

Request for Project Proposals



Solicitation Number: MTEC-18-06-CPP
**“Development and Evaluation of a Cryopreserved Platelet (CPP) Product
for the U.S. Military”**

Issued by:
Advanced Technology International (ATI),
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for the
Medical Technology Enterprise Consortium (MTEC)

Amendment 1

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AMENDMENT 01 – The purpose of this amendment is to update Section 8 to exclude the title page from the page count. The update is made in red, bold text. No other changes are being made.

White Papers Are NOT Required

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1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) and other DoD agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

- (a) biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) deployment of intellectual property (IP) and follow-on production*.

*Note: Pending successful completion of the CPP development effort, USAMMDA may issue a non-competitive follow-on production contract pursuant to 10 USC 2371b section f.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “nontraditional” DoD contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the Proposal Preparation Guide (PPG) and MTEC website.

1.2. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the U.S. Army Medical Materiel Development Activity (USAMMDA) technology objectives. Military relevance is a critical component of Solution Brief submission. Strategic and tactical oversight for the award(s) supported by this RPP will be provided by a combination of the Pharmaceutical Systems (PS) Program Management Office (PMO) at USAMMDA and the Integrated Program Team (IPT) or working group (WG).

Program Objective:

The awardee(s) of this RPP is expected to perform **all** manner of research and development activities, as necessary, to achieve a U.S. Food and Drug Administration (FDA) licensed dimethyl sulfoxide (DMSO) cryopreserved platelet (CPP) product that meets or exceeds U.S. Military requirements (see Table 1) and is commercially sustainable; thus mitigating the risk of exhausted supply in mass casualty situations.

Problem Definition:

Management of severe hemorrhage due to trauma and/or surgical repair of damaged organs and tissues, requires the contemporaneous replacement of large volumes of blood products, including platelets. Platelets are a normal component of blood and a key initiating factor in hemostasis (blood clotting). Current standard of care in both civilian and military settings consists of walking donor, room-temperature stored, apheresis platelets (i.e., liquid stored platelets), which only have a shelf-life of 5-7 days with decreasing efficacy during this period of storage. Platelet supply in an unsettled military theater of operations is inherently limited due to the inability to store current platelet products for more than 5-7 days. In the event of in-theater mass casualty situations, the supply of walking donor apheresis platelets will not meet demand; compromising the ability (and capacity) of U.S. Army field medical teams to curtail bleeding and stabilize patients.

Limitations of current standard of care:

The current standard of care involves utilizing liquid stored platelets (LSP), currently licensed for storage for up to 5 days at room temperature (20 - 24°C) under gentle agitation. The storage requirements impose inherent constraints and compromises availability of the platelets; especially in the theater of operations. Additionally, LSP are available only via walking donor; i.e., they cannot be shipped due to their brief shelf-life.

Leading technology:

The leading candidate for a long-term stored platelet product, by virtue of technological maturity and risk, is dimethyl sulfoxide (DMSO) cryopreserved platelets (CPP). DMSO CPP is a frozen platelet product (regulated as a biologic by the U.S. FDA) composed of γ -irradiated [2500 centigray (cGy)] leukocyte reduced apheresis platelets stored in plasma and anticoagulant citrate dextrose solution A (for up to 57 hours after apheresis), concentrated, and frozen in approximately 6% DMSO at -80°C and stored at \leq -65°C. Hence forward, this candidate will be referred to as CPP. Development of CPP is in direct support of the USAMMDA's line of effort to enhance battlefield management of severe hemorrhage due to combat trauma.

The objective of this program is to achieve an FDA licensed, commercially viable CPP product.

As such, Offerors are expected to conduct all manner of development, test and evaluation activities (as necessary) to achieve an FDA-licensed CPP product that is suitable for use by the U.S. Military. Anticipated activities include (but are not limited to):

- 1) Design and development of a CPP manufacturing process that is compliant with FDA regulations and applicable guidance for current good manufacturing practices (cGMP).
- 2) Design, development, and validation of processes (inclusive of any necessary materials, equipment, and tests/assays) to enable storage and shipment of CPP for U.S. Military use.
- 3) Performance of all necessary non-clinical (in-vitro) studies and clinical trials.
- 4) Execution of all activities commensurate with serving as the IND holder and regulatory sponsor in accordance with 21 Code of Federal Regulations (CFR) 312 subpart D, including all regulatory submissions and regulatory sponsorship.

- 5) Development and maintenance of various management, risk, project, and quality plans/reports (as necessary) to provide documented evidence that the development effort is being effectively managed in accordance with the risk profile.

Note: Government experience thus far has shown that the CPP product will be regulated by the U.S. FDA as a Biologic product.

2. Administrative Overview

2.1. Request for Proposals

Each MTEC Solution Brief submitted must be in accordance with the mandatory format provided in the MTEC PPG, which is available on the Members-Only MTEC website at www.mtec-sc.org. ***White papers are not required for this RPP.*** The DoD reserves the right to award Solution Briefs received from this RPP on a follow-on prototype Other Transaction Agreement (pOTA) or other stand-alone OTAs as necessary to meet mission requirements.

2.2. Funding Availability and Type of Funding Instrument Issued

The U.S. Department of Defense (DoD) currently anticipates up to \$36 Million (M) in funding for Fiscal Years (FY) 18-24, with an expected start date of December 31, 2018 (subject to change). Offerors should propose a budget that demonstrates a best value solution to achieve the objectives described within this RPP. The DoD reserves the right to negotiate available funding up or down based on the Proposed Statement of Work. Any potential follow-on funding would be negotiated based on FDA feedback, cost sharing, partner matching and estimates for additional study completion.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. Funding of Solution Briefs received in response to this RPP is contingent upon the availability of federal funds for this program. Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

It is expected that MTEC will make a single award to a qualified team to accomplish all tasks. The program shall be led by a centralized point of contact at the prime contracting organization. If a single Solution Brief is unable to sufficiently address the entire scope of this RPP's technical objectives (outlined in Sections 5 and 6), several Offerors may be asked to work together in a collaborative manner as a single project team or MTEC may make multiple, individual awards to Performers(s) to accomplish subset(s) of the key tasks.

