NIH funding opportunities

Faculty of Medicine and Health Sciences: Research Development and Support 5 Dec 2022 (#46)

[Click on blue hyperlink for further information]

*The NIH funding opportunities listed below are only a **selection** of pre-screened, currently open health funding opportunities for which **South African institutions are eligible to apply**. For a comprehensive selection of NIH funding opportunities, please visit **www.grants.nih.gov** or **www.sun.ac.za/RDSfunding** (current & archive).*

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

Tygerberg Campus: cdevries@sun.ac.za • Stellenbosch Campus lizelk@sun.ac.za

To prepare an application can take 4-18 months, depending on many factors:

1. Mechanism for which you will apply e.g. U54, R01, D43, K43

2. Requirement of preliminary data

3. Time to assemble the research team

4. Time available to work on the grant, taking into consideration other responsibilities

5. Time for internal review

Parent Announcements

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)

Important Notices

Gearing Up for Transition to FORMS-H Application Forms: As **announced** over the summer, NIH requires the use of updated application forms (FORMS-H) for due dates on or after January 25, 2023. . The How to Apply – Application Guide was updated on October 25 with FORMS-H application form instructions to prepare for the transition. Also see **Guide Notice NOT-OD-23-012.** All form changes are listed in High-level Grant Application Form Change Summary: FORMS-H. A key change in FORMS-H is support for the implementation of the 2023 NIH Data Management and Sharing Policy.

The intended due date for your application determines the correct form version to use.

- DO use FORMS-G form version for application due dates on or before January 24, 2023
- DO use FORMS-H form version for application due dates on or after January 25, 2023
- DO NOT use FORMS-H too early or FORMS-G too late

Notices of Special Interest (NOSI)

NOT-AG-22-048 Advancing the Science of Geriatric Palliative Care. This NOSI encourages research grant applications focused on palliative care in geriatric populations. This NOSI covers studies in a variety of settings including hospitals (and specific sites within hospitals including specialty medical or surgical wards, intensive care units, and emergency departments), post-acute care settings, outpatient clinics and doctors' offices, patients' homes and other residential settings, long-term care facilities, hospices, and other healthcare or community settings. This NOSI encourages both prospective studies and analyses of existing datasets, health and medical records, claims data, or other sources. Leveraging ongoing cohorts, intervention studies, networks, data and specimen repositories, and other existing research resources and infrastructure is encouraged. Study designs may include observational approaches, quasi-experimental designs, and interventional studies. Topics of interest among Institutes and Centers (ICs) participating in this NOSI are summarized below. Applicants are encouraged to contact the Scientific/Research contacts listed below to ensure that proposed aims are consistent with the mission(s) of the intended IC(s). Where IC topic areas overlap, applicants are especially encouraged to contact the respective IC representatives to discuss appropriate arrangements for dual assignment. This notice applies to due dates on or after October 5, 2020 and subsequent receipt dates through September 8, 2023. Submit applications for this initiative using one of the FOAs listed, or any reissues of these announcement through the expiration date of this Notice. Applicants must select the IC and associated FOA to use for submission of an application in response to this NOSI. The selection must align with the IC requirements listed in order to be considered responsive to that FOA. Non-responsive applications will be withdrawn from consideration for this initiative. In addition, applicants using NIH Parent Announcements (listed below) will be assigned to those ICs on this NOSI that have indicated those FOAs are acceptable and based on usual application-IC assignment practices.

NOT-AI-23-010 Administrative Supplements for R25 Data Science Training for Infectious and Immune-mediated Disease Research. The purpose of this Notice of Special Interest (NOSI) is to highlight the interest of participating NIH institutes and centers (ICs) to enhance existing NIH research Education (R25) awards with data science training relevant to infectious- and immune-mediated disease research. Data science is a rapidly evolving field in infectious- and immune-mediated diseases. Some of the most impactful data science takes place in transdisciplinary collaborations between biomedical, behavioral, clinical, and computational scientists. The supplemental work supported by this NOSI will enable existing R25 training programs to offer data science mentoring and training to engage a broader community in data science by improving training programs and transdisciplinary collaboration between biomedical, behavioral, clinical, and computational scientists for research on infectious- and immune-mediated diseases, consistent with the NIH Strategic Plan for Data Science. Application Due Dates: February 13, 2023 and February 13, 2024, by 5:00 PM local time of applicant organization. Applications for this initiative must be submitted using the following opportunity or its subsequent reissued equivalent.

