

Posting Date: July 22, 2024

Closing Date: August 1, 2024 11:30 a.m. ET

Reference Number: 24-040520

To: NCI Bid Board

From: Viviane Rivera  
NCI CCR P-ARC  
[Viviane.rivera@nih.gov](mailto:Viviane.rivera@nih.gov)

Subject: NCI Bid Board Posting – Acquisition of a Remote Patient Temperature Monitoring System

At the National Cancer Institute (NCI), Center for Immuno-Oncology (CIO), intends to assess continuous-temperature-monitoring as alternative method to standard-of-care monitoring (i.e., temperature monitoring every four hours) for early Cytokine Release Syndrome (CRS) detection. CRS is an adverse event that can occur in immunotherapy. The intent is to shorten the time of CRS intervention and ultimately optimize cancer patient care at NIH.

The primary objective of this acquisition encompasses non-R&D support services for the purchase and implementation of an FDA-approved continuous patient temperature monitoring system, to include temperature monitoring patches, supporting mobile/tablet applications, integration of the collected data into the patients' Electronic Health Records at the NIH, early alerts to Android-supported NIH clinical staff, and technical, clinical and program management support services for proper implementation.

The National Cancer Institute plans to purchase Remote Patient Temperature Monitoring System from Blue Spark Technologies, Inc, Westlake, OH 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 if the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on August 1, 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:

The CIO requires a continuous patient temperature monitoring system that is FDA-approved, can wirelessly connect to smart phone and tablets, and can interact with the pre-existing NIH Health Record System (HRS) in a secure manner. The TempTrack temperature monitoring system provided by Blue Sparks Technologies is the only system currently on the market with the capability of sending alerts to Android devices. Other temperature monitoring systems are restricted to iOS devices. Furthermore, the Blue Sparks Technologies TempTrack system can be used with patients of any age, and with patients with heart pacemakers, whereas these populations are excluded by other monitoring systems.

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

<b>REQUEST FOR QUOTATION</b> <i>(THIS IS NOT AN ORDER)</i>		THIS RFQ <input checked="" type="checkbox"/> IS <input type="checkbox"/> IS NOT A SMALL BUSINESS SET-ASIDE	PAGE OF 1	PAGES 1
---	--	--	--------------	------------

1. REQUEST NUMBER <b>24-040520</b>	2. DATE ISSUED 07/22/2024	3. REQUISITION/PURCHASE REQUEST NUMBER 24-040520	4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1	RATING
---------------------------------------	------------------------------	---	--	--------

5a. ISSUED BY NIH/NCI-CCR P-ARC	6. DELIVER BY (Date) 08/15/2024
------------------------------------	------------------------------------

5b. FOR INFORMATION CALL (NO COLLECT CALLS)		7. DELIVERY <input checked="" type="checkbox"/> FOB DESTINATION <input type="checkbox"/> OTHER (See Schedule)
---	--	--

NAME Viviane Rivera	TELEPHONE NUMBER AREA CODE: 240 NUMBER: 760-7125		9. DESTINATION
------------------------	---	--	----------------

8. TO:		a. NAME OF CONSIGNEE Tammy COLE 301-480-6288
--------	--	---

a. NAME	b. COMPANY	b. STREET ADDRESS 9000 Rockville Pike Bldg 10 RM 13N240
---------	------------	--

c. STREET ADDRESS		c. CITY Bethesda
-------------------	--	---------------------

d. CITY	e. STATE MD	f. ZIP CODE 20892	d. STATE	e. ZIP CODE
---------	----------------	----------------------	----------	-------------

10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS (Date) 08/01/2024	IMPORTANT: This is a request for information and quotations furnished are not offers. If you are unable to quote, please so indicate on this form and return it to the address in Block 5a. This request does not commit the Government to pay any costs incurred in the preparation of the submission of this quotation or to contract for supplies or service. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotation must be completed by the quoter.
---	--