The DoD-selected Awards will be funded under the prototype Other Transaction Agreement (pOTA) Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC

administered by the CM, ATI. Strategic oversight for the award(s) supported by this RPP will be provided by the Pharmaceutical Systems PMO at USAMMDA. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the pOTA between the DoD and MTEC. Subsequently, any Solution Brief that is selected for award will be funded through an Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Solution Brief that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Solution Brief that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

Offerors are advised to check the MTEC website periodically during the Solution Brief preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

2.3. Proprietary Information

The MTEC CM will oversee submission of Solution Briefs and Cost Proposals and analyze Cost Proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's Solution Brief and Cost Proposal and the subsequent agreement administration if the Solution Brief and Cost Proposal is selected for award. An Offeror's submission of a Solution Brief and Cost Proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities (e.g., Bill and Melinda Gates Foundation) may be interested in reviewing certain Solution Briefs and Cost Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Solution Brief and Cost Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Solution Briefs and Cost Proposals for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Directors granted access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Solution Briefs or receive any research project funding through MTEC. Additionally, all DoD Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.4. Offeror Eligibility

Offerors must be MTEC Members in good standing.

2.5. Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

Proposals that do not include Nontraditional Defense Contractor or Nonprofit Research Institution participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award.

This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening. Please see the MTEC PPG (Section 3.3.2) for additional details.

2.6. Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

2.7. Nonprofit Research Institution Definition

A Nonprofit Research Institution means an entity whose primary purpose is conducting research and that is (1) described in section 501(c) of the IRS code of 1986, AND (2) exempt from tax under section 501(a) of that code.

2.8. Requirements

If the Offeror asserts either (1) it is a nontraditional defense contractor; (2) proposes a nontraditional defense contractor as a team member/subcontractor; or (3) it is a nonprofit research institution, the Offeror must submit Warranties and Representations (see Attachment 2 of the PPG) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor or nonprofit research institution. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's or nonprofit research institution's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant contribution* includes:

1. Supplying a key technology or products
2. Accomplishing a significant amount of the effort
3. Use of unique skilled personnel, facilities and/or equipment

4. Causing a material reduction in cost or schedule, and/or improvement in performance

2.9. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). If cost sharing is proposed, then the Offeror shall 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.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of DoD-Performer collaboration.

Cash Contribution

Cash Contribution means the Consortium and/or the Awardee (or Awardees' lower tier subawards) financial resources expended to complete the SOW. The cash contribution may be derived from the Consortium's or Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the SOW or specific tasks identified within the SOW. Prior IR&D funds will not be considered as part of the Offeror's cash.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW, and restocking the parts and material consumed.

In-Kind Contribution

In Kind Contribution means the Offeror's non-financial resources expended by the Consortium Members to perform the SOW such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Research Project, and the reasonable fair market value (appropriately prorated) of equipment, materials, intellectual property (IP), and other property used in the performance of the SOW of the Research Project.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on a Consortium Member's cost sharing portion.

See the MTEC PPG for additional details. If the Solution Brief contains multiple team members, this information shall be provided for each team member providing cost share.

2.10. Intellectual Property

Intellectual Property (IP) rights for MTEC Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the DoD and the individual Performers during the entire award period.

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of an Award under the MTEC OTA shall pay MTEC an amount equal to 1% of the total funded value of each research project award. Such deposits shall be due no later than 90 days after the award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.

Additionally, MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Awards:

- **Royalty Payment Agreements**

DoD-funded awards through MTEC will be subject to a 10% royalty on all Net Revenues received by the Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the DoD funding provided.

- **Additional Research Project Award Assessment**

In lieu of providing the royalty payment agreement described above, members receiving Awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4 of the CMA. This additional assessment applies to all awards, whether the award is DoD funded or privately funded.

2.11. Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort would be delivered to the DoD with DoD purpose data rights or unlimited data rights. If this is not the intent, then the Solution Brief should discuss data rights associated with each item,** and possible approaches for the DoD to gain DoD purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Award shall be determined in accordance with the provisions of MTEC Base Agreement.

2.12. Expected Award Date

Offeror should plan on a period of performance (POP) that commences on January 15, 2019. The POP is estimated to take no longer than 7 years, or until the delivery of a product approved by

the FDA is available to the U.S. military. The DoD reserves the right to change the start date through negotiations via the CM and prior to issuing an Award.

2.13. Anticipated Solutions Brief Selection Notification

This RPP will be conducted using a two-staged approach. As the basis of selections is completed for each stage, the DoD will forward their selections to MTEC CM to notify Offerors. Proposers will be notified by letter from the MTEC of the results of the evaluation. Those successful will move forward to the next stage (Step 2: Solution Brief Pitch) of the Solution Brief process while those rejected will gain evaluation rationale for non-selection.

3. Solution Brief

3.1. Solution Brief

The MTEC will use a streamlined, interactive approach for this RPP. Because of the nature of the requirements set forth in this RPP, this streamlined, interactive approach is anticipated to be a better means to highlight Offeror methodologies and skills that should allow the Government to gain a fuller appreciation of the work required to be completed. It provides more freedom and initiative to the Offeror to describe how the Offeror would approach and solve such an action. The following sections describe the formats and requirements of the Solutions Brief.

Offerors who submit Solution Briefs in response to this RPP must submit by the date on the cover page of this RPP. Solution Briefs received after the time and date specified will not be evaluated.

3.2. Solution Brief Submission

Instructions on how to submit are included in the RPP version that is posted on MTEC Members Only Site.

3.3. Submission Format

Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt, .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

MTEC will email receipt confirmations to Offerors upon submission. Offerors may submit in advance of the deadline. **Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces with MTEC's**

submission form. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted.

4. Solution Brief Preparation Instructions

4.1. General Instructions

The Solution Brief and Cost Proposal format provided in this MTEC RPP are mandatory and shall reference this RPP number (MTEC-18-06-CPP). Offerors are encouraged to contact the Point-of-Contact (POC) identified herein up until the Solution Brief submission date/time to clarify requirements.

All eligible Offerors may submit Solution Briefs for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the DoD Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Awards as result of this RPP.

5. Technical Requirements

The USAMMDA's mission is to develop and manage medical materiel to protect and sustain the Warfighter on point for the Nation. We develop, directly through collaboration with commercial partners, medical products that enhance readiness and improve the quality of life of active duty personnel in the operational environment.

As part of the U.S. Combat Casualty Care Research Program, USAMMDA has been developing a frozen, DSMO-treated, biologic platelet product known as CPP. The development of CPP is meant to fill the capability gap created by the inherent shelf life limitations of the product currently used as standard of care (i.e., LSP). The outcome of this program will be an FDA licensed and commercially viable CPP product that meets or exceeds the specifications listed in Table 1.

