NIH funding opportunities

30 Nov 2023 (#38)

Confirm your intent to apply ASAP, but not later than 60 days before the submission date.

See all Important Notices, Parent Announcements and Notice of Special Interest below

Plan your application. Before starting your application attend

1) *Generic Grant Writing Workshop and then the*

2) NIH Grant Writing Workshop

To prepare an application can take 4-18 months.

From submission to receiving a Notice of Award can take 10 months

Important Notices

NOT-HG-24-010 Notice of Pre-Application Webinar for Ethical, Legal and Social Implications (ELSI) Research: PAR-23-293 (R01 Clinical Trial Optional), PAR-23-294 (R21 Clinical Trial Optional) and PAR-23-295 (R03 Clinical Trial Optional). This notice is to alert the community that the NHGRI plans to host a public pre-application webinar to provide an overview of the three Notices of Funding Opportunity (NOFO): Ethical, Legal and Social Implications (ELSI) Research (R01 Clinical Trial Optional) PAR-23-293, Ethical, Legal and Social Implications (ELSI) Exploratory/Developmental Research Grant (R21 Clinical Trial Optional) PAR-23-294, and Ethical, Legal and Social Implications (ELSI) Small Research Grant (R03 Clinical Trial Optional) PAR-23-295. The webinar on Monday, December 11, 2023, at 12:00 PM EST to provide an overview of these three NOFOs. Please register here to participate in the webinar.

Parent Announcements

NOT-OD-23-105 Notice to Extend Parent R01/R03/R21 Parent Notices of Funding Opportunities. Current Key Dates *Expiration Date: May 8, 2023.* **Modified *Expiration Date: May 8, 2024***
Parent Announcements (PA) for unsolicited are broad funding opportunity announcements allowing applicants to submit investigator-initiated applications. They are open for up to 3 years and use standard due dates.

- **PA-20-185** NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- **PA-20-184** Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)
- **PA-20-183** Research Project Grant (Parent R01 Clinical Trial Required)
- **PA-20-200** NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)
- **PA-20-195** NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)
- **PA-20-194** NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)
- **PA-20-196** NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)

Notice of Special Interest

NOT-AG-23-060 Telehealth for People and Families Living with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD). The purpose of this NOSI is to indicate NIA's interest in (1) retrospective and new examinations that determine the impact of telehealth on cost, access, quality, timeliness, and equity of care for people and families living with Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and (2) prospectively identify telehealth care delivery methods that work well for people and families living with AD/ADRD. This notice applies to due dates on or after January 7, 2024 and subsequent receipt dates through November 13, 2024.

NOT-HL-23-120 Leveraging Existing and Accessible Datasets for Implementation Research Strategies and Testing - LEAD FIRST. The goal of this NOSI is to encourage research that maximizes the utility of local-level community datasets by surfacing community insights to inform D&I research which can lead to actionable and sustainable change in communities. This NOSI promotes the use of existing and accessible datasets to inform community-engaged dissemination and implementation (D&I) research on heart, lung, blood and sleep conditions (HLBS) to advance health equity. This notice applies to due dates on or after February 5, 2024 and subsequent receipt dates through January 7, 2027.

NOT-OD-24-026 Advance Data Science Approaches Through Secondary Data Analysis to Reveal Scientific Insights of COVID-19 Testing Technologies (R21). The purpose of this Notice of Special Interest (NOSI) is to support secondary data analysis to address questions and advance scientific inquiry related to SARS-CoV-2 through the existing data resources in the Rapid Acceleration of Diagnostics Data Hub (RADx DataHub), including and in conjunction with other data resources. Applicants must select the IC and associated NOFO to use for submission of an application in response to the NOSI. The selection must align with the IC requirements listed in order to be considered responsive to that NOFO. Non-responsive applications will be withdrawn from consideration for this initiative.

NOT-DC-24-010 Tackling Acquisition of Language in Kids (TALK) R01 Research Projects. The purpose of this NOSI is to encourage applications for R01 research projects to: (1) advance our understanding of why children with various conditions and/or risk factors are late to talk, (2) differentiate developmental trajectories that lead to better outcomes, and (3) evaluate the effectiveness of clinical approaches to improve outcomes. The ultimate goal is to provide parents, caregivers, and professionals with the information they need to help late talking children grow and thrive. This notice applies to due dates on or after January 5, 2024 and subsequent receipt dates through November 6, 2026.

