Request for Prototype Proposal (RPP)

Solicitation Number: HT942726RE009

Analgesic Product for Battlefield Use

Issued by the:

Defense Health Agency Contracting Activity (DHACA)
Research and Development Contracting Division 2
808 Schreider Street
Fort Detrick, Maryland 21702

for the:

Defense Health Agency, Portfolio Acquisition Executive Medical Products (PAE MP),
Warfighter Protection and Acute Care Project Management Office (WPAC PMO)

Request Issue Date: 29 June 2026

Proposal Due Date: 30 July 2026

1. Executive Summary

1.1 Request for Prototype Proposal (RPP)

This RPP is being issued by the Defense Health Agency Contracting Activity (DHACA), in support of the Defense Health Agency (DHA), Portfolio Acquisition Executive Medical Products (PAE MP) located in Frederick, Maryland at Fort Detrick. The requirement is needed by the Warfighter Protection and Acute Care Project Management Office (WPAC PMO) for an analgesic product for battlefield use.

This RPP will result in no more than two awards to develop a United States Food and Drug Administration (FDA) approved, single use analgesic product with an indication for moderate to severe acute pain management.

The prototype project development efforts must be compliant with 21 Code of Federal Regulations (CFR) Part 58 and Part 11 and follow FDA's Guidance for Industry; Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products Guidance for Industry; and Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products. As applicable, data submitted to the FDA must be generated, compiled, and packaged in compliance with FDA Investigational New Drug (IND) submission requirements (Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data (SEND) format).

The drug is primarily intended to be used during Tactical Combat Casualty Care (TCCC) at or near the point of injury in austere environments. The single use analgesic product will be part of the battlefield pain management response during Prolonged Casualty Care (PCC) and used during casualty evacuation (CASEVAC)/medical evacuation (MEDEVAC) and at all Roles of Care (ROC). The goal of developing a single use analgesic product is to have a rapid, single dose/single use product with a specific analgesic indication for moderate to severe pain as part of the Battlefield Pain Management (BPM) Family of Systems (FoS). The BPM FoS will provide for comprehensive closure of the Joint Force's pain management gaps. The long-term goal is to have the single use analgesic product fielded and eventually included in standard issue sets/kits/outfits for the Joint Force, which may be part of a follow-on requirement.

The proposal(s) selected will be awarded under the authority of prototype Other Transaction Authority (pOTA), 10 U.S.C. 4022.

A successfully completed prototype project may lead to a follow-on production contract or transaction in accordance with 10 U.S.C. 4022(f).

1.2 Background

The BPM program addresses the need for austere, pre-hospital TCCC and Large-Scale Combat Operations (LSCO) compatible analgesics for moderate to severe acute pain. BPM is using a FoS approach to address this capability gap. This requirement is to fund FDA approval of a single use analgesic product, which will act as backfill for the loss of both DSUVIA (sublingual sufentanyl)

and Oral Transmucosal Fentanyl Citrate (OTFC). An Emergency Use Authorization may be considered as a strategy for early delivery to the Joint Warfighter. The product will provide a rapid and easy to use, single dose analgesic.

1.3 Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

10 U.S.C. 4022 authorizes DoW organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of personnel of the DoW or improving platforms, systems, components, or materials proposed to be acquired or developed by the DoW, or to improvement of platforms, systems, components, or materials in use by the armed forces. To use this authority for an agreement resulting from this RPP, one of the following conditions must be met:

(A) There is at least one (1) nontraditional defense contractor or one (1) non-profit research institute participating to a "*significant extent*" in the prototype project.

or

(B) All "*significant*" participants in the transaction, other than the Federal Government, are small businesses or nontraditional defense contractors.

or

(C) At least one-third (1/3) of the total cost of the prototype project is to be paid out of funds provided by parties to the transaction other than the Federal Government. NOTE: One statutory condition for the use of a Prototype OT is if the performing team does <u>not</u> include either a Non-Traditional Defense Contractor (NDC) or a small business concern participating to a "significant extent" in the prototype project; when this occurs, it is then required to have at least 1/3 of the total cost of the prototype project to be paid by the parties, other than the Federal Government.

