



**STATEMENT OF OBJECTIVES (SOO)  
DEPARTMENT OF VETERANS AFFAIRS  
NATIONAL PRECISION ONCOLOGY PROGRAM**

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**Prepared By:**

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# VHA National Precision Oncology Program Statement of Objectives (SOO)

## 1. Purpose:

The objective is to actively solicit Industry with the design and development of a next-generation sequencing contract solution inclusive at a minimum of the following scope and/or capabilities:

## 2. Scope: The scope of this contract includes, but is not limited to:

- a) Providing genomic analysis (targeted, with the potential for expansion to whole exome and whole transcriptome analysis) of human tissue samples
- b) Provide Biosample Security, including secure methods of shipping and documentation
- c) Conduct Histopathology review and Deoxyribonucleic Acid (DNA) and Ribonucleic acid (RNA) extraction
- d) Conduct Molecular Analysis
- e) Deliver Analysis reports and Molecular data
- f) Return unused samples and derivatives and Molecular data
- g) All delivery will be through secure shipping (for samples) or secure email (data).

**3. Period and Place of Performance:** The period of performance shall be one 12 month base period, plus four one year option periods. Options are exercised at the discretion of the Government based on funding and/or need. Execution of option years will be dedicated to the development and construction of future additional courseware as directed by the Government. Services will be provided at the Contractor location.

**4. Background:** The Department of Veterans Affairs (VA), National Precision Oncology Program (NPOP) is responsible for the development and oversight of the implementation of Precision Oncology VA-wide procurement initiatives, development and deployment of Genomic Sequencing. The NPOP has identified Genomic Sequencing as a candidate for VHA-wide (otherwise referred to as "national") standardization.

Genomic Sequencing includes genomic analysis (targeted, with the potential for expansion to whole exome and whole transcriptome analysis) of human tumor tissue and/or blood. It is expected that a significant portion of tumor samples will be derived from fine needle aspiration and core needle biopsy. The vast majority of samples will be from the initial tumor biopsy that documents the presence of cancer and will be stored as formalin fixed paraffin embedded (FFPE) samples.

**5. Objectives/Tasks:** The Contractor shall provide a turn-key solution to perform tasks as indicated herein. The quality of any deliverable shall be commensurate with the phase of work (i.e., proof of concept, prototype, alpha, beta, final release, etc.). If at any time, a deliverable or release is found by the government to contain any of the noted errors or omissions, the deliverable shall be considered to be incomplete.

**5.1 Task 1: Collaborative Workspace.** The Contractor will provide a collaborative workspace, such as SharePoint, that allows all members of the team to interact with various aspects of the project. This environment must be accessible to all members of

## VHA National Precision Oncology Program Statement of Objectives (SOO)

the team and consideration of VA firewall issues must be considered. As a minimum this collaborative environment will offer all users the capability to file share various versions of project files, transfer large (<1G) audio and video files and post messages. Collaborative workspace will be updated and maintained as needed or on a weekly basis as a minimum.

**5.1.2 Monthly Progress Report.** The Contractor shall submit monthly progress report addressing the status of all active efforts. A separate project tracking report shall also be sent at an approved frequency that tracks the following project parameters, including:

- a) Project Name and Task Order (TO) Name;
- b) Overall high level assessment of TO progress;
- c) All work in-progress and completed during the reporting period;
- d) Identification of any TO related issues uncovered during the reporting period and especially those areas with a high probability of impacting schedule, performance goals, and their likely impact on schedule, or performance goals;
- e) Explanations for any unresolved issues, including possible solutions and any actions required of the Government and/or Contractor to resolve or mitigate any identified issue, including a plan and timeframe for resolution;
- f) Number of samples for which QA/QC analysis were completed to desired parameters for each of the analysis steps. Source of control material used and the adequacy of the control material must be documented;
- g) Sample success rates at each of the analysis steps.

### **5.1.4 Quality Control**

- Standard QA/QC analysis shall be performed on isolated DNA (and RNA); the Contractor will provide the NPOP with the appropriate quality summary reports generated. The method for determining sub-optimal results and a remediation plan for these tests shall also be provided by the Contractor to NPOP.

**5.2 Task 2: Genomic Analysis.** The Contractor shall provide genomic analysis for the NPOP.

**5.2.1: Analysis tasks.** The Contractor is responsible to provide analysis to support genomic analysis for NPOP. The analysis process shall include the following steps as a minimum:

- a) Providing genomic analysis (targeted, with the potential for expansion to whole exome and whole transcriptome analysis) of human tissue samples

**5.3 Task 3: Biosample security.** The Contractor shall ensure that all biosamples are handled securely from shipment of samples through the documentation phase.

**5.3.1 Samples.** The Contractor shall possess the ability to ship and track shipping of VA samples.

## VHA National Precision Oncology Program Statement of Objectives (SOO)

- The Contractor shall possess ability for sample tracking and management (i.e. utilizing bar coding) to ensure security and traceability of VA samples
- The Contractor shall possess the ability to produce documentation of sample handling and processing attributes/audit trail, etc. that would address sample mixing and sample error tracking
- The Contractor will be responsible for all shipping costs. This includes the cost of shipment of samples from the VA Medical Centers to the Contractor as well as shipment of residual tissue back to the Medical Center. Return of residual tissue can be batched and shipped quarterly.
- The Contractor shall include in their response the shipping requirement which will then be discussed and confirmed/finalized at the kick-off meeting.
- The plan should include details of proposed shipping requirements like method/conditions for shipping, receipt, and acknowledgement of shipments. Specimens are expected to be shipped Monday through Friday so the plan should include specimen receipt Tuesday through Saturday. A sample acquisition protocol should be submitted with the response to this solicitation.

