



Senior Scientific Program Manager

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 Senior Scientific Program Manager (SPM) will provide professional leadership for activities associated with the development and management of research partnerships in pharmacoepidemiology. The SPM will manage a variety of programs and facilitate the creation of a portfolio of pharmacoepidemiology studies conducted and funded by external research partners. Working with scientific committees, the SPM 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 SPM 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 SPM will report to the Scientific Director. A moderate level of travel is required for this position.

Job qualifications:

The SPM 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 SPM should be detail-oriented, proactive, organized, and adept at multi-tasking.

The SPM 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.
- 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 SPM should have:

- A graduate degree in a relevant field (doctoral degree preferred).
- An understanding of pharmacoepidemiology or outcomes research (clinical/epidemiological research background preferred).
- 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 minimum of five (5) years of science administration experience.
- Experience supervising direct reports (preferred).

The SPM reports to: the Scientific Director

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 admin@reaganudall.org