



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 (OST)
Division of All Hazards Response, Science and Strategic Partnerships (DARSS)

Application Period: Open April 18, 2023 – Closes May 17, 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: Social Scientist/Psychometrician

Series: May include 0101, but not limited to.

Location(s): Remote Eligible

Salary: Salary is commensurate with education and experience and starts at \$132,368

Work Schedule: Full Time

Cures Band(s): Band D

Full Performance Band Level: Band D

Travel Requirements: This position requires up to 25% travel.

Bargaining Unit: 3591

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 that 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 [CDRH](#) is to protect and promote the public health by performing essential public health tasks by making sure that medical devices and radiological health products are safe for people in the United States.

The [Office of Strategic Partnerships and Technology Innovation | FDA](#) (OST) provides leadership for all scientific collaborative and emerging technology related activities at CDRH. We represent CDRH with a broad and diverse array of national and international entities including other government agencies, Congress, industry, academia, consumer and patient organizations, and healthcare professional organizations, with mutual interests in medical devices and radiation-emitting products.

Duties/Responsibilities

Serve as a Social Scientist/Psychometrician in the Patient Science & Engagement (PSE) Team. Serves as an expert analyst to provide input regarding patient-reported outcomes (PRO) and other Clinical Outcome Assessments (COAs). Responsible for evaluating a variety of complex study tools, endpoint assessments, and patient-centered outcome issues to support medical device development and evaluation, including through therapeutic clinical trials.

Social Science/Psychometric Consultation

As the technical authority in the specialized scientific area of patient science (which includes patient-reported outcomes, patient-generated health data, and patient preference information), the incumbent performs critical reviews of scientific or technical procedures, methodologies, and investigations for scientific and regulatory policy implications and impact on overall scientific activities and priorities in areas that require extensive interpretation. Serves as the recognized expert authority in planning, conducting, and evaluating patient science studies and approaches to using them, as well as where critical problems need to be resolved and existing methods are inadequate, making it extremely difficult to design studies and gather reliable data. The incumbent explores innovative evaluation methods and tools to assess the benefits and risks of these methods while providing expertise in the formulation of patient science studies' development, utilization, and interpretation in medical product evaluation.

Serves as an expert advisor and technical authority providing liaison and consultation services related to social science on endpoint development, validation, and application in medical device studies. Collaborates with physicians, healthcare professionals, and regulatory and technical experts to ensure that all relevant medical product matters are addressed in relation to study tools, endpoints or applications of patient science issues and concerns. Provides leadership and expert advice and assistance to the CDRH management in defining Social Science analysis issues, conducting analysis of programs, formulating policy and strategy, making project recommendations, conceptualizing new programs or in redesigning ongoing ones, etc., to ensure that they address current and pressing issues. Provides expertise and professional judgment in selecting interventions, and subsequent programming, budgeting, implementation, and evaluation issues.

Collaborates with subject matter experts (scientists, engineers, physicians, statisticians,

regulatory specialists, healthcare professionals, etc.) who are reviewing clinical study results to be certain that regulatory decisions are consistent with standards set in the federal regulations. Assists and collaborates with other members of the team regarding patient-centered outcome study issues and projects. Collaborates with colleagues within CDRH and across FDA to apply current information and insights from the social science research literature to government policy decision making and communications as related to patient-centered regulatory science. Works collaboratively with colleagues from the other medical product centers to develop policies, guidance documents, and standards to inform the development, modification, and use of patient science tools in the evaluation of medical products. Consults with internal/external experts to assure patient-centered-related information is scientifically and clinically adequate.

The incumbent presents at Advisory Committee meetings, participates in the development of new communications to address COA issues, and participates in the writing of guidance's and standards for industry and FDA staff that address patient-centered regulatory science issues pertaining to medical products.

Social Science/Psychometric Technical Resource

Represents the PSE program in meetings with industry representatives, members of other government agencies, and others to provide expert advice on COA-related issues to support medical device labeling claims and study designs. Analyzes, formulates, and develops ideas, concepts, and methodologies for new or revised policies, procedures, and systems for designing, implementing, and evaluating COAs worldwide.

Conducts research in strategy, design techniques, and methodology. Identifies concepts and ideas that have proved successful and develops alternative concepts and techniques for use in a variety of situations. Assesses strategic objectives, program and project design, and methodologies used to determine that they will accomplish established objectives. Considers differences among patients and the types of factors that influence COAs. Analyzes outcomes by utilizing qualitative and quantitative approaches. Utilizes scholastic research that encompass principles, theories, and findings in industrial/organizational psychology, psychometrics, experimental design/evaluation methodology, education, and training technology, and/or cognitive psychology to modify, revise, improve or create programs and projects.

Develops and validates measurements that capture psychological aspects of patients, including symptoms, feelings, perceptions, functions, and perspectives; also brings that expertise to bear on digital health technologies that may capture real world data about the daily lived experience of patients. Reviews and performs an in-depth analysis of published literature and study results to develop tools for COA data collection to support study design features, endpoints, and labeling claims. These tools and related study endpoints or patient preference elicitation issues are broad in scope and affect a significant portion of regulated industry, as well as the public.

Based upon the information derived from COA-related issues and reviews, the incumbent provides expert consultation and advice to sponsors and medical device development tool subcommittees. Contributes to the development and design of medical device development tools that are well defined and reliable measures of treatment benefit. Works with the interdisciplinary scientists, engineers, healthcare professionals, and physicians to be certain that the measures can be reliably interpreted.

Identifies key patient-centered outcome social science issues and constraints that can be overcome by policy, legislative, or other initiatives, working in collaboration within FDA and with external stakeholders. Maintains continuing relations with medical device industry, hospitals, healthcare systems, non-governmental institutions, universities, and other governmental agencies concerned with patient perspective issues. Provides recommendations on COA issues and modifications to proposals where relevant. Prepares briefing materials and provides material on COA activities. Selects and leads assessment teams to provide technical assistance in defining strategic plans and designing specific programs and projects; and participates in evaluations of programs and projects, and of work performed by grantees, contractors, other agencies, and/or FDA. Develops COA approaches that may be applied worldwide.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields for Social Science Series 0101.
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: [OPM Occupational Series Qualification Requirements; https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/0100/social-science-series-0101/](https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/0100/social-science-series-0101/)

How to Apply

How to Apply: Submit resume or curriculum vitae, transcripts with cover letter by May 17, 2023, to CDRHRecruitment@fda.hhs.gov. Candidate resumes may be shared with hiring official within the CDRH with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. Please include the following Job Reference ID in the subject line of your email submission: CDRH/OST/DARSS Social Scientist PBM-4462

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: [User Guide - Obtaining FDA Clearance for New Onboards.docx \(sharepoint.com\)](#)

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 based on 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.

Announcement Contact

For questions regarding this Cures position, please contact Tiffany Bray.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

FDA is an equal opportunity employer.