Please see RPP Section 3. "Proposal Preparation Instructions" and Attachment B for additional details.

Definitions:

Non-Traditional Defense Contractor (NDC) – An entity that is not currently performing and has not performed, for at least a one-year period preceding the solicitation of sources by DoD for the procurement or transaction, any contract or subcontract for the DoD that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 1502 of Title 41 and the regulations implementing such section (see 10 U.S.C. §3014). The phrase "the solicitation of sources" refers to the initial agreement solicitation only. An NDC retains its status for the duration of the prototype project/agreement's period of performance, or for any in-scope work modified under the same agreement.

NOTE: Per the statutory definition, NDCs are all entities that have not performed under a narrowly defined set of circumstances within one year of RPP of the current prototype OT

opportunity. The effect of this narrow definition is that many entities will fall into the NDC category, including nearly all small business concerns, and even those firms that work exclusively with DoD. This is in part due to the exemptions to CAS coverage under 41 U.S.C. §1502 and Revolutionary FAR Overhaul, FAR Part 30, which exempt commercial contracts, Firm Fixed Price contracts based on adequate price competition, and any contract or subcontract with a small business concern, among other exemptions. Further, even where an entity is not outright exempt from CAS coverage, the entity may not have been subject to "full" CAS coverage. This is because full CAS coverage applies only to firms that receive a single CAS-covered contract award of $50 million or more; or received $50 million or more in net CAS-covered awards during its preceding cost-accounting period.

Significant Extent – The Government will consider the totality of the circumstances for EACH proposed prototype project before making a determination as to the significance of expected NDC or nonprofit research institute participation. The government will weigh/consider elements such as, but not limited to, whether the NDC/nonprofit research institution will supply a new key technology, product, or process; supply a novel application or approach to an existing technology, product, or process; provide a material increase in the performance, efficiency, quality, or versatility of a key technology, product, or process; accomplish a significant amount of the prototype project; cause a material reduction in the cost or schedule of the prototype project; or, provide for a material increase in performance of the prototype project. The following are some, but not all, examples of participation to a *significant extent*:

1. Supplying a new key technology, product or process.
2. Supplying a novel application or approach to an existing technology, product or process.
3. Providing a material increase in the performance, efficiency, quality or versatility of a key technology, product or process.
4. Accomplishing a significant amount of the prototype project.
5. Causing a material reduction in the cost or schedule of the prototype project
6. Providing for a material increase in performance of the prototype project.

Cost Sharing – Cost sharing occurs when a portion of the total cost of the project is paid out of funds provided by sources other than the Federal Government. Contributions can be in cash or non-cash form, and costs can be either direct or indirect, so long as they are allowable, allocable, reasonable, and consistently accounted for by the performer. Resource sharing may include labor, materials, equipment, IP rights, and facilities. Foregone fee or profit on another contract or agreement or cost of money is NOT consistent with general cost principles and will NOT be permitted. Profit or fee must NOT be included in resource-shared agreements. Types of cost sharing:

Cash Contribution – Any contribution of funds, services, or materials for which the Recipient is required to pay cash, and which would normally be authorized for reimbursement as a direct or indirect charge to the Agreement. Examples include provision of direct labor, raw materials, and associated indirect costs. Cash contribution does not include foregone profit or fee.

In-Kind Contribution – Any contribution of equipment, facilities, intellectual property, etc. which is necessary for performance of the statement of work for which a usage or depreciation charge is normally assessed versus reimbursement of the actual costs for acquiring or providing the item. Examples include costs associated with the provision or rental of real property, special tooling or test equipment, and foregone licensing fees for software where the Government has no pre-existing right to free use.

