Attachment 19 – Questions and Answers (Q&A) – A00004

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	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?	A00001
	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. **SEE REVISION AND EXTENSION AT Q&A 20 *infra* –A00004**	
	Ref: Task 8 on page 25 of 86 of solicitation	
6	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?	A00001
	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	
	Ref: SF 1449, page 3, SECTION E	
7	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.	A00001
	A; They will be used for both clinical and research purposes.	
	Ref: Page 18 of 86 of solicitation, General Scope	
8	**(The following set of questions 8 through 13 relate to what the Contractor will receive per case)** Q: Will there be already be a pathology report with the primary diagnosis supplied with the FFPE sample being sent for sequencing & analysis?	A00002
	A: Yes, there will be a pathology report with the primary diagnosis supplied with the block or formalin fixed tissue.	

	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 or 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: *When* 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. *Statim*	
	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	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?	A00003
	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: 1X1 1X2 1X3 . . 2X1 2X2 2X3 . . Etc. 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. 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. 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. . Alternative assays induce no change in the Government Estimate, that is, the Government Quantity Estimate(s) per term and line item are unchanged.	

	Evaluation: Price evaluation. The price evaluation of offerors shall consider the comparative evaluation and ranking of the intersection (∩), the "join" across Contract Line Items (CLINS) common to offerors. The Government's price analysis may, but is not required, to include a price realism analysis. 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. 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.)	
	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.)	
16	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).	A00003
	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 Task 8.a (page 25) is amended to read "*Clinical reports shall be signed off by board-certified pathologist or by a licensed bioanalyist and faxed to the medical center where the cancer specimen originated*." Bioanalysts and Pathologists are *key personnel* within the meaning of SECTION E – SOLICITATION PROVISIONS 52.212-1 Instructions to Offerors – Addendum A.a.i.2. and Attachment 8 CONTRACTOR TEAM. Identify and furnish CV for all Bioanalysts on the Contractor Team (Attachment 8).	

	Ref: page 21, paragraph 2.D. Key Personnel. Task 8.a (page 25) Attachment – 8 – Contractor Team	
17	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?	A00003
	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). 52.204-10 is prescribed in FAR 4.1403 and is incorporated into **all** 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 The offeror reports the data at both http://www.fsrs.gov and at https://www.acquisition.gov (and www.sam.gov) 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. 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.	
	Ref: 52.212-1(b)(4) (Instructions to Offerors) SECTION C: C.14 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEF 1998) SECTION E.11 52.212-3 paragraph (b)(2) and (b)(3) Checklist	
18	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.	A00003
	A: No (1) The only permissible *electronic* 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 *supra*).	

	The binders and the CD-ROMs are due in the quantity and format stated in the Instructions to Offerors (A.**a**. and A.b.), at the place stated in SF 1449 (page 1) and at the time stated in Amendment A00003 (block 14). There is no alternative to the quantity, media or the prescribed format. "*Electronically*" and "*Electronic Commerce"* refer to EDA/EDI (electronic data access/electronic data interchange) (Question 17) or to Electronic Submission of Invoices (see SECTION C.10 VAAR 852.232-72) or, in the course of performance of this contract, to a BPE (Attachment – 14 – VA Business Partnership Extranet). EDA/EDI is used in VA FAR 8 (GSA) procurements, in "Reverse Auctions" and in FAR 16 NASA SEWP procurements, none of which are applicable in this solicitation. For more, see FAR 2.101 Definitions *Electronic Commerce* and for comparison and a practical example of the distinction see C.10 VAAR 852.232-72 paragraph (a)(3) on page 44. "Facsimile, email, and scanned documents are not acceptable electronic forms…." [for invoices]. In any case, email is not an acceptable format for submitting offers to this solicitation and there is no electronic commerce method authorized by the solicitation for submitting offers. Ref: SF30 Page 1 (block 14)	
19	Q: Attachment -14 - VA Business Partner Extranet Configuration Worksheet We will be a new Business Partner Extranet. For the Attachment 14 forms, we can provide contact information but it looks like much of the technical information on these forms is to be filled out later or by the VA. Is that correct? A: Some, but not all fields of the form are completed when the VA the contractor reach for and implement the BPE solution for the secure large data file transfer. However, the following fields are able to be completed now, at present, and are part of the offeror's proposal: 2. Enter the name of the Business Partner to the right. The Table "Sessions Initiated by VA systems" is not able to be completed, however the offeror should Complete the table labeled:	A00004

	"Sessions Initiated by Partner systems" On the 2nd tab: New BPE (Tab 2) The offeror shall complete parts (all fields): 1. Enter the Business POC… 2. Enter the Technical POC … 3. Enter the Support POC…. Also show your current topology and proposed topology. The exact architecture of the connectivity will be facilitated by the VA Boston Information Security Officer (ISO) together with the Contractor's Information Security Officer, LAN/WAN Administrator and the VA Network Security Operations Center (VANOSC) and the VA Office of Information Technology Service Delivery & Engineering Division (OIT SDE). Hence, the contractor shall state the maximum identifying information.	
	Ref: Attachment – 14 – VA Business Partner Extranet Configuration Worksheet	
20.	QUESTION 5 *supra* is revised and extended as follows: 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?	
	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. **REVISION AND EXTENSION:** This solicitation is a 100% small business set-aside (SF 1449 page 1, block 10 for the North American Industry Classification System (NAICS US 2012) and the Small Business Administration (SBA) size standard (500 employees) listed in block 10. In accordance with FAR 19.508(e) Section C Contains clause 52.219-14 Limitations on Subcontracting (page 49) The limitations on Subcontracting clause provides:	

Limitations on Subcontracting (NOV 2011)

…

(b) Applicability. This clause applies only to—

(1) Contracts that have been set aside or reserved for small business concerns or 8(a) concerns;

…

(c) By submission of an offer and execution of a contract, **the Offeror/Contractor agrees that in performance of the contract in the case of a contract for—**

(1) **Services (except construction). At least 50 percent of the cost of contract performance incurred for personnel shall be expended for employees of the concern**.

