

Consolidated NGDS Increment 1, Q&A Listing

April 5, 2012

1. Category: Assays

1.Q. How many Biological Warfare Agent (BWA) tests must be optimized in the CP Phase?

A: Minimum of 2 – *Bacillus anthracis* (BA) (2-targets) and Viral Hemorrhagic Fevers (VHF) (3-targets, 2-Ebola & pan-Marburg). This is most likely.

A: Maximum of 6 – BA In-vitro Diagnostic (IVD), BA Environmental, VHF IVD, Tularemia (FT) IVD, Plague (YP) IVD, and Q-Fever (Q) IVD. This is less likely but will be of interest if efficiency can be gained through multiplexing. Once optimized, assay may or may not be used in that form in subsequent phases (tests may be re-optimized into a larger panel, if applicable). Pre-clinical / clinical trials may or may not be started in the next phase for all agents optimized in CP (e.g. BA IVD pre-clinical trial may be started with a BA/YP/FT multiplex assay – with the YP/FT blinded). BG optimization will be removed from CP.

2. Category: Assays

2. Q. Do all BWA test optimizations have to be done in 125 days?

A: No. Only the designated “benchmark” assay has to be done in 125 days. The benchmark” will likely be BA.

3. Category: Sample Matrices

3. Q. What sample matrices must each CP phase BWA test be optimized for?

A: See table in SOW, Section C.3.1.3.1

BA – Buffer, whole blood, NIST soil

VHF – Buffer, Whole Blood, Blood Serum

YP – Buffer and Whole Blood

FT – Buffer and whole blood

Q-Fever – Buffer and whole blood

4. Category: FDA

4. Q. Will a technology which has not yet been FDA approved be considered for Increment 1? By what date must a company have a FDA approved product to be considered?

A: **Yes. Revised Final RFP is expected to include the following language**

“At the time of proposal submission, the proposed system must: 1) be currently under clinical evaluation as an *in vitro* diagnostic (IVD) for the U.S. market (clinical trial); 2) be cleared via a 510K or PMA approval by the FDA as an IVD, or 3) have received approval by the European Medicines Agency (EMA) as an IVD (CE IVD).”

5. Category: RFP Submission Constraints

5. Q. Will a technology that will meet the short and long term objectives of NGDS and will be commercially available by the end of 2012 (in a non-FDA regulated market, but will be manufactured under GMP and ISO protocols) and will be submitting for 510(k) approval and a

CLIA waiver, be considered? If so, by when would the IDE meeting, 510(k) submission and request for CLIA waiver, each need to be submitted?

A: **Yes. Revised Final RFP is expected to include the following language**

“At the time of proposal submission, the proposed system must: 1) be currently under clinical evaluation as an *in vitro* diagnostic (IVD) for the U.S. market (clinical trial); 2) be cleared via a 510K or PMA approval by the FDA as an IVD, or 3) have received approval by the European Medicines Agency (EMA) as an IVD (CE IVD).”

6. Category: RFP Submission Constraints

6 Q. Can a small company address the concerns regarding the capability to efficiently obtain FDA approval be satisfied by either partnering with an organization with FDA approval experience or having or hiring employees or consultants with strong FDA approval experience?

A: **Yes. Revised Final RFP is expected to include the following language**

“At the time of proposal submission, the proposed system must: 1) be currently under clinical evaluation as an *in vitro* diagnostic (IVD) for the U.S. market (clinical trial); 2) be cleared via a 510K or PMA approval by the FDA as an IVD, or 3) have received approval by the European Medicines Agency (EMA) as an IVD (CE IVD).”

Partnering with other companies to increase assay development and FDA clinical trials capacity is acceptable.

7. Category: Consumables

7 Q. Multiple targets are listed for each Disease/Agent assay (e.g. Bacillus Anthracis, 2-3 targets). Are the multiple targets required for redundancy to increase specificity (i.e. reduce false alarm rate), or to determine different characteristics of the Disease/Agent (e.g. speciation, drug resistance)?

