RFP QUESTIONS AND ANSWERS

1) Will a clinical decision support tool be considered as an appropriate method to link patients to the latest treatment information/clinical trials – outside of NCI-MATCH?

   Per the Statement of Objectives, Section VII, "Constraints" (p.25): *"The Contractor shall be validated to perform Next-Generation Sequencing (NGS) for the National Cancer Institute – Molecular Analysis for Therapy Choice (NCI-MATCH) study at the time of contract award."* If an offeror can provide a different tool, it would be considered a supplement to the NCI-MATCH, not an alternative.

2) The RFP indicates that the central lab should "preferably" be certified in all 50 states including NY. For example, a certified CLIA lab in TN and can receive samples from all 50 states, does the RFP require the central lab to have additional licenses from states that require additional CLIA requirements?

   Per the Statement of Objectives, Section VII, "Constraints" (p.25): *"The Contractor must provide specifically demonstrated history of sequencing samples from patients in New York State, and is preferably certified through Clinical Laboratory Improvement Amendments (CLIA) to service all 50 states to include the District of Columbia and Puerto Rico."*

   Offerors are responsible for obtaining and maintaining any specific state licenses necessary.

3) If response to Question #2 is absolute, could the central lab subcontract out the testing from states with additional CLIA certification requirements?

   Our requirement is that the offeror (or subcontractor) be able to sequence cancer patients from all 50 states, Washington DC and Puerto Rico.

4) Which specific genes are to be included into the targeted gene panel list be provided?

   Obviously, currently actionable mutations but proposals should expressly list all specific genes included in each panel.

5) Section 5, objective 7 – returning of unused samples and derivatives. Can the data generated be anonymized from this contract be retained / mined by the respondent for research purposes?

   All data must be returned. If there are specific opportunities to further analyze the data that will have to be discussed with the VA Precision Oncology Program.

6) How many samples per month or per week is expected?

NPOP's estimates 600 samples per month.

7) What plans if any does VA have on anonymizing and then making public the NGS secondary analysis results (VCF, etc)?

The VA will determine what to do with the data, but those efforts are not part of the contract.

8) What timeframe do you wish to move to Whole Exome Sequencing (WES) or Whole Genome Sequencing (WGS)?

NPOP has no estimated timeframe for when it intends to move to WES or WGS.

9) Section B.1. a. Vendor Electronic Invoice Submission Methods references VA's Electronic Invoice Presentment and Payment System – The FSC uses a third-party contractor, Tungsten, to transition vendors from paper to electronic invoice submission.
   a. Please confirm that the VA accepts ANSI X12 837 format.

Per https://www.fsc.va.gov/fsc/edi.asp, the following types of transactions are supported:

Transactions Supported:

- 810 - Invoice
- 811 - Consolidated Service Invoice
- 820 - Payment
- 832 - Catalog *(coming spring 2019)*
- 850/855 - Purchase Order and Acknowledgment
- 856 - Advance Ship Notice
- 860/865 - Purchase Order Change Request and Acknowledgment
- 214 - Carrier Information
- 270/271 - Healthcare Eligibility Benefit Inquiry and Response
- 277CA - Claim Acknowledge
- 277RFAI - Request for Additional Information
- 278 - Healthcare Service Review
- 835 - Healthcare Payment/Advice
- 837D - Dental Healthcare Claim
- 837P - Professional Healthcare Claim
- 837I - Institutional Healthcare Claim
- 997/999 – Acknowledgements

Also, per Tungsten (https://www.tungsten-network.com/customer-campaigns/tungsten/fsc-faqs/#can-I-send-my-invoices-via-EDI-directly-to-the-VA-instead-of-Tungsten-Network): "If your system is capable of sending EDI today, you can send your invoices directly to Tungsten Network as a standard EDI 810 or any other structured data file your software will output."

10. Section B.4 of the Solicitation references that all Genomic Sequencing services offered must be FDA approved. Section B.6.VII goes on to outline requirements for the laboratories which are independent of FDA approval, but would be necessary for non-FDA approved Laboratory Developed Tests (LDTs).
    a. Are offerors limited to only offering genomic sequencing services that are approved by the FDA, per second paragraph in section B.4?
    See below.

    b. Are offerors permitted to offer genomic sequencing services that are not FDA approved (i.e. Laboratory Developed Tests) in lieu of FDA approved services?