1.4 System for Award Management (SAM) Registration

SAM.gov is a centralized web-based tool used by the federal Government's executive agencies as the authoritative source for federal awardee data. SAM's Entity Information module maintains annually self-reported entity information including address and contact information, banking information, and representations and certifications. Companies and other organizations who are prime awardees for OT agreements MUST register in SAM and maintain an active registration status throughout performance. The prime awardee MUST use its Unique Entity Identifier (UEI) from SAM (https://sam.gov). If NAICS code 541714 "Research and Development in Biotechnology (except Nanobiotechnology)" is not currently listed in the Performer's SAM.gov account, it MUST be added prior to award.

2. Requirement Overview

2.1 Award Type

The Contractor shall propose the award type.

2.2 Period of Performance

The estimated Period of Performance (PoP) for the entire effort is eight (8) years.

The estimated PoP for Objective 1 is three (3) years.

The estimated PoP for the non-clinical studies in Objective 2 is two (2) years.

The estimated PoP for Objective 3 is three (3) years (must be executed after the completion of Objective 2 – non-clinical enabling studies).

2.3 Frequency of Funds Obligated

The pOTA is anticipated to be incrementally funded. An incremental funding schedule will be provided upon award.

2.4 Proprietary Information

DHACA will oversee submission of proposals submitted in response to this RPP. DHACA will take the necessary steps to protect all proprietary information and will not use such proprietary information for purposes other than the evaluation of a Vendor's proposal and the subsequent

agreement administration if the proposal is selected for award in accordance with Federal laws and regulations.

Additionally, all Technical Evaluation Panel participants will agree to and sign non-disclosure and conflict of interest documents.

2.5 Intellectual Property

Intellectual Property (IP) rights for this award will be defined in the terms and conditions of the Agreement. As a starting reference point, the Government's standard IP terms have been provided. See Articles 7, 8, and 9 of the Draft OTA for Prototype (Attachment B).Once a successful Vendor has been determined, the presumptive awardee will be required to provide the Government with a list and brief description of any background IP related to the research and development activities contemplated under the proposed agreement, which will be incorporated into the Agreement. The list will include relevant IP such as:

(1) Relevant issued U.S. and foreign patents, which the presumptive awardee partially or wholly owns or is an assignee;

(2) All relevant pending U.S. patent applications, provisional patent applications, PCTs that have not yet expired, and any foreign patent applications, including national stage applications, which the presumptive awardee partially or wholly owns or is an assignee;

(3) Relevant copyrighted/copyrightable works/material in which the presumptive awardee has rights in;

(4) Relevant patent/copyright licenses that the presumptive awardee is party to;

(5) Any relevant patents, patent applications, and/or copyrights owned by third parties that the presumptive awardee has knowledge of; and

(6) Any license with a third party for technology that is or may be necessary for the presumptive awardee to use in order to perform or meet obligations under this Agreement.

2.6 Preliminary Screening & Eligibility

The Government will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP submission instructions. As part of the preliminary screening process, proposals not submitted in accordance with the RPP instructions may be eliminated from the competition or additional information may be requested by the Government. Additionally, the Government reserves the right to request additional information or simply eliminate proposals that have not been proposed in accordance with the RPP submission instructions. One of the primary reasons for non-compliance or elimination during the preliminary screening is not properly demonstrating that the Vendor is an NDC, nonprofit research institution, or not cost sharing (if applicable).

The Vendor must submit Warranties and Representations (Attachment C) specifying the critical technologies being offered and/or the significant extent of participation of the NDC or nonprofit research institution or cost share (if applicable). The NDC may be an individual so long as he/she has a SAM.gov UEI and meets the requirements in the Warranties and Representations. The significance of the NDC's or nonprofit research institution's participation must be explained in detail in the signed Warranties and Representations.

To be eligible for award, a proposal must demonstrate that at least one (1) of the following conditions are met:

Rating	Description
Pass	(A) Demonstrated that there is at least one (1) nontraditional defense contractor or one (1) non-profit research institute participating to a significant extent in the prototype project. or (B) Demonstrated that all significant participants in the transaction, other than the Federal Government, are small businesses or nontraditional defense contractors. or (C) Demonstrated at least one-third (1/3) of the total cost of the prototype project is to be paid out of funds provided by parties to the transaction other than the Federal Government.