Table 1: CPP Product Specifications

[Threshold = minimum acceptance level; Objective = desired level]

Parameter	Threshold (T)	Objective (O)
FDA Licensure	Approval	T = O
Efficacy	75% as efficacious as liquid-stored platelets	99% as efficacious as liquid-stored platelets

Duration of Presence in Blood	Recovery greater than 50% of fresh platelets with 1 day survival	Recovery of greater than 50% of fresh platelets with 7 day survival
Storage Temperature	≤ -65°C	≤ -30°C
Shelf-Life	Greater than 1 year when stored at ≤ -65°C	Greater than 1 year when stored at ≤ -30 [Note: achievement of this objective will enable storage in existing equipment]
Preparation Time	Ready to use in 30 minutes or less	Ready to use in 10 minutes or less
Universality	25% of product must be transfusable to all patients (universal donor)	100% of product must be transfusable to all patients

5.1. Statement of Objective

The Government has been working several years to develop CPP and has summarized this development in Appendix A: CPP Investigators Brochure (IB) & Development Summary. Offerors should leverage the past work of the Government to the maximum degree possible with the overall objective being the most rapid fielding of a CPP product that meets the specifications listed in Table 1. However, if incorporation of the work (or portions thereof) performed by the Government hinder achievement of the objective, the offeror should explain in their Solution Brief.

As stated in section 1.2:

The objective of this program is to achieve an FDA licensed, commercially viable CPP product. As such, Offerors are expected to conduct all aspect of development, test and evaluation activities (as necessary) to achieve an FDA-cleared CPP product that achieves specifications in Table 1 and is (therefore) suitable for use by the U.S. Military and is commercially sustainable.

Anticipated activities include (but are not limited to):

- 1) Design and development of a CPP manufacturing process that is compliant with FDA regulations and applicable guidance for cGMP.
- 2) Design, development, and validation of processes (inclusive of any necessary materials, equipment, and tests/assays) to enable storage and shipment of CPP for U.S. Military use.
- 3) Performance of all necessary non-clinical (in-vitro) studies and clinical trials.

- 4) Execution of all activities commensurate with serving as the IND holder and regulatory sponsor in accordance with 21 CFR 312 subpart D, including all regulatory submissions and regulatory sponsorship.
- 5) Development and maintenance of various management, risk, project, and quality plans/reports (as necessary) to provide documented evidence that the development effort is being effectively managed in accordance with the risk profile.

Of note, previous Government interactions with the FDA have indicated that the CPP product will be regulated as a biologic. Accordingly, the Government anticipates that the pathway to licensure will be novel, requiring frequent interaction with the FDA.

5.2. Regulatory Requirements

In general, the work proposed to achieve the program objective will be required to comply with various regulations throughout the POP and thereafter. The following is a list of applicable regulation and guidance, but is by no means comprehensive. Offerors must integrate compliance activities and demonstrate an understanding of applicable regulations and standards throughout their Solution Brief.

- Army Regulation (AR) 50-1
- 21CFR312 (21 CFR312 subpart D)
- 21 CFR Parts 11, 50,54,56, 58, 210, 211, 312, 314, 600, 601, 606, 607, 610, 630, 820, 822
- ISO 13485
- All submissions should be provided in ICH eCTD format (as required)
- Government furnished information (GFI) and equipment (GFE) and contractor acquired property (CAP) shall be managed according to FAR 52.245-1 (Government Property) and 52.245-1 Alt II (Government Property (Apr 2012) Alternate II
- International Conference on Harmonisation (ICH) guidance documents, including (but not limited to): ICH 1A, Q5C, Q1A(R2), Q2A, Q2B, E6, E2A
- Resident country regulations/guidance (as applicable)
- MedDRA and WHO-DD dictionaries
- CDISC, SDTM, ADaM
- Health Insurance Portability and Accountability Act (HIPPA)
- Any applicable U.S. FDA and/or ICH guidance documents pertaining to the above; as applicable to achieve the program objective
- All travel shall be in accordance with Joint Travel Regulations (JTR)

Upon acquiring GFE or purchasing CAP using government funding, the Offeror shall supply the government with information about each item of equipment/property. This information shall be provided post-award and should include, at a minimum, nomenclature, manufacturer, make/model number, serial number, quantity acquired/purchased, unit cost, and date placed in service.

Restrictions on Animal and Human Subjects: Solution Briefs must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the U.S. Army Animal Use and Review Office (ACURO) and U.S. Army Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Solution Brief Pitch.

These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.

For example, the clinical studies under this RPP shall not begin until the USAMRMC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRMC ORP is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 60 days in their schedule for the ORP review and authorization process.

6. Technical Tasks

Offerors should focus their Solution Briefs on responses to the following three (3) tasks. Responses should be clearly separated by task. Solution Briefs are encouraged to address all 3 tasks and any other activities the Offerors anticipates will be needed in order to achieve the program objective. Although Solution Briefs that propose to meet all of the minimum technical requirements outlined below are preferred, we encourage Offerors to submit even if you cannot currently meet all three tasks. Offerors who cannot meet all three tasks are encouraged to describe any necessary partnerships in their Solution Briefs to satisfy all needs described herein. MTEC would consider composing a team from different Solution Briefs that could address all three tasks in a comprehensive manner.

The 3 technical needs listed below are the minimum necessary requirements based on the DMSO CPP prototype's current stage of development; as anticipated by the Government. The Government is open to additional technical needs or program requirements suggested by the Offeror based on the Offeror's assessment of the CPP program to improve program efficiency, reduce program risk, and/or accelerate fielding. If additional tasks are required, please clearly delineate them as separate tasks from the three mentioned herein, and include their associated costs in the cost proposal as separate tasks.

In Stage 1 of the RPP process, the technical content of the Solution Brief should closely align with the Rough Order of Magnitude (ROM) Pricing (see Attachment B). In Stage 2 of the RPP process, costs should be summarized at the task level. In Stage 3 of the RPP process, costs should be detailed out at the task level in the corresponding Cost Proposal.

6.1. Task 1: CPP Development

As stated above, the Government's objective is to field a CPP product that meets or exceeds the specifications in Table 1 as rapidly as possible. The Offeror should leverage the Government's completed work thus far to the greatest extent possible, as appropriate, to achieve the objective.

The Government anticipates that by providing the GFE and GFI specified in Section 7, the development of CPP will be expedited; thus reducing the program's schedule and associated expenditures. If the Offeror determines this is not the case, the Offeror should provide the rationale and analysis within their Solution Briefs.

The Offeror is expected to complete **ALL** development of CPP with minimal assistance from the Government. Assistance provided by the Government will consist only of:

- Provision of GFE as specified herein
- Provision of GFI as specified herein
- Consultation in regard to Appendix A
- Technical consultation in regard to U.S. Military requirements
- Consultation in regard to decision making within trade space of requirements specified in Table 1
- Participation in meetings with the U.S. FDA

The Government requires the Offeror(s) to perform **ALL** aspects of aspect of development, test and evaluation activities to achieve an FDA-cleared CPP product that is suitable for use by the U.S. Military and commercially sustainable.