    It is preferred that offerors are FDA approved, but not required. If an LDT is considered standard of care and is provided under CLIA certification we will accept those services.

11. Section B.5 Price/Cost Schedule:
    a. Does the offeror need to provide an estimated number of tests that will be used for each listing in the table?

    The offeror is to use the estimated quantities provided when completing Section B.5, Price/Cost Schedule.

    b. If the offeror is not currently able to provide a service listed on the CLIN table, will the RFP be considered non-responsive?
    As stated on p.55 in RFP provision E.1, "Addendum to FAR 52.212-1, Instructions to Offerors – Commercial Items, section B(2)(d)(i): *"Importantly, although the Price/Cost Schedule reflects all of VA's current needs for genomic sequencing test services, Offerors are advised that as new and emerging technology becomes available, VA intends to add additional genomic sequencing testing to this contract by modification, if mutually agreeable to the parties. The PWS should reflect an Offeror's ability to expand the testing services available.*"

    Accordingly, offerors are not required to currently provide all the services requested in the CLIN table of the RFP to receive consideration, but those that demonstrate the ability to expand testing services to include all CLINs may receive a higher evaluation rating.

12. Section B.5:
    a. Are the quantities identified in Section B.5 the maximum quantities for the base year of performance or the base year plus the four option years?

       The estimated quantities provided in Section B.5 are for each individual period of the potential total period of performance, as indicated with the "contract period", "POP Begin", and "POP End" information contained in each CLIN.

       As stated in Section B.5, *"In accordance with FAR 16.504(a) the maximum aggregate dollar value for all task orders awarded under this single-award IDIQ is $TBD, and the minimum dollar guarantee for the single awardee is $5,000.00."*
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    b. If they are just for the base year, can the price be increased in subsequent years? Will the prices be renegotiated if options are exercised? Section E.2(b) (page 59) says that the Government will add the total price for options in evaluating price and implies that option years can have different prices, but there is no place in the pricing form for pricing units during option years.

       The Schedule requires offerors to propose pricing separately for each CLIN for the one-year base period and each of the four one-year optional periods. Prices will not be renegotiated if options are exercised.

13. Section B.6 Statement of Objectives, subsection V. Objective 2-Genomic Analysis: Genomic analysis that includes the following steps as a minimum:
    - Solid tumor next-generation sequencing (NGS), hematologic malignancies NGS panels, liquid biopsy (circulating tumor cell free DNA) for solid tumor and hematologic with the potential for expansion to whole exome, whole transcriptome analysis, and germline testing of DNA) of human tissue samples; and

    a. Does the offeror need to currently have the capability to provide all of these genomic analyses in order to complete the RFP?

       See answer to 11b.

14. The RFP provides that it is for the supply of commercial items, yet the standard commercial item clauses of FAR 52.212-4 do not appear to be included in the Solicitation. There is a reference to an addendum to FAR 52.212-4 on pages 1 and 43 but no indication that FAR 52.212-4 is part of the contract. Did the Government intend to include FAR 52.212-4?
    a. With respect to such clauses, will the offeror be permitted to propose such clauses in lieu of those prescribed by FAR 52.212-4?

b. If FAR 52.212-4 is not in the contract to be awarded, what clauses will govern inspection and acceptance, changes, disputes, definitions, excusable delays, patent indemnity, payment, risk of loss, taxes, terminations (cause and convenience), warranties, and limitation of liability?

Block 27a on p.1 is marked, indicating that the solicitation incorporates by reference FAR 52.212-1 and 52.212-4.

15. With regard to the certification, should the offeror assume that it applies to customers who buy the quantities identified on Section B.5?

Question does not specify which certification is being referred to, but certifications requested in this RFP apply to the offeror, not the VA Medical Centers who will be buying the quantities identified in Section B.5.

16. With regard to the Service Level Agreement Fee in Section C.1(a) (page 33), should the offeror specifically identify the unit price and the 3% fee or add them together in completing the pricing form?
    a. Is the certification in the price proposal applicable to prices before or after the 3% SLA fee is added?
    b. Will sales to authorized contract and agreement users be made at the price including the SLA Fee? In other words, can the SLA Fee be passed on to contract and agreement users?