Notice of Funding Opportunity (NOFO)

1. RFA-DA-25-030 Adolescent Overdose Prevention and SUD Treatment Initiative (R21 - Clinical Trial Not Allowed). This NOFO encourages exploratory and developmental research to better understand adolescent illicit fentanyl use and overdose patterns among adolescents at high risk for overdose (i.e., intentional, unintentional, fatal, and/or non-fatal). Research studies should identify targets for overdose prevention and substance use disorder (SUD) treatment and recovery. Research studies may use a variety of approaches (e.g., leveraging existing data sources, survey research, social network analysis, development of new methods, feasibility research). Outcomes of interest include, but are not limited to, prevalence of overdose and reduction in substance use, particularly fentanyl use or use of substances that are commonly laced with fentanyl; unintentional use/overdose, use/overdose by risk group, stigma, family and environmental risk and protective factors, treatment engagement, adolescents' perceptions of substance use, and optimistic bias. Research studies involving services delivery or interventions are encouraged to consider the companion NOFO, RFA-DA-25-031, Adolescent Overdose Prevention and SUD Treatment Initiative (R34 - Clinical Trial Optional).

Due dates: March 13, 2024. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

Budget: NIDA intends to commit $1,000,000 in FY 2024 to fund 1-2 awards. Direct costs are limited to $275,000 over the 2-year project period, with no more than $200,000 in direct costs allowed in any single year.

2. RFA-FD-24-005 Integrating Machine Learning with Computational Fluid Dynamics Models of Orally Inhaled Drug Products (U01) Clinical Trials Not Allowed. Computational fluid dynamics (CFD) has played a crucial role in providing an alternative bioequivalence (BE) approach for generic orally inhaled drug products (OIDPs), in addition to comparative clinical endpoint or pharmacodynamic BE studies, as a relatively cost- and time-efficient complement to benchtop and clinical experiments that has been widely used in developing and assessing generic inhaler devices.

However, despite the advances in the power of modern computers, there are still some bottlenecks in using CFD due to computational time, limited grid resolution, pre- and post-processing of large simulation data sets, model parameter estimations, and uncertainty quantifications. Machine learning (ML) has been gaining more attention as a potential tool to alleviate such limitations that arise in CFD. The purpose of this grant is to develop a methodology to integrate ML with CFD models of OIDPs to promote alternative BE studies to enhance and accelerate the development and approval of generic OIDPs.

Due dates: March 31, 2024 by 11:59 PM Eastern United States Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for one (1) additional year contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA/CDER intends to commit up to $300,000 in FY 2024 to fund one (1) award. The maximum project period is two (2) years.

3. RFA-FD-24-006 Developing PBPK Model-Based Mechanistic IVIVCs for Long Acting Injectable Suspensions and Implants (U01) Clinical Trial Optional. The objective of this research proposal is to develop physiologically based pharmacokinetic (PBPK) model-based mechanistic in vitro in vivo correlations (IVIVCs) for two major types of long acting injectables (LAIs) such as crystalline suspensions and polymer-based implants by considering their distinct characteristics. The goal of the project is to develop a bottom-up mechanistic PBPK model for these two LAI categories by accounting for the influence of critical formulation attributes of each LAI drug product type to predict its in vivo release mechanism. The model formulation parameters and relevant physiology should be informed with suitable in vitro and in vivo experiments. A suitable preclinical animal model can be used to validate the PBPK model based IVIVCs for both LAI suspensions and polymer-based implants. The use of PBPK modelling provides a unique opportunity to understand how the physicochemical properties of drug molecules/polymer, implant specific properties, critical formulation attributes, and physiology, among other things, influence the in vivo release mechanisms of LAI drug products and their disposition characteristics. Moreover, once developed, a mechanistic PBPK model can help to define the 'safe space' for critical formulation attributes relevant to the reference listed drug (RLD) product, explain sources of PK variability and extrapolate predictions to human subjects by leveraging animal model data and by accounting for species-specific physiological differences.