Anticipated technical development activities include (but are not limited to):

- 1) **CPP Manufacturing and Development**: Design and development of a CPP manufacturing process that is compliant with FDA regulations and applicable guidance for current good manufacturing practices (cGMP).
- 2) **CPP Shipping and Storage Validation**: Design, development, and validation of processes (inclusive of any necessary materials, equipment, and tests/assays) to enable storage and shipment of CPP for U.S. Military use within the contiguous U.S. (CONUS) and in theater (OCONUS).
- 3) **Non-Clinical (In-Vitro) Development**: Performance of all necessary non-clinical (in-vitro) testing / studies as necessary to meet the objective.
- 4) **Clinical Development**: Performance of all necessary clinical testing / clinical trials as necessary to meet the objective.

- 5) IND Holder/Sponsor: Execution of all activities commensurate with serving as the IND holder and regulatory sponsor in accordance with 21 CFR 312 subpart D, including all regulatory submissions and regulatory sponsorship.

In general, the Offeror will be expected to define the deliverables from each task below. It is anticipated that each task will (at minimum) require a technical report deliverable that outlines the results and outcomes of each task. The Offeror will also generate protocols (where applicable (ex: shipping, analytical methods, pre-clinical, clinical) as necessary and provide to the Government for review prior to execution.

Subtask 1.1: CPP Manufacturing and Development

Note: *The following is partially based on U.S. FDA feedback to the Government that the CPP product will be regulated as a Biologic product.*

The Offeror will be required to manufacture according to FDA-registered Blood Establishments to assure identity, strength, quality, and purity of the investigational product.

Ultimately, the Offeror must be able to develop a cGMP-compliant CPP manufacturing process that is capable of providing the CPP product, to an adequate degree of cGMP compliance, and in sufficient quantities to support the development, testing, and clinical trial efforts; as well as (ultimately) cGMP production in sufficient quantities post-licensure to meet the needs of the Government and to ensure global access and commercialization of the product(s).

Validation of the manufacturing process must support the various *in vitro* quality measurements depicted in the chemistry, manufacturing, and control (CMC) section of the approved IND application and subsequent submission and U.S. FDA approval of a Biologics License Application (BLA).

Utilize the previously established Master Production Records for the closed system cGMP manufacturing process (in an open space) for CPP (as defined by FDA according to correspondence and communication), produce lots of CPP as required to support the development effort and achieve the objective.

The Offeror will be expected to perform (at a minimum) the following activities associated with the manufacture of CPP throughout the POP:

- Technology Transfer (as required): The Government anticipates that Offerors will leverage the work completed thus far by the Government to accelerate development and achieve the program objective. Accordingly, the Government anticipates that the Offeror will elect to utilize existing Master Batch Production records to develop the manufacturing process.

- Manufacture and ship CPP in sufficient quantities to support the development effort, and in to an adequate degree of compliance (see section 5.2 for applicable regulation and guidance) in accordance with the stage of development.
- Develop requisite documentation (as needed) ex: SOP, SSP, protocols, final reports, etc.
- Implement and/or validate equipment and/or computer-related systems as necessary for manufacturing, production and/or testing. Maintain equipment and/or systems throughout the POP.
- Staff manufacturing operations with qualified and appropriately trained personnel and staffing levels commensurate with the needs of the project, throughout the PoP.
- Full product characterization.
- Biocompatibility testing.
- Assay development, qualification and validation.
- Refine and optimize CPP to achieve the shelf-life objective parameter (See Table 1)
 - Note: this task should be budgeted separately
- Stability studies:
 - The Government anticipates that the Offeror will continue to utilize OriGen Biomedical's 27% DMSO bag and the overall closed fill system to determine suitability for the processing, storage, and delivery of CPP (see Appendix A). Accordingly, the Offeror shall continue stability studies at multiple time points, conduct design evaluation, and execute container/closure system refinements (as necessary) to achieve the program objective.
 - Additional bag design and construction may be required related to the methodology described in the CPP satellite sample validation protocol (see GFI). Such bag design may be necessary for the FDA required quality control sampling as a release criteria.
- Determine stability of CPP of thawed CPP at room temperature (24°C) [Option]
 - Note: The Government has preliminary results showing the 4 hour shelf-life at room temperature. However, the Government is interested in extending the current 4-hour post-thaw shelf life at room temperature. The Offeror shall explore the possibility of extending post-thaw shelf life utilizing alternative platelet additive solutions; as an alternative to the current saline reconstitution fluid. The Offeror shall include this subtask in its solution brief and propose all related costs as an optional subtask to be exercised based on availability of funding (budget separately as an option). This option will be evaluated as part of the Offerors submission and may be exercised either at the time of award or via a post award modification based. The Offeror will be notified prior to exercising this optional subtask.
- Validation of the manufacturing process.
- Qualify suppliers (i.e., establish, implement, and maintain a supplier qualification program).
- Establish, implement, and maintain quality assurance and quality control functions

- Change controls; deviations/out-of-specifications; corrective and preventive actions; investigations; and qualification/validation activities.
- Generate manufacturing and manufacturing-related documentation in compliance with applicable FDA and ICH regulations and guidance; including eCTD format (when applicable).

Based on prior FDA direction/feedback to the Government, the Government anticipates that manufacturing of CPP will be completed at a central contract manufacturing organization (CMO) and shipped to the clinical sites (ex: blood banks) at $\leq -65^{\circ}\text{C}$. Note: The product is stored at $\leq -65^{\circ}\text{C}$, therefore an ultralow freezer is needed at each clinical site. For the product usage, CPP has to be thawed in a standard 35°C to 37°C water bath (i.e., Helmer). Again, Offerors should indicate (within their Solution Brief) if their strategy indicates deviating from what the Government anticipates.

Please see Appendix A for a development summary.

Subtask 1.2: CPP Shipping and Storage Validation

Throughout the development effort, the Offeror will be required to properly ship cGMP manufactured clinical material to designated clinical trial facilities, laboratories, and storage facilities (as applicable). In addition, the product will require long-term stability testing to support FDA licensure and its use in clinical trials. Work in this areas is also related to satisfying sponsor responsibilities under 21 CFR 312 subpart D. Activities under this task include, but are not limited to:

- Ensure cold chain management and accountability of all investigational product.
- Purchase suitable shipping materials in adequate quantities to ensure successful product shipment while minimizing risk.
- Develop shipping procedures/methods and validate as necessary to minimize risk to the product during shipment.
- Conduct testing and evaluation of up to two potential container solutions in order to determine the best performing solution (inclusive of method and materials) for successfully shipping CPP into the European and Pacific Theaters of Operations while maintaining appropriate cold chain.

