PRESOLICITATION NOTICE

2026 NIAID Omnibus Broad Agency Announcement
HHS-NIH-NIAID-BAA2025-1

Presolicitation Notice Information

Service Code: AN 12 – Health R&D service
NAICS Code: 541715 – R&D in Physical, Engineering, and Life Sciences (except Nanotech and Biotech)

Introduction:

The National Institute of Allergy and Infectious Diseases (NIAID), one of 27 institutes of the National Institutes of Health, an agency within the Department of Health and Human Services (DHHS), conducts and supports research to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. Through a variety of research grants and contracts, NIAID's Division of Microbiology and Infectious Diseases (DMID) specifically supports extramural research to develop new medical countermeasures (MCMs) against potential agents of bioterrorism, drug-resistant pathogens, and emerging and re-emerging infectious diseases. This Broad Agency Announcement (BAA) is soliciting proposals to advance the research and development of promising candidate therapeutics, vaccines, and diagnostics for biodefense and emerging infectious diseases.

The Research Areas included in this NIAID OMNIBUS BROAD AGENCY ANNOUNCEMENT No. HHS-NIH-NIAID-BAA2025-1, as well as the projected amounts of available funding, are discussed below. Dates for receipt of proposals will be identified separately for EACH Research Area within the solicitation.

Description:

Research Area 001 – Development of Candidate Therapeutics, Vaccines, and In Vitro Diagnostics for Antimicrobial-Resistant (AMR) Bacterial or Fungal Pathogens

For Research Area 001, there are three (3) separate Topics – A, B, and C. Offerors may submit a proposal in response to Topics A, B, and/or C. If proposing to multiple Topics, Offerors must submit separate technical and business proposals for each Topic.

Topic A: Therapeutics for AMR Bacterial or Fungal Pathogens

The objective of Topic A is to develop new therapeutic products against severe infections and/or drug-resistant strains of the following bacterial and fungal pathogens:

a. *Pseudomonas aeruginosa, and/or Acinetobacter baumannii*; OR
b. *Candida auris, Cryptococcus spp., Aspergillus fumigatus*, and/or *Mucorales*.

For the purpose of this Topic, "therapeutic" activity refers to the cure of disease, by elimination or substantial reduction of infective pathogens, by administration of a pharmaceutical agent after symptoms of disease are clinically observable. An antimicrobial therapeutic candidate refers to an advanced lead series, optimized leads, or product candidate, that is a new chemical entity and either a small molecule (e.g., natural products, nucleosides, or peptides of </= 40 amino acids), monoclonal antibody or a nanobody conjugate/fusion product, or a bacteriophage product. The following are not included: proteins, other biological entities, and conjugates of such entities (except monoclonal antibodies, nanobodies and bacteriophages).

This Topic will support lead optimization, pre-clinical Investigational New Drug (IND) enabling studies, and clinical Phase I trials of lead candidates with demonstrated therapeutic activities. For some pathogens, the development of a therapeutic product under the U.S. Food and Drug Administration's (FDA) Animal Rule will be supported.

Topic B: Vaccines for AMR Bacterial Pathogens

The objective of Topic B is to protect human health and well-being by advancing vaccine candidates for the following ESKAPE bacterial pathogens: *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa*, and Enterobacter species.

For the purpose of this Topic, the definition of a lead vaccine candidate is a candidate in which the antigen(s), adjuvant (if applicable), vaccine platform (e.g., mRNA, viral vector, subunit, etc.), and delivery route have been selected and are clinically relevant (i.e., intended for the final clinical product), for which proof-of-concept immunogenicity in relevant animal model(s) has already been demonstrated.

This Topic will support the advancement of a promising lead candidate from pre-clinical testing through IND submission to the FDA, as well as Phase I clinical trial conduct.

Topic C: *In Vitro* Diagnostics for AMR Fungal Pathogens

The objective of Topic C is to develop innovative platform technologies to speed the identification of infection from among a broad panel of fungi and to profile the phenotypic antifungal susceptibility. This emphasis aligns with NIAID's goal of addressing persistent

challenges in adequate clinical management associated with mycological infections and alleviating the burden of antifungal resistance.

The diagnostic test system must detect analytes from at least one, and preferably several, of the following agents and markers:

- *Candida* spp. and associated resistance markers
- *Aspergillus fumigatus* and associated resistance markers
- *Coccidioides* spp.
- *Mucorales*

Funding for Research Area 001: NIAID estimates that one to two awards may be issued for this Research Area for a total cost of up to $8.5 million for the non-severable base period across all contracts (direct and indirect costs combined). The total duration of a proposed contract should be consistent with the nature and complexity of the offeror's proposed research. The total performance period comprised of the base and any options proposed by an Offeror should not exceed five (5) years.