A. At a minimum multiple targets are needed for specificity. Then, in addition to those targets, additional targets may be proposed to provide speciation and resistance information.

8. Category: Source Selection Question/Performance Specification

8. Q. How is the overall evaluation conducted? Is there a trades analysis between [T] and [O] specifications, or “Important” and “Desired” evaluation ratings to measure the overall system performance?

A. Refer to Section M.3.2.1.2 for the definition of Green-Acceptable with respect to Critical, Important, and desired P-Spec thresholds. Qualitatively, the number of thresholds met above the minimum and number of objectives met contribute to ratings above green.

9. Category: COTS Analyzer

9. Q. If the offeror’s current commercial product does not meet certain “Important” or “Desired” evaluation criteria, but the offeror already has under development an upgraded

version of the current commercial product that meets such criteria, can project funding be used to complete the development of the upgraded product?

A: No. The intent of the NGDS Contract is not to “Build To” the NGDS P-spec after contract award. Vendor Modifications after source selection may invalidate Govt testing needed to support a fielding decision. Proposed vendor configuration changes that do not jeopardize prior FDA clearances may be proposed and adjudicated via a formal Engineering Change Proposal Process.

10. Category: RFP Submission Constraints –Number of Proposals

10. Q. Can the offeror’s proposal include different instrumentation using the same technical approach but capable of different run throughput, e.g. a mobile or hand-held product capable of testing 1 sample at a time for multiple analytes, and a man-portable “bench-top” product capable of testing multiple samples, and/or multiple analytes simultaneously?

A: See Section L.2.13 . In this case, offer may submit 2 proposals

11. Category: Consumables/Performance Spec

11 Q. For the environmental sample matrices, LOD is provided in absolute units (e.g. 10 pfu) in some cases, rather than as a concentration (e.g. 10 pfu/mL). What is the expected sample volume of the matrix to achieve the absolute LOD?

A. In the Final RFP, all LODs will be expressed as a concentration.

12. Category: Source Selection Timeline

12 Q. What is the estimated proposal due date? What is the estimated award date / project start date?

A: Estimates Proposal due date is **45-60 days** after RFP release – on or about **27 April**.
Estimated award date is between **30 August** to 30 Sept.

13. Category: Source Selection Plan

13 Q. How many awards will be issued for the CP phase?

A: Govt is estimating 3 awards dependent upon available funding and the quality of proposals received

14. Category: Contract Scope

14 Q. Is there a maximum total award, or total award per year for each proposal?

A. The estimated contract ceiling is \$200M inclusive of base period and all options. There is no specific per year total. The Ceiling includes scope for all acquisition phase of the NGDS program and optional scope for other federal agencies.

15. Category: Source Selection Scope/Contract Award

15 Q. The proposal should include that for the CP, TD, and Post MS C phases, or just the CP phase?

A. The proposal should address all requirements of the RFP, inclusive of CP, TD and PD (post MS C).

16. Category: Proposal Submission Requirements – “Bid Sample”

16 Q. A Bid Sample is required to be responsive to this solicitation. Will the Government provide compensation for the Bid Sample, or return the Bid Sample after a period of time?

A: Update: the no cost Bid Sample will be removed as a proposal requirement. – updated 9 April 2012

17. Category: NGDS Program Vision (Tactical Variant)

17 Q. Is it the Government's intention to replace the JBTDS identifier with NGDS?

A. Potentially. The NGDS Tactical Variant Prototype, if the options are exercised, would be one of several candidates planned to be evaluated by the JBTDS program office. Use of the NGDS Tactical Variant by the JBTDS program is not mandatory at this time.

18. Category: NGDS (Tactical Variant) Consumables-Food & Water Assays)

18 Q. Will Food and Water assays be rolled into JBTDS? Is the intention to ultimately use the NGDS as the common platform for all systems (detection, ID, BWA pathogens)?

A. JBTDS questions should be directed to the JPM Biological Defense program office for definitive answers. Food and water assays are not known to be a part of the JBTDS CONOPS. It would be significant cost savings to the Government for there to be a common materiel solution between the NGDS, CALS and JBTDS programs.