Note: See “CPP Mock Shipment Study”, (SriSai Biopharmaceutical Solutions, LLC, Document No. 17MI-0001.01-SR.01, January 2018). This report will be provided as GFI.

The Government will enable the Offeror to coordinate with the Armed Services Whole Blood Processing Laboratories (ASWBPL) at McGuire AFB, New Jersey and at Travis AFB, California. This coordination will assist the offeror in developing adequate methods/procedures for shipping CPP into each theater and identifying points of contact in theater to receive the test shipments. These procedures will most likely include in-transit receipt and re-packing of CPP at each ASWBPL prior to forward shipping into theater in order to maintain proper cold chain.

Please see Appendix A for more detailed description of completed Government work in this area, including packaging, marking, and labeling.

Subtask 1.3: Non-Clinical (in-Vitro) Development

In compliance with applicable regulations and guidance per Section 5.2, the Offeror shall complete all activities necessary to complete non-clinical (in-vitro) development (any non-clinical needs) as required to achieve the objective. The Government anticipates activities under this subtask to include (but not limited to):

- Develop requisite documentation (as needed), for example, standard operating procedures (SOPs), Study Specific Procedures (SSP), protocols, final reports, etc.
- Provide (and ship) product in adequate quantities to complete necessary non-clinical studies.
- Data management.
- Statistical support.
- Technology transfer (as required).
- Equipment Qualification and Validation.
- Refine and optimize CPP to achieve the objective shelf life parameter (See Table 1)
 - Note: The Offeror shall include this subtask in its solution brief and propose all related costs as an optional subtask to be exercised based on availability of funding (this task should be budgeted separately as an option)
- Two-site in vitro study: The Government anticipates that Offeror will need to conduct a two-site in vitro study (repeat of a prior performed study) with an objective to characterize the in vitro phenotype of CPP and compare it to apheresis platelets that have been held under standard blood banking conditions for 5 days, both of which have undergone a simulated transfusion in vitro.

Subtask 1.4: Clinical Development

In compliance with applicable regulations and guidance per Section 5.2, the Offeror shall complete all necessary activities to complete clinical development (as required) to achieve the objective, including, but not limited to:

- Clinical study site selection and preparation.
- Develop requisite documentation (as needed), for example, SOPs, SSP, protocols, final reports, etc., and archive as required by regulation/guidance.
- Clinical study execution.
- Activities to achieve sufficient and rapid recruitment of study volunteers.
- Provide (and ship) product in adequate quantities to complete necessary clinical studies.
- Provide clinical data management to support the clinical studies (e.g., data management services, system configuration, validation, eCRF, data query generation and resolution, medical coding (using the MedDRA Dictionary and the WHO-Drug Dictionary), database locking or unlocking, data transfer, data reconciliation, and reporting).
- Assay development, qualification, and validation.

- Clinical Statistical Support: Provide statistical support to facilitate clinical studies planning, design and data analysis for inclusion in regulatory submissions and final study reports. Statistical support shall include, but is not limited to, advising on protocol design; sample size calculations, development of statistical analysis plans; implementation and/or purchase of statistical analysis software (SAS) Institute software unless otherwise specified); performance of statistical analyses; and development of tables, listings and figures illustrating such analyses for inclusion in regulatory submissions and final clinical study reports.
- Technology transfer (as required).
- Equipment Qualification and Validation.
- Implement Clinical Data Monitoring Committees (also known as Data and Safety Monitoring Boards (DSMBs) or Data and Safety Monitoring Committees (DMCs)) or Data Review Committees (DRC)) as needed to achieve objective.
- Execute required activities as commensurate with serving as the regulatory sponsor and IND holder throughout clinical development (see Subtask 1.5).

Note: Access to the documents detailing the ongoing Phase 1/2a dose escalation study (IND # 14047) will be provided as GFI. A literature publication detailing previous Phase 1 studies is available in the open literature at <http://www.ncbi.nlm.nih.gov/pubmed/22671278>.

Note: The Government anticipates that the Offeror will leverage the work completed by the Government (see Appendix A). Accordingly, the Government anticipates initiation of clinical development in Phase 2.

Subtask 1.5: IND Holder/Sponsor

As stated earlier, in Section 1.2:

*The awardee(s) of this RPP are expected to perform **all** manner of research and development activities, as necessary, to achieve a U.S. FDA licensed DMSO CPP product that meets or exceed U.S. Military requirements (see Table 1) and is commercially sustainable; thus mitigating the risk of exhausted supply in mass casualty situations.*

Accordingly, the Offeror will be responsible for successfully performing all activities commensurate with the role of being the Sponsor and IND holder as defined in 21 CFR 312 subpart D; as well as other regulatory requirements and associated regulatory affairs and regulatory compliance activities (as necessary) to successfully achieve the program objective. This requirement applies to all regulatory submissions requisite achieving the program objective; including (but not limited to) the BLA submission to the U.S. FDA.

The Government intends to transfer the existing IND (#14047) to the awardee. However, the Offeror may outline other RPP approaches within their Solution Brief if such approaches will expedite and/or de-risk the development of CPP.

In addition, the Offeror shall prepare and maintain a Technical Data Package (TDP) that includes all necessary documentation and technical data and reports collected and prepared during the development effort funded by the Government.

Note: USAMMDA PSPMO is seeking clarification on whether CPP will be regulated as a blood product or biologic given the recent allowance to manufacture the CPP product according to the Blood Product Establishments. The FDA's final decision has implications with respect to the regulatory burden (additional regulation requirements for biologics) as well as application fees, establishment fees, drug program fees and cost for any subsequent post-marketing BLA supplements. Offerors are advised to write their Solution Brief with the assumption that the CPP product will be regulated as a biologic, but also explore other avenues to achieve the objective.

6.2. Task 2: Low Rate Initial Production

Production and shipment of licensed CPP (with a specified unit quantity and shelf-life to be determined) for U.S. Army Low Rate Initial Production (LRIP). The Offeror shall produce, release, and ship to the Government three separate lots of CPP. These three lots will represent LRIP quantities. The Government will request LRIP only after FDA product licensure.

- The total LRIP requirement will be 1500 units broken down into three (3) one-year options 500 units per year. Product delivery schedule will be 41 or 42 units of CPP per month.
- Each unit of LRIP CPP shall have at least 11 months of shelf life remaining at time of shipment.
- LRIP shall be shipped to specified US Army facilities as determined at a later time.
- Each unit of LRIP CPP shall be shipped in compliance with a validated shipping methods.
- Each unit of LRIP CPP shall be in compliance with FDA approved ISBT product labeling.

