

DEVELOPMENTAL RESEARCH PROJECT (DRP) APPLICATION GUIDELINES

BACKGROUND AND PURPOSE

The newly established Metropolitan AntiViral Drug Accelerator (MAVDA), which seeks to develop small molecule antiviral drugs against SARS-CoV-2 and other viruses of pandemic potential, requests applications from highly qualified candidates for Developmental Research Projects (DRPs).

DRPs are intended to expand the scope and range of current research and investigators involved in antiviral discovery, allowing for testing of novel ideas (with limited preliminary data) and development of new technologies. DRPs are limited to one or two years, with a range of \$200,000 to \$250,000 in direct costs per project per year.

ABOUT MAVDA

MAVDA was created to engage world-class virologists and academic drug discovery experts, as well as industry professionals centered largely in New York City and New Jersey to develop small molecule drugs suitable for outpatient use against SARS-CoV-2, and other coronaviruses and viruses of pandemic potential. The MAVDA program, led by **Dr. David Perlin** (Center for Discovery and Innovation-Hackensack Meridian Health) and **Dr. Charles Rice** (Rockefeller University), is one of nine national antiviral centers of excellence funded by the National Institutes of Health (NIH)/ National Institute of Allergy and Infectious Diseases (NIAID) under the <u>Antiviral Drug Discovery (AVIDD) Centers for Pathogens of Pandemic Concern</u>. AVIDD research centers target SARS-CoV-2 and other viruses with pandemic potential such as paramyxoviruses, bunyavirales, togaviruses, filoviruses, picornaviruses, and flaviviruses.

MAVDA currently supports Five Projects from academia and industry representing a diverse portfolio of targets and approaches. An integrated network of Pharma-style science cores with highly experienced Core directors ensure that compound identification and optimization proceed efficiently with clear 'Go/No Go' criteria to support compound maturation. The overall MAVDA performance is guided by a world-class scientific advisory Board consisting of industry and academic experts who have developed more than a dozen antivirals and related anti-infectives.

Current MAVDA institutional members include the Center for Discovery and Innovation at Hackensack Meridian Health, Rockefeller University, Columbia University, Memorial Sloan Kettering, Rutgers University, the Tri-Institutional Therapeutics Discovery Institute, Merck, and Aligos Therapeutics, Inc.



The objectives of the MAVDA research centers are to

- Use structural and systems methods to identify potential drug targets shared across key viral pathogens and to generate a diverse pool of novel antiviral lead series and drug candidates with potential to address SARS-CoV-2, as well as to quickly pivot to address future viral outbreaks or pandemics.
- Develop inhibitors of 3CLpro, as a proven and highly desirable target. Development of other important targets include Nsp14 and Nsp16 MTase, ExoN, PLpro, Nsp13 helicase, RdRp, as well as identification of novel targets.
- Develop approaches to identify novel compounds resulting in validated Hits, early Leads, Leads suitable for immediate optimization, and optimized Leads at or ready for IND-enabling and de-risking studies.

APPLICATION DEADLINES AND AWARD DATES

January 5, 2023 – The deadline for receipt of draft-applications (3-page)

March 1, 2023 – Notify selected candidates to submit a full application (PHS 398 form)

April 1, 2023 – Deadline to submit PHS 398 application

May 16, 2023 – Award start date

ELIGIBILITY CRITERIA

Ineligible proposals will not be reviewed. If you have any questions regarding your eligibility, please contact MAVDA Grants Staff at MAVDAgrants@hmh-cdi.org before submitting a proposal.

- 1. Hold a MD, DO, PhD, ScD, or equivalent degree.
- 2. Eligible candidates include applicants with an academic/faculty appointment with the ability to serve as the principal investigator based on their respective university/institutional policy.
- 3. Have a history of and commitment to antiviral translational research.
- 4. The project objectives should align with the MAVDA priorities and objectives.
- 5. Agree to commit at least 10% effort to the DRP project.
- 6. Agree to provide information about subsequent research productivity and funding for the duration of the DRP, as well as a final report.
- 7. U.S. citizenship is not required; however, all research must be conducted in the U.S.
- 8. Applications are encouraged from underrepresented racial and ethnic groups, women, members of minority groups, and people with disabilities.



GRANT PROCESS

The MAVDA DRP application is a **2-step process**. Only selected candidates will be invited to submit the full application (PHS 398 form) to NIH/NIAID.