Rating	Description
Fail	(A) Did NOT demonstrate that there is at least one (1) nontraditional defense contractor or one (1) non-profit research institute participating to a significant extent in the prototype project. or (B) Did NOT demonstrate that all significant participants in the transaction, other than the Federal Government, are small businesses or nontraditional defense contractors. or (C) Did NOT demonstrate at least one-third (1/3) of the total cost of the prototype project is to be paid out of funds provided by parties to the transaction other than the Federal Government.

If cost sharing is proposed, then the Vendor must state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution; provide a description of

each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). **Foregone fee or profit on another contract or agreement, or cost of money is not to be consistent with general cost principles and will NOT be permitted. Profit or fee must NOT be included in resource-shared agreements.** The resources used as the share do not have to come from the lead or prime performer but can come from any of the performing team's members or third-party resource-sharing. What is important for the Government team to know at the time of award is how the aggregate share will be split amongst the team or their financiers and whether the team has the authority to utilize and commit the resources they propose to share.

3. Proposal Preparation Instructions

3.1 General Instructions

This section provides general guidance for preparation of the proposal as well as specific instructions on the format and content of the proposal. The proposal submitted must contain three (3) separate volumes. Volume I Technical, Volume II Management, and Volume III Administrative and Cost must be submitted in accordance with these General Instructions. If a Vendor fails to submit their proposal in accordance with these instructions, the Government may reject the entire proposal and may not be evaluated for award.

The Vendor's proposal must include all requested data and information and must be submitted in accordance with the instructions in this RPP. Vendors who have not submitted proposals in accordance with the RPP instructions may be eliminated from the competition entirely or additional information may be requested by the Government. Additionally, the Government reserves the right to request additional information or simply eliminate proposals entirely that have not proposed in accordance with these Section 3.1 General Instructions.

The proposal must be clear, concise, and must include sufficient detail for effective evaluation and for substantiating the validity of stated claims. The proposal must not simply rephrase or restate the Government's requirements but rather must provide convincing rationale to address how the Vendor intends to meet these requirements. The Vendor should assume that the Government has no prior knowledge of the Vendor's capabilities and will base its evaluation solely on the information presented in the Vendor's proposal.

Elaborate brochures or documentation, binding, detailed artwork, or other embellishments are unnecessary and not desired.

If the Vendor believes the requirements in these instructions contain an error, omission, or are otherwise unsound, the Vendor must immediately notify the DHACA Agreements Specialist, listed in this RPP, in writing, with supporting rationale.

3.2 Organization of Proposal

<u>General</u>

The Vendor must prepare the proposal as set forth in the Proposal Organization Table below. The titles and contents of each volume must contain the documents as indicated in the Proposal Organization Table. The three (3) separate and distinct volumes are:

Volume I: Technical;
Volume II: Management; and
Volume III: Administrative and Cost

Proposal Organization Table

Volume	Section Title	Page Limit
Volume I: Technical	Cover Page (with POC contact information)	2 pages
	Table of Contents	1 page
	Technical Approach: - Non-clinical and clinical studies/trials that will be conducted and the associated process to be obtained/achieved to support submission to the FDA for approval of the Single Use Analgesic Product for Battlefield Use Regulatory Strategy	20 pages
	Attachment B – Draft OTA for Prototype (Terms and Conditions), Sub Attachment 1 – Statement of Work (SOW) with milestones	No Page Limit
Volume II: Management	Cover Page (with POC contact information)	2 pages
	Table of Contents	1 page
	Management Approach: - Project Management Plan (PMP) (with Integrated Master Schedule (IMS), Identification of Key Personnel, Subcontractor Management Plan (SMP), Risk Management Plan, Spend Plan, Quality Management Plan, and Work Breakdown Structure (WBS))) - Commercial Manufacturing Sales Plan	20 pages
	Teaming Agreement (if applicable)	No Page Limit
Volume III: Administrative and Cost	Cover Page (with POC contact information)	2 pages
	Table of Contents	1 page
	Attachment B – Draft OTA for Prototype (Terms and Conditions) Review	Not Applicable
	Attachment C – Warranties and Representations	Not Applicable
	Attachment D – Prohibition on Contracting with Malign Foreign Talent Programs	Not Applicable
	Attachment E – Cost Sheet Template with priced milestones	Not Applicable
	Written Cost Narrative (with support documentation)	No Page Limit

