

*Questions and Answers for BARDA Biological Nonclinical Studies Network (NSN)
RFP-16-100-SOL-00008*

1. **Q:** When is the cut off for questions?
A: The next (and final) cut off for questions is noon EST on June 8, 2016.
2. **Q:** Could you please confirm what amount the small business plan should be based on.
A: The basis of the plan should be the maximum ordering amount of the IDIQ, \$45,000,000.
3. **Q:** What date should be used as the start date for costing purposes?
A: Please use assumed start date for costing purposes of November 1, 2016.
4. **Q:** Would it be possible to allow the due date for the hard copy submission to occur a few days after the electronic submission?
A: No, both the hard copy and electronic submission are due on the same day at the same time.
5. **Q:** Could BARDA please clarify if the resumes should be 3 or 5 pages in maximum length?
A: To clarify, the resumes should be 3 pages in length
6. **Q:** Does the technical volume requirement of a 50 page limit to include the sample task order response or are additional pages allowed for the task order response section?
A: The technical volume requirement of 50 pages does include the sample task order response.
7. **Q:** BARDA requests a bioanalytical strategy built around filgrastim detection in blood (Analytical Services STO). However, the costing elements described have contingencies built around single and multiple analytes as well as additional matrices. Would BARDA like the potential contractors to “fill in” only those elements used in the STO technical response? Or would BARDA like costs included for a general strategy built around a small molecule, biologic, etc.?
A: Offerors should include only elements used in the Sample Task Order response.
8. **Q:** BARDA requests a “juvenile toxicity study” be performed in support of a 14-day administration of an IV-administered small molecule in adults and children. It is unclear from the information provided whether BARDA is suggesting that the proposed contractor provide a study design and costing for “a single study” or whether BARDA would like the proposed contractor to build “a program” (i.e. multiple studies) around approval/s (IND, NDA, etc.) of the molecule. Further it is unclear whether “previous studies” that have shown effects of administration (e.g., testicular toxicology, immunotoxicity, CV and respiratory) were formal regulatory studies supporting clinical trials or nonGLP, research-based studies. Please clarify 1) at what stage of the development the products lies, and 2) whether the proposed contractor is to provide background assumptions around a program design or a single study. Based on the latter please clarify whether the contractor is to provide costing for a single study or all studies that may be required for approval, IND, etc.

*Questions and Answers for BARDA Biological Nonclinical Studies Network (NSN)
RFP-16-100-SOL-00008*

A: The Offeror should propose for a single study.

9. **Q:** In Section L.5.2. “Business Proposal – Components” paragraph (5) “Section 5: Past Performance,” the RFP states, “The Offeror shall provide a list of the last five (5) contracts completed during the past three years and all contracts currently in process. ...Any previous activities with BARDA must all be included in the submitted past performance list.”
. Additionally, with regards to the completed questionnaire (Attachment #10) the RFP states, “In addition to the above requested information, the Offeror shall submit a completed questionnaire (Attachment #10) for each of the contracts listed. ..It is the responsibility of the Offerors to ensure submission of these questionnaires to be delivered directly from their references to the Government.” Please clarify whether the requirement to submit past performance questionnaires applies to contracts currently in progress or only to completed efforts. Would you consider limiting the required number of references to three to five?

A: Five references for past performance using either/or a combination of in progress (current) and completed (past) efforts is acceptable.

10. **Q:** In Attachment #3 “Sample Request for Task Order Response - Toxicology Services (TS),” Objective 2 states, “In patients, the molecule will be administered by intravenous infusion (iv) at doses of 400-800 mg twice daily.” Please confirm whether “mg” is the intended unit of measurement, or if it should be “doses of 400-800 mg/kg twice daily.”

A: It should read “In patients, the molecule will be administered by intravenous infusion (iv) at doses of 400-800mg per subject twice daily.”

11. **Q:** Could you please clarify if the sample request for Task Order Response-Animal Model Testing (AMT) (Attachment #2) is to be proposed fixed-price or cost-reimbursement.

