



**Title 21 Vacancy Announcement**  
**Mathematical Statistician**  
**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)**

**Summary:**

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

The mission of the Center for Biologics Evaluation and Research (CBER) 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.

The Office of Biostatistics and Pharmacovigilance (OBPV) provides comprehensive statistical, pharmacovigilance, and epidemiological evaluation of data submitted to the Center in support of regulatory requirements. OBPV evaluates 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 Biostatistics (DB) develops and evaluates statistical methodologies for analyzing preclinical, clinical, laboratory, real world, and epidemiological data and collaborates with scientists in the Center and across the FDA on original research projects of common interest. DB provides statistical expertise and insight in the development of standards and guidance, in designing studies, and analyzing and interpreting the results. DB performs a comprehensive statistical review and recommends an appropriate action of licensing applications (biologics license application (BLA), premarket approval (PMA), new drug application (NDA)) and supplements for safety and efficacy, in coordination with other Center components.

**Overview:**

<b>Area of Consideration:</b> The Public
<b>Open &amp; Close Dates:</b> January 7, 2025 – January 22, 2025
<b>Position:</b> Mathematical Statistician* <i>*Multiple selections can be made from this announcement</i>
<b>Salary:</b> Starting at \$117,962 and is set to commensurate with education and experience
<b>Band:</b> C
<b>Occupational Series:</b> 1529
<b>Duty Location:</b> White Oak Campus, Silver Spring, MD.
<b>Remote Job:</b> No
<b>Telework Eligible:</b> Yes – as determined by agency policy.
<b>Travel Required:</b> 25% or less
<b>Appointment Type:</b> Permanent
<b>Work Schedule:</b> Full Time

<b>Competitive Service:</b> Yes
<b>Promotion Potential:</b> Band C
<b>Supervisory Status:</b> No
<b>Security Clearance:</b> Yes - Background Investigation
<b>Drug Test:</b> No
<b>Bargaining Unit:</b> 3591

**You must be a U.S. Citizen or U.S. National.** Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

**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](#)

#### **Duties:**

The incumbent serves as a Mathematical Statistician within the Division of Biostatistics (DB) under the Office of Biostatistics and Pharmacovigilance (OBPV). This position reports to a Branch Chief within DB. 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. As a recognized authority, the incumbent reviews statistical methods for the analysis of data, primarily from clinical studies. The incumbent 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.

Specifically, the Mathematical Statistician will:

- Act as statistical consultant for a range of other problems, e.g. manufacturing quality, laboratory experimental design/analysis, etc.
- Suggest changes to clinical trial protocols, including statistical methods and trial design and conduct issues.
- Apply currently accepted statistical methods where appropriate; identify situations where commonly used techniques or measures are not appropriate; and if necessary, develop new methods or modifies existing methods to meet the requirements of specific projects.
- Perform 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.
- Verify applicants' critical statistical analyses and perform additional analyses as needed.
- 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.
- Represent the FDA in meetings and keeps supervisor abreast of progress and potential problems.
- Provide 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, receive for resolution unique, far-reaching, and previously unresolved problems in statistical analysis.
- Work in collaborative multidisciplinary groups with scientists, engineers, and physicians, translating medical questions and concerns into appropriate statistical analyses and communicating results.
- Collaborate with statisticians from sponsor companies and academic statisticians to develop new statistical methods and learn about new methods as they are being developed.
- Write summaries and develop reports and papers regarding statistical or clinical trial issues; give briefings/presentations to other statisticians, other professional colleagues, FDA advisory panels, and upper management; and provide 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.
- Maintain knowledge of the professional literature of the field.
- Attend conferences to retain and enhance professional competency and participates in activities of relevant professional societies.
- Performs other duties as assigned.

## Requirements:

### Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- 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](http://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 Requirement: 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.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.
- **If you are serving or have served in the last 5 years as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. See [Political Appointee FAQ - OPM](#) for more.

## Qualifications:

### **Basic Qualification Requirements:**

*In order to qualify for this Title 21 (Cures) position, the candidate(s) must meet the following **requirements:***

- **Education:** A bachelor's degree or higher in mathematics, statistics, or in a related math field. Degrees in math education are not related. The degree must be from an accredited program or institution.  
OR
- Experience in managing, supervising, leading, or performing (1) scientific work that involves designing, developing, and adapting mathematical methods and techniques to statistical processes or (2) research that relates to the basic theories and science of statistics.

### **Desired Professional Experience/Qualifications:**

*The experiences and qualifications listed below are considered preferable/desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

- Our ideal candidate will possess a master's or doctoral degree in statistics, biostatistics, bioinformatics, or a related field.
- Candidate would ideally have at least three years of relevant data analysis experience in clinical trials and/or other clinical studies.

**If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional 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 further information, visit the [U.S. Department of Education website for Foreign Education Evaluation](#).**

**How you will be evaluated:** You will be evaluated for this job based on how well you meet the qualifications above.

**This is a Title 21 announcement:** Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

## 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](#).

### How to Apply:

Please submit **electronic resume or curriculum vitae** (for each position held, please be sure to clearly define the number of years by month and year, all completed trainings, and clearly describe duties and accomplishments). Please also submit **SF50 (if applicable)**, **latest PMAP (if applicable)**, **unofficial transcripts**, **Foreign Credit Evaluation (if applicable)**, and **letter of interest (Word or PDF)** with ***"Title 21 CBER/OBPV/DB Mathematical Statistician, Band C"*** in the subject line to: [CBERHumanCapital@fda.hhs.gov](mailto:CBERHumanCapital@fda.hhs.gov). **Applications will be accepted through January 22, 2025.**

### Announcement Contact:

For questions regarding this Title 21 (Cures) position, please contact [CBERHumanCapital@fda.hhs.gov](mailto: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.*