**11. SCHEDULE (Include applicable Federal, State and local taxes)**

ITEM NUMBER (a)	SUPPLIES/SERVICES (b)	QUANTITIES (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)
001	Catalog: TT-300-999, Remote Monitoring Kit (3-72hr)	54	ea	0.00	\$0.00
	Software Lic & Serv Training Program management API License/Feed	1	ea	0.00	\$0.00
<p>Notice of Intent: If submitting a capability statement, please e-mail only 1 copy of the technical capability statement to: Viviane Rivera @ viviane.rivera@nih.gov</p> <p>See attached statement of work.</p> <p>This will be awarded as a Firm-Fixed Price Contract</p>					

12. DISCOUNT FOR PROMPT PAYMENT	a. 10 CALENDAR DAYS (%)	b. 20 CALENDAR DAYS (%)	c. 30 CALENDAR DAYS (%)	d. CALENDAR DAYS
				NUMBER PERCENTAGE

NOTE: Additional provisions and representations  are  are not attached.

13. NAME AND ADDRESS OF QUOTER	14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION	15. DATE OF QUOTATION
a. NAME OF QUOTER		

b. STREET ADDRESS	16. SIGNER	
	a. NAME (Type or print)	b. TELEPHONE

c. COUNTY			AREA CODE
-----------	--	--	-----------

d. CITY	e. STATE	f. ZIP CODE	c. TITLE (Type or print)	NUMBER
---------	----------	-------------	--------------------------	--------

# STATEMENT OF WORK (SOW)

## 1.0 TITLE

Acquisition of a Remote Patient Temperature Monitoring System (TempTrack by Blue Spark Technologies)

## 2.0 BACKGROUND

The Department of Health and Human Services (HHS), National Institutes of Health (NIH), National Cancer Institute (NCI), Center for Cancer Research (CCR), Center for Immunology (CIO), explores fundamental questions of cancer immunotherapy through rigorous preclinical studies and translates these findings into clinical trials with the goal of developing novel immunotherapeutic therapies for a spectrum of cancers. An adverse event of immunotherapy is Cytokine Release Syndrome (CRS), which can develop when the patient's immune system responds overly aggressively to the treatment. Prompt treatment is key to reducing these exaggerated immune responses since this condition can affect multiple organs. Because fever is a typical symptom in CRS patients, CIO will assess *continuous-temperature-monitoring* (CTM) as alternative method to *standard-of-care monitoring* (i.e., temperature monitoring every four hours) for early CRS detection, with the intent to shorten the time of CRS intervention and ultimately optimize cancer patient care at NIH.

## 3.0 SCOPE

This acquisition includes the purchase and implementation of an FDA-approved continuous patient temperature monitoring system, to include temperature monitoring patches, supporting mobile/tablet applications, integration of the collected data into the patients' Electronic Health Records at the NIH, early alerts to Android-supported NIH clinical staff, and technical and clinical support services. All data shared or generated throughout the duration of this Purchase Order shall remain or become the sole property of the U.S. Government.

## 4.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

## 5.0 CONTRACT REQUIREMENTS

The Contractor shall provide the following supplies and services:

**STATEMENT OF WORK (SOW)**

Item	Product No.	Product Description	Qty	Unit Price	Discount Unit Price	Amount
1	TT-300-999	Blue Spark Technologies Remote Monitoring Kit (3-72hr)	54	\$107.00	\$53.50	\$2,889.00
2	/SW LICENSE & S	Blue Spark Technologies Annual software service license	1	\$12,000.00	\$6,000.00	\$6,000.00
3	/API LICENSE	Blue Spark Technologies Application Programming Interface (API) license/feed	1	\$5,000.00	\$2,500.00	\$2,500.00
4	/TRAINING	Training on the Blue Spark Technologies remote monitoring system; to include two Remote Monitoring Training Kits (TT-300-504)	1	\$5,000.00	\$2,500.00	\$2,500.00
5	/PROGRAM MANAGE	Annual Program Management	1	\$15,000.00	\$7,500.00	\$7,500.00
6	SHIPPING	Quarterly shipping of the Remote Monitoring Kits	4	\$15.00	\$15.00	\$60.00
Total Amount:						\$21,449.00

**5.1 PRODUCT FEATURES/SALIENT CHARACTERISTICS**

The following minimum product features/characteristics are required for this requirement:

**5.1.1 Temperature Tracking System**

1. The temperature tracking system shall be an FDA-approved medical device for continuous temperature monitoring (FDA classification: thermometer, electronic, clinical, 21CFR 880.2910).
2. The temperature tracking system shall be applicable for inpatient and for outpatient use.
3. The system shall be applicable to by patients of any age and shall not interfere with other medical devices (e.g., heart pacemakers).
4. The temperature tracking system shall allow clinicians to protect patient data through unique identifiers (patient IDs).

