NIH NATIONAL CANCER INSTITUTE

Posting Date: June 14, 2024 24, 2024

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

Reference Number: 24-032965

To: NCI Bid Board

From: Christine Buntz NCI CCR P-ARC christine.buntz@nih.gov

Subject: NCI Bid Board Posting for Software Service for labs research on pain interference and pain intensity for the Pediatric Oncology Branch (POB) POP: 07/01/2024 to 06/30/2025.

The National Cancer Institute Division of 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 purchase of the Option A – Study License is essential for being able to evaluate and collect extensive qualitative research to accurately capture patients' PNF-related pain experiences. Neurofibromatosis 1 (NF1 is a genetic disease with multiple clinical manifestations, including plexiform neurofibromas (pNF) that can cause pain and may significantly impact daily functioning of - life. Patient-reported outcomes are useful in trials for conditions that are disabling and chronic like NF1, where symptom reduction and improved functioning and quality of life currently are important treatment outcomes, which may occur with pNF tumor shrinkage. The License would provide a library of critical data/information needed to accurately assess individuals pain in their natural environments.

The National Cancer Institute plans to purchase a Software Service Option A – Study License from MetricWire, Waterloo, Ontario 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 June 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:

Metricwire Inc is the only company that sells a software license that was able to properly obtain custom electronic PRO pain measures, security and privacy needs, research and patient dashboards, send communications and alerts, implement the mobile app and web-based platforms, and troubleshoot any issues. Metricwire's software flexibility gives them the ability to customize each individual's application/portal and creates a user-friendly portal for each individual. Market research was conducted and vendors were contacted however, the vendors were not able to meet the requirements that were need for this project.

Attached Documents: SF18 Statement of Work

52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment. FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (JAN 2014) is applicable and available in full text upon request.

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			8. TO:					Pamela WOLTERS 240-760-6035				
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001	Option A - Stud 3-5 Investigator Needed ~150 Participan NF1 Surveillanc POP: 07/01/2024 Notice of Inten please e-mail of statement to: O christine.buntz See attached s This will be aw Contract	Accounts ts Total e Study 4 to 06/30, t: If subm only 1 co Christine :@nih.go	+ Site Staff / /2025 hitting a cap oy of the te Buntz @ v t of work. a Firm-Fix	oability staten chnical capa ked Price	bility	1	ea		0.00		\$0.00	
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1.0 TITLE

Electronic Patient-Reported Outcome Pain Measures (PAINS-pNF and PII-pNF) for use in the NF1 Surveillance Study

2.0 BACKGROUND

Neurofibromatosis 1 (NF1) is a genetic disease with multiple clinical manifestations, including plexiform neurofibromas (pNF) that can cause pain and may significantly impact daily functioning and quality of life (QOL). Patient-reported outcomes (PROs) are useful in trials for conditions that are disabling and chronic like NF1, where symptom reduction and improved functioning and QOL currently are important treatment outcomes, which may occur with pNF shrinkage. A critical step toward approval of drugs to treat pNFs in addition to pNF tumor volume is to be able to evaluate clinical symptoms, such as pain, in natural history studies and clinical trials. Currently, no valid PRO measures exist that are specific to the NF1 population to assess pNF-related pain or its functional impact on an individual's life.

The Health Psychology and Neurobehavioral Research (HPNB) Program of the Pediatric Oncology Branch (POB), conducted a study to collect extensive qualitative research to modify existing pain interference and pain intensity PRO measures to ensure they accurately capture patients' pNF-related pain experiences. From the qualitative data, we developed the PAin INtensity Scale-pNF (PAINS-pNF) to assess pNF-related pain intensity and the Pain Interference Index-pNF (PII-pNF) to assess pNF-related pain interference in everyday life. The PAINS-pNF needs to be administered every evening for two consecutive weeks (it takes about 1-2 minutes to complete) and the PII-pNF assessing pain interference will be administered at the end of the week (it takes about 5 minutes to complete) for two consecutive weeks. Administration needs to occur in participants' homes to assess their pain more accurately in their natural environments.

After developing these pain measures, we sought a digital health company that we could collaborate with to design the measures to look and function exactly like the ones we used in qualitative interviews with patients and so they could be administered remotely on a range of devices including computers, tablets, and smartphones. We conducted marketing research as well as full and open competition in 2022, and identified a vendor, Metricwire, for this purpose. The study to evaluate the reliability, validity, and feasibility of these new PRO pain measures currently underway and enrolling participants. These measures also have been accepted into the FDA Clinical Outcome Assessment Program.

The current products and services required in this Statement of Work is to <u>use the two PRO pain</u> <u>measures we previously developed with Metricwire in a new natural history study of indvidiuals</u> <u>with NF1 and high risk tumors</u> (PI: Brigitte Widemann). The assessment of pNF-related pain using these custom-made PRO measures based on POB research is important for understanding the natural history of pain symptoms, how they may manifest with different types of tumors, and if changes in pain my be a sign of a tumor transforming from benign to malignant. These data then can be compared to the results of clinical trials evaluating treatments for pNF and pain. For these reasons, conducting pain assessments using these custom-made PRO measures (PAIN-pNF and PII-pNF) in the home environment on a mobile app or web-based platform, including

notification reminders to complete, is critical for obtaining accurate data. They also have potential to expand access to diverse participants and conduct evaluations remotely. These are the only measures and platform currently available to assess pNF-related pain in this upcoming NF1 Surveillance study being conducted in the POB, NCI.