The Offeror's unit pricing should be inclusive of the 3% SLA fee. Any task orders issued under the base IDIQ contract will contain the prices that are inclusive of the 3% SLA fee.

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17. What are the medical liability insurance requirements in Section C.15? The amount is blank.

See Amendment 0002 Attachment 2 for revised C.15

18. For Evaluation Factor III, Socioeconomic Consideration, could you please confirm that the offeror does not have to include a subcontracting plan or represent it has a subcontracting plan at the time the offer is submitted?
    a. How, if at all, will the subcontracting plan be evaluated and whether it needs to be in place at the time the proposal is submitted? Will the apparent successful offeror be permitted to revise the plan?

See p.57, E.1. ADDENDUM to FAR 52.212-1 INSTRUCTIONS TO OFFERORS—COMMERCIAL ITEMS, B, iii, "Subcontracting Plan" for details regarding subcontracting plans.

See p.62, E.3 ADDENDUM to FAR 52.212-2 EVALUATION – COMMERICAL ITEMS, B, ii, "Socioeconomic Consideration" for details regarding how the subcontracting plan will be evaluated.

19. For Evaluation Factor IV, Offer, Amendments, and Certifications/Representations, could the VA please state explicitly what certifications are required? Is SAM registration sufficient to satisfy the requirement for representations and certifications required under FAR 52.212-3?

    Offerors are required to be certified in SAM. Businesses certifying themselves as SDVOSB or VOSB must also must be registered in the Vendor Information Pages (VIP) at http://www.vip.vetbiz.gov/, and verified by the CVE at the time of award to receive credit under the Socioeconomic Considerations evaluation factor.

20. Part C of Section E.1 (pp. 58-59) requires the offeror to attach the Wage Determinations on the DOL web site for the state and county in which the services will be performed to the offeror's Volume 1 – which is the technical proposal. We wish to confirm that they should not be attached to the price proposal?

    Correct; per p.59 of the RFP*, "The wage determination(s) used by the offeror shall be submitted in Volume I".*

21. Part E.2(a) on p. 59 states "Technical is significantly more important than Price, which is significantly more important than the Socioeconomic Consideration Factor." However, E.3 has socio-economic concerns as the second most important factor. Could you please reconcile the two sections or clarify the order of importance?

    The order of importance for evaluation factors is, in descending order: Technical Approach, Price, and Socioeconomic Considerations.

22. With respect to past performance as an evaluation factor, has the Government determined that past performance is not an appropriate evaluation factor of the acquisition under FAR 15.304(c)(3)(iii)?

    Yes, the Government has determined Past Performance is not an appropriate evaluation factor in accordance with FAR 15.304(c)(3)(iii).

23. Section *B.7 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) COMPLIANCE*

    Veterans treated by a sequencing provider that is allowed to retain a copy of data de-identified in accordance with HIPAA during and after the contract will have

contributed to an ever-growing database of patient diagnoses, treatments, and outcomes. This will serve to improve the accuracy of precision medicine for others, including veterans, afflicted by cancer in the future. Is the Government amenable to permitting the providing company to retain a de-identified copy of the sequencing and corresponding clinical data?

See Amendment 0002 Attachment 2 for revised B.7.

24. Section *B.4 Technology Refresh* states that all genomic sequencing services offered by the contractor must be "state-of-the-art," defined as "the most recently designed method approved by the FDA and are announced for marketing purposes." Veterans treated by a CAP/CLIA certified labs are provided world class next-generation sequencing and analysis. Can you please clarify that sequencing within a CAP/CLIA certified lab is considered "state-of-the-art" as defined by the proposal?

CAP/CLIA certification is not based on the platform technology used to sequence. In the application, NPOP will look for the offeror to provide evidence as to why their platform technology e.g. hydridization capture; amplification-based in NGS is preferable.

25. Section *B.6 STATEMENT OF OBJECTIVES* subsection VII state "The Contractor must provide specifically demonstrated history of sequencing samples from patients in New York State."

Numerous providers of next-generation sequencing are CAP/CLIA certified and provide well-regarded services. Very few firms hold New York State licensure, and this requirement would significantly limit the competition as most firms would be deemed ineligible for the contract. Is the Government amenable to working with firms who have sequenced in New York state for research use only and who are in the process of applying for New York state licensure?

Offerors must be currently providing sequencing services to patients in the State of New York in a clinical setting, not solely for research use.