- PA-20-272 - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

NOT-OD-23-031 Administrative Supplements to Promote Research Continuity and Retention of NIH Mentored Career Development (K) Award Recipients and Scholars. This is the reissuance of Notice of Special Interest (NOSI): Administrative Supplements to Promote Research Continuity and Retention of NIH Mentored Career Development (K) Award Recipients and Scholars (NOT-OD-20-054). The overarching goal of this program is to enhance the retention of investigators facing critical life events who are transitioning from mentored career development awards to research independence and to minimize departures from biomedical research workforce. This supplement program is intended to ensure continuity of research among recipients of mentored career development (K) awards by providing supplemental research support to help sustain the investigator's research during a period in which the PD/PI experiences critical life events which have the potential to impact research progress or potential productivity. Administrative supplements must support work within the scope of the original project. For the purposes of this program, critical life events that would qualify for consideration include childbirth, adoption, serious personal health issues or illness and/or debilitating conditions, high-risk pregnancy, and primary caregiving responsibilities of an ailing spouse, child, partner, parent or a member of the immediate family during the project. Evidence that the circumstance may affect advancement of the mentored career development award or productivity must be provided. In circumstances in which the critical life event is pending and is expected to occur during the project period, the supplement request may be submitted in advance of the event. Detailed personal health information such as specific diagnoses or medical conditions is not required or necessary to be considered for this supplement. Mentored individual K awardees who are recipients of the K awards referenced below are encouraged to apply. For retention supplements to support first-time NIH R01-Equivalent Awards, see companion NOSI (NOT-OD-23-032). The administrative

supplement budget is limited to 1 year. The application budget cannot exceed a maximum direct cost of $70,000. Flexible use of supplemental funds is highly encouraged to support successful research within the scope of the parent project, including supported effort of additional personnel, computational services, supplies and equipment to sustain the research of the PD/PI of the individual K award during a critical life event. Supplement funds may not be used for PI salary support during the regular or extended period of the grant. PD/PIs of K43 awards are eligible for this award.

NOT-OD-23-032 Administrative Supplement for Continuity of Biomedical and Behavioral Research Among First-Time Recipients of NIH Research Project Grant Awards. This is the reissuance of Notice of Special Interest (NOSI): Administrative Supplement for Continuity of Biomedical and Behavioral Research Among First-Time Recipients of NIH Research Project Grant Awards (NOT-OD-20-055). The overarching goal of this program is to enhance the retention of investigators facing critical life events who are transitioning to the first renewal of their first independent research project grant award or to a second new NIH research project grant award. Retention at the first renewal or continuous NIH research project grant support is crucial for sustaining both the ongoing research NIH has made an investment in and for retaining diverse talent in the biomedical research workforce. This program supports "at-risk" investigators as identified in the NIH Next Generation Researchers Initiative (see https://grants.nih.gov/ngri.htm). This retention program seeks to maintain the productivity of current first-time recipients of eligible independent NIH research project grant awards who are dealing with a critical life event(s), such that they can remain competitive for the first renewal of their award or for a second research project grant award. For retention supplements to support the transition from K award to independence, see the companion NOSI (NOT-OD-23-031).

Funding Opportunity Announcements (FOA)

1. Secondary Analysis of Existing Datasets in Heart, Lung, and Blood Diseases and Sleep Disorders (R21 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-036** **Type: R21**

Application Due Date: February 28, 2023 through to January 07, 2026. Applications are 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.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) encourages R21 applications that propose to conduct secondary analyses using existing human datasets in areas relevant to the National Heart, Lung, Blood Diseases and Sleep Disorders Institute (NHLBI) scientific mission. The FOA aims to stimulate the use of existing human datasets to investigate novel scientific ideas, and/or generate new models, systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. Generation of new primary data is not allowed. NHLBI and other funding sources often produce data with utility beyond the hypotheses and questions the original projects were designed to address. However, the data cannot be exploited due to a lack of support. This FOA provides the support to stimulate the use of existing dataset(s) for secondary analysis.

