



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 Biostatistics (DB)

Application Period: February 12, 2024 – February 23, 2024	
Area of Consideration: FDA-wide 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. Multiple positions may be filled by this job announcement.	
Position: Mathematical Statistician Team Lead	Series: 1529
Location: Silver Spring, MD	Salary: Starting at \$139,395
Telework Eligible: Yes – as determined by agency policy.	Travel Requirements: 25% or less
Work Schedule: Full Time	Bargaining Unit: 3591
Cures Band: D	Full Performance Band Level: D
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 (FDA or Agency) 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 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.

Duties/Responsibilities

The incumbent serves as a Mathematical Statistician Team Lead within the Division of Biostatistics (DB) as well as a specialist in statistical methodology and its applications and collaborate with other Divisions in CBER regarding the evaluation of regulated studies and the conduct of primary research activities. Specifically, the incumbent is responsible for ensuring that the organization’s strategic plan, mission, vision and values are communicated and integrated into the team’s strategies, goals, objectives, and work and communicates to the team milestones.

Specifically, the Mathematical Statistician Team Lead will:

- Coaches the team in the selection and application of appropriate problem solving methods and techniques.
- Leads the team in identifying, distributing, and balancing workload among employees; arranging for team member training; monitors and reports on the status and progress of work. Reports to the team on progress in meeting team milestones and deadlines for completion of assignments.
- Serves as a nationally authoritative regulatory review scientist, providing technical leadership and guidance for regulatory activities in the areas of vaccines, blood products and cellular, tissue and gene therapies.
- Reviews memos written by team members for and performs reviews of and IND and IDE submissions, 510(k) applications and BLA, NDA and PMA submissions and supplements, especially those related to vaccines, cancer immunotherapies, leukemia, cell therapies, and rare diseases including inherited blood disorders.
- Provides recommendations to CBER review organizations, review scientists, and the regulated industry. Represents the Center at local, state, and national meetings on statistical matters concerning OVR, OBRR, and OTP-related products.
- Determines the adequacy of statistical data and analyses submitted by an applicant regarding the safety and effectiveness of a regulated vaccine or blood or advanced therapy product. Determines if statistical data or other information are necessary within the context of applicable laws, policies, regulations, and guidelines.
- Participates in meetings between the Center and regulated industry and advises on adequacy of statistical aspects of study plans and product development.
- Participates in activities of professional societies regarding the design, conduct, and analysis of regulated clinical trials, and other related statistical methodology. As necessary, the incumbent will attend special conferences, hearings, etc. with industry as well as the professional community, and may serve on committees, organize sessions, give oral or poster presentations, etc.
- Confers with other federal government agencies on joint projects and programs, mutual problems, and areas of interest, etc.
- Performs other duties 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.
- 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.
- 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 below Education Requirements 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 Requirements:

A bachelor’s degree or higher in mathematics, biostatistics, statistics, or in a related math field. Degrees in math education are not related. The degree must be from an accredited program or institution.

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](#).

Desired Professional Experience, Skills, or Education

- Our ideal candidate will possess a Ph.D. or equivalent terminal degree in biostatistics, statistics, or a closely related field.
- Candidate would ideally have relevant data analysis experience in clinical trials and/or other clinical studies.

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). **No assumptions will be made regarding your experience.** Along with your electronic resume or curriculum vitae, please submit a copy of unofficial transcript(s), SF50 (if applicable), latest signed PMAP (if applicable), and letter of interest with ***"CURES CBER/OBPV/DB Mathematical Statistician Team Lead"*** in the subject line to: CBERHumanCapital@fda.hhs.gov. Applications will be accepted through February 23, 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.

