Posting Date: November 13, 2024

Closing Date: November 23, 2024, 11:30 a.m. ET

Reference Number: 25-001437

To: NCI Bid Board

From: Viviane Rivera NCI CCR P-ARC

Viviane.rivera@nih.gov

Subject: NCI Bid Board Posting – Custom 10x Genomics Visium/Space Ranger Spatial Transcriptomics Analysis Services of KS in Abemaciclib Study

At the National Cancer Institute (NCI), The Pediatric Oncology Branch is dedicated to improving outcomes for children and young adults with cancer and genetic tumor predisposition syndromes. We conduct translational research that spans basic science to clinical trials. Our clinical studies are performed in an environment that supports our patient's medical and emotional needs, alongside cutting edge scientific research.

The primary objective of this purchase is to obtain use of cutting-edge spatial transcriptomic analysis to investigate cell phenotypes within the bone marrow, focusing on the identification of factors associated with HLH-like toxicities and CRS following CD22 CAR T-cell therapy.

The National Cancer Institute plans to purchase the utting-edge spatial transcriptomic analysis from University of Michigan, to perform this work. This is not a request for competitive quotation. However, if any interested party believes it can meet the attached requirements, it may submit a statement of capabilities. The capability statement must be in writing and must contain information and material in sufficient detail to allow NCI to determine is the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on November 23, 2024, ET. A determination by the Government not to compete this requirement based upon responses to this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.

#### Sole Source Justification:

Extensive market research was conducted to identify other potential sources capable of providing the specialized spatial transcriptomic analysis required for this project. Searches were performed in scientific journals, industry publications, and technical resources to determine if any other institution or business could offer the same combination of expertise, technology, and proven success in analyzing human bone marrow samples in the context of HLH-like toxicities and CRS after CD22 CAR T-cell therapy. This research confirmed that, to date, no other institution has demonstrated the capacity to perform the specific spatial transcriptomic work in human bone marrow that is critical to this project. The University of Michigan remains the only organization with documented success in this area, having completed preliminary work that has already produced promising results.

**Attached Documents:** 

SF18

Statement of Work

FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (JAN 2014) is applicable and available in full text upon request

REQUEST FOR QUOTATION  (THIS IS NOT AN ORDER)				THIS RFQ IS IS NOT A SMALL BUSINESS SET-ASIDE PAGE OF PAGES  1 1 1							
1. REQUEST NUMBER 2. DATE ISSUED POTS 25-001437 11/13/2024			3. REQUISITION/PURCHASE REQUEST NUMBER POTS 25-001437			4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1			RATING		
5a. ISSUED BY  5b. FOR INFORMATION CALL (NO COLLECT CALLS)					ECT	6. DELIVER BY (Date) 12/30/2024					
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					760-	BER -7125	9. DESTINATION a. NAME OF CONSIGNEE				
8. TO: a. NAME b. COMPANY							Christopher CHIEN 240.858.3833				
D. GOINI ANT							10 Center Dr, Bldg 10 Rm 1W-3840				
c. STREET ADI	DRESS						c. CITY				
d. CITY				e. STATE f. ZIP CODE			d. STATE e. ZIP CODE MD 20892				
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2	NovaX 10B 300	) cycle				0.15					\$0.00
3	Nova Sequenci	ng w/o flov	w cell			0.15					\$0.00
	Notice of Intent statement, plea technical capak Rivera viviane.r See attached S	ase email c pility staten rivera@nih statement c	only 1 cop nent to Vi .gov of Need.	y of the viane							
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12. DISCOUNT FOR PROMPT PAYMENT					( )					NUMBER	PERCENTAGE
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b. STREET ADDRESS				2 NA		a. NAME (Type or print)	16. SIGNER			h TEI E	EDHONE
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### 2.1 **OBJECTIVE**

The primary objective of this project is to analyze the bone marrow niche of patients with acute lymphoblastic leukemia (ALL) before and after CAR T cell therapy to identify factors associated with subsequent life-threatening inflammatory complications. The Advanced Genomic Core plans to use the Visium spatial gene expression platform developed by 10x Genomics for the retrospective investigation of patient bone marrow samples that are formalin fixed and paraffin embedded (FFPE). The initial SOW will serve as a pilot to determine the feasibility of this approach using our samples, prior to embarking on a larger study.