Budget: The NHLBI intends to commit up to $2,187,000 per year in total costs for new awards in Fiscal Years 2024, 2025, and 2026. NHLBI may fund up to eighteen new awards per year in Fiscal Years 2024, 2025, and 2026. Application budgets may request up to $75,000 in direct costs per year. Investigators are encouraged to request what is well-justified for their proposed research. Applications exceeding this amount will not be reviewed. The total project period may not exceed 2 years.

2. National Institute on Aging (NIA) Multi-site Clinical Trial Implementation Grant (R01 Clinical Trial Required)

Letter of Intent: 30 days prior to the application due date **Hyperlink: PAR-23-057** **Type: R01**

Application Due Date: March 07, 2023 through to October 05, 2025. Applications are 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.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) invites applications for implementation of investigator-initiated multi-site interventional clinical trials (all phases). The trials should be hypothesis-driven, milestone-defined, and related to NIA's research mission. Information about NIA's mission can be found on the NIA website.

Budget: Application budgets are not limited but need to reflect the actual needs of the proposed project. The scope of the proposed project should determine the project period. The maximum project period is 5 years. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 8 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

3. Innovative Molecular and Cellular Analysis Technologies for Basic and Clinical Cancer Research (R61 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-002** **Type: R61**

Application Due Date: March 01, 2023, September 01, 2023. Applications are 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.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) solicits grant applications proposing exploratory research projects focused on the early-stage development of highly innovative technologies offering novel molecular or cellular analysis capabilities for basic, clinical, or epidemiological cancer research. The emphasis of this FOA is on supporting the development of novel capabilities involving a high degree of technical innovation for targeting, probing, or assessing molecular and cellular features of cancer biology. Well-suited applications must offer the potential to accelerate and/or enhance research in the areas of cancer biology, early detection and screening, clinical diagnosis, treatment, control, epidemiology, and/or address issues associated with cancer health disparities. Technologies proposed for development may be intended to have widespread applicability but must be focused on improving molecular and/or cellular characterizations of cancer biology. Projects proposing the application of existing technologies where the novelty resides in the biological or clinical target/question being pursued are not responsive to this solicitation and will not be reviewed. This funding opportunity is part of a broader NCI-sponsored Innovative Molecular Analysis Technologies (IMAT) Program.

Budget: NCI intends to fund an estimate of 17 awards, corresponding to a total of $4,200,000, for fiscal year 2024. Future year amounts will depend on annual appropriations. Application budgets are limited to $150,000 per year (direct costs). The total project period request may not exceed 3 years.

4. Advanced Development and Validation of Emerging Molecular and Cellular Analysis Technologies for Basic and Clinical Cancer Research (R33 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-003** **Type: R33**

Application Due Date: March 01, 2023, September 01, 2023. Applications are 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.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) invites grant applications proposing exploratory research projects focused on further development and validation of emerging technologies offering novel capabilities for targeting, probing, or assessing molecular and cellular features of cancer biology for basic, clinical, or epidemiological cancer research. This FOA solicits R33 applications where major feasibility gaps for the technology or methodology have been overcome, as demonstrated with supportive preliminary data, but still requires further development and rigorous validation to encourage adoption by the research community. Well-suited applications must offer the potential to accelerate and/or enhance research in the areas of cancer biology, early detection and screening, clinical diagnosis, treatment, control, epidemiology, and/or address issues associated with cancer health disparities. Technologies proposed for development may be intended to have widespread applicability but must be focused on improving molecular and/or cellular characterizations of cancer. Projects proposing the application of existing technologies where the novelty resides in the biological or clinical target/question being pursued are not responsive to this solicitation and will not be reviewed.This funding opportunity is part of a broader NCI-sponsored Innovative Molecular Analysis Technologies (IMAT) Program.

Budget: NCI intends to fund an estimate of 10 awards, corresponding to a total of $4,300,000, for the fiscal year 2024. Future year amounts will depend on annual appropriations. Application budgets are limited to $300,000 per year (in direct costs). The total project period request may not exceed 3 years.