19. Category: RFP SOW Content (Emphasis Area?)

19 Q. In the early draft RFP dated 26 Mar 2012, you stated “...The NGDS program will seek the development of a syndromic approach to diagnostics...” (see 2.0) How is this requirement weighted relative to other requirements and with respect to sample-type?

A. Statements in the background sections of Section C and the P-Spec are not specially weighed in the source selection. The P-Spec 3.2.3.3 addresses Simultaneous analysis. Contractors in the CP Phase are required to provide recommended assay configurations for IVD (clinical samples), and BWA and Non-BWA environmental sample assays through the conduct of various studies (SOW para C.3.1.4) to include their approach for screening/syndromic kits that would increase the clinical utility of IVD assays and reduce the burden to operators from environmental sample types. Section L.4.1 requires that the Offeror provides a narrative how Section C tasks will be addressed. Section L.4.2 requires that Offeror’s provide a narrative of to what degree P-Spec metrics are addressed.

20. Category: FDA IVD Kit Timeline

20 Q. How were the FDA clearance time lines derived?

A. JPM CBMS, BSV Program Experiences. The JPM BSV has cleared 7 IVD BW and Non-BW agent kit with the FDA in the last six years. Based our FDA experiences in this area, we believe the SOW IVD kit timelines of 4.5 months for assay optimization, 9 months for pre-clinical trials tests, and 6 months to complete the Clinical trial are achievable. Yes, contractor planning efforts to support the clinical trials need to start during the pre-clinical trials test efforts as outlined in SOW Enclosure A.

21. Category: NGDS Increment 1, Program Vision – Technology Constraint

21 Q. NGDS as announced is nucleic –acid centric, when will protein based assays find diagnostic utility in NGDS, if at all?

A. The NGDS P-spec is intended to be technology agnostic listing only limits of detection and Clinical sensitivities that are known to be effective for the intended mission.

22. Category: NGDS Program (Increments 2 & 3)

22 Q. When will host biomarkers be addressed in the NGDS life cycle?

A. Offer’s can propose any technical approach that will meet FDA guidelines for clearance as an in-vitro diagnostic. If biomarker based approaches are insufficiently mature during Increment 1 they may be proposed for NGDS Increment 2.

23. Category: RFP SOW Consumables Question-Focus

23 Q. It seems NGDS in the current format is focused on only a few targets (Ba, YP, FT, Q-Fever and VHF). When will Toxins agents be looked at in NGDS lifecycle.

A. The NGDS program does have the requirement to replace the Joint Biological Agent Identification and Diagnostic System (JBAIDS) which in turn drives the priorities for the first IVDs to be cleared on the NGDS. Toxins are included in the Section C Enclosures and there is scope in Section C to take a toxin IVD through FDA clearance when a mature technical and clinical trial approach is available. Toxin assay development is included in the NGDS SOW, Para C.3.3.3.6.2 in the PD phase.

24. Category: NGDS Program (Increments 2 & 3)

24 Q. Is there going to be NGDS Increment 2, Increment 3, etc., within the NGDS current life cycle of NGDS?

A. The JPM CBMS FY14 POM submission currently includes early development funds (MB4) for NGDS Increment 2, starting in FY14. The FY14 DoD budget, however, will not be finalized until Nov/Dec 2012 when it is submitted to OMB.

25. Category: NGDS Program (Increments 2 & 3)

25 Q. Does NGDS program find any diagnostic value for host-immune response of BWAs?

A. Yes. Host response approaches will likely be required for diseases with low concentrations in the body and for Pre-symptomatic screening of large populations.

26. Category: NGDS Technology - Toxins

26 Q. What is the requirement for the capability to detect protein toxins? If the technology is incompatible with protein detection, it was mentioned that this option would not be exercised. Shouldn’t this be part of the evaluation of the potential systems in the proposal review process?

