

Reagan-Udall Foundation for the FDA

Job Description

Title: Scientific Director, IMEDS

Reports to: Executive Director

Supervisory Responsibility: Project Manager(s)

The Reagan-Udall Foundation for the FDA 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.

The Foundation is seeking an entrepreneurial Research Director for its flagship program, Innovation in Medical Evidence Development and Surveillance (IMEDS). This position would be ideal for a motivated individual interested in joining a small but growing team, rolling up their sleeves, expanding their skills, and growing their career.

IMEDS is based on the FDA's Sentinel Initiative designed for post-market drug safety surveillance. The Foundation provides scientific and management oversight while working with many partners that include an analytic center and data partners who are integrated delivery systems and/or insurers.

Job Purpose:

The Scientific Director will lead the implementation of sponsor supported research studies that utilize the IMEDS distributed database. He/she will serve as the IMEDS operation center principal investigator for all studies. The Director will create a strategic approach to developing partnerships, and will assist the Executive Director with operations, communications, education, and outreach efforts. This position will work closely with the Director of Marketing and Communications to increase awareness of the program.

Duties and Responsibilities:

- Provide expert level consultation on epidemiological issues to a variety of stakeholders
- Interpret and develop reports of study results for sponsors
- Develop Statements of Work for partners and sponsors
- Critically review and/or edit publications, manuscripts, and draft proposals as needed
- Provide input on study design and analysis for pharmacoepidemiologic studies
- Interact and communicate regularly with other study team members (analytic center, data partners, sponsor--and as needed with FDA)
- Maintain current knowledge of epidemiological methods, data resources as well as their applications in benefit-risk evaluation
- Identify and coordinate resources needed to attain project and study timelines
- Provide subject matter expertise, guidance, and direction to internal and external stakeholders
- Assist in the development and establishment of processes and procedures to maximize operational excellence

- Evaluate the IMEDS database of health insurance claims and or medical records and/or patient or other reported data for the feasibility of epidemiological studies and/or safety surveillance in addressing questions on drug safety, drug utilization, or effectiveness
- Develop and maintain an understanding of organizational priorities
- Responsible for managing project deliverables and timeline
- Oversee the activities of study staff
- Mentor scientific or research staff
- Other duties as assigned

Qualifications:

Doctoral degree required; Ph.D/PharmD/DrPH in epidemiology/public health

Experience:

5-8 years' related experience gained at a non-profit, corporate, higher education or healthcare institution. Requires experience in the practical application of epidemiologic methods in the specialized field of pharmacoepidemiology. Experience as a principal investigator with a record of publications. Knowledge of administrative health care claims databases and observational studies is also required.

Requirements/Competencies:

- Excellent organizational and management skills
- Outstanding listening and communication skills—both written and oral
- Ability to develop and meet schedules
- Excellent analytical skills
- A strong understanding and experience interacting with the FDA is preferred
- Demonstrated professional and political aptitude; team and diplomatic skills
- Able to manage multiple priorities and take an entrepreneurial approach to problem solving
- Follow best business practices
- Establish and maintain positive working relationships with others, both internally and externally, to achieve the goals of the organization
- Ability to establish relationships with key stakeholders; good conflict management and negotiation skills
- Demonstrated ability to translate strategy into action
- Positively influence others to achieve results that are in the best interests of the organization
- Assess problem situations to identify causes, gather and process relevant information, generate possible solutions, and make recommendations and/or resolve the problem
- Excitement about the mission and vision of the organization

Candidates will need to submit a CV, cover letter, references, and salary requirements to apply for this position. No relocation assistance is provided.