



**Title 21 Vacancy Announcement eputy Division Director (DBV)
U.S. 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: March 22, 2023 – April 5, 2023

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: Deputy Division Director (Supervisory
Mathematical Statistician)

Series: AD-1529

Location(s): Silver Spring, MD

Salary: Starting at \$155,700

Work Schedule: Full-Time

Cures Band(s): Band E

Full Performance Band Level: Band E

Travel Requirements: 25% or less

Bargaining Unit: 8888

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 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 (OTC) 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.

The mission of the Office of Biostatistics (OB) is to provide CDER, FDA and external stakeholders with statistical leadership, expertise, and advice to foster the expeditious development of safe and effective drugs and therapeutic biologics for the American people and to protect the public health by applying statistical approaches for monitoring the effectiveness and safety of marketed drugs and therapeutic biologic products.

The incumbent serves as the Deputy Division Director for any of the divisions within the Divisions of Biometrics V (DBV), Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research and provides professional leadership and direction to subordinate supervisors and division staff.

Duties/Responsibilities

As **Deputy Division Director (Supervisory Mathematical Statistician)**, the incumbent is responsible for planning, coordinating, and evaluating the administrative and technical programs and activities.

- Provides statistical, methodological, and data management information and advice, including providing analytical and consultant services within the scope of policies and programs.
- Organizes work, establishes priorities, and administers the division operations. This includes operating through the team leader(s) to render guidance on policy and administrative matters and taking responsibility for the productivity of the division and quality of work product within the division, particularly as it pertains to clinical outcome assessments (COAs), biomarker qualifications, real world evidence (RWE) and complex adaptive and Bayesian designs.
- Participates with the DB Director, in the process for the evaluation and regulatory decision recommendations of new drug applications (NDAs), biologics license application (BLAs), and other type of submissions pertaining to drug and biologic products handled by the division.
- Advises the Office Director, Center Director, and other FDA officials on the statistical aspects of FDA's regulatory responsibilities in the areas of drug and biologic products as put forth in the Federal Food, Drug and Cosmetic (FD&C) Act.

Supervisory Responsibilities: Participates with the Division Director in aspects of managing functions within the Division such as directing the drug group under regulatory authority of the Division through team leaders providing expertise at the Division level.

Supervises subordinate supervisors and employees responsible for performing the varied and broad regulatory review functions of the division related to the highly complex requirements of the Agency which are constantly changing and often involve extensive coordination. Twenty-five percent or more of the workload of the division is at the GS-13 level.

Manages and directs a professional regulatory review program segment(s) which is a major portion of a Center regulatory review office and impacts directly on the Agency mission to protect the public health. The program segment(s), functions, and activities of the division directly and significantly impact the work of the regulated industry, other Federal agencies, State, local and foreign governments, industry and professional organizations, public interest groups, and the general public.

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:

[Mathematical Statistics Series, AD-1529](#)

Desired Education:

The ideal candidate should possess at least a master-level degree in biostatistics or statistics/epidemiology/mathematics from an accredited institution of higher learning or other research masteral degree widely recognized in U.S. academe as equivalent to a MS/MA.

Professional Experience:

Our ideal candidate will possess:

- Experience serving as an expert and consultant in the development of new statistical methodology or the adaptation of new methods to the regulatory process.
- Skill in providing managerial leadership for a technical administrative program.
- Experience conducting statistical research and review of studies submitted in support of regulatory drug or biologic applications.
- Experience evaluating and applying statistical methodology to provide scientific support for regulatory decisions regarding mathematical scientific initiatives.
- Ability to function within a regulatory environment and problem solve to meet challenging demands
- An understanding of Federal Regulations related to the work of the Center for Drug Evaluation and Research
- Prior senior leadership experience and excellent interpersonal skills; ability to organize and motivate people in the successful accomplishment of routine tasks.

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 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

Applicants should submit a letter of interest (cover letter) and current resume or curriculum vitae by **April 5, 2023**, 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 'OB/DBV Deputy Division Director' in the subject line of the email.

Announcement Contact

For questions regarding this Cures position, please contact the Office of Translational Sciences recruitment and outreach liaison at 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.