Research Area 002 – Development of Direct Acting Antivirals (DAA) for Viral Families of Pandemic Potential

This Research Area aims to develop safe and effective antivirals to combat viruses of pandemic potential, as well as to build sustainable platforms for targeted drug discovery and the development of a robust pipeline of candidates. Proposals MUST focus on antivirals that:

- Directly modify viral target function (not through the modulation of the host responses); AND
- Act by reducing viral burden in early stages of disease; AND
- Act against viruses of pandemic potential (i.e., Bunyaviridae, Coronaviridae, Filoviridae, Flaviviridae, Orthopoxviridae, Paramyxoviridae, Picornaviridae, and Togaviridae); AND
- Are new chemical entities limited to small molecules (e.g., natural products, nucleosides, or peptides of </= 40 amino acids) and nanobody conjugates/fusion products that are directly acting on viral targets and functions (not through the modulation of the host responses); AND
- Have safety profiles and suitable routes of administration for broad outpatient use.

For the purpose of this Topic, "therapeutic" activity refers to the elimination or substantial reduction of infective pathogens by administration of a pharmaceutical agent after viral challenge. A "therapeutic" candidate refers to an advanced lead series, optimized leads, or product candidate, that is a new chemical entity and either a small molecule (e.g., natural

products, nucleosides, or peptides of </= 40 amino acids) or nanobody conjugate/fusion product. The following are not included: proteins, monoclonal antibodies, other biological entities, and conjugates of such entities.

Research Area 002 will support lead optimization, pre-clinical (IND enabling) studies, and/or Phase I clinical trials. Proposed products are not required to be narrow-spectrum and may include other pathogens in their spectrum of activity, provided one of the listed pathogens is in the primary indication of the proposed Target Product Profile (TPP). Product development under the FDA's Animal Rule (21 CFR 314 subpart I) will be supported if appropriate to the proposed pathogen target.

Funding for Research Area 002: NIAID estimates that three to four awards may be issued for this Research Area for a total cost of up to $20 million for the non-severable base period across all contracts (direct and indirect costs combined). The total duration of a proposed contract should be consistent with the nature and complexity of the offeror's proposed research. The total performance period comprised of the base and any options proposed by an Offeror should not exceed five (5) years.

The Omnibus BAA is governed by Federal Acquisition Regulation (FAR) 6.102(d)(2) and FAR 35.016, as well as the NIH Policy Manual, Manual Chapter 6035, Broad Agency Announcements. A BAA may be used as a solicitation mechanism for basic and applied research directed toward advancing the state-of-the-art or increasing knowledge or understanding and that part of development not related to the development of a specific system or hardware procurement. BAAs are general in nature, identifying areas of research interest, and shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated.

Offers submitted in response to this BAA will be required to submit separate detailed technical and business proposals designed to meet the Technical Objectives described for each Research Area and/or Topic proposed. The Statement of Work (SOW), including the specific technical requirements and performance specifications, shall be developed and proposed by the Offeror, not the Government.

Proposals received in response to this BAA are NOT evaluated against each other since they are not submitted in accordance with a common SOW issued by the Government. Instead, Research and Technical Objectives will be provided in the BAA that describe individual Research Areas in which the Government is interested. Proposals received in response to the BAA will be evaluated in accordance with the Evaluation Factors for Award specified in the announcement. The Government reserves the right to conduct discussions with all, some, one, or none of the proposals received in response to this BAA. If discussions are conducted, the Government reserves the right to suggest modifying, adding or deleting

milestones, decision points, research plans, processes, schedules, budget or product. The Government also reserves the right to make awards without discussions. Additionally, the Government reserves the right to accept proposals in their entirety or to select only portions of proposals for award. Multiple awards are anticipated. Selection for award under this BAA will be based upon the evaluation factors, importance to the agency programs, and the availability of funds.

Any responsible offeror may submit a proposal which shall be considered by the Agency. This BAA will be available electronically on or about November 22, 2024 and may be accessed through Sam.Gov: https://www.sam.gov/. This notice does not commit the Government to award a contract.

For this solicitation, the NIAID requires proposals to be submitted online via the NIAID electronic Contract Proposal Submission (eCPS) website. Submission of proposals by facsimile or e-mail is not acceptable. For directions on using eCPS, go to the website: https://ecps.nih.gov and then click on "How to Submit."