Volume	Section Title	Page Limit
	Accounting System capability & POCs for DCMA/DCAA (if applicable)	1 page

Submission Format
Each volume must be submitted electronically in searchable PDF format. For the Project Management Plan (PMP) in addition to a high-level presentation in PDF format as part of the Volume I: Technical submission, the Vendor must submit an electronic copy in Microsoft Project with milestones and tasks. The files must be virus and malware free and must not be password protected. Files must not include hyperlinks. The electronic submission must be compatible with Microsoft Office and Adobe Acrobat.

Volume Content
Each volume must be written on a standalone basis. Each volume must contain a cover page and table of contents. Each page must be numbered and include the RPP number and Vendor name. For Volume 1 Technical cover page, please be sure to include a point of contact and point of contact with the authority to negotiate on behalf of the Vendor. The information in each volume must be specific and complete as well as legible, clear, and concise. Per the instructions, the Vendor must provide as specifically as possible, the actual methodology it proposes to use to accomplish and satisfy all requirements. By submitting a proposal, the Vendor represents that it will be responsible for meeting the requirements specified in the RPP. The Vendor must not merely reiterate the objectives or reformulate the requirements specified in the RPP.

Labeling
To request protection from Freedom of Information Act (FOIA) disclosure as allowed by Other Transaction Authority 10 U.S.C. 4021, Vendors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis.

3.3 Volume I: Technical

Cover Page
The Vendor must include a cover page for this volume.

Table of Contents
The Vendor must include a table of contents for this volume.

Technical Approach
The Vendor must submit a written technical approach which effectively demonstrates the Vendor's clear understanding and approach to achieving all the objectives outlined in the SOO. In addition, the Vendor must also describe non-clinical and clinical studies/trials that will be conducted and the associated process to be obtained/achieved to support submission to the FDA for approval of the Single Use Analgesic Product for Battlefield Use as well as a SOW with milestones. The SOW with milestones shall include the tasks necessary and align the IMS.

Regulatory Strategy

The Vendor must submit a regulatory strategy for FDA approval. The regulatory strategy must be described in sufficient detail to allow the Government to assess the appropriateness of the strategy, probability of success, and regulatory risks.

Attachment B, Draft OTA for Prototype (Terms and Conditions), Sub Attachment 1 – SOW
The Vendor must fill out and submit – SOW template with milestones. The Vendor must fill in the specific tasks to be completed for each objective. The SOW must include all the necessary tasks required to accomplish the SOO and align with the IMS. **The Vendor's SOW is the primary document detailing the tasks proposed.**

3.4 Volume II: Management

Cover Page
The Vendor must include a cover page for this volume

Table of Contents
The Vendor must include a table of contents for this volume.

Management Approach
The Vendor must submit a written management approach which effectively demonstrates the Vendor's clear understanding and approach to achieving all the objectives outlined in the SOO. The management approach consists of: Project Staff selection, Project Management Plan (PMP) (with Project Staff Selection, SMP, IMS, and WBS), Commercial Manufacturing Sales Plan, and Regulatory Strategy. Vendors must include technical and corporate experience that reflect the ability to execute the SOO. Any relevant experience achieving FDA approval and commercializing must also be included.

Project Management Plan (PMP) (Deliverable 6 of the SOO)
The Vendor must provide a PMP detailing the approach to managing the project schedule, project risks, cost control, testing timeline and includes sufficient detail to allow the Government to assess overall management strategy and project control measures. The PMP must include an IMS, Identification of Key Personnel, SMP, Risk Management Plan, Spend Plan, Quality Management Plan, and WBS.

