TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
Division of All Hazards Response, Science, and Strategic Partnership (DARSS)
Patient Science and Engagement (PSE)

Position: Data Scientist (Psychometrician)

Series: The position of Interdisciplinary Scientist may be filled by candidates from the following occupational series: Social Science (0101), Psychology (0180), Miscellaneous Administration and Program Series (0301), General Health Scientist/Epidemiologist (0601), General Mathematics and Statistics (1501), Mathematical Statistician (1529), and Statistician (1530),

Location(s): Silver Spring, Maryland, FDA Headquarters, , White Oak Campus

Travel Requirements: This position may require up to 25% travel.

Application Period: Wednesday, June 9, 2021, through Friday, July 23, 2021

Salary: Salary starts at $122,530 and is commensurate with education and experience.

Conditions of Employment: United States Citizenship is required

Special Notes: This position is being filled under an excepted 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 the authority. Additional information on 21st Century Cures Act can be found here.

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 mission of the Center for Devices and Radiological Health (CDRH or Center) is to protect and promote the public health by performing essential public health tasks designed to ensure medical devices, diagnostic products, and radiological equipment, to include new and emerging technologies, are safe, reliable, and effective for the American people.

Within CDRH, the Office of Strategic Partnerships and Technology Innovation (OST or Office) provides leadership for all scientific, collaborative, and emerging technology related activities at the Center. The Patient Science and Engagement Program (PSE or Program) is the component of the Office that focuses on developing and cultivating relationships with patient advocacy organizations, health care, regulatory, and scientific communities and organizations, industry,

and other patient-centric associations that are focused on patient experiences, preferences, and reported outcomes, across the total product lifecycle and the patient's lifespan, as it relates to medical devices. Specifically, the Program conducts in-depth analyses on the patients' use and responses to therapeutic and diagnostic medical devices and their impact on health outcomes, as well as the safety, effectiveness, and impact of medical devices on quality of life.

Position Summary:
CDRH is seeking an experienced, innovative, and team oriented human data scientist who is dedicated to improving health outcomes and the quality of life of patients through the advancement of therapeutic and diagnostic medical devices. In this position, you will conduct comprehensive qualitative and quantitative psychometric analysis on the use and impact of medical devices and combination products, regulated by the Center, across the entire patient spectrum. As a critical member of the PSE multidisciplinary team, you will report directly to the Assistant Director and will be responsible for providing expert evaluation of clinical studies submitted by industry to include design, methodology, endpoints, assessment tools, and software. You will also evaluate the consistency and validity of industry reported information, as well as conduct real-world data assessment of medical device usage, patient-reported outcomes s, clinical and caregiver reported outcomes, as well as performance outcomes. You will review advertisements, and labeling related to the design and intended use of medical devices in patients. You will also design, coordinate, and conduct studies to develop or modify clinical outcome assessment instruments.

Duties/Responsibilities:
As a Psychometrician you will perform the following:

- Utilize your expertise in human data science to develop and implement psychometric analysis plans to evaluate clinical study data, to include https://www.ncbi.nlm.nih.gov/books/NBK338448/def-item/glossary.clinical-outcome-assessment/ (such as patient-reported outcomes), evidence to support their measurement properties, compliance information, and outcomes related to the therapeutic and diagnostic benefits of medical devices, diagnostic equipment, and combination products, based on intended use.
- Serve as the voice in human data science and collaborate with colleagues across the Office, Center and Agency to develop guidance documents, policies, and standards regarding the use of clinical outcome assessments in the evaluation of medical devices, diagnostic equipment, and combination products.
- Evaluate manufacturers' data to ascertain if mathematical and statistical methods, procedures, study design, and clinical claims presented are supported by validated statistical analysis and treatment data.
- Assist in the development of assessment tools that support study design methodology, endpoints, and reliably evaluate and measure manufacturer claims and treatment benefits.
- Offer expert statistical and psychometric interpretations of design methodology and data captured in the development of statistical and technical reports and presentations.
- Keep abreast of innovative approaches in clinical study design techniques, methodology, biostatistics, and psychometrics.
- Serve as an expert consultant and liaison on cross-functional teams within the Office, Center, and Agency related to the development, utilization, and interpretation of patient-based studies, in particular endpoint development, validation, and patient elicitation methods.

- Evaluate the validity of psychometric instrument scores designed to capture psychological aspects of patients, to include symptoms, feelings, quality of life, and perceptions surrounding health status and medical device usage.
- Represent the Program, Division, and Office at industry, standards, and FDA advisory panel meetings to share expert position regarding study design, assessment tools, endpoints, and data collected related to patient reported experiences and outcomes with the use of medical devices.
- Engage and collaborate with patient advocacy groups, industry, healthcare, and scientific communities to ensure all relevant medical concerns will be addressed by studies with the prescribed assessment tools and endpoints.
- Provide expert consultation to Division and Office leadership on programmatic plans, health care community, scientific, and industry related trends, significant concerns, and adverse event reported data regarding medical devices, diagnostic equipment, and combination products regulated by the Center.
- Collaborate in the development, coordination, and implementation of policies and study designs to assure medical products, especially those novel in nature and with emerging technologies, appear to be safe, effective, and reliable.

Professional Experience/Key Requirements:

To qualify for this position, you must demonstrate in your resume the necessary qualifying experience for this position, which is equivalent to the following:

- Knowledge and experience with applying psychometric analysis methods such as classical test theory, item response theory, and item factor analysis. Experience in developing, applying, and/or validating psychometric instruments and patient-centered outcomes.
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- Evidence of a strong commitment to data quality, validation, and transparency.
- Demonstrated proficiency in the use of statistical and psychometric software.
- Contribute to recommendations which speak to the safety, efficacy, and reliability medical products or procedures, based on validated study data.
- Demonstrated proficiency in written and verbal communication skills, as well as team work

Desirable Education:

Applicants with advanced degrees in psychometrics, clinical psychology, neuropsychology, quantitative psychology, , , , mathematical statistics, or educational measurement are highly desired.

Conditions of Employment:

- A probationary period may be required.
- Background and/or Security investigation required.
- All applicants born male, on (or after) 12/31/1959, must be registered with the Selective Service System OR have an approved exemption.
- This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

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 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.

How to Apply:

Submit an electronic resume or curriculum vitae, cover letter containing a brief summary of scientific accomplishments, SF-50 (if applicable), and a copy of unofficial transcripts all in one document (**Adobe PDF**) to CDRHRecruitment@fda.hhs.gov, with Job Reference code ***"2021-OST-DARSS-PSE-01"*** in the subject line. Applications will be accepted through **July 23, 2021.**

Candidates must possess the required individual occupational requirements to qualify for the appropriate series applicable to the position. Please use the following link to determine the series for which you qualify: https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/#url=List-by-Occupational-Series

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