



Associate Director for Research

The Reagan-Udall Foundation for the FDA (the Foundation) is a non-profit organization that works to support the mission of the FDA by advancing regulatory science and research. The Foundation establishes public-private partnerships between FDA and external stakeholders to facilitate innovation in science and health.

Job description:

The Associate Director for Research will provide professional scientific leadership for activities associated with the development and management of research partnerships in pharmacoepidemiology. The Associate Director will lead sponsored research projects and facilitate the creation of a portfolio of pharmacoepi- epidemiology studies funded by sponsors and conducted by external research partners. The Associate Director will work with leading experts from government agencies (including NIH and FDA), industry, non-profit organizations, and academia to design, promote, fund and monitor the progress of pharmacoepi-related projects. The research portfolio includes large-scale collaborative observational and/or clinical trials, along with studies designed to develop and meet regulatory requirements for post-market surveillance of regulated products.

The Associate Director may also supervise the efforts of one or more Program Managers who ensure that individual research projects in the portfolio are conducted in a timely and effective manner, and within budgetary constraints. The Associate Director will report to the Scientific Director.

Job qualifications:

The Associate Director should be intellectually and scientifically flexible to work with funding and research partners in technical areas s/he does not consider to be his/her primary area of expertise. The Associate Director should be a self-starter, detail-oriented, proactive, organized, and adept at managing multiple research projects.

The Associate Director should have a demonstrated ability to:

- Lead and facilitate multi-disciplinary, public/private sector teams.
- Manage a diverse portfolio of clinical/real-world data/epidemiological research projects in the field of pharmacoepidemiology, or similar field.
- Understand scientific data management processes, intellectual property rights, and publication processes and procedures.
- Develop, execute, and manage grants and contracts.
- Develop and manage budgets and expenses.

The Associate Director should have:

- An understanding of pharmacoepidemiology or outcomes research (clinical/epidemiological research background preferred).

- Experience in investigator-led research activities, either as a principal investigator or co-investigator. Experience working with big data from healthcare settings (informatics background preferred).
- A familiarity with FDA regulations for post-authorization studies (primarily) and drug or biological product development (secondary).
- A graduate degree in a relevant field (doctoral degree preferred).
- A minimum of five (5) years of science administration experience.
- Experience supervising direct reports (preferred).

The Associate Director for Research reports to: the Scientific Director.

Travel requirements: Light (less than 5% of time)

Key words: Scientific program management; science administration; research administration; public-private partnership; pharmacoepidemiology; clinical research; post-market surveillance; observational studies; real-world data; real-world evidence

To apply:

Email your cover letter, resume, three references and your salary requirements to
careers@reaganudall.org