

FOA: Developing Digital Therapeutics for Substance Use Disorders

OVERVIEW

The Department of Health and Human Services National Institutes of Health (NIH) has released a Funding Opportunity Announcement (FOA) to support the development of digital therapeutics (DTx) to treat substance use disorders (SUD). DTx may include clinical-grade mobile, web, or other software-based platforms designed to deliver safe and effective SUD treatment (e.g., improving medication adherence, treatment of withdrawal, etc.). DTx are available 24/7, do not require transportation, and are not limited by clinician time, so that interventions are accessible and highly reproducible.

Applicants' SUD interventions may be completely delivered by the DTx or may include a reduced number of face-to-face interactions with a clinician. However, DTx does not include wellness apps or telehealth platforms that connect to a clinician. Applications may focus on the pre-clinical and/or clinical development and testing of new DTx or existing DTx developed for other conditions.

The full FOA is available [here](#). Applications for the first round are due on September 8th, with additional application rounds accepted through 2024 as outlined in the FOA.

FUNDING

Awards will be allocated in two phases as follows:

Phase	Timeframe	Description	Funding
UG3	Up to two years.	Focused on moving the intervention forward to the next state of design and testing and determining specific milestones to be accomplished by the end of the period.	\$500,000 in funding for direct costs annually.
UH3	Up to three additional years.	Additional support following the successful completion of UG3 phase activities and milestones and the next step in development towards FDA authorization.	Unrestricted, but must reflect the needs of the project.

ELIGIBLE APPLICANTS

Eligible applicants include the following:

- Not-for-profit organizations;
- For-profit organizations (including small businesses);
- Faith- or community-based organizations;
- Regional organizations;
- Public housing authorities; and
- Public or private institutions of higher education.

Applicants may submit more than one application; however, each application must be scientifically distinct.

APPLICATION

Proposals will be scored based on the following criteria:

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

Reviewers may also evaluate additional items when determining scientific and technical merit of the proposed project, including study timeline and protections for human subjects, among others.

Timeline

The first round of applications is due on September 8th. Applicants are encouraged, but not required, to submit a non-binding letter of intent 30 days prior (by August 9th for the first round) to NIDALetterofIntent@mail.nih.gov.

Application submission questions may be submitted to grantsinfo@nih.gov. Scientific/research questions may be submitted to Will Aklin at aklinwm@nida.nih.gov or Kevin Walton at kevin.walton@nih.gov. Financial/grants management questions may be submitted to Pam Fleming at pflaming@mail.nih.gov.