is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)