The hour and date specified for receipt of Offers remains unchanged.

Offerors must acknowledge receipt of the amendment by Amendment number(s) and date of the amendment. Include a statement of acknowledgement in your proposal submission. Failure of acknowledgement may result in rejection of your offer.

Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

**PURPOSE OF SOLICITATION AMENDMENT**

The purpose of this amendment is to provide responses to questions received regarding the solicitation. The responses are offered for information only and do not modify or become part of this solicitation. Additional amendments may be provided as needed to address further questions and their related responses. All potential offerors are advised to refer back to all previous amendments for additional questions and clarification.

**SPECIFIC RESEARCH AREA QUESTIONS**

The Government’s responses to questions received regarding this solicitation are as follows:

*Division of Microbiology and Infectious Diseases (DMID),*
**Research Area 004: Development of Broad Spectrum Therapeutic Products for Biodefense, Anti-Microbial Resistant Infections and Emerging Infectious Diseases**

**Question 1:** For this BAA, must the objective/scope of the proposal include concurrent develop and testing of clinical efficacy for two or more viral infections, e.g., two different species within the alphavirus family (such as Chikungunya and Mayaro), or can clinical development focus on one indication, with the option to expand to a second indication in the future?

**Answer 1:** For purposes of this BAA, at the time of proposal submission the candidate broad-spectrum therapeutic antiviral shall have activity against more than one virus family or have activity against two or more virus species from virus families listed in Sections 2a and 2b on page 29. Proposed development and testing of the candidate for more than one indication is not a requirement of this BAA; however, the structure of the specific Technical Approach proposed is at the discretion of the offeror.

**Question 2:** Pages 28 and 29 of the solicitation states that the candidate antibacterial broad-spectrum therapeutics product must display activity against the pathogens listed on the 2013 CDC Antibiotic Resistance Threats list (subparagraph a), and one of the bacterial pathogens listed in subparagraph b. Would a broad spectrum candidate that has activity against a number of the bacteria in list a. (CDC 2013 ARTs in the US Report) and against one, possibly two organisms from list b. (but not all organisms listed) be considered responsive to this Research Area?

**Answer 2:** Page 29 of the solicitation, Research Area 004, Section 1. Antibacterial Broad-spectrum Therapeutics, states that candidate antibacterial therapeutic products must meet all of the criteria identified. Thus, a candidate therapeutic that displays activity against one or more of the bacterial threats listed in the 2013 CDC Antibiotic Resistance Threats report, must also display activity against the effects of one or more of the identified bacterial pathogens in Section 1.b. to be considered responsive.

**Question 3:** Page 33 of the solicitation, Subsection C. DMID: RESEARCH AREAS 004 and 005 – Additional Technical Proposal Instructions, Item 1. CANDIDATE PRODUCT PROFILE (p.33) and Item 2. PRODUCT DEVELOPMENT PLAN (p.33-34) appear to require similar information in their respective subsections. For example, both Candidate Product Profile subsection a. and Product Development Plan subsection b. request “the intended use/indication of the lead production/formulation/design and the biodefense/public health gap the product is intended to fill.” Is it NIAID’s expectation that proposals include similar/duplicative information in both sections, or should an offeror refer back to other sections if the information has already been addressed?

**Answer 3:** As stated in the solicitation, proposals must include both a Candidate Product Profile (synopsis) and a Product Development Plan (more detailed in description). Each document is expected to stand on its own, thus duplicate information should be repeated in the appropriate section of the Candidate Product Profile and Product Development Plan.

**Question 4:** In reference to page 33 of the solicitation, Subsection C. DMID: RESEARCH AREAS 004 and 005 – Additional Technical Proposal Instructions, Item 2. PRODUCT DEVELOPMENT PLAN (p.33-34) and Item 3. WORK PLAN (p.34-36). Product Development Plan requirements appear to be focused more on a high-level overview of the candidate and its planned development to approval, while the Work Plan (p.34-36) appears focused on a detailed description of the proposed activities within the project’s period of performance. However, page
34 under Product Development Plan states “The Product Development Plan should detail the specific tasks and stages to be performed with contract funding that can be reasonably completed within the period of performance.” Should an offeror include a description of the specific tasks proposed, in addition to addressing subsections a.-h. under Product Development Plan? Or should an offeror address subsections a.-h. under Product Development Plan, and use the Work Plan section to provide a detailed description of the specific tasks and stages to be performed with contract funding within the proposed period of performance?

Answer 4: The Tasks and Stages identified in the Product Development Plan should present a high-level objective focused description of the project. The specific details that will be implemented at each task/stage should be described in the Work Plan.

Question 5: In reference to page 33 of the solicitation, Subsection C. DMID: RESEARCH AREAS 004 and 005 -Additional Technical Proposal Instructions, Item 5. REGULATORY COMPLIANCE, QUALITY CONTROL & ASSURANCE, and DATA MANAGEMENT (p. 37):

Is the use of GLP, GMP, and GCP mandatory for this contract? Will a justification of providing quality results using our current lab practices be sufficient for the plan requested?

Answer 5: Product development to support IND submission and clinical trials under this BAA should be conducted in adherence with the Food and Drug Administration’s and any other pertinent regulatory and compliance requirements including GLP, GMP, and GCP without exception.

Question 6: In reference to page 33 of the solicitation, Subsection C. DMID: RESEARCH AREAS 004 and 005 -Additional Technical Proposal Instructions, Item 6. UNIFORM COST ASSUMPTIONS, subparagraph d. ‘Programmatic Presentations and Meetings”:

Meeting Item 3) - External Advisory Group Meetings (p. 38)

The following language is included: “Compensation for this role will be provided by the Contractor with contract funds as approved by the Contracting Officer and will be commensurate with the specific roles and duties assigned to the members.

NOTE: DO NOT identify or propose External Advisory Group members in the technical or business proposal. Do not contact specific individuals regarding service on the External Advisory Group in advance of contract award.”

Can NIAID clarify the NOTE? Is the offeror allowed to budget funds to compensate the External Advisory Group without identifying specific names, or is the External Advisory Group not allowable in the budget? If proposing funds for the External Advisory Group is not allowed, how will the offeror provide funding for this group?

Answer 6: Proposals should include costs in the budget for compensation of the External Advisory Group, but should NOT identify members by name in the proposal.

Division of Microbiology and Infectious Diseases (DMID),
Research Area 005: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases

Question 1: Would a Respiratory Syncytial Virus vaccine candidate be responsive to the BAA? (RSV does not appear to be listed as an NIAID Category A, B, and C priority pathogen: (https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens).
Answer 1: RSV would not be considered responsive. As stated on page 31 of the solicitation, the objective of Research Area 005 is the development of vaccines for use in post-event settings following the intentional release of a NIAID Category A, B, or C Priority Pathogen, or in response to naturally-occurring outbreaks of infectious diseases caused by these pathogens or Zika virus. Only proposed candidate products aimed at these pathogens are eligible.