

Request for Project Proposals



Solicitation Number: MTEC-17-03-CTTHS
Cellular Therapy for the Treatment of Hemorrhagic Shock (CTTHS)

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

Request Issue Date: July 14, 2017

Proposal Due Date: August 14, 2017
Noon Eastern Daylight Time

White Papers Are Not Required

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1 Executive Summary

1.1 Purpose

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 Government 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.

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” government 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.

This solicitation, issued by the MTEC Consortium Manager (CM), represents a Request for Project Proposals for MTEC’s support of the United States Army Medical Research and Materiel Command’s (USAMRMC’s) Combat Casualty Care technology objectives. Strategic oversight for the award(s) supported by this RPP will be provided by USAMRMC.

Trauma is the leading cause of death for individuals between the ages of 1–44 and the third leading cause of death in the U.S. overall, accounting for approximately 180,000 fatalities each year, of which up to 20% are potentially preventable. 75% of traumatic deaths occur during the first 3 days after injury, and are primarily due to uncontrolled hemorrhage and traumatic brain injury (TBI). After 3 days, the remaining 25% of deaths accumulate at a low but steady rate and result from a complex interplay of inflammation, vascular compromise and dysfunctional coagulation associated with the initial tissue injury, shock and resuscitation. Clinical manifestations include acute kidney injury (AKI), acute respiratory distress syndrome (ARDS), venous thromboembolic disease (VTE), and Multiple Organ Failure (MOF), and cerebral edema and ongoing cellular death after TBI. Current treatments for these inflammatory conditions are supportive and efficacy trials for new interventions have all failed. Consistent and robust evidence supports the positive impact of rapid treatment for severe injuries including restoration of perfusion, oxygen delivery and wound coverage, however achieving rapid evacuation to damage control and definitive surgical treatment may prove impossible in future combat theaters. As a result the military requires therapies which

can mitigate the potential impacts of severe injuries and delays to surgical interventions in order to prevent mortality from combat wounds.

Pre-clinical, and some limited clinical, data support the hypothesis that cellular therapies may be of use in mitigating the sequelae of severe injury. Numerous studies have documented improved organ function, reduced secondary organ (e.g. lung, kidney) injuries and improved survival with cellular therapy. In response to these and other findings of potential utility for cellular therapies, industry and academic institutions have developed prototype cellular therapy products which require further assessment in well-designed clinical studies to refine and advance the development of this prototype trauma therapeutics.

Therefore, **MTEC is seeking to support a Phase II clinical study to evaluate the safety and efficacy of cellular therapy in the treatment of hemorrhagic shock in severely injured patients.**

Later stage projects would be the most relevant to this request, such as those that are ready for human trials within 12 months. MTEC prefers that projects should be either entering formal FDA supportive clinical trials or preparing documentation for upcoming regulatory submission to the FDA. This is not meant to support pilot lot manufacturing for animal study purposes. The proposal should include a clear description of the current status of the product.

It is expected that many of the actual cellular therapy projects may still be at the academic level, yet the manufacturing and clinical trial requirements demanded are most suited to industry. MTEC, therefore, considers that a teamed approach may have the greatest level of success, especially considering that the eventual goal is to transition products to industry for FDA approval.

Since this request is for technologies that are fairly advanced, it is anticipated that the Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to bring leveraged funding/cost share to complete the project goals.

Each MTEC research project proposal submitted must contain both a Technical and Cost Proposal Volume as described in Section 3 of this request and 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 Government reserves the right to award proposals received from this RPP on a follow-on Other Transaction Agreement (OTA) or other stand-alone OTAs as necessary to meet mission requirements.

1.2 Funding Availability and Type of Funding Instrument Issued

The U.S. Government (USG) currently has available approximately \$2 million (M) for Fiscal Year (FY) 2017.

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 proposals 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.

MTEC anticipates that a single award will be made to a qualified team composed of multiple investigators/institutions responsible for partnering with the USG to accomplish all tasks. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

The Government-selected Research Project Awards will be funded under OTA Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the OTA between the USG and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the Members-Only MTEC 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 proposals 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 proposal 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 proposal preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

1.3 Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's proposal and the subsequent agreement administration if the proposal is selected for award. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CM responsibilities. As part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g. foundations, organizations, individuals, venture groups) that awards 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 proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your proposal

Cover Page, please indicate your willingness to allow MTEC Officers access to your Technical Proposal for the purposes of engaging in outreach activities with these private entities. MTEC Officers granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit research project proposals, nor receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

1.4 Offeror Eligibility

1.4.1 Membership

Offerors must be MTEC Members in good standing.

