Opportunity Title: Clinical Pharmacology Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2018-0211

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

Reference Code FDA-CDER-2018-0211

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), The Center for Drug Evaluation and Research (CDER), Office of Translational Sciences/Office of Clinical Pharmacology.

This project proposes a systematic analysis of the failed efficacy trials for tumor necrosis factor-alpha (TNFa) inhibitors in Poly-articular juvenile idiopathic arthritis (PJIA) to evaluate the reasons for failure and provide comparative analysis to the TNFa inhibitors that have been successful. The ultimate aim will be to access the possibility of full or partial extrapolation of efficacy in PJIA population based on the currently available data from 5 approved TNFa inhibitors in rheumatoid arthritis (RA).

Under the guidance of a mentor the participant may be involved in various trial design elements like study design, population and endpoints will be compared in order to find any difference that could potentially lead to difference in results; assessing adequacy dose selected for pediatric evaluation by exposure matching between adults and pediatric age groups; evaluating differences in placebo effect between pediatric studies versus adults and between various efficacy studies; addressing impact of immunogenicity on PK and PD.

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 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

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is required for participation in this program. The appointment is part-time (15-20 Hours) or 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.

Qualifications

A senior year Ph.D. student in Pharmacometrics/Clinical Pharmacology familiar with conducting data reformatting, population PK analysis, statistical analysis, PK/PD modeling and simulation. Qualified masters degree candidate may be considered provided the candidate demonstrates strong quantitative skills.

Well-versed in using PK/PD modeling softwares like NONMEM/Pharsight Phoenix and statistical software like R/SAS; with a publication history in peer reviewed journals is desired.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (1 👁)
  - **Mathematics and Statistics** (2 👁)