Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Pharmacovigilance (OBPV)
Division of Analytics and Benefit-Risk Assessment (DABRA)
Analytics and RWE Branch (ARWEB)

Application Period: July 12, 2024 – July 25, 2024

Area of Consideration: The Public
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*
*Multiple selections can be made from this announcement

Series: Data Scientist (0301)

Location(s): White Oak Campus, Silver Spring, MD

Salary: Starting at $139,395 and is set commensurate with education and experience.

Work Schedule: Full Time

Telework Eligible: Yes – as determined by agency policy.

Title 21 Band: Band D

Full Performance Band Level: Band D

Travel Requirements: 25% or less

Bargaining Unit: 3591

Note: Incentives may be authorized; however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment, or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.

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 is the federal agency responsible for protecting the public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by helping to ensure the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA's programs are national in scope and effect, and the agency's activities have a direct and significant impact on multi-billion-dollar industries, in addition to protecting the health and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 scientists, physicians, regulatory and other personnel stationed throughout the United States.

The Center for Biologics Evaluation and Research (CBER) is a Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. CBER protects and advances the public health by ensuring that biological products are safe, effective, and available to those who need

them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

The mission of the Office of Biostatistics and Pharmacovigilance (OBPV) involves evaluating the safety and efficacy of the spectrum of CBER products throughout their entire lifecycle, from preclinical to post-marketing. OBPV scientific disciplines include experts in epidemiology, statistics, medicine, risk analysis, public health, genomics, and other scientific areas.

The Division of Analytics and Benefit-Risk Assessment (DABRA) improves the efficiency, consistency, and rigor of the methods used by the office to evaluate the safety and effectiveness of CBER regulated products and develops and applies new methods and tools for improving observational epidemiological studies, data mining, and comparative effectiveness studies, and other quantitative aspects of the evaluation of the risks, benefits, and use of biologic products. DABRA leads the OBPV's programs on quantitative benefit-risk assessment, Real-World Evidence (RWE), and analytics and informatics projects, work that supports the office's review, regulatory and public health missions. DABRA works with OBPV, other CBER offices, and across the centers to conduct Digital Health Technology (DHT)s-related reviews and activities. These activities include but are not limited to, development of DHTs guidance and participating in public and industry meetings on DHTs-related topics and discussions. DABRA also operates the High-performance Integrated Virtual Environment (HIVE), which consists of a high-performance computing cluster (HPC) with petabyte scale high-availability storage; a sophisticated web-based genomics analysis platform; support for machine learning in Python and R; and a team of expert bioinformaticians, computer scientists, and software developers.

The Analytics and Real-World Evidence (RWE) Branch (ARWEB) within OBPV leads the office's programs on Real-World Evidence, analytics, and informatics projects, supporting the office's review, regulatory, and public health missions. ARWEB develops capability and policy for the use of real-world evidence in regulatory decisions. The HIVE, located within ARWEB, performs complex data analysis on next-gen sequencing experiments, adds custom analytics and pipelines to the HIVE platform, trains, and support users, and assists with big data transfer and storage. It is a cloud-based environment optimized for the storage and analysis of extra-large data, like Next Generation Sequence (NGS) data, Mass Spectroscopy files, Confocal Microscopy images and others.

Duties/Responsibilities

The incumbent serves as a Data Scientist in the High-performance Integrated Virtual Environment (HIVE) for the Analytics and Real-World Evidence (RWE) Branch (ARWEB) within the Division of Analytics and Benefit-Risk Assessment (DABRA) under the Office of Biostatistics and Pharmacovigilance (OBPV). This position reports to the Branch Chief of ARWEB. The HIVE Data Scientist serves in multiple capacities as the OBPV lead on regulatory applications of next generation sequencing (NGS) analysis technologies, as senior subject matter expert in bio-medical informatics project review and grant applications; and as computational biology and bioinformatics services coordinator and project lead for NGS technology support services regarding research, scientific resources, and administrative activities. The HIVE Data Scientist collaborates with FDA researchers and reviewers by using a combination of biology and bioinformatics expertise to plan and assist in executing bioinformatics and statistical analysis on research projects and regulatory reviews containing next generation sequencing (NGS), genomics, cellular biology, neuroscience, pharmacology, computational biology, and/or structural biology data.

Specifically, the Data Scientist will:

- Assist OBPV leadership on activities that affect Agency and Interagency-wide public health projects and initiatives relating to data analysis of next generation sequencing and bioinformatics issues and opportunities.
- Contribute to scientific manuscripts to be published in peer-reviewed journals. When software development is required to implement new bioinformatics or statistical analysis in the FDA HIVE, will pilot novel bioinformatics algorithms and analysis visualizations for the FDA HIVE, using Linux, SAS, R, and C++. Informs senior officials on current bioinformatics and structural biology algorithms, industry practices, and their application to biomedical research and scientific review of human drugs and therapeutic biologics.
- Use expertise in standards development to work with FDA and external stakeholders to develop, pilot, and implement data standards for the regulatory submission of clinical and nonclinical study data and NGS,

including Clinical Data Interchange Standards Consortium (CDISC) standards and the High-performance Integrated Virtual Environment (HIVE) BioCompute Object trial standard.

- Initiates contact and provides expert technical advice and direction to contractors. Keep the Contracting Officer informed on progress, proposed contract modifications, validity of claims, analysis of proposals, and assessment of contract time extensions.
- Direct and/or manage the development and design of large, new, and unusually complex computer systems, systems software, or related technology and equipment that impact national programs, and result in major advancement in the state-of-the-art of broad technologies.
- Interact with internal customers and colleagues to understand business processes, gather requirements, develop analysis methodologies, and coordinate ongoing iterative development of data products.
- Provide strategic and technical guidance and hands-on support in the transfer of any required data needed for a product team. Identify, adapt, and manage changes to products or programs in response to evolving user needs.
- Lead prioritization of new data analytics, development of review and surveillance processes that incorporate new artificial intelligence methodologies and assures statistical and scientific validity of guidance documents and outreach activities for these initiatives.
- Solve technical problems by writing code and explaining data architecture and design to both technical and non-technical audiences and delivers reports and relevant information to support the needs of leadership and product teams.
- Perform other duties as assigned.

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.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption. Visit www.SSS.gov for more info.
- 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: A bachelor's degree or higher in mathematics, statistics, computer science, informatics, data science, engineering, operations research, bioinformatics, economics, public health, computational biology, physics, or related scientific or technical field. The degree must be from an accredited program or institution.

OR

Professional Experience: Comparable work in or demonstrated understanding in data science or a related field (through portfolios, certifications, etc.).

Desired Professional Experience, Skills, or Education:

- Knowledge and experience with next generation sequencing, machine-learning, artificial intelligence, natural language processing, robotics, and other methods to apply to premarket review and postmarket surveillance for CBER-regulated products.
- Demonstrated experience in written and oral communications techniques required to prepare and deliver reports and presentations on study results and other critical data and information.
- Experience using concepts, principles, and practices related to data management, data reliability, data validity, and data analysis.
- Demonstrated experience communicating highly technical information in a clear matter.

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: 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.

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

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

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

Please submit electronic resume or curriculum vitae (please be sure to clearly define the number of years using month and year training completed, in addition to describing duties performed during that time period), SF50 (if applicable), latest signed PMAP (if applicable), a copy of your unofficial transcripts (if applicable), and letter of interest with ***"CURES CBER/OBPV/DABRA/ARWEB Data Scientist, Band D"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through **July 25, 2024.**

Announcement Contact

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

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

FDA is an equal opportunity employer.