A. The RFP is meant to be technology agnostic. If the candidate system can meet the performance requirements for pathogen(s) identification, **and is in FDA clinical trials, FDA**

cleared, or CE IVD cleared for in vitro diagnostic use, then it can be bid by the contractor. The offeror's narrative of the ability to address the SOW tasks is assessed under L.4.1.

27. Category: Industry Day Presentation Posting

27 Q: Will the Industry day presentation be posted online?

A: Yes, by the end of this week (April 6, 2012, COB).

28. Category: FDA IVD Clearance Timeline

28 Q. How were the schedules for FDA clearance derived?

A: See Q&A No. 27 above. Also, FDA clearance schedules were derived from past examples and while keeping in mind evolving FDA guidance and what FDA allows for biological warfare agents with respect to contrived samples.

29. Category: FDA Interaction

29 Q. Is the FDA aware of the aggressive NGDS timelines? And is FDA aware that multiple companies will be approaching FDA for clearance, etc.?

A: Yes, FDA is aware. NGDS program staff have met with FDA to discuss the acquisition strategy and FDA is aware that there will be multiple pre-IDE applications and requests for meetings from vendors within the base period of performance.

30. Category: IVD Assay Development and Clinical Samples

30 Q: Is it the Government's intent that the Government will provide clinical samples for testing?

A: The Government will provide inactivated BWA materials and, if live agent testing is required, will provide access to Government facilities to perform that testing. The Government anticipates that most sample matrices will be commercially available. The Government will investigate stockpiling clinical specimens to reduce schedule risk for both the Government and the Contractor.

31. Category: IVD and Environmental Assay Development

31Q: Is the Government going to allow all spiked/contrived samples?

A: The Government expects scientifically justifiable proposal from vendor and anticipates that the contract awardee(s) will sponsor the application. The Government understands the need to share the burden of acquiring the necessary samples and will facilitate access to those samples to the extent possible. It will be the contractor's responsibility to provide the samples types as specified by the FDA in response to the contractor's Pre-IDE FDA submission package.

32. Category: Assay Consumable Screening Panels/Syndromic Panels

32 Q:The Draft RFP indicates syndromic panels should be included when possible. How are they expected to be included and what types? How would that be weighted?

A: See Q&A No. 26. This information is included in Section 2.0 (Program Scope) of the draft RFP and is, therefore, not a specific requirement. Specific requirements are listed in Section L. That being said, screening panels if applicable to the contractor's COTS analyzer design, can/should

be included in the contractor's assay kit design studies in SOW para C.3.1.4. (IVD, BWA Environmental, Non-BWA Environmental).

33. Category: NGDS Increment I Contract Value

33 Q: Is the \$200M ceiling just for pre-Milestone C?

A: No. The presumed \$200M contract ceiling prices includes the competitive Prototyping (CP) Phase, follow-on Technology Demonstration (TD) Phase, and Production/Deployment (PD).

34. Category: Multiple NGDS RFPs

34 Q: Has the Government considered putting out one RFP for competitive prototyping and a different RFP for post-CP phase?

A: Alternate contract approaches were considered

35. Category: RA Costing

35 Q: Will the Government pay for regulatory activities?

A: The Government contract award is intended to include payment for: development of pre-IDE; travel to FDA to conduct IDE meetings; development of clinical protocols; clinical trial sites support; equipment used in pre-clinical trials; conduct of clinical and pre-clinical trials; preparation and submission of 510K submission. Contract awardee(s) will be the sponsor of submissions to the FDA, with all attendant responsibilities.

36. Category: Consumable Sample Quantities in SOW

36 Q. For the production/deployment phase, is the number of samples listed the maximum anticipated per year or lifetime?

A: Currently the number of samples listed is for the lifetime time frame, keeping in mind that the samples are expected to be spread over 5-10 years. Quantities will be reviewed for the Final RFP.

37. Category: FDA Experience Requirements

37 Q: Would a company that has been through the FDA clearance process for a related instrument that is different than the one that would be submitted in response to this RFP be considered to have met the FDA clearance requirement?

