Opportunity Title: Quantitative assessment of endpoints in IBD Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2015-0091

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

Reference Code FDA-CDER-2015-0091

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 There are several biologics approved for Crohn's Disease (CD) and Ulcerative Colitis (UC) in adults. There is little or minimal quantitative understanding on the discriminatory power of endpoints for dose selection or to assess treatment effect, adequate duration of clinical trials, timing of assessment of induction of response or remission or the appropriate early predictors of long term response.

The goal of this project is to systematically evaluate the data available from in-house biologic license applications (BLAs) for UC and CD with an aim of streamlining the clinical trials and improve clinical trial outcomes with respect to the following goals :

• Identify and propose 'More discriminatory' endpoints for dose selection and/or approval. This will provide good quantitative rationale of the endpoints that should be used for dose selection and/or approval.
• Evaluate approaches that could reduce the duration of registration trials where possible thus shortening the drug development cycle.
• Identify adequate endpoint-assessment time points for induction of response or remission.
• Identify early predictors/indicators of long-term response/remission to aid in treatment decisions. This will allow the reassessment of benefit/risk in a patient early on to make treatment discontinuation decision preventing unnecessary exposure of drug to the patient.

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

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interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon the recommendation of FDA and contingent on the availability of funding. 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 or the program administrator, and there are no fringe benefits paid. The desired appointment start date is November 30, 2015.

Qualifications

- A Doctoral degree in clinical pharmacology, PK-PD, pharmacometrics or a related field received within the last five years. Students currently pursuing a Doctoral degree in the aforementioned areas are also encouraged to apply.
- Hands on experience with modeling and simulation softwares (for e.g., NONMEM, Phoenix, SAS or Splus/R, etc.) is required. Knowledge of statistics is desired.
- Good understanding of PK/PD of biologics is desired.
- Good communication and interpersonal skills are desired for effectively working in a multidisciplinary review team.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Academic Level(s):** Any academic level.
- **Discipline(s):**
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (1 👁)