…

(End of clause)

Before submitting its offer and in the course of performaning the contact, the offeror/contractor is subject to this constraint.

The VA seeks a contracted solution to its requirement with as comprehensive a solution as possible, which includes a spectrum of assays one of which is Transcriptome. The solution offered by the contractor at the same time should mitigate, not increase, schedule and performance risk. Here, risk, means, data security risk, subcontractor risk, sample risk, program control risk, etc.
The offeror should explicitly identify what processes are subcontracted out and identify the subcontractor (name, email, phone, fax address, DUNS #, nature of agreement, history of contractual relationship with subcontractor) and the risk controls that the offeror has implemented to control the risk.
Subcontracting is not prohibited under this contract; so for example, your overhead functions, such as, , paper shredding, janitorial, biohazard disposal, instrument O&M (Operations and Repair) etc., are reasonably subcontracted however, core Elemental functions, such as data curation, transcriptiome analysis and Task (SOW functions should clearly be stated as to the Subcontractor and the risk controls.
The VHA may elect to avoid, mitigate or accept the risk, either at time of award, or in the course of

	performance of the contract. The VHA may elect not to award a line item, and award some other permutation of line items (risk avoidance); the VA may elect to award, again for example, the transcriptome line item (risk acceptance), or the VA may elect to mitigate the risk later in the course of performance of the contract (by additional controls via the changes clause, or via partial termination of the Contract Line Item for convenience or the Government). Subcontracting compounds the data security problem and general contract administration overhead costs, such that the risk mitigation or acceptance may be cost prohibitive and the VHA may elect a risk avoidance strategy. The VA looks with disfavor upon broker, conduit, shell, "pass through" enterprises who are mere "aggregators" or surrogates. The VA Office of Inspector General (OIG) has an aggressive compliance and fraud detection program and publishes its audits and prosecutions on its web site. The VHA looks to the offeror for transparency and complete disclosure in the offeror's proposal. Ref: Section C.15 – (paragraph (19) clause 52.219-14 Limitations on Subcontracting. http://www.ecfr.gov/cgi-bin/text-idx?SID=137cde8960b0b63969339ab5cdbd576a&node=se48.2.52_1219_614&rgn=div8	
21	Q: Do we need to fill the blanks in SECTION B.7/B.8 Price Cost Schedule of the solicitation (the big 85 page document) if we complete the attachment in .xls format? Below is what says in the checklist file, which confused me: SECTION B.7/B.8 Price Cost Schedule (ATTACHMENT 1) Did you complete in native .xls or .xlsx format all (yellow) price elements of your FFP pricing for CLNs 101 through 509 for all five (5) terms? A: Do we need to fill the blanks in SECTION B.7/B.8 Price Cost Schedule of the solicitation (the big 85 page document) if we complete the attachment in .xls format? Yes; both pages 31 through 40 (of the SF 1449) *and* ATTACHMENT – 1- PRICING TERM 1 – Through TERM 5, in native .xls/.xlsx format on CD ROM. The purpose of the Yellow highlight is to draw the offeror's attention to the distinction between the data fields where the offeror submits its offered price, versus certain data fields, like the Government Quantity Estimate of Assays which *are not* supplied by the offeror. The checklist is modified to read: *"Did you complete pages 31 through 40 of the SF 1449?"* A.**a.**iii is amended to append: Complete the offeror pricing fields on pages 31 through 40.	A00004

	Cross check and proofread all Summations.	
	Ref: iii Tab 3 Pricing (ATTACHMENT 1 PRICING TERM 1 – TERM 5.xlsx.	
22	Q: This is on the check list and we are not sure what we need to do for it: _____ SECTION C – Contract Clauses – Did you identify for C.14 52.227-5 US Government PTO issued patents the practice of which in the course of this contract you request the VA to indemnify you?	A00004
	A: Clause 52.227-5 is provided for at FAR 27.201-2(e), The checklist wording is not accurate. The wording is corrected to read: Did you identify for C.14 52.227-5 US Government PTO (Patent and Trademark Office) issued patents the practice of which in the course of this contract you request the VA to waive indemnification by the Contractor? However the clause is not on point and it is deleted from the checklist. The FAR clauses at 52.227-1, Authorization and Consent and 52.227-2, Notice and Assistance Regarding Patent and Copyright Infringement are sufficient for this solicitation and contract.	
	Ref: ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL., PETITIONERS v. MYRIAD GENETICS, INC., ET AL. (569 US 12-398 June 13, 2013)	
	[END Q&A – END ATTACHMENT – END A00004]	