A: While having been through the FDA clearance process reduces the company's perceived risk, it does not resolve the risk associated with having to obtain FDA clearance for the proposed instrument. To bid on the solicitation, the Offeror's candidate COTS system needs to be FDA cleared.

38. Category: "Bid Sample" Requirements

38 Q: Is an assay kit for every FDA-cleared assay for the instrument required to be delivered with the "Bid Sample"? Or a sampling of the kits?

A Update: Bid sample requirement has been removed

Q: What if the kit configuration is 500 assays? **N/A**

39. Category: Bid Sample” Requirements

39 Q: “Bid Sample” needs to be included with CDs and binders? When does it have to be delivered and where?

A: Update: the Bid Sample will be removed as a proposal requirement.

40. Category: CP-TD-PD Phase hardware Delivery Schedule Requirements.

40 Q: As a contractor, system delivery timeline outlined in the draft RFP will be very difficult to meet.

A. The Government plans to relook at the hardware and consumables SOW deliverables timelines. The NGDS program office will provide further clarification in the updated SOW based on feedback during Industry Day.

41. Category: JBTDS (Tactical Variant)

41 Q: Will NGDS replace JBTDS?

A: JBTDS is only under guidance to consider NGDS, but is not required to use it. JBTDS could carry competitive prototyping for identifiers into the EMD phase. NGDS intent to facilitate consideration of NGDS technology by JBTDS.

42. Category: NGDS Food and Water Assay as Part of JBTDS

42 Q: Will food and water assays be part of JBTDS?

A: See Q&A No. 25. Also, Out of our lane/scope of this RFP... but it’s in the CALS CONOPS, not JBTDS.

43. Redundant and Omitted.

44. Category: NGDS Technology Question

44. Q Is the Government only considering assay-based tests?

A: See Q&A No. 21. The proposed instrument must at match the requirements of the RFP which intended to be technology agnostic.

45. Category: NGDS RFP Consumable Agent targets

45. Q. Will final RFP include list of all targets?

A: Specific GFI relating to assay designs will only be communicated after contract award. The number of targets relating to the scope of development will be reviewed. SOW para C.3.1.3.1 provides a notional list of target assays for the CP and TP phases. The RFP Enclosure C, D, and provides a more complete listing of potential assay targets for the entire NGDS Increment I program over the next 8-10 year. As noted in the industry day briefing, the priority for CP Phase consumable BW agent targets are Ba, and VHF. The Government, however, reserve the right to exercise options for other agents listed in the paragraph table, to include assay optimization during the CP and TD program Phases.

46. Category: NGDS SOW Deliverable Quantities (Systems & Consumables)

46 Q. The SOW contains Min and max numbers in the system and consumables delivery tables. Which number should be used for budgeting (min. or max. # of samples)?

A: An expected value will be added to aid in planning and proposing.

47. Category: NGDS RFP Content – JBTDS Spec

47. Q. When will the JBTDS performance spec available?

A: The Government program office will be provided as an attachment to final RFP.

48. Category: NGDS Technology Focus?

48 Q: How does type of technology play into how it will be assessed during the source selection?

A: The Government evaluation process is noted in Section M of the RFP. The Evaluation factors are clearly stated in RFP.

49. Category: NGDS TD Phase number of Contractors

49. Q: Your Government Industry Day briefing implies only one system will make it past the CP Phase- True?

A: Yes, only 1 system is PLANNED. Actual depends upon proposal received, final program requirements and available funding.

50. Category: NGDS - “Open Platform”

50. Q. Is an “Open Platform” a requirement on NGDS Increment 1 requirement?

A: The openness of the system design should be part of the L.4.4 narrative. It is desirable for other Government agencies to be able to develop content on the selected NGDS Increment 1 system. The NGDS program is based on teaming with potential partners outside the DoD Chem Bio defense field, like USAMRIID, WRAIR, BARDA, the CDC, etc.