(a) IMS
The Vendor must provide a project schedule in Microsoft Project that includes summary tasks and a minimum of 3 levels of subtasks (summary, subtask, sub-subtask 1, 2, 3, etc.) that covers the scope of activities from project initiation through final activities (clinical studies and full-rate manufacturing).

(b) Identification of Key Personnel
The Vendor must identify Key Personnel (e.g., Project Manager, Technical Lead, Regulatory Subject Matter Expert, Manufacturing Lead, and Commercialization Subject Matter Expert). Key Personnel is defined as critical roles essential for project success and list their specific qualifications.

(c) SMP
The Vendor must provide a SMP that describes how the performer will identify, select, manage, and oversee subcontractors to ensure successful execution of the pOTA project. The SMP should be concise, complete, and tailored to the proposed effort. This includes consultants as well.

(d) Risk Management Plan
The Vendor must provide a Risk Management Plan that identifies significant risks to project success, root cause of the risk, the impact and probability of risk realization, and mitigation strategies for each risk.

(e) Spend Plan
The Vendor must provide a Spend Plan that estimates the monthly disbursement of funds to perform proposed tasks to achieve the Government's objectives and goals.

(f) Quality Management Plan
The Vendor must provide a Quality Management Plan that outlines how they will establish and maintain current Good Manufacturing Practices (cGMP) and a Quality Management System (QMS) compliant with 21 CFR Part 820 and ISO 13485 throughout the entire manufacturing process, from initial pilot production to commercialization.

(g) WBS
The Vendor must provide a work breakdown structure that organizes tasks and provides a clear roadmap for project execution. The WBS should be clearly defined, including deliverables and tasks.

Commercial Manufacturing Sales Plan
The Vendor must describe the company's strategy to generate revenue and business opportunities, outlines a strategy to move candidate product into the Market, and describes current and anticipated market landscape and resources required to address the opportunity of the candidate product.

Teaming Agreement (if applicable)
The Vendor must include evidence (e.g., statement of intent to enter into a teaming agreement) of sub-performer/vendor relationships, if sub-performers/vendors are proposed.

NOTE: Vendors who propose consultants, subawardee(s) and/or contractual arrangements with foreign organizations or foreign collaborators must provide additional justification explaining why the foreign organization or foreign individual can carry out the scope of work more effectively than a U.S. organization or U.S. individual.

3.5 Volume III: Administrative and Cost Volume

Cover Page
The Vendor must include a cover page for this volume.

Table of Contents
The Vendor must include a table of contents for this volume.

Attachment B – Draft OTA for Prototype (Terms and Conditions)
This is a generic sample agreement for the Vendor's awareness; terms are subject to change. The Vendor is not required to submit a redline version (i.e. track changes). Terms and conditions are subject to negotiation following selection for award.

Attachment C – Warranties and Representations
This volume must include complete Attachment C – Warranties and Certifications. (Reference Section 2.8 of the RPP).

Attachment D – Prohibition on Contracting with Malign Foreign Talent Programs
This volume must include a complete Attachment D – Prohibition on Contracting with Malign Foreign Talent Programs.

Attachment E – Cost Sheet Template with priced milestones
The Vendor must include all formulas and calculations for review. The cost sheet must show proposed dollar values for the entire effort, including all direct and indirect costs and fees, where applicable. All cost/budget information must be addressed ONLY in Volume III: Administrative and Cost. Do not address cost in the Volume I Technical or Volume II Management. The cost proposal/budget submitted under Volume III: Administrative and Cost must include a Microsoft Excel file, showing all formulas and links, including applicable sub-performer/vendor costs/budget. Estimated levels of effort, labor hours, labor categories, consultant services, travel, material, quantities, etc. may be referenced/addressed in the other two Volumes, but no cost information may be used in Volume I Technical or Volume II Management.

