



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 Translational Sciences (OTS)

Application Period: December 14, 2022 – December 28, 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: Data Scientist

Series: AD-0301

Location(s): Silver Spring, MD

Salary: Starting at \$126,233

Work Schedule: Full-Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 3591

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 FDA's 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 mission of the Office of Translational Sciences (OTS) is to empower a diverse, collaborative, and high performing workforce to champion innovation and advance global human drug development.

Duties/Responsibilities

As a **Data Scientist**, the incumbent supports the conceptualization, designs, and conduct of leveraging data into knowledge management efforts and regulatory science within the Center. The incumbent will assist with identifying actual or potential problems, trends, and opportunities in Center marketing application actions and recommends solutions leveraging internal and external data to senior management for consideration.

- Conceptualizes, designs, and conducts simple and complex studies leveraging internal and external data to produce analyses and recommendations regarding CDER drug marketing applications.
- Evaluates and recommends the most appropriate analytical methods for a single project including recommending the appropriate analytical techniques to uncover current, historic, and likely future trends in CDER drug marketing application actions (e.g., approvals). Techniques include all aspects of data science, with particular focus on forecasting using machine learning techniques, including random forest models, survival models, classification models, regression models, mixed effect models, and other relevant techniques as applicable to the specific challenges at hand.
- Provides expertise in the data fields for CDER drug marketing applications and knowledge of other databases with an emphasis on enhancing data quality.
- Develops approaches for the validation, integration, reconciliation, harmonization, and standardization of data fields regarding drug marketing applications across disparate regulatory databases across CDER.
- Serves as a senior analyst in the appropriate design and application of processes.
- Oversees the development and implementation of natural language processing techniques to mine data from regulatory documentation.
- Leads the research of novel analytical approaches to implementation and exploration of options, production, and implementation of tools and methodologies.
- Cultivates relationships with offices and data owners across CDER focused on regulatory science data.
- Represents the Knowledge Management Team in presentations and other collaborations across FDA.
- Serves as an expert in the applications of programming tools, including (but not limited to): R, R Studio, Python, Structured Query Language (SQL).
- Serves as an expert in the development of visualization tools and dashboard development and deployment including (but not limited to): R Shiny, Tableau, Qlik, and Power BI.
- Serves as an expert on CDER drug marketing application data and its application within the FDA's knowledge management paradigm. Presents analytical work

products to Center and program leadership in support of regulatory science efforts.

- Provides guidance on CDER drug marketing application data and its application within the FDA's knowledge management paradigm. Presents analytical work products to senior analyst in support of regulatory science efforts.
- Responsible for moderately complex contributions to complex projects led by more senior analysts.
- Builds an infrastructure and internal culture to support data science and analytics needs and skills within OTS and CDER.
- Works collaboratively with junior analysts in the management of moderately complex projects.

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.

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:

There are no Individual Occupational Requirements for this position.

Desired Education:

Our ideal candidate will possess educational training in such fields of statistics, or similar computationally intensive field providing the skills necessary to serve as an expert data scientist.

Desired Professional Experience:

Our ideal candidate should possess:

- Education and/or professional experience commensurate with that of an expert data scientist.
- Skill in applying the principles, concepts, tools, and methodologies related to data science, particularly utilizing and emphasizing forecasting and predictive analytical techniques, including machine learning techniques.
- Demonstrated analytical ability, judgement, discretion in executing Food & Drug Law activities.
- Ability to select, interpret, and apply relevant guidelines to determine appropriate course of action.
- Skill in working independently and collaboratively across organizational boundaries.
- Moderate to Advanced Project Management experience preferred
- Experience effectively and efficiently communicating with various audiences, both verbally and in writing.

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 level investigation, and the incumbent has access to documents and facilities.

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 later.

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

Applicants should submit a letter of interest (cover letter) and current resume by **December 28, 2022**, to: CDEROTSHires@fda.hhs.gov

Please adhere to the following submission protocol:

- **Cover letter and resume should be one combined PDF document with the following naming convention: Last Name, First Name.**
- **Reference 'OTS-IO Data Scientist' in the subject line of the email.**

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".

Announcement Contact

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

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

FDA is an equal opportunity employer.