51. Category- NGDS Software Requirements

51. Q. Is being DII COE compliance, Level 8, an NGDS platform requirement?

A. Not at the time of award. DII COE requirements are listed in the NGDS Performance Specification. As noted in the Industry Day briefing, and Section L and M of the RFP, a contractor's COTS systems does not have to meet all the requirements noted in the P-Spec. (The Government is purchasing an FDA cleared COTS platform, and the government has no plans to make the selected NGDS CP systems compliant with all the features in the P-Spec. Compliance with the P-Spec requirements is noted in Section M, para M.3.2.1.2. and Section L, para L.4.2. The important/ranking of various P-Spec requirements are noted in the P-Spec Table 3, para 4.0, Verification Methods: Critical, Important, and Desirable. Also, see Q&A No. 9.

52. Category: NGDS P-Spec Requirement (Who should submit?)

52. Q.: Does it make sense to submit a proposal if the system that is not field portable?

A.: The Government cannot tell a company whether or not to propose. However, the specifications for weight and size laid out in the RFP should be considered as guidelines. Furthermore, the primary intended use is with deployable combat support hospitals.

A: System Weight has been changed from an Important metric to a Critical metric.

53. Category: NGDS P-Spec System Characteristics

53. Q. If weight is a potential elimination criterion, it should be considered "critical" in the P SPEC, not simply important

A. The Government will relook at the way in which this and other criteria are designated in the P-Spec table as "Critical, Important and/or Desirable."

A: System Weight has been changed from an Important metric to a Critical metric.

54. Category: NGDS CP Consumables Assays

54. Q. Is the Government looking for a separate assay for each VHF or for a combined assay.

A. Several VHF targets will be required. The assay format proposed may vary based on the contractor's technical approach. If Multiple VHF targets can be combined into a single assay logistical costs would be reduced and there would be lower burden to the operator. (See SOW para C.3.1.3.1, Table: C.3.1.3.1.8/.9).

55. Category: NGDS Consumables Target Cost

55. Q. Does the Government have a target cost/test?

A. A Target Cost is not currently defined in the RFP, although lifecycle costs and sustainability are critical for the successful broad adoption of the NGDS by users and consumable costs are a key component of this. The Government will further consider this question.

56. Category: NGDS Consumables

56 Q. Do incumbents have assays already finished or in the pipeline to meet the Government's needs? Is the playing field level?

A.: There is no NGDS incumbent. The Government intends to make multiple awards in the CP Phase.

57. Category: NGDS Sample Matrices

57. Q. Different sample matrices may require an investment up-front for altering sample preparation steps; are these cost reimbursable on the CP and TD development CLINs?

A. The offeror's should propose the full cost of assay optimization for the required sample types. The Government realizes that different sample type requirement may/will impact the contractor's up-front preparation steps; these costs should be reflected in the contractor's price proposal for various assays selected for development in the SOW, para C.3.1.3.1, see table.

58. Category: NGDS Increment 1 Acquisition Strategy

58. Q.: Why not just focus on having a more detailed, clearer RFP addressing just the CP phase, and then follow up with a second RFP for Post-CP activities?

A.: As previously discussed, this has been considered by the JPEO CBD/JPM CBMS team, and the Government believes the current contracting approach is appropriate.

59. Category: NGDS Cost Accounting System Requirement – EVM

59 Q. Some companies do not have DoD military contracts, and work only in the commercial market. Being encumbered with extensive DoD funds management regulations is not desirable and could force some companies to "push away from the table," specifically EVM and cost accounting system requirements. Is this oversight mandatory for NGDS?

A. The BSV-NGS team agrees that Earned Value Management (EVM), Section L, para L.5.4, is a burden on both contractors and the Government team, but it is currently a DoD requirement for contracts with Cost Plus CLINs that exceed a dollar threshold (over \$50M); this requirement cannot be waived. A DCMA audit may be conducted on bidders Cost Accounting Systems to determine that an adequate accounting system is in place; this audit will be arranged by the NGDS program office during the RFP source selection to ensure that each contractor in the competitive range, is qualified to receive a contract award. The Government plans to have an EVM CLIN in the NGDS contract(s) to allow contractors to recover all cost associated with this DoD cost accounting system management requirement.