

Attachment 18 – Questions and Answers (Q&A)

Solicitation Number: VA24114R0712

The following are Questions and Answers (Q&A) relating to this solicitation.

#	Q & A and Reference	Amendment #
1	Q: How long is the [offer] review process?	A00001
	A: The offeror is required to extend a “firm” offer for ninety (90) days. The VA review process may be up to ninety days, however it is foreseeable that the award decision(s) will be made sooner.	
	Ref: [Reference: SF1449, page 1, block 20]	
2	Q: When will we receive the decision?	A00001
	A: Successful and unsuccessful offerors will receive notification of the decision via fax and phone call from the Contracting Officer supplemented with a mailed letter.	
	Ref: [Reference: SF1449, Section B, page 5, paragraph B.1.1.a Contract Administration Data and Section E FAR 52.212-1 Instructions to Offerors, (para. (c) and (f)(5) and Section E Evaluation of Commercial Items paragraph (c).]	
3	Q: "Statement of Work" (SOW) is mentioned a few times in the solicitation. Is it the same as "Performance Work Statement (PWS)"?	A00001
	A: Yes, as used in this solicitation, Statement of Work (SOW) is the same as (a synonym for) “Performance Work Statement: (PWS) and “Performance Based Statement of Work” (PBSW).	
	Ref: [Reference: Section B Performance Work Statement (PWS) infra]	
4	Q: . Is it possible to collect saliva (we can provide a kit for that) to obtain matched normal? We routinely request both tumor and normal samples in order to analyze tumor-specific as well as germ-line alterations. As there are typically few somatic mutations among the sea of germ-line variants, it's important that any germ-line mutations be filtered out. If no matched normal is available, we will filter out the germ-line variants using bioinformatics methods.	A00001
	A: Saliva will not be provided. We will be able to provide blood specimens for the majority of subjects.	
	Ref: General Scope, page 18 of 86 of solicitation	

5	<p>Q: What is the policy on subcontracting? Our firm focuses on DNA analysis (i.e., targeted and whole exome sequencing). For transcriptome analysis, we have evaluated vendors and subcontracted with one vendor. Can we include them in the RFP or we should focus on what we will perform in our lab?</p> <p>A: We are OK with subcontracting as long as details are provided regarding the specific subcontractors. BTW, costs for DNA analysis and transcriptome analysis should be given separately.</p> <p>Ref: Task 8 on page 25 of 86 of solicitation</p>	A00001
6	<p>Q: . In VA241-14-R-0712-006 (the spec file), Question #4, "Instructions to Offerors A(a)(i)(6) and (7)" was mentioned. Where can we find it?</p> <p>A: Form SF 1449 page 3, SECTION E – SOLICITATION PROVISIONS; follow the ellipses to the page index for SECTION E - SOLICITATION PROVISIONS résumés***** 52.212-1 Instructions to Offerors—Commercial Items. (APR 2014) ***** Addendum: Instructions to Offerors</p> <p>Ref: SF 1449, page 3, SECTION E</p>	A00001
7	<p>Q: Will the VA cases be mainly for clinical decision or for research? Since the prices for the clinical test and research-use-only test are different, we would need such information to calculate the cost.</p> <p>A: They will be used for both clinical and research purposes.</p> <p>Ref: Page 18 of 86 of solicitation, General Scope</p>	A00001
8	<p>(The following set of questions 8 through 13 relate to what the Contractor will receive per case)</p> <p>Q: Will there be already be a pathology report with the primary diagnosis supplied with the FFPE sample being sent for sequencing & analysis?</p> <p>A: Yes, there will be a pathology report with the primary diagnosis supplied with the block or formalin fixed tissue.</p>	A00002

