

Office of Biomedical Advanced Research and Development Authority
(BARDA) Division of Research, Innovation & Ventures (DRIVE)

Special Instructions 016 Issuance for Easy Broad Agency
Announcement (EZ-BAA) BAA-20-100-SOL-0002



The purpose of these Special Instructions is the following:

1) Re-open Area of Interest (AOI) #5 as part of the EZ-BAA:

AOI #5: ReDirect (Repurposing Drugs in Response to Chemical Threats)

I. INTRODUCTION AND OVERVIEW INFORMATION

A. Development Opportunity Objective:

Under these Special Instructions 016, BARDA is re-opening AOI #5 as part of its EZ-BAA (BAA-20-100-SOL-0002). Under this AOI, we are seeking abstract submissions for the following:

AOI #5: ReDirect (Repurposing Drugs in Response to Chemical Threats)

The availability of effective medical countermeasures (MCMs) against chemical threats are critical in the treatment of their acute health effects. Necessary attributes of effective MCMs against chemical threats include ease of administration during a mass-casualty situation and rapid efficacy as a post-exposure therapy. Drug repurposing is a strategy that is used to identify new uses for FDA approved or late-stage investigational therapeutics that are outside of their original clinical indication. The identification of existing compounds for repurposing as MCMs holds the potential to expand current response capabilities to chemical threats, as well as potentially mitigating the costs and risks associated with conventional drug discovery.

BARDA is requesting abstract submissions for projects that repurpose existing therapeutics as MCMs against chemical threats (cyanide, opioids, nerve agents, chlorine, sulfur mustard, etc.). These therapeutics should have a strong mechanistic justification for potential use as MCMs. Ideal candidates for MCMs should have a known safety profile from previous clinical indications or development and be safe and effective for the entire population, including at-risk populations such as pediatrics, geriatrics, pregnant women, and immunocompromised individuals. MCM candidates should:

- 1) Already be approved or in late-stage clinical development for a conventional indication similar to the symptomology associated with exposure to a chemical agent; and
- 2) Utilize improved delivery routes or mechanisms that provide ease of administration (including, but not limited to, reformulation of existing products) to large numbers of exposed individuals during mass casualty situations. Priority will be given to products manufactured in the United States.

Therapeutics that are eligible for drug repurposing may target any of the following:

Pulmonary Agents: Development of MCMs to prevent and treat lung damage (including pulmonary edema, pneumonitis, and fibrosis) resulting from exposure to agents such as chlorine, sulfur mustard and phosgene.

Opioids: Development of MCMs to treat life-threatening respiratory depression caused by opioid overdose. These post-exposure treatments should be quick-acting and effective against a variety of opioids, including synthetic opioids such as Fentanyl. Candidates should have a mechanism of action different from existing opioid receptor antagonists.

Vesicants: Development of MCMs that limit harmful aspects of exposure to vesicating agents such as sulfur mustard and Lewisite. Particular preference is given to drugs with potential to ameliorate the long term effects of exposure including Mustard Gas Keratopathy.

Blood/Metabolic Agents: Development of MCMs to treat acute poisoning from agents such as cyanides. Antidotes should be easily administered by first responders in personal protective equipment. Preference is given to those cyanide antidotes that are also effective against smoke inhalation-related exposure.

Nerve Agents and Organophosphorus (OP) Pesticides: Development of MCMs to treat life-threatening and long-term effects of nerve agents and OP pesticides. Antidotes should be easily administered by first responders in personal protective equipment.

Computational approaches to identify candidates for drug repurposing: Development of improved methods to rapidly identify FDA approved or late stage candidate compounds that can be repurposed against any of the aforementioned chemical threats.

To be considered responsive under this AOI, respondents should have:

- 1) A drug that is a candidate for repurposing as a MCM against pulmonary agents, opioids, vesicants, blood/metabolic agents, nerve agents, or organophosphate pesticides; and
- 2) A FDA approved drug, or one that has completed Phase 2 trials as evidenced by a clinical study report; and
- 3) A clear rationale as to why the candidate would be efficacious as a chemical MCM.

Priority will be given to MCMs developed in the United States.

B. Eligible Respondents & Scope Parameters:

These Special Instructions are 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. To clarify, an entity must have an active registration with <https://sam.gov> at the time of submission to be reviewed. If not, submissions 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 submit a request to schedule a market research call. 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 #2: Infection Severity and Solving Sepsis (solvingsepsis@hhs.gov)

AOI #5: ReDirect (chemrepo@hhs.gov)

AOI #6: Beyond the Needle (beyondtheneedle@hhs.gov)

AOI #8: Bringing Laboratory Testing to the Home (homediagnostics@hhs.gov)

AOI #9: Digital Health Tools for Pandemic Preparedness (digitalhealth@hhs.gov)

AOI #10: NGS-based Agnostic Diagnostic for Respiratory RNA Virus Pathogens (NGS@hhs.gov)

AOI #11a: Home-based, Over-the-Counter Diagnostics for the Detection of SARS-CoV-2 (COVID19_homeDx@hhs.gov)

AOI #11b: Enabling Technologies to Support Home-Based Diagnostics for SARS-CoV-2 Acute Infection (COVID19_homeDx@hhs.gov)

AOI #12: Mitigating Long-term Effects (MILE) of Respiratory Distress (HostTx@hhs.gov)

AOI #2 will be open for abstract submissions through **5:00 PM ET on 15 January 2022**, unless otherwise extended.

AOI #5 will be open for abstract submissions through **5:00 PM ET on 31 March 2022**, unless otherwise extended.

AOIs #6, #8, and #9 will be open for abstract submissions through **5:00 PM ET on 03 February 2023**, unless otherwise extended.

AOI #10 will be open for abstract submissions through **5:00 PM ET on 30 November 2021**, unless otherwise extended.

AOIs #11a and #11b will be open for abstract submissions through **5:00 PM ET on 15 January 2022**, unless otherwise extended.

AOI #12 will be open for abstract submissions through **5:00 PM ET on 30 April 2022**, unless otherwise extended.

C. Number of Awards:

Multiple awards are anticipated and are dependent upon the program priorities, scientific/technical merit of submissions, how well 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.

Additionally, award(s) expected to be made under these Special Instructions will be less than \$750,000 in total Government funding. 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. Special Instructions Application Process:

These Special Instructions will follow the same submission process and review procedures as those established under the EZ-BAA. For complete details, please read the EZ-BAA solicitation in its entirety. DRIVE takes the protection of Respondent information very seriously to ensure that information is safeguarded in full compliance with all applicable regulations and law.

IMPORTANT NOTE: Awarded partners under each of these AOIs will be required to share any collected de-identified data in an effort to advance the field and knowledge. Interested partners are encouraged to commercialize their technology and algorithms but data collected through the use of Government funding will be made available through full Government purpose rights.