Office of Biomedical Advanced Research and Development Authority
Division of Research, Innovation & Ventures (DRIVe)
Easy Broad Agency Announcement EZBAA-22-100-SOL-00003

The purpose of Amendment #034 is the following:

1) Reopen the following Area of Interest (AOI):

AOI #22: ReBooT

2) Revise the following Area of Interest (AOI):

AOI #22: ReBooT

3) Pause the following Area of Interest (AOI):

AOI#24: RePAIR

INTRODUCTION AND OVERVIEW INFORMATION

A. Development Opportunity Objective:

Under this Amendment, DRIVe is doing the following:

1) Reopening the following research Area of Interest (AOI):

AOI #22: ReBooT

2) Revising the following research Area of Interest (AOI):

AOI #22: ReBooT

We are now seeking abstract submissions for the following AOI:

AOI #22: ReBooT

Antiviral therapeutics have the potential to impact multiple viruses that utilize conserved mechanisms of action for infection, require specific host proteins for infection, or share conserved viral proteins. Typically, antivirals are advanced for one indication, but they may have efficacy against other related pathogens. As the commercial market for products targeting filoviruses is small and evaluation of candidates requires access to BSL4 facilities, product developers have limited incentive to test candidate products against filoviruses. Under the ReBooT program, the Antivirals and Antitoxins (AVAT) program aims to support the testing and evaluation of candidate antiviral therapeutics that have been developed past Phase 1 clinical trials for another indication, but which have a mechanism of action likely to be effective against filoviruses (including but not limited to Ebola virus, Sudan virus, and Marburg virus). Successful efforts could be considered for follow-on support under an EZ-BAA+ award or under the BARDA Broad Area Announcement (BAA-22-100-SOL-00003).

BARDA is requesting abstract submissions for projects that evaluate investigative or licensed/approved therapeutics as medical countermeasure (MCM) against filoviruses. The candidates may include direct acting antivirals or host directed products. Candidates should either have the potential to complement existing therapies by improving patient outcomes or serve as effective monotherapies against filoviruses. Broad spectrum antivirals with anticipated efficacy against multiple species or genera of viruses are preferred. Also, products that are orally available and have room temperature storage will be preferred. The ReBooT program will primarily focus on supporting preclinical efficacy studies in animal models of filovirus disease; such proposals should clearly delineate the proposed study design; laboratory partners, if required; outcome measures; and proposed threshold for study success, which could guide go/no go decisions for follow on funding. Proposals focusing on chemistry manufacturing and controls (CMC) activities, safety/toxicity, or other studies that will facilitate evaluation of the product as a viable candidate to treat filovirus infection will also be considered.

To be considered responsive under this AOI, respondents should propose late-stage (post-Phase 1) or licensed antiviral products meeting the following requirements:

1) *In vitro* data against filoviruses and/or *in vivo* efficacy data in appropriate preclinical models of filovirus disease and/or a mechanism of action that is anticipated to have efficacy against filoviruses; and
2) Known and acceptable safety and toxicology profiles evidenced by Phase I results OR licensed for another clinical indication and with the potential to undergo label expansion; and
3) Freedom to operate for other indications.

Out of scope candidates:

1. Phase I failures or withdrawn from market for safety reasons as well as drugs with black box labels.
2. Vaccines.

Future amendments to this AOI may expand the scope of interest to other RNA viruses of pandemic potential.

3) Pausing the following research Area of Interest (AOI):

AOI #24: RePAIR

B. Eligible Respondents & Scope Parameters:

This Amendment is open to all responsible sources as described in the EZ-BAA. Abstract submissions that do not conform to the requirements outlined in the EZ-BAA may be considered non-responsive and will not be reviewed. An entity must have an active registration with https://sam.gov at the time of submission to be reviewed. If not, the abstract submission will not be reviewed and will be rejected. Please do not attempt to submit an abstract if your registration is not active in https://sam.gov.

IMPORTANT NOTE: Interested vendors are strongly encouraged to request and schedule a pre-submission call before submitting an abstract. This request should include the project title, key project staff, and a brief description of the proposed project. Please submit the requests to the following:

AOI #22: ReBooT (reboot@hhs.gov)
AOI #24: RePAIR (repair@hhs.gov)

The closing dates for abstract submissions for the AOIs are listed below.

Area of Interest	Closing Date for Abstract Submissions
#22	12:00pm ET on April 30, 2025
#24	12:00pm ET on November 27, 2024

C. Number of Awards:

Multiple awards are anticipated and are dependent upon the program priorities, scientific/technical merit of abstract submissions, how well the abstract submissions fit within the goals of the AOI, and the availability of funding. The program funding is subject to change based on the Government's discretion.

Funding is limited, so we encourage any interested vendors to reach out to the respective program as soon as possible before submitting an abstract.

D. Amendment Application Process:

This Amendment will follow the same submission process and review procedures as those established under this EZ-BAA, unless otherwise noted. For complete details, please read the EZ-BAA in its entirety along with all amendments.

IMPORTANT NOTE: Respondents who are awarded a contract under each of these AOIs will be required to share any collected, de-identified data to advance the field and knowledge. Interested Respondents are strongly encouraged to commercialize their technology and algorithms, however, note that consistent with BARDA's mission and federal standards, data collected through the use of government funding will be delivered to BARDA for government usage pursuant to applicable regulations and law.