



**Title 21 Vacancy Announcement**  
**Department of Health and Human Services (HHS)**  
**Food and Drug Administration (FDA)**  
**Center for Drug Evaluation and Research (CDER)**  
**Office of New Drugs (OND)**  
**Office for Drug Evaluation Science (ODES)**

**Application Period:** 1/26/22 -2/9/22

**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:** Associate Director for Digital Health Technologies

**Series:** 0601

**Location(s):** Silver Spring, MD

**Salary:** Starting at \$148,484

**Work Schedule:** Full-time

**Cures Band(s):** Band E

**Full Performance Band Level:** Band E

**Travel Requirements:** 25% or less

**Bargaining Unit:** 8888

**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 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 Drug Evaluation and Research (CDER) 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 and prescription drugs, including biological therapeutics and generic drugs.

OND is a dynamic, purpose-driven organization dedicated to the review of new drug applications, interactions with the pharmaceutical industry and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multi-disciplinary organization engaged in the oversight of human drug trials in the United States, in review of new drug applications (NDAs) and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over-the-counter (OTC) drug products.

## Duties/Responsibilities

The Associate Director for Digital Health Technologies (DHTs) is the principal advisor to the ODES Office Director in matters relating to DHTs. DHTs encompass systems that use software, connectivity, computer platforms and systems for healthcare and related purposes. Applications include general wellness apps, to medical device apps applications, to and systems generating data that may be used in drug trials, including decentralized clinical trials. The major duties and responsibilities include but are not limited to:

- Formulates goals and objectives of the DHT program for the Office of Drug Evaluation Sciences and is responsible for creating policies, procedures, and organizational structures necessary to achieve the stipulated goals. Provides oversight and coordination of activities involving DHTs, including meeting with foreign regulatory counterparts to compare approaches to qualifying DHT-based clinical outcome assessments and biomarkers.
- Coordinates activities to achieve congressional mandates regarding DHTs, including Prescription Drug User Fee Act (PDUFA VII) FDA commitments relating to guidance document development, demonstration projects and public workshops.
- Provides expert advice on DHTs and serves, as assigned, on cross Office/Center working groups related to DHTs. These activities often require technical expertise, integrated evaluation throughout OND and CDER, and coordination with other Agency components because of their potential broad impact on FDA programs and public health. Also provides expert advice to the FDA's Office of the Commissioner for congressional inquiries and testimony.
- Monitors the work of OND clinical divisions regarding DHTs in clinical trials and Office and Center personnel involved in DHT work. Engages OND senior leadership to develop the infrastructure necessary to support DHT activities within OND and to provide a coordinated, aligned approach across OND clinical review divisions. Supports education and training of OND personnel on incorporating DHTs in clinical development programs.
- Represents OND, CDER, and FDA on DHTs at scientific, medical, and academic national and international meetings and forums, including meetings with counterpart foreign officials and government agencies. The incumbent acts as a focal point for the regulated pharmaceutical industry and academia in developing common interest research efforts to (i) leverage resources; (ii) support the development of appropriate regulatory

guidance and policy; (iii) identify, define, articulate and coordinate DHT-related activities; and (iv) research problems and issues to inform and develop strategies and solutions.

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.

In order 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:** General Health Science Series, 0601 - Bachelor's or graduate/higher level degree: major study in an academic field related to the medical field, health sciences or allied sciences appropriate to the work of the position. This degree must be from an educational program from an accrediting body recognized by the U.S. Department of Education (external link) at the time the degree was obtained. For more information please see: [\[OPM Occupational Series Qualification Requirements\]](#)

**Desired Education:** Competitive candidates will have earned a doctoral or medical degree in life or biomedical sciences, pharmacology, chemistry, biology, or a related field.

**Professional Experience:**

- Strong organizational, analytical, and interpersonal skills.
- Research experience in chemistry, biology, pharmacology, toxicology, or a related field of biomedical science.
- Experience participating in peer-review committees designed to evaluate regulatory science research projects for competitive funding.
- Experience writing, evaluating, and submitting grants for submission to competitive funding agencies.
- Knowledge of the financial and technical resources available at FDA to support regulatory science research is strongly preferred.

## 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/High Risk

## 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. Safer Federal Workforce Task Force guidance on other Federal agency safety protocols based on vaccination status—including guidance on protocols related to masking, distancing, travel, testing, and quarantine—remains in effect.

## 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

How to Apply: Submit resume or curriculum vitae with cover letter by 2/9/2022 to: [ONDIORecruitment@fda.hhs.gov](mailto:ONDIORecruitment@fda.hhs.gov). Candidate resumes may be shared with hiring official within the CDER with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”. Please reference Job Reference ID: **OND-ODES-DHT-001**

## Announcement Contact

For questions regarding this Cures position, please contact Lisa Conrad at [ONDIORecruitment@fda.hhs.gov](mailto:ONDIORecruitment@fda.hhs.gov)

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

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