### 3.0 SCOPE

This project aims to utilize the 10x Genomics Visium technology to analyze bone marrow samples obtained from patients diagnosed with Acute Lymphoblastic Leukemia (ALL). Ethical considerations and informed consent procedures will and have been followed throughout the sample collection process. Additionally, an MTA is in place to transfer these samples for further evaluation. With these bone marrow samples, the 10x Visium workflow will be used, involving sample preparation, library construction, sequencing, imaging, and subsequent data analysis. The analysis will encompass a wide range of bioinformatics and statistical methods to extract spatial and molecular information from the data and identify cellular heterogeneity, gene expression patterns, and cellular interactions within the bone marrow microenvironment. The ultimate deliverable will be a comprehensive report of raw data from the contractor. From this, investigators will summarize the findings, including potential biomarkers or therapeutic targets.

The expected outcomes of this project from the contractor include comprehensive raw data file generated from Visium by 10x typically in the form of a sequencing output file. Specifically, it is a raw sequencing data file in a standard file format, such as FASTQ or BAM. This file contains the raw sequence reads obtained from the Visium library construction and sequencing process. Each read corresponds to a specific fragment of RNA captured from the tissue sections on the Visium slide. The raw data file includes information such as the sequence read quality scores, read identifiers, and the genomic coordinates of the fragments.

In addition to the sequencing data file, there may be accompanying image files that capture the spatial information of the tissue sections. These images provide visual representation of the captured RNA fragments on the Visium slide and help correlate the molecular information with the spatial location of the cells within the tissue.

It is important to note that the specific file formats and contents of the raw data files can vary depending on the version of the 10x Genomics Visium platform and the analysis pipeline used. The raw data files serve as the starting point for subsequent data processing, alignment, and analysis steps to extract meaningful insights from the Visium data which will be analyzed by the investigator. The contractor will ensure timely completion of the project within the defined timeline.

# 4.0 CONTRACT REQUIREMENTS/ AND PERSONNEL QUALIFICATIONS

The contractor is responsible for executing the Visium10x Genomics platform on bone marrow samples obtained from patients with ALL. Their responsibilities include ensuring the proper handling and processing of the samples, performing the sample preparation steps for Visium library construction, coordinating the sequencing process, and facilitating the imaging of the tissue sections. Additionally, the contractor is expected to generate a complete raw data file, such as a FASTQ or BAM, that encompasses the sequencing data and imaging information, ensuring that it is properly documented and organized for downstream analysis. This raw data files should contain all necessary information for subsequent

bioinformatics analysis, allowing for the extraction of spatial and molecular insights from the bone marrow samples.

#### 5.0 TYPE OF ORDER

This is a firm fixed price purchase order.

### 6.0 PERIOD OF PERFORMANCE

The period of performance shall be for 90 days from date of received materials. 12/30/24-12/29/25

#### 7.0 PLACE OF PERFORMANCE

Office of Research, University of Michigan Medical School C560 MSRB II, 1150 W. Medical Center Dr. Ann Arbor, MI 48109-0674

## 8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

All deliverables shall be transferred electronically per the following deliverable schedule:

DELIVERABLE	DELIVERABLE DESCRIPTION / FORMAT REQUIREMENTS	DUE DATE		
#1 Sequencing Output File	FASTQ or BAM	Within 45 days of when specimen received		
#2 Image files that capture spatial information of tissue sections		Within 45 days of when specimen received		

# 9.0 PAYMENT

Payment shall be made <u>single and in full</u>. Payment authorization requires submission and approval of invoices to the COR and NIH OFM, in accordance with the attached payment provisions listed below:

The following clause is applicable to all Purchase Orders, Task or Delivery Orders, and Blanket Purchase Agreement (BPA) Calls: PROMPT PAYMENT (JUL 2013) FAR 52.232-25. Highlights of this clause and NIH implementation requirements follow:

