# 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 #021 is the following:**

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

**AOI #27:** Stopping Secondary Spread

## INTRODUCTION AND OVERVIEWINFORMATION

# A. Development Opportunity Objective:

Under this Amendment, DRIVe is doing the following:

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

**AOI #27:** Stopping Secondary Spread

We are seeking abstract submissions for the following AOI:

**AOI #27: Stopping Secondary Spread [S3]**
*Pharmaceutical Medical Countermeasures for Interruption of Respiratory Virus Transmission*

Person-to-person transmission of respiratory viral pathogens gives rise to outbreaks/pandemics, viral evolution, and the emergence of new strains that resist treatment and evade immunity. Interrupting respiratory disease transmission cycles is a critical component of public health efforts, but current strategies are exclusively non-pharmaceutical in nature (e.g., masking, social distancing, quarantine). Current medical countermeasures (MCM; i.e., vaccines and therapeutics) are designed to prevent severe respiratory disease but their impact on viral shedding / person-to-person transmission is variable. To that end, the overarching goal of the Stopping Secondary Spread (S3) program is the advancement of novel MCMs that block the person-to-person transmission of respiratory viral pathogens.

For this program, a "transmission blocking agent" either:

1. reduces the likelihood of transmission of respiratory viruses from infected individuals (i.e., mitigates the spread of a viral respiratory pathogen from actively infected cases to close contacts); or
2. reduces the likelihood of respiratory infection following exposure (i.e., prevents infection in a healthy individual who was recently exposed to an actively infected case).

The S3 program aims to develop, evaluate, and ultimately advance investigational products for which the primary endpoint is the interruption of respiratory disease transmission. Whether used as part of outbreak/pandemic response or as a strategy for seasonal respiratory diseases, transmission blocking agents that prevent secondary spread of pathogens would be complementary to traditional drugs and vaccines that have the goals of disease treatment and prevention.

Respiratory viral pathogens of particular interest to BARDA are influenza and SARS-CoV-2, given their pandemic potential, the existence of well-established assays and animal models, and known pathways for clinical evaluation and regulatory approval. Investigational product proposals that are targeted toward other common respiratory viral pathogens may be considered if appropriate justification for alternatives is provided (e.g. current stage of development, availability of existing pre-clinical/clinical data, proof of concept in established pre-clinical models, evaluation of suitable drug-device combinations, etc.).

The ideal Target Product Profile (TPP) of transmission blocking agents is detailed below.

| | |
|---|---|
| Direct route of administration | Targeted delivery of therapeutic to the upper respiratory tract (e.g., nasal, nasopharyngeal, or oropharyngeal compartment) |
| Easy to administer | Delivery of agent by self-administration or by a non-health care professional |
| Immediate biologic activity | Product immediately active after administration with a duration of activity ~8-12 hours |
| Low reactogenicity profile | Minimal local and systemic side effects |
| Patient access | Ideally available over-the-counter to minimize barriers to access and use |
| Target population | Products may target either or both adults and pediatrics as appropriate |
| *Note: Investigational products are not expected to meet each of the TPP characteristics as outlined above. Rather, it is acceptable if, at the time of proposal submission, an investigational product meets key criteria, and the focus of the proposal is on the improvement/optimization of a product and/or process within the period of performance of a potential award* | |

**Abstracts will be evaluated on their alignment with the TPP and their responsiveness to the requirements detailed in the AOI:**

- Clear description of either: (1) direct acting and/or platform-based anti-viral products that can be repurposed towards other viral threats as needed; (2) broad spectrum products with pathogen agnostic mechanisms of action (which may include but are not limited to host-directed therapeutics, etc.)
- Focus on influenza, SARS-CoV-2, or a common respiratory pathogen in a relevant animal model (e.g., ferret, cotton rat, hamster, pig, or non-human primate). Abstracts that propose use of murine models of respiratory viral pathogen transmission will be deemed non-responsive to the AOI
- Compelling preclinical evidence for the potential utility of the investigational product as a transmission blocking agent against viral variants. If offerors present compelling preclinical efficacy data in a relevant animal model but have not yet conducted IND-enabling studies, the proposed work may include evaluations of investigational product safety and toxicity
- If the proposed product requires a specific device for delivery, the abstract or the studies must demonstrate drug-device compatibility with the animal model to be tested
- Evaluation of investigational product efficacy against a single priority pathogen with impact on viral transmission as the primary study endpoint
- Product reformulation efforts may be considered if the abstract includes existing efficacy data in relevant animal models (e.g., ferret, rat, hamster, swine, etc.) and the proposed work compares efficacy of the new formulation against the original formulation
- Inclusion of a clearly articulated plan for clinical evaluation, regulatory approval, and eventual product commercialization

**For this program, the following topics will be considered "out of scope":**

- Evaluation of vaccine candidates for impact on virus or disease transmission
- Evaluation of non-pharmaceutical interventions (i.e., masks or other personal protective equipment) to mitigate virus or disease transmission
- Evaluation of sanitizers or cleaning products not intended for use in humans
- Proposals on use of murine models for disease transmission

**Note: Due to the anticipated high interest for this program, abstracts will be reviewed at the end of the open period and not on a rolling basis. Offerors are encouraged to schedule a market research call with BARDA in advance of abstract submission.**

## 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 #27:** Stopping Secondary Spread (S3@hhs.gov)

The closing date for abstract submissions for this AOI is listed below.

| Area of Interest | Closing Date for Abstract Submissions |
|---|---|
| #27 | 12:00pm ET on May 3, 2024 |

Note: To streamline the EZ-BAA, all Areas of Interest will be open for a few months at a time following a staggered approach. This is being done to encourage high-quality submissions earlier in the fiscal year allowing adequate review time. Depending on programmatic need and funding availability, Areas of Interest may be reopened for another period of time.

## 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.