5. Innovative Biospecimen Science Technologies for Basic and Clinical Cancer Research (R61 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-004** **Type:R61**

Application Due Date: March 01, 2023, September 01, 2023. Applications are 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.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) solicits grant applications proposing exploratory research projects focused on the early-stage development of highly innovative technologies that improve the quality of the samples used for cancer research or clinical care. This includes new capabilities to address issues related to pre-analytical degradation of targeted analytes during the collection, processing, handling, and/or storage of cancer-relevant biospecimens. The overall goal is to support the development of highly innovative technologies capable of maximizing or otherwise interrogating the quality and utility of biological samples used for downstream analyses. This FOA will support the development of tools, devices, instrumentation, and associated methods to preserve or protect sample integrity, or establish verification criteria for quality assessment/quality control and handling under diverse conditions. These technologies are expected to accelerate and/or enhance research in cancer biology, early detection and screening, clinical diagnosis, treatment, or epidemiology, or address issues associated with cancer health disparities, by reducing pre-analytical variations that affect biospecimen sample quality. Projects proposing the application of existing technologies where the novelty resides in the biological or clinical target/question being pursued are not responsive to this solicitation and will not be reviewed.

This funding opportunity is part of a broader NCI-sponsored Innovative Molecular Analysis Technologies (IMAT) Program.

Budget: NCI intends to fund an estimate of 4 awards, corresponding to a total of $1,000,000, for the fiscal year 2024. Future year amounts will depend on annual appropriations. Application budgets are limited to $150,000 per year (in direct costs). The total project period request may not exceed 3 years.

6. Advanced Development and Validation of Emerging Biospecimen Science Technologies for Basic and Clinical Cancer Research (R33 Clinical Trial Not Allowed)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-005** **Type: R33**

Application Due Date: March 01, 2023, September 01, 2023. Applications are 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.

Funding Opportunity Announcement: This Funding Opportunity Announcement (FOA) solicits grant applications proposing exploratory research projects focused on further development and validation of emerging technologies that improve the quality of the samples used for cancer research or clinical care. This includes new capabilities to address issues related to pre-analytical degradation of targeted analytes during the collection, processing, handling, and/or storage of cancer-relevant biospecimens. This FOA solicits R33 applications where major feasibility gaps for the technology or methodology have been overcome, as demonstrated with supportive preliminary data, but still require further development and rigorous validation to encourage adoption by the research community. The overall goal is to support the development of highly innovative technologies capable of maximizing or otherwise interrogating the quality and utility of biological samples used for downstream analyses. This FOA will support the development of tools, devices, instrumentation, and associated methods to preserve or protect sample integrity, or establish verification criteria for quality assessment/quality control and handling under diverse conditions. These technologies are expected to accelerate and/or enhance research in cancer biology, early detection and screening, clinical diagnosis, treatment, or epidemiology, or address issues associated with cancer health disparities, by reducing pre-analytical variations that affect biospecimen sample quality. Projects proposing to use existing technologies where the novelty resides in the application of the technology or the biological or clinical question being pursued, and not the technical capabilities being developed, are not appropriate for this FOA and will not be reviewed. This funding opportunity is part of a broader NCI-sponsored Innovative Molecular Analysis Technologies (IMAT) Program.

Budget: NCI intends to fund an estimate of 2 awards, corresponding to a total of $900,000, for fiscal year 2024. Future year amounts will depend on annual appropriations. Application budgets are limited to $300,000 per year (in direct costs). The total project period request may not exceed 3 years.

7. Revision Applications for Incorporation of Novel NCI-Supported Technology to Accelerate Cancer Research (R01 Clinical Trial Optional)

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-CA-23-006** **Type: R01**

Application Due Date: March 01, 2023, September 01, 2023. Applications are 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.

Funding Opportunity Announcement: The purpose of this Funding Opportunity Announcement (FOA) is to encourage revision applications from currently funded NCI R01 research projects. The applicants should propose to expand upon the original research question(s) or otherwise accelerate progress for the parent study by incorporating a new technical approach or instrument developed through support from the NCI Innovative Molecular Analysis Technologies (IMAT) program. Awards from this FOA are meant to incentivize independent validation and accelerate the adoption of these emerging technologies by appropriate research communities. As a component of the NCI IMAT program, this FOA aims to promote interdisciplinary collaboration in the development of innovative tools and methods that enable cancer research and accelerate scientific discovery.