Due dates: March 31, 2024 by 11:59 PM Eastern United States TimeApplicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for two (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA/CDER intends to commit up to $600,000 in FY 2024 to fund two (2) awards. The maximum project period is three (3) years.

4. RFA-FD-24-008 Evaluating the Cutaneous Pharmacokinetics of Topical Drug Products Using Pharmacokinetic Tomography (U01 Clinical Trial Required) The purpose of this funding opportunity is to support the research and development necessary to advance non-invasive (e.g., quantitative tomography-based) technologies, including the development of apparatus, methods, study designs, and methods of data analysis, to characterize and compare the rate and extent to which a topically applied drug becomes available at or near a site of action within the skin in vivo. The expectation is that the funded work will produce an accurate, sensitive and reproducible approach that rapidly measures the (relative) amount of drug present in the skin at a series of depths below the skin surface, which can be utilized to monitor the cutaneous pharmacokinetics (PK) of the drug at selected depths (e.g., in the epidermis) by repeated, serial measurements over time. The intent is to support the eventual development of an alternative, scientifically valid, in vivo cutaneous PK-based approach that can be used to efficiently demonstrate the bioequivalence (BE) of topical products.

Due dates: March 31, 2024 by 11:59 PM Eastern United States Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for

two (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA/CDER intends to commit up to $250,000 in FY 2024 to fund one (1) award. The maximum project period is 4 years.

5. RFA-FD-24-009 Improving Predictability of Food-Drug and Drug-Drug Interaction Risks by Utilizing In Vitro Simulated Gastrointestinal Dissolution Model for High-Risk Oral Drug Products (U01) Clinical Trial Optional. The purpose of this funding opportunity is to examine the utility of an in vitro simulated gastrointestinal (GI) dissolution model for the assessment of in vitro performance of amorphous solid dispersion (ASD) drug products under different clinically relevant conditions. The goal is to develop and validate the in vitro mechanistic methodology to provide an improved understanding of impact of food and acid reducing agents on the absorption for test and reference listed drug (RLD) drug products, taking into consideration their potentially different formulations and manufacturing. The bio predictive in vitro mechanistic methodology is intended to correlate the in vitro observations to in vivo outcomes, help define types of in vivo bioequivalence (BE) studies needed for ASD drug products, and inform regulatory decision-making related to mitigating the risk of potential failure modes for therapeutic equivalence for high-risk generic oral drug products.

Due dates: March 31, 2024 by 11:59 PM Eastern United States Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for two (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA/CDER intends to commit up to $500,000 in FY 2024 to fund two (2) awards. The maximum project period is three (3) years.

6. PA-23-317 Competing Revisions to Existing NIH Single Project Research Grants and Cooperative Agreements (Clinical Trial Optional). The National Institutes of Health (NIH) hereby notifies NIH award recipients that funds may be available for revision applications to support the expansion of existing projects and/or programs within the awarding Institute or Center (IC) identified in the competitive revision Notice of Special Interest (NOSI). Only applications submitted in response to a NOSI published by an NIH Institute or Center will be allowed to apply to this NOFO.

Due dates: See the competitive revision NOSI for any applicable Application Due Dates.

Budget: Specific budget limits may be specified in the competitive revision NOSI. Application budgets must be reasonable and must reflect the actual needs of the proposed project. The project and budget periods must be within the currently approved project period for the existing parent award. Unless otherwise instructed in the competitive revision NOSI, applicants may request up to two years of support. The parent award must have a minimum of two years remaining within the current project period at the time of application submission.

7. PAR-24-067 Prevention and Intervention Approaches for Fetal Alcohol Spectrum Disorders (R34 Clinical Trial Optional). This Notice of Funding Opportunity (NOFO) for R34 planning grant applications focuses on prevention and intervention strategies for fetal alcohol spectrum disorders (FASD) throughout the lifespan. The intent of this NOFO is to support research that advances (1) prevention approaches to reduce prenatal alcohol exposure and incidence of FASD and (2) interventions for FASD. It is expected that research conducted via this mechanism will consist of studies that are a pre-requisite for preparing and submitting subsequent applications for larger scale FASD prevention or intervention studies. Applicants interested in exploratory phased projects may consider NOFO (PAR-24-068***, the R61/R33 option***).