6.3. Task 3: Administrative / Program Management

The Offeror will be responsible for performing all necessary program management activities to ensure adequate performance of the effort and appropriate risk management to ensure achievement of the program objective. As such, the Offeror(s) are expected to explain their program management approach. Expected deliverables under this task include (but are not limited to) the following (as necessary) to provide documented evidence that the program is being effectively managed in accordance with the risk profile:

- Integrated Management Plan (can include sub elements of IMS, RMP).
- Integrated Master Schedule.
- Risk management plan (RMP)/report and associated activities.
- Sub-contractor management plan.
- Quality management plan/reports.
- Project plan (i.e., a detailed Gantt chart based on program risk assessment/management).
- Regulatory Strategy and Regulatory Plan.

- Commercialization Plan.
- Monthly, quarterly, and annual status reports.

In formulating a Solution Brief, Offerors are not expected to develop and submit the aforementioned plans. However, Offerors are expected to explain their overall management approach and explain how the plans will (both individually and collectively) support effective management of the program leading to achievement of the program objective.

This task also includes various administrative activities required to effectively manage a program and successfully meet the program objective. Work in this area includes (but is not limited to):

- Schedule meetings (with the Government), create agendas, manage attendee lists, and produce meeting materials (ex: read-ahead materials).
- Convene meetings to obtain consensus on the deliverable product expected of the meeting.
- Present Gantt Charts to the Government and other meeting attendees and report on status of project deliverables/action items.
- Formal presentation update example below (or Summary of Accomplishment for the Period and Objectives for Next Period) shall include (but not limited to):
 - Project Information
 - Administrative Information
 - Results: task progress this Period (per task)
 - Program Management and Reporting
 - Work Planned For Next Reporting Period

Note on Risk Management Plan and the conduct of Risk Management:

The Government has been increasingly emphasizing the need for robust risk management. The Offeror will be expected to show evidence that active risk management is being conducted throughout the POP.

7. Government Furnished Resources

Solution Briefs may assume that the government will make available the following materials and information as part of successful CPP contract award:

- Transfer of the current OTSG-held IND # 14047
- Clinical grade lots of CPP were manufactured by the previous contract manufacture organization and will be available for cross checking and manufacturing process validation.
- “CPP Mock Shipment Study”, (SriSai Biopharmaceutical Solutions, LLC, Document No. 17MI-0001.01-SR.01, January 2018)
- The following documents are provided as GFI prior to award in Appendix A:

- Procedures Manual Master Table of Contents
- TMRL 100: Master Production Record – Cryopreservation of Apheresis Platelets
- TMRL 805: Current Specifications for Manufacturing of Cryopreserved Platelets
- TMRL 806: Weight of DSMO to add for Freezing Platelets
- Final Report: ‘In Vitro Comparison of Cryopreserved Platelets to Apheresis Platelets’ (February 27, 2018)
- Other available government-furnished documentation and laboratory protocols including (but not limited to): documents supporting the performance of thrombin-generation assays (TGA), manufacturing methodologies, clinical site feasibility documentation, Phase 2 clinical protocol, investigator brochure, informed consent form, complete trial master file documentation, and all prior FDA regulatory correspondences and communications.

8. Solution Brief Preparation

8.1. Preparation of the Solution Brief & Solution Brief Pitch

Offerors submitting Solution Briefs in response to this RPP will be required to submit using the following steps outlined below:

Step 1: Solution Brief

The Offeror shall submit a Solution Brief, which describes the overall technical concept and approach along with the viability toward the Offeror’s specific effort. The following sections shall be included in the Solution Brief:

- **Title Page** (excluded from the page limit) must include the following information:
 - Title of Solution Brief
 - Offeror’s name and contact information (such as name of the organization, point of contact’s name, email address, phone number, mailing address, etc.)
 - Statement that “This Solution Brief is submitted pursuant to the RPP MTEC-18-06-CPP”
 - Dates of submission and signature of official authorized to obligate the institution contractually
 - Willingness to allow MTEC Officers access to your Solution Brief for the purposes of engaging in outreach activities with private sector entities: Indicate YES or NO [As part of MTEC’s mission to incorporate philanthropic donations, MTEC frequently makes contact with private sector entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operate in research areas that are aligned with those of MTEC. Additional private entities may be interested in reviewing certain Solution Briefs and Cost Proposals within their program areas, allowing opportunities to attract supplemental

funding sources. Please indicate your willingness to allow MTEC access to your Solution Brief for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed NDAs and OCI statements.]

- **Overall Approach:** [Outline the proposed methodology in sufficient detail to show a clear course of action as it relates to the topic area of interest. This section should identify any pilot or existing commercial methodology/technology or the development of such during the course of the work. If novel technology or methods are to be employed, then identify the path to maturation. This section should highlight the approach, support technology, personnel, and operational knowledge. Please indicate any aspects that might be proprietary.]
- **Experience:** [The Solution Brief shall describe the experience of the Principal Investigator, key personnel, partner organizations, and associated subject matter experts that are required to meet the program’s objective and requirements. Identify any work of a similar nature that could be used to gauge the effectiveness and worthiness of the technical or methodological approach. This section should not highlight the contractual details of relevant experience, but should emphasize past work that is relevant and similar in nature (complexity, size, requirements) to this request and how that work’s outcome relates to the expectations set forth in this RPP. Offerors should indicate how much of this relevant experience and past effort they will leverage for the proposed effort. Offeror may choose format and method of conveying this. If a novel approach is proposed, describe how this approach differs and why it may be more feasible than current commercial standards.]
- **Clinical Trial Protocol Development and Execution:** [The Solution Brief shall describe strategies and concepts for the clinical trials design to rapidly advance development of the CPP product. It is expected that Offerors will demonstrate expertise in and propose innovative approaches to clinical trial design. It is expected that Offerors will have established processes and demonstrated experience in overcoming challenges in regulated clinical trials of products regulated as biologics.]
- **Product Development Strategy:** [The Solution Brief shall recommend an overall CPP product development strategy that includes regulatory, clinical development, manufacturing and commercialization plan. Clearly describe the “start point” of the proposed work. Include information about IP/Data Rights Assertions.]
- **Project Management Plan:** [The Solution Brief shall describe the overall project management plan. Please refer to Section 6.3 for detail on what is expected here.]
- **Data Rights:** [If applicable, complete the below table for any items to be furnished to the DoD with restrictions. An example is provided below.]