26. *Section E.2 52.212-2 EVALUATION—COMMERCIAL ITEMS*:
Solicitation Section B.6, sub-section IX (Contract Type) and Section E.5 state that the Government anticipates awarding a Firm Fixed Price (FFP) Indefinite Delivery, Indefinite Quantity (IDIQ) contract. However, several other sections in the solicitation (e.g. item iii. on page 63) refer to a fixed unit price (FUP) contract. The price schedules in RFP B.5 clearly indicate a FUP contract. Moreover, solicitation section C.5 states: "The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract." These statements would be consistent with a FUP, not a FFP, contract. A FUP contract will give the Government flexibility in the quantities ordered. Will the

Government please confirm that the awarded contract is to be fixed unit price (FUP), not firm fixed price (FFP)?

No, the awarded contract is anticipated to be a Firm Fixed Price (FFP) based on the proposed and awarded pricing contained in Section B.5, Price/Cost Schedule.

27. Section E.2 *52.212-2 EVALUATION—COMMERCIAL ITEMS* states "Technical is significantly more important than Price, which is significantly more important than the Socioeconomic Consideration Factor." Then, in Section E.3 ADDENDUM to FAR 52.212-2 EVALUATION – COMMERCIAL ITEMS subsection A, the contract states "Non-price factors when combined are significantly more important than price." and lists non-price factors as Technical Approach and Socio-economic Considerations and price factors as Price. Will the Government please confirm the order of importance for each factor listed in the evaluation rubric?

    The order of importance for evaluation factors is, in descending order: Technical Approach, Price, and Socioeconomic Considerations.

28. Section E.3 *ADDENDUM to FAR 52.212-2 EVALUATION – COMMERCIAL ITEMS* in subsection B, refers to the Past Performance Information Retrieval System (PPIRS) evaluation factor. The RFP states, "If there is no assessment data available in PPIRS, the apparent successful offeror will receive a neutral past performance rating. If the apparent successful offeror's available PPIRS information demonstrates an overall rating of Satisfactory or better, the Contracting Officer will proceed with award; if not, the Contracting Officer will eliminate the apparent successful offeror from consideration." This implies that any rating other than satisfactory (including a neutral rating) will warrant elimination. Will the Government please confirm that a contractor with a neutral rating is still eligible for award and will not be eliminated?

    In accordance with FAR 15.304(a)(2)(iv), *"In the case of an offeror without a record of relevant past performance or for whom information on past performance is not available, the offeror may not be evaluated favorably or unfavorably on past performance."* Therefore, an offeror with a neutral rating is still eligible for award and will not be eliminated from consideration based on past performance.

29. Do any of the tests need to be clinically approved assays and run in CLIA-certified clinical laboratories? If so, do you have any special requirements for clinical state licenses? Does a clinical report need to be generated and signed off by CLIA director?

This is a clinical program and NGS results are used for treatment decisions. Therefore, assays must be run in a CLIA/CAP certified clinical laboratory. The clinical report needs to be signed off by the pathologist who reviewed the data and analysis.

30. Is pan cancer NGS panel acceptable, or is disease-specific NGS panel required?

As stated on p.55 in RFP provision E.1, “Addendum to FAR 52.212-1, Instructions to Offerors – Commercial Items, section B(2)(d)(i): “The PWS shall clearly illustrate the Offeror’s ability to provide Solid Tumor Next-Generation Sequencing (NGS), Hematologic Tumor (Liquid biopsy for Solid Tumor and Hematologic malignancy NGS panels), and Complete Panels (Whole Exome and Whole Transcriptome) mutational burden for genomic biomarker testing services to VA Clinicians and Hospitals nationwide.” Accordingly, the Government’s preference is to use disease specific panels; however, a pan-cancer NGS panel is potentially acceptable.

31. What is the sample type we would be receiving? Will the samples be received in batches or trickle in?

As referenced in Objective 2 (p.21) and Objective 3 (p.23) of the Statement of Objectives, samples will be human tissue. Tumor tissue will be prepared from FFPE archived samples. Fresh plasma samples will be sent for analysis of solid tumor cell- free DNA, so-called liquid biopsies. Samples from blood and bone marrow aspirates will be analyzed (for hematological malignancies). Samples will typically not be batched.