	Ref: page 20, paragraph 5	
9	Q: Will the contractor receive a clinical synopsis with each case including prior imaging, diagnosis under consideration, initial path report, patient history, clinical notes, physician contact, etc)?	A00002
	A: No. Just the pathology report.	
	Ref: Page 20, paragraph 5	
10	Q: Will there be clinical contacts for the sample?	A00002
	A: MAVERIC (VA Boston Healthcare System) will serve as the point of Contact. We have access to the clinical contacts and can facilitate communication.	
	Ref: Page 20, paragraph 3	
11	Q: Are we receiving FFPE block or samples in formalin or both?	A00002
	A: In most cases a tissue block will be submitted, but in a few cases formalin fixed tissue will be submitted	
	Ref: page 19, paragraph 3	
12	Q: What is the approximate % of samples that are FNA vs core biopsy vs resected tumor vs other?	A00002
	A: About two thirds of cases will be diagnosed from surgical pathology specimens, either biopsies or resection specimens. About one third of cases will be diagnosed from cytology FNA specimens. In most cases tissue blocks of biopsies, resected tissue, or FNA cell blocks will be submitted. For example, at Boston at total of 115 cases of primary lung cancer were diagnosed in FY2013. Of these cases 77 were diagnosed by surgical pathology, either biopsy or excision, and 38 cases were diagnosed by cytology. The breakdown of diagnoses were squamous cell carcinoma, 42 cases, adenocarcinoma, 56 cases, small cell neuroendocrine, 10 cases, large cell neuroendocrine, 2 cases, non-small cell carcinoma, unclassified, 4 cases, other, 1 case. 6 cases of 36 were positive for EGFR, and 0 cases of 30 were positive for ALK.	
	page 19, paragraph 3	
	Ref: NONE.	
13	Q: Any further details on the sample types/amounts you will be sending would be welcome information.	A00002
	A: None.	
	Ref: NONE	
14.	Q: <i>When</i> shall we send our ATTACHMENT – 5 – PAST PERFORMANCE SURVEY to our references whom we are listing on ATTACHMENT – 6 – REFERENCE ROSTER?	A00002
	A: Immediately, now. <i>Statim</i>	
	Ref: SECTION E – SOLICITATION PROVISIONS ADDENDUM: Instructions to Offerors A.a.ii (para 1 and para 2) (Comment: At this juncture the offeror should self-assess the feasibility of accomplishing the required	

	tasking of SECTION E – SOLICITATION PROVISIONS ADDENDUM : Instructions to Offerors before the due date (page 1, SF 1449 block 8).	
15	<p>Q: We plan to offer two (2) targeted panels. Our tests can be run in two modes: matched tumor/normal or tumor-only. Matched tumor/normal is more expensive but provides better results. Therefore, we would like to propose 2x2= 4 possible scenarios. Should we fill out the pricing excel file 4 times, each with different unit price?</p> <p>A: The commercial acquisition permits the offer of alternative proposals, including the alternative pricing proposal that you have put forth in your question. There is value in having both modes (matched tumor/normal and tumor-only) available to us for our current application. Ultimately the decision to utilize one mode versus another is dependent upon the price per test and the volume of tests required, so knowledge of the unit price in each possible scenario would be very helpful. You must clearly label the alternative pricing proposal, with, for example:</p> <p>1X1 1X2 1X3 . . 2X1 2X2 2X3 . . Etc.</p> <p>Where 101, 102, 103, denominate “Tumor only” And 1X1, 1X2, 1X3 denominate “Matched tumor/normal”, so as to clearly differentiate the assay(s) that are qualitatively different than “Tumor only” and quantitatively different in CPT (Cost per test) price.</p> <p>Offerors shall furnish information on assays that are beyond “tumor normal” assay, such information shall support the offerors assertion of value and support the price per test proposed.</p> <p>The offer of any and all alternatives must be accompanied by firm-fixed pricing both in Section B – Schedule and in Attachment – 1 – Pricing Term and for all terms (all tabs) and with a narrative that describes the assay.</p> <p>. Alternative assays induce no change in the Government Estimate, that is, the Government Quantity Estimate(s) per term and line item are unchanged.</p>	A00003