A: The AMT sample task order is cost reimbursement.

12. **Q:** Could conducting a study ... constitute as meeting the mandatory criteria for eligibility for an Analytic Services award?

A: In order to meet the Mandatory Criteria an Offeror must provide a list that includes at least one GLP study in the past three years. If an Offeror cannot provide a list that includes at least one GLP study in the past three years, then the Mandatory Criteria has not been met.

13. **Q:** In some countries outside of the US, it is a requirement that laboratories claiming compliance with GLP are registered with a National GLP Compliance Monitoring Program. Can BARDA confirm if Organizations that are not currently registered with their National Program, but have been previously (and with the intention to re-register in the future if required) will meet the Mandatory Criteria in the first instance?

A: The Offeror should be able to provide documentation of conducting at least one GLP study within the past three years in order to meet the Mandatory Criteria requirement.

14. **Q:** Is the GLP study requirement mandatory?

*Questions and Answers for BARDA Biological Nonclinical Studies Network (NSN)
RFP-16-100-SOL-00008*

A: Yes.

15. **Q:** Animal Model Development work, in accordance with the principles of GLP has been undertaken in the designated timeframe of the last three (3) years, however, GLP accredited studies have not. Can BARDA please confirm whether this would preclude us from further consideration for an award of an Animal Model Testing (AMT) IDIQ.

A: The Offeror will have to make its own determination regarding whether it can meet the Mandatory Criteria and Objectives to be considered for award.

16. **Q:** Can BARDA confirm that the same GLP study, or studies, used for the Animal Model Testing (AMT) proposal be used as eligibility for the AS proposal, regardless if assays have been used?

A: Documentation of assay work using any of the GXP standards is considered acceptable for meeting the mandatory criteria for Analytical Services.

17. **Q:** We are contemplating to respond to the subject RFP, in particular to the Analytical Services subject area. The RFP document states that a response should be provided to all 5 Technical Capabilities. It is not clear to us, however, whether all requirements listed under each of the Technical Capabilities (C.1.AS.1 through C.1.AS. 14, C.2.AS.1-C.2.AS.2, C.3.AS.1-C.3.AS.2, C.4.AS.1-C.4.AS.2, C.5.AS.1-C.5.AS.2) should be addressed in a proposal.

A: Please provide a response (to the best of your ability) to all of the objectives within each Technical Capability under the Analytical Services subject area. Section C of the RTOR (page 7) states a response must be provided for each of the listed Technical Capabilities to be considered for evaluation. "Please ensure that your proposal clearly addresses each of the above five technical capabilities in your SOO submission."

18. **Q:** Attachment 1 Table 1. Price Factors pg 105 - Does the government require price estimate for single and multi-assay development, validation and sample analysis for non-routine matrices?

A: The Offeror should use its own judgment in preparing a cost estimate based upon the Price Factors identified in Attachment 1 Table 1.

19. **Q:** When submitting past performance information, should the offeror include contracts where work was completed (or is currently being completed) as a subcontractor and not a Prime on a BARDA contract?

A: Past performance information should not be restricted to BARDA contracts (whether contractor or subcontractor) and should include any organization for which the Offeror provided services.

20. **Q:** Please clarify BARDA's request as set forth in the 2nd paragraph. Please confirm that the past performance request is limited to those contracts relevant to the scope of this RFP. Also please confirm that the "any previous activities with BARDA" should be limited to those within the past 10 years and relevant to the scope of this RFP.

*Questions and Answers for BARDA Biological Nonclinical Studies Network (NSN)
RFP-16-100-SOL-00008*

A: It is acceptable to limit past performance to those contracts relevant to the scope of this RFP. All previous activities with BARDA since its establishment in 2006 should be included.

21. Q: Is a non-US service provider eligible to submit a proposal?

A: Yes.

22. Q: Would you please advise where all of the Appendixes are located?

A: The Attachments listed in Section J are included within the PDF document.