Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Medical Policy (OMP)
Immediate Office (IO)

This position is being reposted due to a technical issue.
Any applicant who did not receive confirmation or receipt should reapply and ensure confirmation of receipt.

Application Period: October 21,2024 - November 1, 2024

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Supervisory Associate Director for Real World Evidence Analytics (RWE) (Supervisory Physician)

Series: AD- 0602

Location(s): Silver Spring, MD

Salary: Starting at $195,000

Work Schedule: Full-Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: Up to 20%

Bargaining Unit: 8888

Relocation Expenses Reimbursement: You will NOT qualify for reimbursement of relocation expenses in accordance with agency policy.

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority.
Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Version: 11/2021

Introduction

The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

The mission of Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

The Office of Medical Policy (OMP) is responsible for directing medical policy programs and strategic initiatives, including evaluation of real-world evidence with a focus on supporting approval of new indications both in the pre- and post-market setting as mandated by 21st Century Cures Act. OMP provides leadership and scientific advice in novel clinical trial designs, in particular the use of new technologies, and direction in policy issues related to human subject protection and good clinical practices. OMP accomplishes its mission through the development of regulation, guidance documents, and procedures related to medical policy issues.

The Immediate Office (IO) within the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) promotes and protects public health by providing scientific and regulatory leadership in the development of medical policy pertaining to drug development, drug bioresearch monitoring, human subject protection, post market surveillance processes, and the science and efficiency of clinical trials. It supports innovative approaches to clinical trials that include the use of technology, real world evidence and decentralized clinical.

Duties/Responsibilities

As the **Supervisory Associate Director for Real World Evidence Analytics (RWE) (Supervisory Physician)**, the incumbent provides strategic vision for the agency's effort to evaluate and promote the use of RWE to advance drug development and to further evaluate the safety and effectiveness of marketed therapies. Resource management at this level involves major decisions and actions with direct and substantial effect on the organizations and programs managed.

- Serves as the principal external spokesperson for the Center for RWE, as well as a senior spokesperson for related efforts to increase the efficiency and utility of clinical trials through use of real-world data, artificial intelligence, digital technology, and advanced analytics.
- Communicates with international regulators through leadership of the FDA-EMA RWE Cluster and related international regulatory liaison mechanisms.
- Provides strategic and clinical guidance for agency review of RWE submissions by managing input from senior CDER, OCE, CBER, and CDRH staff as Chair of the Medical

Policy and Program Review Council RWE Subcommittee and any future bodies that would coordinate, guide, coordinate, and advice CDER on RWE submissions, policies, and projects.

- Provides matrixed leadership for guidance development workgroups composed of staff from multiple CDER Super-Offices as well as CBER and CDRH to identify scientific and policy challenges and manage contracts and grants totaling millions of dollars.
- Leverages prior FDA review and technology transfer experience as well as information from a trans-FDA RWE Subcommittee to identify key hurdles for the adoption of RWE. Reviews and initiate demonstration projects to close these gaps in real world data utilization.
- Manages staff and serves as a member of the FDA Sentinel Executive Committee which provides governance among OC, CDER, CBER, and CDRH with respect to core Sentinel activities as well as specialized sub-systems within Sentinel such as FDA-Catalyst.
- Engages in external and internal stakeholder outreach and communication regarding best practices in data quality, study design, and other foundations of real-world evidence generation and clinical trial optimization by planning and participating in FDA-sponsored public meetings convening thought leaders across sectors.
- Supports the Super Office Director with subject matter expertise on various clinical, policy, technical, regulatory, and management matters related to the Office's guidance and scientific policy activities. The incumbent is able to provide authoritative responses for requests from the US Congress, trade associations, foreign governments, other parts of the agency and the public.
- Uses high degree of originality in devising new and adapting existing methods and techniques to resolve problems and fulfill objectives.
- Creates and oversees the formulation of long-range plans with respect to the Agency's evaluation of real-world evidence, which may require the application of clinical, epidemiological, and regulatory knowledge.
- Provides technical assistance to other professionals in the organization on the use of real-world evidence to evaluate effectiveness, and/or safety use cases.
- Keeps the Super Office Director, informed of programs, resources, and related considerations that would impact the Agency's evaluation of real-world evidence.

Supervisory Responsibilities: Manages multiple projects and provides leadership to the RWE Analytics Team. Supervises and evaluates scientists who serve as experts in their field. Provides technical and administrative direction and supervision 25 percent or more of the time to subordinate staff performing the work and functions of the organizational unit. Obtains resources and manages over $22 million in agency resources to ensure that the work performed is of proper scientific quality and meets the objectives of the agency.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required

documents, and any other job-related requirement before or after appointment.

- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959, must be registered with the Selective Service.
- One-year supervisory probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.
    b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

In order to qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement:

Physician, AD-0602 Series:

Education: A degree from an accredited program or *institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. *Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

AND

Graduate Training: In addition to a degree, a candidate must have had at least one year of supervised experience providing direct service in a clinical setting. For purposes of this standard, graduate training programs include only those internship, residency, and fellowship programs that are approved by accrediting bodies recognized within the US or Canada.

Desired Education: Our ideal candidate will possess a degree from an accredited program or institution in Doctor of Medicine, Doctor of Osteopathic Medicine, or equivalent. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates.

Desired Professional Experience:
Our ideal candidate will possess:

- Demonstrated leadership ability in a regulatory, pharmaceutical industry, academic, or contract research organization setting.
- Ability to organize and lead the development of surveillance and real-world evidence generation systems.
- Experience with benefit risk assessments and FDA labeling.
- Experience and/or knowledge of the procedures of other global regulators, such as the European Medicines Agency.
- Experience launching and scaling analytical solution and digital health platforms to meet regulatory needs.
- Experience working with multi-national consortia or organizations such as the World Health Organization.
- Expertise in clinical informatics with experience and knowledge of clinical trial protocols, electronic health records systems, disease and patient registries, and medical claims data is desirable.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or

university. For more information about this requirement, please visit the Recognition of Foreign Qualifications | International Affairs Office (ed.gov)

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/High Risk

A background security investigation will be required for all appointees. Appointment will be subject to applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation maybe required later.

Applicants are also advised that all information concerning qualifications is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information, please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor. Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

Reasonable Accommodation Policy

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis. A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits.

Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

Submit resume or curriculum vitae with cover letter by **November 1, 2024,** to: Debbie Begosh, debbie.begosh@fda.hhs.gov. Candidate resumes may be shared with hiring official within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference Job Reference ID: **T-40-42 Supervisory Associate Director** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact debbie.begosh@fda.hhs.gov.

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FDA is an equal opportunity employer.