## STATEMENT OF WORK (SOW)

5. The temperature data shall be wirelessly and securely be transmitted to a cloud service that is compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
6. The temperature tracking system shall have the capability to directly integrate the data into existing Electronic Health Records (EHRs) through an Application Programming Interface (API).
7. The temperature data shall be accessible through web-based, tablet, and mobile phone applications (Android and iOS).
8. The system shall have the capability of providing audible and/or visual notifications for rising body temperatures on Android and on iOS supported devices.

### 5.1.2 Temperature Monitoring Patches

The temperature monitoring patches shall fulfill the following minimum salient characteristics:

1. The patches must conform to the ASTM E1112-00 standard ( $\pm 0.1^{\circ}\text{C}$  or  $\pm 0.2^{\circ}\text{F}$  over the temperature range of the device), which is required for all clinical digital thermometers.
2. The temperature monitoring devices shall consist of comfortable, latex-free, water-resistant, adhering patches.
  1. The patches must provide accurate temperatures when placed correctly in the axilla.
  2. The patches shall not be affected by skin tone (i.e., no optical components).
  3. The temperature range measured by the patches shall be between approximately  $30^{\circ}\text{C}$  to  $43^{\circ}\text{C}$  ( $86^{\circ}\text{F}$  to  $109.3^{\circ}\text{F}$ ).
  4. The patches shall be able to continuously monitor body temperature for up to 72 hours.
  5. The patches shall not store any Patient Identifiable Information (PII).

### 5.2 TASKS

Independently and not as an agent of the Government, the Contractor shall provide all labor, materials, and equipment required to perform the following tasks:

#### 5.2.1 Task 1: Smartphone/Tablet Applications

1. Immediately upon award, the Contractor shall provide access to the most recent versions of the smart phone and tablet applications which support the use of the temperature monitoring patches on Android and iOS operating systems.

## STATEMENT OF WORK (SOW)

2. Access may be granted remotely through an application store, secure link, quick-response (QR) code, or another method mutually agreed upon with the TPOC.
3. Access shall be granted to an unlimited number of end users (NIH staff) for the full duration of the award at no additional cost to the Government.

### 5.2.2 Task 2: Product Delivery

1. The Contractor shall make a scheduled quarterly delivery of the temperature monitoring devices as indicated in the table below:

Delivery	Catalog No.*	Description	Quantity
1 <sup>st</sup>	TT-300-999	Remote Monitoring Kit (3-72hr)	14
2 <sup>nd</sup>	TT-300-999	Remote Monitoring Kit (3-72hr)	14
3 <sup>rd</sup>	TT-300-999	Remote Monitoring Kit (3-72hr)	13
4 <sup>th</sup>	TT-300-999	Remote Monitoring Kit (3-72hr)	13

*(\* Note: The Contractor shall contact the NCI Technical Point of Contact (TPOC) and the Purchasing Agent in the event an upgraded product by the original manufacturer becomes available during the period of performance. The Government will decide if the Contractor shall substitute the product to the most recent version.*

The temperature monitoring patches shall be delivered to the following address:

Att.: Kathy Lee-Wisdom  
(Phone: 240-858-3525)  
10 Center Drive, Building 10, Room 13N254  
Bethesda, MD 20892

2. Within one (1) week of award, the Contractor shall confirm the schedule for the deliveries with the NCI Technical Point of Contact (TPOC; see Section 9.0 below). The first delivery is anticipated to take place within two (2) weeks of award.
3. For each delivery, the Contractor shall provide a shipping tracking number to the TPOC.
4. Each delivered item shall be from a recent production lot to ensure maximum shelf-life, with an expiration date of at least thirty-six (36) months from the date of delivery.