2.1 **OBJECTIVE**

The primary purpose of this acquisition is to administer the PAINS-pNF and PII-pNF measures, developed by the HPNR group of the POB, NCI via a mobile application or web-based platform on the longitudinal NF Surveillance protocol (001696; PI: Dr. Brigitte Widemann). These two pain electronic PRO measures need to be administered in participants' homes using mobile devices or a computer to obtain the most accurate assessment of pNF-related pain. These data will allow us to accurately assess these aspects of pNF-related pain intensity and pain interference to better understand the patterns of pain over time in individuals with high risk tumors. Since the PAINS-pNF is administered daily, the use of Metricwire allows the administration of the measures and for participants to be notified automatically when it is time for them to be completed. Thus, the study team will be able to collect more accurate data with less staff burden and the participants can complete the measures from home, which is more convenient and will reduce patient burden during clinic visits.

The POB will work with the Contractor to use the Metricwire mobile app and web-based platform to administer these two PRO pain measures easily to youth, parents, and adults from the comfort of their homes according to the protocol schedule using a range of devices including computers, tablets, and smartphones of the participants. The administration of these PRO measures will be deployed automatically at specific times per the protocol and the participants will be notified on their devices to complete the measures. In addition, there is no personally-identified information needed to download or use the app, and the study team can enroll and monitor the participants responses and message them securely through the Metricwire researchers' dashboard. Finally, Metricwire has a support team to trouble shoot any problems or help the study team, and the data is secure and can be downloaded into an excel file.

3.0 SCOPE

Metricwire will provide the POB with their a mobile and web-based software platform to adminster the PAINS-pNF and PII-pNF for the 10-year longitudinal NF1 Surveillance Study. This software platform will allow facilitate remote data collection in a secure and confidential manner in the participants' homes via their own smartphone/mobile devices or via web links with no personally-identifiable information required. The mobile or web application will enable study participants to complete electronic versions of the pNF-related pain intensity (PAINS-pNF) and pain interference (PII-pNF) measures in their homes daily prior to clinic visits for the NF1 Surveillance Study per outlined in the study protocol.

POB also requires the software platform to provide a researchers' secure portal through which the research team will enroll, monitor, and have access participants' data. The Contractor's team

also will provide training on the administration of these questionnaires as well as to be available for support to troubleshoot any technical problems as needed during the study.

4.0 CONTRACT REQUIREMENTS/ AND PERSONNEL QUALIFICATIONS (IF APPLICABLE)

The contractor will provide the two custom-made electronic PRO measures, the PAINS-pNF and the PII-pNF, and administer them remotely to participants enrolled in the 10-year longitudinal NF1 Surveillance Study on a secure mobile app or web-based platform. The PAINS-pNF will be administered every evening at a time specificed by the participant for 2 weeks prior to an upcoming clinic visit while the PII-pNF will be administered at the end of the second week.

The Contractor shall perform the following tasks:

- 4.1 <u>Project Management Plan</u>: The Contractor will provide a project management plan for the scope of the project to describe the implementation of each of the required tasks.
- 4.2 <u>Task #1</u>: Metricwire provides the PAINS-pNF and PII-pNF measures to be administered via the secure Metricwire mobile app or web-based platform per protocol sent automatically for completion with notifications
- 4.3 <u>Task#2</u>: Metricwire will securely host the research portal at nih.metricwire.com. This platform is equipped with security features tailored to comply with the National Institutes of Health (NIH) Information Security guidelines.
- 4.4 <u>Task #3</u>: Training provided to study investigators in the first 2 months as needed
- 4.5 <u>Task #4</u>: Metricwire will provide customer support for trouble-shooting over the period of performance as needed
- 4.6 <u>Task #5</u>: Metricwire will provide secure download of research data over the period of performance, as needed.

5.0 **TYPE OF ORDER**

This is a Non-Severable Firm Fixed-Price Purchase Order.

6.0 PERIOD OF PERFORMANCE

The period of performance shall be from July 1, 2024 to June 30, 2025.

7.0 PLACE OF PERFORMANCE

Pediatric Oncology Branch (POB), Behavioral Health Core Health Psychology and Neurobehavioral Research Program National Cancer Institute, National Institutes of Health

Address: Center for Cancer Research, National Cancer Institute Building 82, Room 105 9030 Old Georgetown Rd Bethesda, MD 20896-8200

8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

Complete deliverables schedule listed below.

DELIVERABLE	DELIVERABLE DESCRIPTION / FORMAT REQUIREMENTS	DUE DATE
#1	Metricwire provides the PAINS-pNF and PII-pNF measures to be administered via the secure Metricwire mobile app or web-based platform per protocol sent automatically for completion with notifications	July 1, 2024
#2	Metricwire will securely host the research portal at nih.metricwire.com. This platform is equipped with security features tailored to comply with the National Institutes of Health (NIH) Information Security guidelines.	July 1, 2024
#3	Training provided to study investigators in the first 2 months as needed	July 1 to Aug 31, 2024
#4	Metricwire will provide customer support for trouble-shooting over the period of performance as needed	July 1, 2024 to June 30, 2025
#5	Metricwire will provide secure download of research data over the period of performance, as needed	July 2024 to May 2025

9.0 PAYMENT

Payment shall be made once in one installment. 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 the 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: ContractNumber; 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.
 - 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 <u>that match</u> 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.
- Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or servicesperformed, as applicable, and that <u>match</u> 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)