



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 Strategic Programs (OSP)

Application Period: November 4, 2022 - November 18, 2022

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: Operations Research Analyst, ADSS

Series: AD-1515

Location(s): Silver Spring, MD

Salary:

\$74,950 (Band A)

\$89,834 (Band B)

\$106,823 (Band C)

Work Schedule: Full Time

Cures Band(s): Band A/B/C

Full Performance Band Level: Band C

Travel Requirements: 25% or less

Bargaining Unit: Bargaining Unit

Relocation Expenses Reimbursement: You may 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) 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 are 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 Strategic Programs (OSP) serves the Center Director, and the super office directors who lead major operations involved in regulatory oversight of human drugs. OSP's functional capabilities include strategic planning and management, negotiation with major external stakeholders over future work commitments and resource commitments, and process and program design and management.

The mission of the Analytics and Data Services Staff (ADSS) is to serve as the Center's technical experts in the development of specialized and informative management and performance reports and to be the primary reporting source for all reporting on new drugs, biologics, biosimilars and generic drug review programs. ADSS also conducts qualitative and quantitative analyses (e.g. risk analysis, statistical modeling and machine learning techniques) to support CDER senior management in their decision making.

Duties/Responsibilities

As an **Operations Research Analyst**, the incumbent will conduct and/or participate in the analysis of program policy and operations. This work will provide a basis for, and have a direct effect on, decisions affecting major Center regulatory policies and programs. The incumbent will utilize tools and techniques and other appropriate analytical methodologies from disciplines such as data science, operations research, statistics, economics, computer science and decision science.

Band A:

- With guidance and support from project team members, reviews relevant data sets and understands appropriate methods for analysis, and/or communicating results to inform decision-making.
- With guidance from director and employees of higher grades, applies proper techniques and tools to conduct an analysis of given data/information and respond appropriately to questions and/or requests from customers to provide insight to decision makers.

Band B:

- Compiles, analyzes, and reports data using different analytical and statistical techniques in order to solve problems and as needed to develop relevant predictions across the Center. These techniques include, but are not limited to, statistical modeling, feature engineering, machine learning, predictive modeling, and data mining.
- After completing customer engagements, develops benchmarks or other metrics to

individually conduct impact assessments and determine whether the desired outcomes were attained.

Band C:

- Independently collects, reviews, and analyzes unstructured or structured quantitative and qualitative data related to specific programs/policies/initiatives from disparate sources (i.e., using appropriate querying tools), reviews it for integrity and validity, and investigates its merit, worth, and/or signification in order to deliver clean, clear, useful, and correct data to internal customers for analysis and decision making.
- Develops more complex set of methods and/or models (e.g., functions, documenting code, machine learning and data mining algorithms) to complete an analysis. Determines the appropriate time to apply proper technical language and appropriate algorithms within specific programs and systems (i.e., SQL, OBIEE, Statistical Analysis System (SAS) Python, R) so they may create desired outputs to solve a challenging defined customer problem.

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 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.

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: Operations Research Series, AD-1515

Degree: in Operations Research; or at least 24 semester hours in a combination of operations research, mathematics, probability, statistics, mathematical logic, science, or subject-matter courses requiring substantial competence in college-level mathematics or statistics. At least 3 of the 24 semester hours must have been in calculus.

Possess a graduate level or higher degree in a technical or scientific field from an accredited institution of higher learning. For more information please see: [OPM Occupational Series Qualification Requirements](#)

Desired Professional Experience:

Our ideal candidate will possess:

- Educational training and experience in such fields as statistics, mathematics, data science, operations research or similar computationally intensive fields providing the skills necessary to serve as an operations research analyst.
- Experience in applying the principles, concepts, tools, and methodologies related to business intelligence, data reporting, data analysis and operations research.
- Experience with SQL, R, and Python programming languages.
- Demonstrated skill and experience developing complex queries and high-quality analytical work products in support of program operations and policies.
- Demonstrated ability to work independently and collaboratively across organizational boundaries.

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 [U.S. Department of Education website for Foreign Education Evaluation](#).

Security Clearance Requirements

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

If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for an appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

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

Vaccination Requirements

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply. Federal agencies may request information regarding the vaccination status of selected applicants for the purposes of implementing other workplace safety protocols, such as protocols related to masking, physical distancing, testing, travel, and quarantine.

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 18, 2022**, to: Reza.Kazemi-Tabriz@fda.hhs.gov. Candidate resumes may be shared with hiring official within CDER 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-22-903-A**

How I Will Be Evaluated

Candidates may be evaluated based on an interview, review of requested work samples, writing samples, most recent performance evaluation(s), professional references, results of an oral presentation or work-related test. Failure to comply with any of the additional assessment

requirements will result in removal from further consideration.

Announcement Contact

For questions regarding this Cures position, please contact Reza.Kazemi-Tabriz@fda.hhs.gov.

The U.S. Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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