Written Cost Narrative with Support Documentation
This narrative must provide a detailed and comprehensive description of proposed labor, hours, direct, indirect, and other direct costs, estimating techniques used and allocation methods that correlate in sufficient depth with the tasks in the SOW. The Vendor must provide cost build up data for labor rates beginning with the unburdened labor rate through application of indirect and profit and/or fee. The Vendor must not propose labor rates that are derived from blending two or more separate Performers or sub-Performers. Proposed indirect must be based on Vendor's current Forward Pricing Rate Agreement and/or three-year historical trend. The narrative must indicate how the proposed cost is realistic, reasonable, and complete. Rates and cost information is required for the Government to properly perform a cost analysis of the proposal. The Vendor must provide a copy of their current Forward Pricing Rate Agreement, or like documentation, that supports the proposed indirect rates.

Compliance with these instructions is mandatory and failure to comply may result in rejection of the Vendor's proposal. Unrealistically low or unreasonably high proposed costs, initially or subsequently, may be grounds for considering the proposal unacceptable, either on the basis that the Vendor does not understand the requirement or has otherwise made an unrealistic or unreasonable proposal.

Supporting Cost Information:

Labor. For each year, the specific direct and indirect labor rates utilized to price the proposal must be identified and include labor hours, labor positions, employee names, and escalation rate. The same detailed support data must be furnished for all proposed sub-performers. Labor escalation rate may NOT exceed three (3%) per year.

Direct labor rates/positions must identify the baseline (i.e. unburden rate) plus projected escalation for each year and the methodology for computing labor rates (i.e. composite) must be shown. For example: 3 months of FY24 + 9 months of FY25 divided by 12 = the average labor rates for the award period of performance. The Vendor and each proposed subcontractor must state their business fiscal year. The Vendor is advised that projected escalation must be applied to both exempt and non-exempt labor positions.

Indirect Rates. Provide current rates for Fringe, Overhead, Material Handling, General and Administration (G&A), and/or any other indirect costs for all efforts proposed. Provide forward pricing agreements, if applicable. If forward pricing agreements are not in place, include rate calculation methodology and historical trend for the last three-year period to assist with evaluating proposed rates. Please provide relevant rate agreements from cognizant government agencies.

Sub-performers. For each year, the Vendor must submit a complete breakdown of costs/pricing for all sub-performer(s) proposed as well as the method by which the prime Vendor has determined subcontractor pricing fair, reasonable, and realistic.

Consultants. For each year, list proposed consultants by name, if known. For each consultant, describe: (1) nature of services (2) timeframe service will be provided, (3) tasks/milestones supported, (4) hourly rate/fee, and (4) and any other related cost (e.g., travel, per diem) as well as why the consultants needed, the method by which the Prime Vendor has determined consultant costs fair, reasonable, and realistic. **Signed letters of commitment must clearly identify the Consultant's name, service provided, timeframe of service and agreed-to salary/hourly rate and other pertinent conditions (if applicable).**

Materials and Supplies. For each year, provide a detailed listing of materials and supplies, quantity, unit price, and basis of estimates (e.g., vendor quotes, catalog pricing, subcontractor estimates). Competitive historical price information of prior purchases is adequate. For all direct purpose/sole-sourced materials and supplies, provide a consolidated price summary of individual material quantities being proposed and the basis of estimate. If vendor quotes are the basis of estimate, please provide the quotes. If catalog pricing, please provide the business name and relevant inventory number.

Equipment. For each year, provide a list of all proposed equipment to be purchased in support of the Agreement. The list must include equipment description, manufacturer, manufacturer's address, model and stock number, estimated unit price and with what tasks/milestones the equipment is associated.

Travel. For each year, provide the number of travelers, purpose, origin (from), destination (to), and duration of all travel, along with a detailed breakdown of pricing. All travel must be in accordance with federal travel and per-diem regulations.

Other Direct Costs. For each year, list direct costs not included in the above categories (e.g., special tooling, computer services, preservation, packaging, shipping, etc.). Provide the basis of estimate for each.

