

Drug Development Tools Research Grants – Accepting Applications through May 25, 2021

Purpose

The U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER), intends to support research activities that enable progress in drug development tool (DDT) qualification through a [Funding Opportunity Announcement \(FOA\) open now through May 25, 2021 for FY21.* The cycle will be repeated for the next two years and it reopens from February through May 3, 2022 and 2023 for FY22 and FY23, respectively.*](#) With this funding opportunity announcement (FOA), issuance of new cooperative agreements are anticipated under Limited Competition to support research to continue the development of drug development tools that have **an accepted Letter of Intent (LOI)** within [a drug development tool qualification program within either CBER or CDER](#) (Animal Models, Biomarkers, Clinical Outcome Assessments, and Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program). The LOI needs to be fully ACCEPTED (the determination letter of LOI acceptance to the project has been issued by FDA) and the project is in the active status with FDA, working toward a goal of FDA qualification by the closing date of the FOA. The grants will be used to further the development of tools that, once qualified, will be made publicly available to fill unmet needs in drug development.

*Funds Available and Anticipated Number of Awards will be determined later, contingent upon the Agency budget approval and the program priority.

Inquiries

Please direct all inquiries to the appropriate [DDT qualification program](#) for your DDT project and cc CDER-DDTGrantsContracts@fda.hhs.gov and york.tomita@fda.hhs.gov.

OR for administrative questions, please contact

Shashi Malhotra
Grants Management Specialist
Office of Operations, Office of Finance Budget & Acquisitions
Office of Acquisitions and Grants Services, HFA-500
U.S. Food and Drug Administration
Tel: 301-402-7592
shashi.malhotra@fda.hhs.gov