Due dates: February 16, 2024 through to October 16, 2026. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

Budget: The budget during the three-year project period may not exceed $450,000 direct cost, with no more than $225,000 direct cost requested in a single year. The project period is limited to 3 years.

8. RFA-FD-24-010 Identification of Drug-related and Formulation-Related Factors that Result in Alcohol Dose Dumping of Modified Release Oral Drug Products (U01) Clinical Trial Not Allowed. Modified release (MR) oral drug products are considered to have a high risk for alcohol dose dumping (ADD) because they contain large quantities of drug(s), designed to release over a prolonged period of time. Accidental exposure of these products to alcohol can result in the relatively rapid release of large quantities of drug with severe side effects, including death. To mitigate

this risk, the FDA recommends conducting an in vitro alcohol dose dumping assessment in 0%, 5%, 20%, and 40% alcoholic dissolution media for all prospective generic versions of MR oral drug products.To date, ADD assessments have not been harmonized globally. For instance, the U.S. FDA recommends testing up to 40% alcoholic media while the European Medicines Agency recommends testing up to 20% alcoholic media. This type of difference can present a challenge for formulators designing products for multiple markets, as historical data has shown release from MR oral products do not always follow a linear response (either increasing or decreasing) to increasing alcohol concentrations. In addition, interpretation of an ADD assessment may be limited by the inability of the test to predict in vivo behavior. The purpose of this research is to develop tools that 1) facilitate the development of MR generic drug products that have a low potential for ADD, 2) support regulatory decision making during the assessment of such products, and 3) provide evidence that enables FDA to develop more specific recommendations for efficiently demonstrating a low or comparative potential of alcohol dose dumping for MR oral drug products containing high risk drugs.

Due dates: March 29, 2024 by 11:59 PM Eastern United States Time. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for one (1) additional year contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA/CDER intends to commit up to $250,000 in FY 2024 to fund one (1) award. The maximum project period is two (2) years.

9. RFA-FD-24-011 Synthesis and Biological Activity Assessment of Different Diastereomers in siRNA Drug LEQVIO (Inclisiran) (U01) Clinical Trial Not Allowed. The purpose of this research is to systematically evaluate the diastereomeric composition of LEQVIO (Inclisiran), an FDA-approved, N-acetyl galactosamine (GalNAc)-conjugated siRNA drug, and to understand the biological/pharmacological activity of each diastereomer in LEQVIO through stereo chemically controlled synthesis and biological activity assessment using in vitro and animal models. The proposed studies will focus on 1) synthesis of each diastereomer of LEQVIO (Inclisiran) in stereo chemically pure form; 2) assessment of the biological activity of each stereo chemically pure diastereomer in inhibiting PCSK9 activity using in vitro assays and in a transgenic mouse model; 3) development of analytical methods to identify and characterize the stereochemical structure of each diastereomer in LEQVIO; and 4) assessment of the individual contribution of each diastereomer to the overall pharmacological activity of LEQVIO. Tools developed in this research can also be applied to other similar GalNAc-conjugated siRNAs specifically, and other siRNAs in general. Knowledge gained from this research will also contribute to the sameness evaluation of generic siRNAs, and to the quality control of oligonucleotide drugs.

Due dates: March 31, 2024 by 11:59 PM Eastern United States Time. Due by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. **Letter of Intent:** 30 days prior to the application due date.

Budget: The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Award(s) will provide one (1) year of support and include future recommended support for two (2) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA/CDER intends to commit up to $300,000 in FY 2024 to fund one award. The maximum project period is three (3) years.

Faculty of Medicine and Health Sciences **Research & Internationalisation Development & Support (RIDS) & Grants Management Office (GMO)** 009 Kth Floor, Teaching Block, Tygerberg Campus.	**Stellenbosch Campus** **Division for Research Development (DRD)** 2041 Krotoa Building, Ryneveld Street
Enquiries: cdevries@sun.ac.za / fmhsgmo@sun.ac.za	**Enquiries:** research@sun.ac.za
Add "*Interest in NIH opportunity*" in the subject line. Add the *notice number* in the text of the email.	