Accounting System

Although the requirements of the Revolutionary FAR Overhaul, FAR 16.301-3(a) do not apply, an expenditure-based OT agreement that provides for payment based on amounts generated from the awardee's financial or cost records require the awardee to have an accounting system capable of identifying the amounts/costs to individual agreements/contracts AND complying with Generally Accepted Accounting Principles (GAAP). The accounting system should have effective controls over all project funds, including Federal funds and any required resource share. The system should have complete, accurate, and current records that document the sources of funds and the purpose for which they are disbursed. The accounting system should have procedures for ensuring that the project funds are only for purposes permitted by the terms and conditions of this agreement. **If the Vendor is currently performing under other expenditure-based (i.e., cost reimbursement) Federal procurement contracts OR assistance agreements/grants, the Vendor is subject to the SAME standards for financial management/accounting systems that apply to those other Federal awards.**

The Vendor MUST describe how the capability of its accounting system meets these requirements.

If the Vendor has any active Federal contracts AND assistance agreements/grants, the cognizance Defense Contract Management Agency (DCMA) and Defense Contract Audit Agency (DCAA), or other Government agencies, name, email address, and telephone number MUST be provided.

4. Proposal Evaluation

4.1 General

Potential award will be based on the Government's proposal evaluation and subsequent exchanges with the Vendor (if needed). The Government reserves the right to reject the Vendor's proposal, and to award no agreement at all, depending on the quality of the proposals submitted and the availability of funds. The proposal must be complete, arrive by the date and time indicated in this RPP, and be compliant with all RPP General Instructions.

4.2 Proposal Revisions

The Agreements Officer may request or allow proposal revisions to clarify and document understandings reached during negotiations. The Agreements Officer may establish a cut-off date only for receipt of final proposal revisions. The request for final proposal revision must advise

the Vendor that the final proposal revision must be in writing and that the Government intends to make award without further revisions.

4.3 Evaluation Factors for Award

Every proposal will get a comprehensive review and evaluation in accordance with the evaluation factors. The Government will select the proposal/proposals that it determines to be most advantageous.

Evaluation Factors for Award

Factor Number	Evaluation Factors
1	Technical Approach
2	Management Approach
3	Cost

4.3.1 Factor I – Technical Approach

The Vendor's technical approach will be evaluated to the degree it effectively demonstrates and addresses the required content/information from Section 3.2 and 3.3 above and effectively demonstrates a clear understanding and approach to achieving all the objectives outlined in the SOO.

4.3.2 Factor II – Management Approach

The Vendor's management approach will be evaluated to the degree it demonstrates and addresses the required content/information from Section 3.2 and 3.4 above and overall demonstrates appropriate and effective management approach/strategy for maintaining project schedule, project risks, price control, and quality management.

4.3.3 Factor III – Administrative and Cost

The Vendor's proposal will be evaluated to determine whether the proposed Warranties and Representations, Prohibition on Contracting with Malign Foreign Talent Programs Cost Sheet Template, and Written Cost Narrative are realistic, reasonable, and complete.

5. Proposal Submission

RPP Questions Due: Submitted in writing no later than: 10 July 2026

Proposals Due: 30 July 2026

Questions and proposals must be submitted in writing to Peter Mitchell, DHACA Agreements Specialist via email at peter.d.mitchell8.civ@health.mil and Shannon Lertora, DHACA Agreements Officer via email at shannon.p.lertora.civ@health.mil.

6. Attachments

- Attachment A – SOO
- Attachment B – Draft OTA for Prototype (Terms & Conditions)
    - Sub Attachment 1 – SOW
- Attachment C – Warranties and Representatives
- Attachment D – Prohibition on Contracting with Malign Foreign Talent Programs
- Attachment E – Cost Summary Sheet
- Attachment F – Contract Data Requirements List (CDRL) A001 FDA Regulatory Data (REFERENCE ONLY)
- Attachment G – Data Item Description (DID) No. DI-TCSP-82040, Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration (REFERENCE ONLY)

(end of RPP)