Opportunity Title: Disease Progression Modeling in Clinical Trials Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2017-0036

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

Reference Code FDA-CDER-2017-0036

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 Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in the Office of Clinical Pharmacology/Division of Clinical Pharmacology.

This project proposes to conduct research to understand the “Placebo response” in clinical trials for analgesics used to manage different kinds of painful conditions. The research will generate disease progression models in different pain therapeutic areas (subchronic, chronic, neuropathic, nociceptive pain etc.) that could be used to plan clinical trials with drugs of different mechanisms of action.

Participants may be involved in: identifying the best disease model (linear, Weibull model, etc) for a subchronic pain disease (such as post-herpetic neuralgia); identifying the best disease model (linear, Weibull model, etc) for a chronic pain disease (such as osteoarthritis); identifying the best model that predicts time course of clinical endpoint (pain related) with regard to placebo for subchronic indications, the differences or similarities in placebo response in different clinical trials for subchronic pain indications (such as PHN) and; identifying the best model that predicts time course of clinical endpoint with regard to placebo response in chronic pain diseases.

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 6-12 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.

Qualifications Applicants must be enrolled in or have received a Pharm.D., Ph.D. within five years of the desired starting date. Post-doctoral experience in

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advanced statistical approaches to clinical trial evaluation; and a track record of research publication is desirable. Experience with biostatistical data analysis software such as NONMEM, SAS, JMP, R, etc., will be required for successful completion of this project.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (2 👁)