Budget: NCI intends to fund an estimate of 3 awards, corresponding to a total of $600,000, for fiscal year 2024. Future year amounts will depend on annual appropriations. Application budgets may not exceed $150,000 in direct costs per year. Applicants may request support for up to 2 years, not to exceed the remaining number of years on the parent grant.

8. Novel Approaches to Support Therapeutic Development in Ultra-Rare Cancers (U01) Clinical Trial Optional

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-23-008** **Type: U01**

Application Due Date: February 27, 2023, by 11:59 PM Eastern 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.

Funding Opportunity Announcement: The purpose of this NOFO is to encourage new approaches to support therapeutic development in ultra-rare pediatric and adult cancers, including molecularly-defined subsets of more common cancers.

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 FOUR (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance.FDA/OC intends to commit up to $1,000,000 in FY 2023 to fund 1-2 awards. The scope of the proposed project should determine the project period. The maximum project period is FIVE years.

9. Evaluation of Oral Modified Release Dosage Forms to Support the Approval of Additional Strengths (U01) Clinical Trial Not Allowed

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-23-013** **Type:**

Application Due Date: March 15, 2023 by 11:59 PM Eastern 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.

Funding Opportunity Announcement: The FDA guidance, Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA (Aug 2021), provides recommendations for demonstrating the bioequivalence of additional strengths of a proposed modified release drug product. The recommendations involve evidence to demonstrate the same drug release mechanism and similar dissolution profiles across strengths, as well as ratios of drug excipients across strengths that are appropriate for the drug release mechanism. The purpose of this project is to determine the critical quality attributes for different release controlling platform technologies and to determine the appropriate factors to scale the formulation for additional strengths. The outcomes of this research are intended to support generic drug development and regulatory decision making.

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 $200,000 in FY 2023 to fund one (1) award. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

10. Designing and Performing a Virtual Bioequivalence Trial for Physiologically-Based Pharmacokinetic and other Mechanism-Based Models (U01) Clinical Trial Not Allowed

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-23-016** **Type: U01**

Application Due Date: February 15, 2023, by 11:59 PM Eastern 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.

Funding Opportunity Announcement: The purpose of this funding opportunity is to develop a workflow for designing and performing a reliable virtual bioequivalence study by leveraging a physiologically-based pharmacokinetic (PBPK) model, validated for its intended purpose, to detect formulation differences between the reference standard product and a prospective generic drug product. The workflow will explore considerations and reasonable assumptions related to performing a virtual bioequivalence assessment using mechanistic modeling and simulation tools of increased complexity, such as PBPK models.

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 2023 to fund one (1) award. The scope of the proposed project should determine the project period. The maximum project period is two (2) years.

11. Population Pharmacokinetic Modeling of Systemic Pharmacokinetic Data to Inform Bioequivalence in Regional Lung Exposure (U01) Clinical Trial Not Allowed

Letter of Intent: 30 days prior to the application due date **Hyperlink: RFA-FD-23-017** **Type: U01**

Application Due Date: February 28, 2023, by 11:59 PM Eastern 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.

Funding Opportunity Announcement: Orally Inhaled Drug Products (OIDPs) are complex drug-device combination products. To establish bioequivalence for locally acting OIDPs, FDA is currently using a weight-of-evidence approach which generally includes a combination of in vitro BE studies; in vivo pharmacokinetic (PK) studies and comparative clinical endpoint (CCEP) or pharmacodynamic (PD) studies; along with formulation sameness and device similarity. For some OIDPs, both CCEP and PD studies can pose a challenge due to a lack of sensitivity to detect formulation differences. The purpose of this funding opportunity is to support research that will use modeling and simulation to investigate the feasibility of assessing formulation differences in regional lung exposure based on systemic PK concentration data to establish BE for OIDPs with different drug and product properties.

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 $500,000 in FY 2023 to fund up to two (2) awards. The scope of the proposed project should determine the project period. The maximum project period is TWO (2) years.