## STATEMENT OF WORK (SOW)

### 5.2.3 Task 3: Integration with EHR System

1. Within three (3) weeks of award, the Contractor shall implement the API and complete the integration of the temperature monitoring system with the NIH Electronic Health Record (EHR) system.
2. The Contractor shall ensure immediate alerts on rising temperatures to pre-existing Android-supported cell phone devices (“Zebra phones”) used by NIH clinical staff.

### 5.2.4 Task 4: Web Data Access

1. Within one (1) week of completion of system integration, the Contractor shall provide access to the data collected under this order through a secure website.
2. This shall include unique, password protected logins for the TPOC and for NIH clinical staff.
3. The website shall enable the TPOC to download all raw data collected under this requirement in .xlsx, .csv, or similar format.

### 5.2.5 Task 5: Training

1. At a date and time agreed upon with the TPOC, the Contractor shall provide onsite training for up to fifteen (15) NIH staff members on the proper use of the temperature monitoring system. The training is anticipated to occur within one (1) month of award.
2. The training shall be conducted by a factory-trained, certified product specialist.
3. The training shall include two Remote Monitoring Training Kits (TT-300-504) at no additional cost to the Government.

### 5.2.6 Task 6: Technical and Program Management Support Services

1. The Contractor shall provide real-time unlimited technical 24/7 support services via phone and email by trained technical support personnel for use of the temperature monitoring system. The Contractor shall use their best efforts to respond to all technical support requests reported via telephone and email within one (1) hour.
2. The Contractor shall provide unlimited clinical support services via phone and email by its medical affairs personnel during regular business hours (9:00 AM – 5:00 PM EST, excluding weekend and federal holidays). This shall include consultations with the TPOC to determine the optimal clinical implementation of the temperature monitoring system.
3. The Contractor shall participate in study phone calls to coordinate the monitoring of body temperature of newly enrolled patients. A total of 54 study calls is anticipated.

## **STATEMENT OF WORK (SOW)**

### **5.2.7 Task 7: Final Data Report**

The Contractor shall provide the TPOC with a compilation of all raw data collected under this order in Excel file format or another electronic format mutually agreed upon.

### **6.0 WARRANTY**

The Contractor shall warrant all supplies furnished under this award against any defects in design, material, or manufacture for a period of at least twelve (12) months from date of delivery provided under, or as part of this award. The warranty shall not exclude or limit the Governments rights for an Implied warranty as established in the terms and conditions of clause 52.212-4. The Contractor shall also warrant and imply that all items delivered as a result of this order are merchantable and fit for use for the particular purpose described in the order in accordance with FAR 52.212-4(o).

If a defect results in lost or decreased performance of supplies or services furnished under this order, the Contractor shall cover all parts, materials, labor, and/or travel expenses required to repair or replace the supplies at no additional cost to the Government. Supplies which are repaired or replaced shall be warranted for the remainder of the initial warranty period or for 90-days – whichever is greater.

### **7.0 PERIOD OF PERFORMANCE**

The Period of Performance shall be 8/15/24 - 8/14/25.

### **8.0 PLACE OF PERFORMANCE**

All services shall be conducted at the Contractor's facilities.

### **9.0 REPORTS/DELIVERABLES AND DELIVERY SCHEDULE**



## STATEMENT OF WORK (SOW)

<b>Deliverable</b>	<b>Description</b>	<b>Due Date</b>
Smartphone/tablet application	Remote access to the most recent versions of the smart phone and tablet applications which support the use of the Blue spark Technologies temperature monitoring patches on Android and iOS operating systems. To be provided through a method agreed upon with the TPOC.	Immediately upon award
Shipping dates	Confirmation of all shipping dates; to be coordinated with the TPOC	Within one (1) week of award
1 <sup>st</sup> delivery of CTM kits	Blue Spark Technologies TempTrack temperature monitoring kits (fourteen (14) packs of three (3) 72-hr patches)	Anticipated to occur within two (2) weeks of award
System integration	Completion of API implementation, integration with EMR, and Android alert set up	Within three (3) weeks of award
Web data access	Access to the data collected via secure, password protected website. To be provided remotely to the TPOC and NIH clinical staff as appropriate.	Within one (1) month of award
Training	Onsite training for up to 15 NIH staff members on the proper use of the temperature monitoring system	Anticipated to occur within one (1) month of award
2 <sup>nd</sup> delivery of CTM kits	Blue Spark Technologies TempTrack temperature monitoring kits (fourteen (14) packs of three (3) 72-hr patches)	At the beginning of the second quarter of the award; shipping date to be confirmed with the TPOC
3 <sup>rd</sup> delivery of CTM kits	Blue Spark Technologies TempTrack temperature monitoring kits (thirteen (13) packs of three (3) 72-hr patches)	At the beginning of the third quarter of the award; shipping date to be confirmed with the TPOC

