



Title 21 Vacancy Announcement
Department of Health and Human Services (HHS)
U.S. Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Translational Sciences (OTS)

Application Period: November 7, 2022 – November 16, 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: Mathematical Statistician

Series: AD-1529

Location(s): Silver Spring, MD

Salary: Starting at \$106,823

Work Schedule: Full Time

Cures Band(s): C

Full Performance Band Level: C

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 the Center for Drug Evaluation and Research 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 Mathematical Statistician position is in the Office of Biostatistics (OB), Office of Translational Science (OTS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

The Office of Biostatistics is responsible for reviews in all therapeutic areas CDER supports and can be as diverse as cardio-renal, oncology, rare diseases, and antimicrobial products. Incumbents have an opportunity to employ a broad variety of statistical procedures relevant to pre-clinical and clinical evaluation decisions for new and generic drugs as well as new and biosimilar biologics and the emerging fields of quantitative risk assessment and pharmacogenomics.

The Office of Biostatistics is seeking individuals with strong statistical methodology skills and an interest in biomedical applications to serve as mathematical statisticians. Incumbents work with multidisciplinary teams of review scientists in a dynamic, highly challenging, and innovative atmosphere of development, evaluation, and research of drug and therapeutic biologics.

Duties/Responsibilities

As a **Mathematical Statistician**, the incumbent reviews statistical methods for the analysis of data, primarily from clinical studies. The incumbent may also act as statistical consultant for a range of highly complex other problems, e.g., manufacturing quality, laboratory experimental design/analysis, etc. The incumbent serves as a specialist in statistical methodology and its applications and collaborates with other FDA scientists in the evaluation of regulated studies and the conduct of primary research activities. Suggests changes to clinical trial protocols, including statistical methods and trial design and conduct issues. Applies currently accepted statistical methods where appropriate. Identifies situations where commonly used techniques or measures are not appropriate; if necessary, develops new methods or modifies existing methods to meet the requirements of specific projects.

Performs statistical reviews of investigational applications such as INDs and IDEs, evaluating proposals for the design, conduct, and analysis of regulated clinical studies. Performs statistical reviews of marketing applications such as BLAs, NDAs, PMAs and 510(k)s and supplements for adequacy of design, conduct, analysis, and appropriateness of resulting inferences and conclusions. Verifies applicants' critical statistical analyses and performs additional analyses as needed.

Provides statistical regulatory support, evaluating and suggesting changes to clinical trial protocols, statistical methods, and clinical trial design/conduct issues, and analyzes data from clinical studies using specialized statistical software and general programming languages. As a recognized statistical expert, the incumbent may receive for resolution unique, far-reaching, and previously unresolved problems in statistical analysis.

Writes summaries and develops reports and papers regarding statistical or clinical trial issues; gives briefings/presentations to other statisticians, other professional colleagues, FDA advisory panels, and upper management; and provides technical guidance, consultation and leadership with other professionals within the FDA, other government agencies, foreign governments or non- government organizations toward developing solutions to joint projects, programs and other problems of mutual interest.

Suggests and verifies methods and analyses in pilot studies, clinical trials, laboratory studies and other research projects to assure validity of inferences obtained from these studies. The incumbent, in coordination with his/her supervisor, renders judgments on such projects and must be prepared to defend those judgments as necessary in conferences, public forums, and in interactions with other government or private entities. Represents the FDA in meetings and keeps supervisor abreast of progress and potential problems.

Works in collaborative multidisciplinary groups with scientists, engineers, and physicians, translating medical questions and concerns into appropriate statistical analyses and communicating results. Collaborates with statisticians from sponsor companies and academic statisticians to develop new statistical methods and learn about new methods as they are being developed.

The incumbent maintains knowledge of the professional literature of the field. Attends conferences to retain and enhance professional competency and participates in activities of relevant professional societies.

Performs other duties as assigned.

Supervisory responsibilities: None

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, 1529](#)

Degree: that included 24 semester hours of mathematics and statistics, of which at least 12 semester hours were in mathematics and 6 semester hours were in statistics, or a combination of education and experience -- at least 24 semester hours of mathematics and statistics, including at least 12 hours in mathematics and 6 hours in statistics, plus appropriate experience, or additional education.

Desired Skills, Experience, or Education:

- Skill in applying broad areas of statistical theory, including techniques to originate and develop new statistical methods.
- Ability to provide consultation and/or analyze data from studies utilizing sophisticated analytical techniques.
- Knowledge as an authority on the review and conduct of various studies.
- Skill and sound judgement in relevant statistical analysis of data and providing rapid responses.
- Skill in planning and executing all phases of statistical analysis and leading work/studies.

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 with a Risk Level of Moderate

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 **November 18, 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 'Mathematical Statistician-Band C' 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

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