Opportunity Title: FDA COVID-19 & Other Quantitative Systems Pharmacology Fellowship
Opportunity Reference Code: FDA-CDER-2020-0569

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2020-0569
How to Apply	**Connect with ORISE...on the GO!** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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
- One educational or professional recommendation

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

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

|	
Application Deadline	3/31/2021 3:00:00 PM Eastern Time Zone
Description	***Applications will be reviewed on a rolling-basis.**

A research opportunity is available in the Office of Translational Sciences Office of Clinical Pharmacology (OCP), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project will be developing quantitative systems pharmacology models that combine pharmacokinetics, pharmacodynamics, and underlying biology to study the efficacy and safety of drugs for various diseases or conditions. Example areas of modeling are: models that combine viral life cycle, human immune responses, and drug actions to predict efficacious drug combinations to treat COVID-19, modeling the relationship between opioid-receptor interactions and respiratory depression.

Under the guidance of a mentor, the participant will learn to develop individual components of mechanistic models, such as pharmacokinetic models, pharmacodynamic models, systems biology models, and combine them into a prediction framework to evaluate drug efficacy/safety in various areas.

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.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can
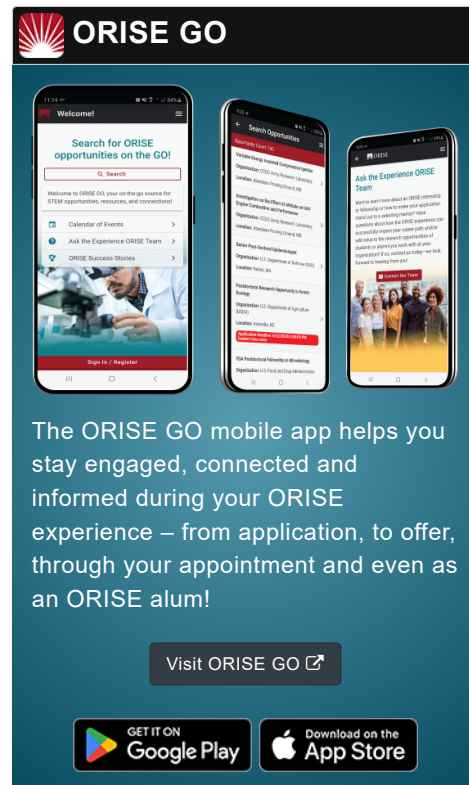
Opportunity Title: FDA COVID-19 & Other Quantitative Systems Pharmacology Fellowship
Opportunity Reference Code: FDA-CDER-2020-0569

complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate should be currently pursuing or have received a master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Modeling dynamic systems using ordinary or delay differential equations
- Developing mechanistic pharmacokinetics/pharmacodynamics model
- Modeling human immune system
- Developing electrophysiology models to simulate action potentials
- Modeling receptor binding kinetics
- Developing parallel computing programs in a high performance computing environmen
- Familiar with programming languages such as R/Matlab

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Engineering** (2 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)
  - **Physics** (1 👁)