# I. Invoice Requirements

A. An invoice is the Contractor's bill or written request for payment under the contract for supplies delivered or services performed. A proper invoice is an "Original" which must include the items listed in subdivisions 1 through 12, below, in addition to the requirements of FAR 32.9. If the invoice does not comply with these requirements, the Contractor will be notified of the defect within 7 days after the date the designated billing office received the invoice (3 days for meat, meat food products, or fish, and 5 days for perishable agricultural commodities, dairy products, edible fats, or oils) with a statement of the reasons why it is not a proper invoice. (See

exceptions under II., below.) Untimely notification will be considered in the computation of any interest penalty owed the Contractor.

- 1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephonenumber, e-mail and mailing address of point of contact).
- 2. Remit-to address (Name and complete mailing address to send payment).
- 3. Remittance name must match exactly with name on original order/contract. If the Remittance name differs from the Legal Business Name, then both names must appear on he invoice.
- 4. Invoice date.
- 5. Unique invoice #s for all invoices per vendor regardless of site.
- 6. NBS document number formats must be included for awards created in the NBS: Contract Number; Purchase Order Number; Task or Delivery Order Number and Source Award Number (e.g., Indefinite Delivery Contract number; General Services Administration number); or, BPA Call Number and BPA Parent Award Number.
- 7. Unique Entity Identifier (UEI) which is in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number.
- 8. Federal Taxpayer Identification Number (TIN). In those rare cases where a contractor does not have a UEI number or TIN, a Vendor Identification Number (VIN)must be referenced on the invoice. The VIN is the number that appears after the contractor's name on the face page of the award document.
- 9. Identify that payment is to be made using a three-way match.
- 10. Description of supplies/services **that match** the description on the award, by line billed.\*
- 11. Freight or delivery charge must be billed as shown on the award. If it is included in the itemprice do not bill it separately. If identified in the award as a separate line item, it must be billed separately.
- 12. Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or servicesperformed, as applicable, and that **match** the line items specified in the award.\*

NOTE: If your invoice must differ from the line items on the award, please contact the Contracting Officer before submitting the invoice. A modification to the order or contract may be needed before the invoice can be submitted and paid.

Shipping costs will be reimbursed only if authorized by the Contract/Purchase Order. If authorized, shipping costs must be itemized. Where shipping costs exceed \$100, the invoice must be supported by a bill of lading or a paid carrier's receipt.

B. The Contractor shall submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov with a copy to the approving official, as directed below.

The Contractor shall submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer's Representative:

Approving Official: Contracting Officer

Name- Email Address-

Contracting Officer's Representative Name- Email Address-

### II. Invoice Payment

- A. Except as indicated in paragraph B., below, the due date for making invoice payments by the designated payment office shall be the later of the following two events:
  - 1. The 30th day after the designated billing office has received a proper invoice.
  - 2. The 30th day after Government acceptance of supplies delivered or services performed.
- B. The due date for making invoice payments for meat and meat food products, perishable agricultural commodities, dairy products, and edible fats or oils, shall be in accordance with the Prompt Payment Act, as amended.

### **III.** Interest Penalties

- A. An interest penalty shall be paid automatically, if payment is not made by the due date and the conditions listed below are met, if applicable.
  - 1. A proper invoice was received by the designated billing office.
  - 2. A receiving report or other Government documentation authorizing payment was processed and there was no disagreement over quantity, quality, or contractor compliance with a term or condition.
  - 3. In the case of a final invoice for any balance of funds due the contractor for supplies delivered or services performed, the amount was not subject to further settlement actions between the Government and the Contractor.
- B. Determination of interest and penalties due will be made in accordance with the provisions of the Prompt Payment Act, as amended, the Contract Disputes Act, and regulations issued by the Office of Management and Budget.

# IV. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (November 2021)

- (a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
- (b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.
- (c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial products or commercial services.

(End of Clause)

### V. HHSAR 352.232-71 Electronic Submission of Payment Requests (February 2, 2022)

- (a) Definitions. As used in this clause—
  Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.
- (b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.
- (c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.
- (d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of Clause)