**Title 21 Vacancy Announcement Physician**
**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)**

**Application Period:** July 15, 2024 – August 2, 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:** Physician

**Series:** AD-0602

**Location(s):** Silver Spring, MD

**Salary:** $165,000 - $262,150

**Work Schedule:** On-site (Telework Eligible)

**Cures Band(s):** Band C

**Full Performance Band Level:** Band C

**Travel Requirements:** 25% or less

**Bargaining Unit:** 3591

**Relocation Expenses Reimbursement:** You may 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**

# 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 the 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 effectiveness, comparative effectiveness, and comparative safety use cases 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.

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 trial processes to improve the efficiency and quality of drug development.

## Duties/Responsibilities

As a **Physician**, the incumbent serves as a scientific and regulatory subject-matter expert for Real-World Evidence (RWE) analytics in the Immediate Office of the Office of Medical Policy (OMP). The incumbent will be responsible for gathering, processing, and evaluating information related to Real-World Evidence (RWE). The responsibilities are aligned with activities related to internal Agency processes, external stakeholder engagement, demonstration projects, and guidance development. The corresponding activities require independent judgment on matters of significance to drug development and approvals. The incumbent also helps to develop various policies for Real-World Evidence (RWE) studies given that existing policies were developed for clinical trials.

- Develops policies for human subjects' protection for real-world evidence studies given that existing policies were developed for clinical trials.
- Serves as an advisor to the Associate Director of OMP for Real-World Evidence (RWE) Analytics. Coordinates with other offices and centers— including the Office of New Drugs, Office of Surveillance and Epidemiology, Office of Biostatistics, Oncology Center of Excellence, and others—in finding ways to enhance communication within and across CDER offices to achieve optimal implementation of the 21st Century Cures Act.
- Applies expert clinical knowledge on diseases, therapeutics for diseases, and clinical research to the assessment of drug and biologic product submissions. Evaluates submissions in terms of the proposed data sources being fit-for-use, the design being adequate to general valid evidence, and the conduct of the study meeting regulatory requirements.
- Provides authoritative recommendations for the review of Real-World Evidence (RWE)-based submissions involving drugs and biological products during internal Agency

meetings, meetings with sponsors, as well as in preparation of reviews, labeling, and press releases. Provides input on all elements of drug and biological product submissions, including information related to principles of clinical medicine, study design, and data analysis.

- Provides scientific and general input on Real-World Evidence (RWE)-related guidance in support of meeting mandates under the 21st Century Cures Act. These guidance documents cover topics including sources of real-world data, data standards, various categories of study design and types of real-world evidence, as well as regulatory issues.
- Evaluates the comments submitted to the docket in converting draft guidance to final guidance.
- Provides oversight of FDA-supported demonstration projects involving Real-World Evidence (RWE); these demonstration projects can be characterized in terms of having goals to improve or better understand real-world data sources, real-world evidence design methodology, and RWE tools.
- Interacts with the external teams conducting RWE-related demonstration projects as necessary, with responsibilities to monitor progress, answer questions, and report to the Associate Director of OMP for RWE Analytics on a regular basis.

**Supervisory Responsibilities**: N/A

## 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 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 graduate-level training in epidemiology, statistics, clinical informatics, or similar fields of study.

**Desired Professional Experience:**
Our ideal candidate will possess:

- Experience working with clinical trials or observational (non-interventional) studies, drug labeling, pharmacovigilance, risk- benefit assessment, federal regulations, and/or guidance development. This experience can have been gained in a regulatory, academic, pharmaceutical company, or contract research organization setting.
- Experience in advanced medical theories, practices, and technologies typified by completion of an approved residency program supplemented by clinical or

research experience.

- Experience needed in clinical medicine, clinical trials, epidemiology, biostatistics, or other fields relevant to the new drug review process.

## 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/Moderate 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 **August 2, 2024,** to: **CDER-OMP IO** Jobs at CDER-OMP-IO-Jobs@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-40-36. Physician in email subject line.

## Announcement Contact

For questions regarding this Cures position, please contact to CDER-OMP-IO-Jobs@fda.hhs.gov**.**

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*FDA is an equal opportunity employer.*