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded exclusively at private expense	Restricted	Organization XYZ	Milestones 1, 3, and 6
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	DoD Purpose Rights	Organization XYZ	Milestone 2

- **Cost Share:** [It is anticipated that Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to discuss the ability to bring leveraged funding/cost share to complete the project goals.]
- **Non-traditional defense contractor, nonprofit research institution, or 1/3 cost sharing:** [Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution, or the ability to meet 1/3 cost sharing requirement. Refer to Sections 2.5-2.8 for more information.]
- **Rough Order of Magnitude (ROM) Pricing:** [Refer to Attachment B].

The Solution Brief is limited to fifteen (15) pages (**excluding** cover page), 12 point font (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. Solution Briefs **exceeding the 15 page limit will not be accepted.**

MTEC will email receipt confirmations to Offerors upon submission of Solution Briefs. Offerors may submit Solutions Briefs in advance of the deadline.

Solution Brief Evaluation:

The CM will distribute all Solution Briefs to the Government for evaluation. Solution Briefs will be evaluated based on the following criteria:

- Feasibility of the proposed solution and its alignment with the RPP’s topic area. This includes such factors as (1) ability to execute the research, (2) technical ability, and (3) soundness of product development strategy.
- Relevancy, thoroughness, and completeness of the proposed methodology/plan/strategy (e.g., the technical and managerial soundness of the methodological approach to satisfy the documented needs) to meet the Government specifications listed in Table 1 and the program objective described in Section 1.2.
- Strength of the organization/team proposed to complete the work and its financial stability to potentially continue the maturation of the system beyond the scope of this RPP.
- Estimated ROM costs represent reasonable value for proposed solution offered.
- Inclusion of nontraditional or small business participation, nonprofit research institution, or a 1/3 cost share.

Upon review of the Solution Briefs, Offerors may be invited into Step 2 of the Solution Brief process. Offerors who are not invited to proceed into Step 2 will be provided feedback.

Step 2: Solution Brief Pitch:

In Step 2, the Offeror(s) will provide a virtual or in-person “pitch” of the proposed project along with a SOW/Milestone Payment Schedule (MPS) and ROM Pricing (see Attachment A) during a meeting with the Government sponsors for the research. The pitch should provide more details about the technical and business viability of the proposed work outlined in Phase 1. Specifically, the pitch should include the following:

- **Description:** [The Offeror will provide a more robust description of their approach and emphasize why this approach is expected to result in a successful outcome. This approach should follow the SOW/MPS provided with the pitch.]
- **Progress:** [The Offeror will describe the milestones provided with objective, quantifiable, and measurable metrics that will be used to measure progress during the period of performance/delivery schedule and describe the oversight managerial methods that will be employed to maintain a quality and timely performance.]
- **Relevant Experience:** [The Offeror will convey details related to key personnel and past performance(s) that demonstrate relevance to the scope of the proposed work and build confidence in the team’s capabilities.]
- **Effectiveness (Opportunity and Risk):** [The Offeror will identify, assess, evaluate and clearly convey items (for known-knowns; known-unknowns and potential unknown-unknowns) for opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project Cost, Schedule, Performance

measure of effectiveness. The Offeror will identify objective measures and metrics used to assess each item, the triggering event(s), the expected result of Opportunities and Risk (if risk is unmitigated) item, and the mitigation plan for each identified risk item.]

- **Data Rights Assertions:** [The Solution Brief Pitch will identify any and all proprietary and/or intellectual property involved in the efforts and any associated restrictions that may possibly affect the Government's use of the property in any way whatsoever. Offeror must describe pathway to developing this into a product that can be used by the DoD and other potential customers (if applicable). Include relevant information about existing royalty agreements. See Section 2.10 for format.]
- **Cost:** [The Solution Brief Pitch must present summarized costs at the task level.]
- **Statement of Work and Milestone Payment Schedule submission:** [One Word (.docx or .doc) or PDF file. Separately, a Word (.docx or .doc) version of the SOW and MPS and a Word (.docx or .doc) are required. See Attachment A for additional information.]

If desired, the Government can request additional information related to specific areas of interest to be included in the pitch. The request for such information will be provided at the end of Step 1 and at the time of invitation to advance into Step 2.

The information discussed during the pitch provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the Solution Brief and the Offeror's capabilities. The pitch should be restricted to **a maximum of 1 hour** with a total time of 2 hours to include questions from the Government and discussion. Any materials that will be presented during the pitch or included as supplementary material must be provided at least 72 hours prior to the meeting date. If an in-person meeting cannot be accommodated by the Offeror, then a minimum of a telephonic discussion accompanied by written support material will be required. Briefing slides or documents or a combination thereof can be used to support this effort.

Evaluation of Step 2: The Government will evaluate the information provided in each Offeror's Solution Brief (Step 1) and the Solution Brief Pitch (Step 2) to determine which solution(s) provide(s) the greatest value to the Government. Such a determination will be based on the following criteria:

- Most Important (of equal importance)
 - Performance: Overall technical approach and how well Offeror's solution enhances the DoD mission described in the RPP; including processes described to identify and manage risks/opportunities
 - Schedule: Suitability of the notional schedule, including processes described to identify and manage risks/opportunities.

- Cost: The parity of the relationship between the Offeror's solution and ROM costs, and whether a superior technical approach is warranted at a higher estimated cost.
- Risk-Opportunity: Identification of risks (with supportable mitigations) and opportunities with the Offeror's approach with objective measurable metrics.
- Less Important (of equal importance)
 - Relevant Experience.
 - Assessment of the potential impact of data rights assertions.

At the conclusion of the Step 2 evaluation, Offerors who are favorably evaluated will be invited to submit a final solution brief (which may be amended from the initial brief to incorporate discussion points from the government interaction) and a cost proposal.

Step 3: Cost Proposal

The Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC and/or Government with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following and be completed in accordance with Section 3 of this RPP and the PPG.

- **Cost Proposal submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (Appendix B) required. Separately, Section II: Cost Proposal Formats (by Task) either in Excel (.xlsx or .xls) or PDF format is required.
- **Warranties and Representations:** If Nontraditional Defense Contractor participation is proposed, Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.
- **Royalty or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Assessment Fee or the Royalty Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.

8.2. Cost Proposal

MTEC will make cost proposal formats available on the Members-Only MTEC website. **The Cost Proposal (by Task) formats provided in the MTEC PPG are mandatory.** Refer to the MTEC PPG for additional details.