	<p>Evaluation: Price evaluation. The price evaluation of offerors shall consider the comparative evaluation and ranking of the intersection (\cap), the "join" across Contract Line Items (CLINS) common to offerors.</p> <p>The Government's price analysis may, but is not required, to include a price realism analysis.</p> <p>You may add rows and columns to the Attachment -1 – Pricing .xlsx spread sheet, but you shall clearly delineate which assays you are describing. The "Print Preview" format must support 8.5" X 11" portrait or landscape orientation. price analysis and the "roll-up" (Summation) of line items.</p> <p>An assay, such as you describe shall also be addressed in your response to the Specification (e.g. Attachment – 4 - Specification 1, 7, 8, 9, 32, 35, etc.)</p>	
	<p>Ref: SECTION B.7 Price/Cost Schedule; SOW 10.0 ESTIMATED QUANTITIES AND 12.0 SECTION E - SOLICITATION PROVISIONS – 52.212-1 Instructions to Offerors – Commercial Items A.a.(iii), Attachment – 4 - Specification 1, 7, 8, 9, 32, 35, etc.)</p>	
16	<p>Q: The Laboratory Director of our Company is a board-certified MD, not a pathologist. He/She signs our clinical reports. The solicitation stated that "Clinical reports shall be signed off by a board-certified pathologist and faxed to the medical center where the cancer specimen originated." (P25, Task 8).</p> <p>A: All original surgical pathology reports from VA Boston are signed by a board-certified pathologist. The primary pathologist is responsible for selecting the tissue block to send to the reference laboratory (Vendor). The reference laboratory is expected to supply supplementary information such as genomic data in the present case (rather than diagnostic information). For our purposes, it is therefore not necessary to have a board-certified pathologist sign off on the final clinical report returned to the medical center. Rather, the clinical report shall be signed by a board-certified pathologist or by a licensed bioanalyst</p> <p>Task 8.a (page 25) is amended to read</p> <p><i>"Clinical reports shall be signed off by board-certified pathologist or by a licensed bioanalyst and faxed to the medical center where the cancer specimen originated."</i></p> <p>Bioanalysts and Pathologists are <i>key personnel</i> within the meaning of SECTION E – SOLICITATION PROVISIONS 52.212-1 Instructions to Offerors – Addendum A.a.i.2. and Attachment 8 CONTRACTOR TEAM.</p> <p>Identify and furnish CV for all Bioanalysts on the Contractor Team (Attachment 8).</p>	A00003

	<p>Ref: page 21, paragraph 2.D. Key Personnel.</p> <p>Task 8.a (page 25)</p> <p>Attachment – 8 – Contractor Team</p>	
17	<p>Q: In b (4) of the End Addendum (page 64 of the solicitation, we are unclear about 52.204-10, reporting executive compensation and first tier subcontract awards. Where should this be included, and what specifically do you need? A list of our Executive's Compensation packages?</p> <p>A: The text of the clause and its prescription are available at the web sites listed in: SECTION C: C.14 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998).</p> <p>52.204-10 is prescribed in FAR 4.1403 and is incorporated into <u>all</u> solicitations and resulting contracts and certain grants and funding agreements issued on or after March 1, 2011 See C.14 252.2 or the following hyperlinks for the text of the clause and its requirements: www.ecfr.gov, https://farsite.hill.af.mil/ or https://acquisition.gov/far/index.html</p> <p>The offeror reports the data at both http://www.fsr.gov and at https://www.acquisition.gov (and www.sam.gov)</p> <p>The offeror does not submit the data required by the clause to the Contracting Officer, nor does the offeror submit the data as part of its proposal.</p> <p>By its signature in block 30a, 30b, 30c (SF 1449 page 1) and by via its "Representations and Certifications ("Reps and Certs") www.sam.gov and SECTION E – SOLICITATION PROVISIONS the offeror affirms that it is in compliance with federal procurement laws.</p> <p>Ref: 52.212-1(b)(4) (Instructions to Offerors)</p> <p>SECTION C: C.14 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)</p> <p>SECTION E.11 52.212-3 paragraph (b)(2) and (b)(3)</p> <p>Checklist</p>	A00003
18	<p>Q: May we submit the offer electronically to you by Friday 5pm (as stated on page 64 of the 85 page solicitation offer, with the over-nighted binders to follow.</p> <p>A: No</p> <p>(1) The only permissible <i>electronic</i> submission under this solicitation and contract are the Offerors on-line "Reps and Certs" via www.sam.gov (See paragraph Section E - 52.212-1(b)(8))) and the usual e-commerce self-reporting (see Question 17 <i>supra</i>).</p>	A00003