## STATEMENT OF WORK (SOW)

4 <sup>th</sup> delivery of CTM kits	Blue Spark Technologies TempTrack temperature monitoring kits (thirteen (13) packs of three (3) 72-hr patches)	At the beginning of the fourth quarter of the award; shipping date to be confirmed with the TPOC
Final Data Report	Compilation of all raw data collected under this order in Excel file format or another electronic format mutually agreed upon; to be provided to the TPOC by email	One (1) week prior to award expiration

Regardless of format, all digital content or communications materials produced as a deliverable under this contract, shall conform to applicable Section 508 Standards to allow Federal employees and members of the public with disabilities to have access to and use of information and data that is comparable to the access to and use of information and data by Federal employees or by members of the public who are not individuals with disabilities. Remediation of any materials that do not comply with the applicable Section 508 requirements as set forth below, shall be the responsibility of the Contractor. HHS guidance regarding accessibility of documents can be found at <https://www.hhs.gov/web/section-508/making-files-accessible/create-accessible-pdfs/index.html>. Federal government-wide guidance regarding accessibility of documents can be found at <https://www.section508.gov/>, including the documents describing the preferred method of authoring and testing documents produced in Microsoft Word 2013 or later, Microsoft Excel, and files formatted as PDF.

### 10.0 TECHNICAL POINT OF CONTACT

The Technical Point of Contact (TPOC) is responsible for inspection and acceptance of all deliverables in relation to this requirement and will serve as the Government's primary point of contact throughout the duration of the requirement. All efforts must be coordinated with this individual. The TPOC for this requirement is:

Name: Nick Tschernia  
Email: [nick.tschernia@nih.gov](mailto:nick.tschernia@nih.gov)  
Phone: 240-506-3532

Note: The TPOC has limited authority as defined within this Statement of Work. The TPOC does not have the authority to commit or obligate Government funds, or make changes to the terms and conditions of the purchase order. As such, any changes to the purchase order must be

## STATEMENT OF WORK (SOW)

performed by a warranted Government Purchasing Agent with appropriate delegated authority to do so.

### **11.0 INSPECTION AND ACCEPTANCE**

Pursuant to FAR clause 52.212-4, all work described in the SOW to be delivered under this purchase order is subject to final inspection and acceptance by an authorized representative of the Government. The authorized representative of the Government is the NCI Technical Point of Contact (TPOC) who is responsible for inspection and acceptance of all services, materials, or supplies to be provided by the Contractor.

Regardless of format, all digital content or communications materials produced as a deliverable under this purchase order, shall conform to HHSAR 352.239-79 Information and Communication Technology Accessibility (FEB 2024) (Deviation). See attached terms and conditions for additional details.

All written drafts and final deliverable products shall be submitted as an electronic copy in draft format for review, comment, and approval by the TPOC. Final copies of approved drafts shall be delivered to the TPOC within 3 business days after receipt of the Government's comments. If requested, final deliverable products shall be submitted in an electronic format. Other quantities and formats may be submitted after prior approval from the TPOC. All deliverables shall be sent electronically as; Microsoft Excel 2013, Microsoft Excel, or Adobe Portable Document Format (PDF), unless otherwise approved by the TPOC.

The NIH shall have 30 days in which to review and accept the deliverables provided by the Contractor. If no comments or request for revisions are provided within 30 days, the deliverables shall be considered acceptable.

### **12.0 PAYMENT**

Payment shall be made quarterly in equal amounts of \$5,362.25.

(Purchasing agent will add most recent payment clauses)