**5.3.1 Samples: Data.** The Contractor shall possess the ability to securely transfer electronic data in a manner that is acceptable to the VA.

- The Contractor shall possess the ability to electronically return analysis results and all data files via Secure File Transfer Protocol (SFTP) or via secure web service that is acceptable to VA
- The Contractor shall provide an electronic portal or other electronic means to provide real-time tracking of testing requests by VA facilities, tracking of sample shipment, and tracking of testing, billing/invoicing that includes patient identifying information, sending VA facility, vendor sample ID number, and cancer type. For each submitted sample, the Contractor shall associate a sample ID, patient identifiers (complete name, complete SSN, DOB, sex), sending VA facility name and number, diagnosis using standardized terms and codes acceptable to VA (e.g., ICD-O-3), test status (complete, failed with reason, or in process with expected completion date) and assemble this information into a secure web service. It is preferable that results files be available within the same electronic delivery system and that there be an API to allow bulk data retrieval by program staff.
- The Contractor shall provide raw data files as well as the summary statistics for the DNA as well as RNA sequencing on every sample to include DNA sequence files (e.g., FASTQ or BAM) through a secure web service.
- Annotated variant file and reference sequence shall also be provided by the Contractor and include PDF report, report content in structured format acceptable to VA (e.g., JSON, XML), variant call file, (VCF) using the most recent VCF format specification and also acceptable to VA.
- The Contractor shall also provide technical information describing file formats and file sizes of annotated variant files, reports (and associated structured components of reports) and reference sequences

## VHA National Precision Oncology Program Statement of Objectives (SOO)

- Contractor shall supply completed DNA genotyping data including: raw data (possibly image files- to be discussed at a kick-off meeting), genotype calls, quality scores, and any other relevant data deemed to be useful for analysis/storage/reanalysis purposes for the VA samples. Data for genotype calls (VCF, etc.) should be provided concurrently with the report, which shall include for human readable (i.e., PDF) and structured (e.g., JSON, XML) formats. Data transfer will be by secure electronic transmission.
- Contractor will discuss how long they can retain all data files (FASTQ, BAM, Variant) from time of test completion. Desired length is 1 year minimum.

**5.3 Task 4: Histopathology review and Deoxyribonucleic Acid (DNA) and Ribonucleic acid (RNA) extraction.** The Contractor shall provide a pathology review to confirm the presence of cancer, percentage of cancer cells in the tissue specimen, determine tissue quality for testing, and extraction of and quality assessment of DNA and possibly RNA.

- Vendors will propose their recommended testing approach among target or whole exome sequencing and using either a laboratory reference or germ-line DNA as the comparator for variant calling. Vendors may also propose performing whole transcriptome sequencing of tumor samples.
- The Contractor shall provide technical plans for DNA and RNA isolation (where applicable) from tumor or blood samples and provide information on assay validation and quality control procedures.
- If applicable, the Contractor shall also include in the proposal their strategy for RNA sequence analysis of tumor samples to identify altered expression of genetic variants that are actionable (such as gene fusions) or validation variants by integration with exome sequencing data.
- The Contractor shall include in their response the outer boundaries of tissue types, sample quality, input DNA necessary, and quantity necessary for testing.

**5.5 Task 5: Conduct Molecular Analysis.** The Contractor shall possess the ability to manufacture or purchase and process all the required molecular analysis reagents, chips, and required bioinformatics tools/workflows.

**5.6 Task 6: Provide Analysis Reports and Molecular Data.** The Contractor shall describe the bioinformatics tools and pipelines used for data computations. The Contractor shall include in the proposal their data analysis strategy including their plans for sequence analysis, calls against reference builds or germ-line sequences and algorithms for variant calling, copy number analysis, or other genomic alterations.

**5.7 Task 7: Return Unused Samples and Derivatives and Molecular Data.** The VA will provide the Contractor with human samples. Contractor shall store samples safely and process as required. At the completion of the project all unused samples shall be returned and certified to that fact by the Contractor as specified by VA policies unless otherwise notified in writing by the VA Project Director. All materials and patient samples utilized during the course of the contract are the property of the Department of Veterans Affairs and must be handled in a confidential and secure manner. The

## VHA National Precision Oncology Program Statement of Objectives (SOO)

Contractor must outline in their response their planned lab standard operating procedures (SOPs) methods for handling and securing of samples including paper and electronic documents. This plan shall be required at the time of submitting the proposal. The plan should include details of proposed shipping requirements like method/conditions for shipping, receipt, and acknowledgement of shipments. This plan will be approved and finalized prior to contract award.

### Minimal Technical Requirements:

- The Contractor shall be validated to perform NGS sequencing for the NCI MATCH study within 6 months of contract award
- Laboratory credentials: College of American Pathologists (CAP), and Clinical Laboratory Improvement **Amendments** (CLIA) to service all states.

### Deliverables:

- The estimated timeframe from receipt of human tissue sample to final data analysis report is 4 weeks
- Monthly Progress Report

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