STEP 1: DRAFT APPLICATION

Deadline: January 5, 2023

The draft-application (3-page equivalent) is an easy to fill out google form. The instructions for filling out the form are provided below. All questions are required unless stated otherwise. Where noted, templates are available for download.

Section 1 of 7: General Information about MAVDA and the DRP Program

Enter valid email address.

Section 2 of 7: Personal Information

Enter name (First name, Last name)

Current Position Title

Current Employer (Name of Department, University/Institution)

Name and email address of Department Chair

Highest Education (mark all that apply)

Email Address (enter your work email address)

Telephone number (mobile/work phone)

Postal Address (include House/Apt number, street name, City, State and Zip code)

Section 3 of 7: Biosketch

Please upload your Biosketch in this section of the form. <u>Click here</u> to download NIH Biosketch template. The Biosketch should be in PDF format for upload.

Section 4 of 7: Research Section

- 1. Project tile
- 2. Project Summary (300-word limit)

The executive summary should include a short abstract of the project. The abstract should outline how the project directly complements or facilitates one or more primary objective(s) of the MAVDA. The project should be exceptionally innovative.

3. Specific Aims and Research Plan

Research Plan (3 Page limit)

Times New Roman/Arial. Font size: use at least 11 pt and at least ½ inch margins

This should include the following elements: specific aims, background and significance, previous work directly related to this research (if available), research plan and methods. The project must



directly complement or facilitate one or more primary objective(s) of the MAVDA and be exceptionally innovative. The application should propose a high-risk/high-return project with clear potential for delivering transformational results or paradigm shifts.

- 4. Indicate virus family you propose to investigate (Check all that apply)
- 5. Indicate Drug Discovery Stage

Select the primary stage of drug discovery that best fits your proposal (Check all that apply).

Section 5 of 7: Preliminary Budget

Please use the template provided here for <u>budget and justification</u>. Convert file into a PDF format for upload.

Section 6 of 7: Demographic Information (Optional)

MAVDA and the NIH are committed to promoting a diverse and inclusive workplace. Given that policy, we are soliciting responses to the demographic items in this grant application.

Your responses are voluntary and confidential.

The MAVDA-DRP Program is committed to supporting a strong, diverse, and inclusive research workforce. If you choose to provide information such as gender, race and ethnicity, or disability status, it will be used to help MAVDA and our granting programs study applicant demographics through analysis of de-identified aggregate data. Such demographic information will not be available to the reviewers of your research proposal. The information requested includes gender, race, and ethnicity.

Section 7 of 7: Validation

This section allows you to acknowledge that you are eligible to apply for this grant and have approval from your institution and/or employer. It also allows you to certify the accuracy of the information provided.

STEP 2: FULL-APPLICATION

Deadline: April 1, 2023

Detailed information for submission of PHS398 can be found here.

EVALUATION CRITERIA

Significance

 Does the proposed project address an important problem or crucial barrier in the Drug Discovery field for the development of antiviral drugs. For example, as framed by the NIAID Antiviral Program for Pandemics.



- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- Does the project directly complement or facilitate one or more primary objective(s) of the MAVDA?
- Does the application propose a high-risk/high-return project with clear potential for delivering transformational results or paradigm shifts?
- Does the project have potential to advance to a full MAVDA research project or to be competitive in attracting future additional peer-reviewed extramural research funding?

Applicant

• Qualifications and adequacy of the applicant and ability to conduct the proposed research.

Innovation

- Is the project exceptionally innovative? Does the application challenge and seek to shift current research or preclinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- What is the strength of the scientific premise, i.e. the quality and strength of the prior research used as a basis for the proposed research question? Please refer to NIH guidelines for more clarification.

Approach

- Is the research project well-conceived, with clear hypotheses, potential alternative outcomes, and a strong scientific premise, as defined by the NIH guidelines on rigor & transparency?
- Are the overall strategy, methodology, and analyzes well-reasoned and appropriate to accomplish the specific aims of the project?

Environment and Training

 Are the research facilities, resources, and training opportunities adequate and appropriate, including faculty capable of productive collaboration with the candidate?

Budget

Reviewers may comment on whether funding is well utilized and sufficient for the proposed project.

CONTACT INFORMATION

If questions arise about your application and the review process, contact MAVDAgrants@hmh-cdi.org