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

8.3. Solution Brief and Cost Proposal Preparation Costs

The cost of preparing Solution Briefs and Cost Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

9. Selection

The CM will conduct a preliminary screening of submitted Solution Briefs to ensure compliance with the RPP requirements. Solution Briefs that do not meet these requirements may be eliminated from the competition or additional information may be requested. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see RPP Section 2.6). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	DESCRIPTION
PASS	<p>Offeror proposing an MTEC research project meets at least ONE of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses, nonprofit research institutions, or nontraditional defense contractors.; or • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	<p>Offeror proposing an MTEC research project does NOT meet any of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses, nonprofit research institutions, or nontraditional defense contractors.; or • Offeror provides at least one third of the total project cost as acceptable cost share

Based on the results of the evaluation of the Solution Brief, the Solution Brief Pitch and Cost Proposal, Offerors may be selected for funding or not selected. Table 2 below provides a summary of the adjectival ratings that will be used for both Step 1 and Step 2 evaluations.

TABLE 2- GENERAL MERIT RATING ASSESSMENTS	
RATING	DESCRIPTION
OUTSTANDING	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
GOOD	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
ACCEPTABLE	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
MARGINAL	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
UNACCEPTABLE	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

The RPP review and award process may involve the use of contractors as subject-matter-experts or reviewers; where appropriate, the U.S. Government (USG) will employ NDAs to protect information contained in the RPP as outlined in Section 1.4.

10. Points-of-Contact

For inquiries, please direct your correspondence to the following contacts:

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Manager, Ms. Lisa Fisher, mtec-contracts@ati.org
- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org

- Questions concerning membership should be directed to Ms. Stacey Lindbergh, MTEC Executive Director., execdirect@officer.mtec-sc.org.
- All other questions should be directed to Ms. Kathy Zolman, MTEC Program Manager, kathy.zolman@ati.org

Once an Offeror has submitted a Solution Brief, the DoD and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

11. Acronyms/Abbreviations

ACURO	U.S. Army Animal Use and Review Office
ASWBPL	Armed Services Whole Blood Processing Laboratories
ATI	Advanced Technology International
BLA	Biologics License Application
CAP	Contractor acquired property
CAS	Cost accounting standards
CFR	Code of Federal Regulations
cGMP	Current good manufacturing practices
cGy	Centi-gray
CM	Consortium Manager
CMA	Consortium Member Agreement
CMC	Chemistry, manufacturing, and control
CMO	Contract manufacturing organization
CONUS	Contiguous U.S.
CPP	Cryopreserved platelet
DoD	Department of Defense
DMC	Data and Safety Monitoring Committee
DMSO	Dimethyl sulfoxide
DRC	Data Review Committee
DSMB	Data and Safety Monitoring Board
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
GFE	Government furnished equipment
GFI	Government furnished information
HIPPA	Health Insurance Portability and Accountability Act
HRPO	Human Research Protections Office
IACUC	Institutional Animal Care and Use Committee
IB	Investigators Brochure
ICH	International Conference on Harmonisation
IMP	Integrated Management Plan
IMS	Integrated Master Schedule
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IPT	Integrated Program Team
IRB	Institutional Review Board
IR&D	Independent Research and Development
JTR	Joint Travel Regulations

LRIP	Low Rate Initial Production
LSP	Liquid stored platelets
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
OCONUS	Outside the contiguous U.S.
ODC	Other Direct Charges
ORP	Office of Research Protections, USAMRMC
PMO	Program Management Office
POP	Period of performance
pOTA	Prototype Other Transaction Agreement
PPG	Proposal Preparation Guide
PSPMO	Pharmaceutical Systems Program Management Office
RMP	Risk management plan
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SAS	Statistical analysis software
SOP	Standard operating procedure
SOW	Statement of Work
SSP	Study Specific Procedures
TDP	Technical Data Package
TGA	Thrombin-generation assay
USAMRMC	U.S. Army Medical Research and Materiel Command
USAMMDA	U.S. Army Medical Materiel Development Activity
USG	U.S. Government, specifically the DoD
WG	Working Group

Attachment A: Statement of Work (SOW)

The SOW developed by the Lead MTEC member organization is intended to be incorporated into a binding agreement if the Solutions Brief is selected for award. If no SOW is submitted, there will be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Statement of Work

Submitted under Request for Project Proposal (*Insert current Request No.*)

(Proposed Project Title)

Introduction/Background (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

Scope/Project Objective (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

Requirements (*To be provided initially by the Offeror at the time of submission to be finalized by the Government based on negotiation of Scope/Project Objective.*)

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the Cost Proposal. Subtasks need not be priced separately in the Cost Proposal.

Deliverables (*To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding.*)

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Milestone Payment Schedule *(To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects for funding. The milestone schedule included should be in editable format (i.e., not a picture))*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports (due the 20th of Mar, Jun, Sep, Dec), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

Milestone No.	Significant Event/Accomplishments Description of Deliverables	Due Date	Total Program Funds	Total Cost Share
1				
2				
3				
Total				

Shipping Provisions *(The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)*

- The shipping address is:

Classified Shipments:
Outer Packaging
Inner Packaging

Reporting *(The following information, if applicable to the negotiated SOW, will be provided by the Government based on negotiation)*

- Quarterly Reports – The MTEC research project awardee shall submit a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)
- Annual Technical Report – The project awardee shall submit an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)
- Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)
- Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)

Attachment B: Rough Order of Magnitude (ROM) Pricing

Sufficient cost information to substantiate the proposed cost as realistic and reasonable for the proposed effort must be provided to ensure that a complete and fair evaluation of the cost or price can be conducted. **Use the example table format and template below to provide an initial ROM.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the “Subcontractor” section of the table.

Labor	<i>\$ 100,000.00</i>
Labor Hours	<i>1,000.0 hrs</i>
Subcontractors	<i>\$ 50,000.00</i>
Subcontractors Hours	<i>500.0 hrs</i>
Consultants	<i>\$ 10,000.00</i>
Consultants Hours	<i>100.0 hrs</i>
Material/Equipment	<i>\$ 75,000.00</i>
Other Direct Costs	<i>\$ 1,000.00</i>
Travel	<i>\$ 5,000.00</i>
Indirect costs	<i>\$ 48,200.00</i>
Total Cost	<i>\$ 289,200.00</i>
Fee (Not applicable if cost share is proposed)	<i>\$ 0.00</i>
Total Cost (plus Fee)	<i>\$ 289,200.00</i>
Cost Share (if cost share is proposed then fee is unallowable)	<i>\$ 290,000.00</i>
Total Project Cost	<i>\$ 579,200.00</i>

Appendix A: Investigator's Brochure and Development Summary

Found on the MTEC Members-Only site.