1.4.2 Inclusion of Nontraditional Defense Contractors

Proposals that do not include Nontraditional Defense Contractor 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 criteria during the Compliance Screening. Please see the MTEC PPG (Section 3.3.2) and RPP (Section 4), for additional details.

1.4.3 Cost Sharing

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *The extent of cost sharing is a consideration in the evaluation of proposals (RPP Section 3.2.2).* 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.).

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

For additional information regarding Nontraditional Defense Contractors and Cost Sharing, please see the Cost Share Guidance document available on the Members-Only portion of the MTEC website www.mtec-sc.org.

1.5 Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project 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 government and the individual performers during the entire award period.

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of a Research Project 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 research project 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 Research Project Awards. 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 Research Project Awards:

Royalty Payment Agreements

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

Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving Research Project 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 research project awards, whether the award is Government funded or privately funded.

1.6 Expected Award Date

Offeror should plan on the period of performance beginning November 1, 2017 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

1.7 Anticipated Proposal Selection Notification

As the basis of selections are completed, the Government will forward their selections to MTEC CM to notify Offerors.

2 Full Proposal

2.1 Full Proposals

Full Proposals in response to this RPP, must be received by the date on the cover page of this RPP. Proposals received after the time and date specified will not be evaluated.

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format provided in the MTEC PPG is mandatory. MTEC will post any general questions received and corresponding answers (without including questioner's proprietary data) on the Members-Only MTEC website.

2.2 Proposal Submission

Full proposals shall be submitted by the date and time specified on the cover page using the submission form located here: <https://secure.ati.org/mtec/mtec-proposal.html>. Select Solicitation Number (MTEC-17-03-CTTHS) on the proposal submission form.

Do not submit any classified information in the proposal submission.

2.2.1 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.

- **Full technical proposal submission:** one Word (.docx or .doc) or PDF file. Separately, a Word (.docx or .doc) version of the SOW and Milestone Payment Schedule (Appendix A of the proposal) and a Word (.docx or .doc) or PDF file of Regulatory Correspondence (Appendix C of the proposal) are required.
- **Full 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 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.

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

3 Proposal Preparation Instructions

3.1 General Instructions

The Technical Proposal and Cost Proposal must be submitted in two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. The proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (MTEC-17-03-CTTHS).

Offerors are encouraged to contact the POC identified herein up until the proposal submission date/time to clarify requirements. Offerors are to propose a Milestone Payment Schedule which

should include all significant event/accomplishments that are intended to be accomplished as part of the project, a planned completion date (based on months post award), the expected research funding expended towards completing that milestone, and any cost share, if applicable. The Milestones and associated accomplishments proposed should, in general, be commensurate in number to the size and duration of the project. A milestone is not necessarily a physical deliverable; it is typically a significant R&D event. Quarterly and final technical reports may be considered deliverables, but they are not milestones. Please include quarterly and final technical reports as part of the Milestone Payment Schedule, without an associated cost.

All eligible Offerors may submit proposals 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 Government Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Research Project Awards as result of this RPP.

3.2 Technical Proposal

3.2.1 Technology Objectives

This call requests proposals for cell therapies that can be used to treat the inflammatory complications that arise after traumatic injury. (Note, this request is not looking for cell therapies that can be used to achieve hemostasis.) The intent of this action is to forward at least one cell therapy prototype into a Phase II clinical trial. Therefore, the products being brought forth must be ready to enter the clinical stage within a short window and have all of the regulatory requirements for IND prepared for submission as a minimum. The focus of this effort is the actual clinical study and not the manufacturing of product, albeit the product must be made available under GMP standards to move forward. If manufacturing is required, that must be stated and the cost identified accordingly.

MTEC seeks proposals from investigators comprising multi-disciplinary teams from a wide spectrum of disciplines including, but not limited to, engineering, translational research, and clinical research.

Proposed projects must be based on logical reasoning and sound scientific rationale. Please note that awards are not to be exploratory in nature and require a foundation of preliminary data.

Deliverables of the Proposed Work should include:

1. Produce clinical grade prototype cellular therapy agent in sufficient quantity to conduct a clinical assessment in a trauma patient population. Assessment needs to account for relevant regulations for prototypes to be administered to humans and ensure documentation of appropriate quality and process controls. The proposer will come forth with the appropriate protocol and surgical procedure that will serve as the basis for evaluation and supports labeling as a hemorrhagic shock therapeutic.

2. Develop a clinical study to assess mechanistic and outcome based patient responses to administration of cellular therapies with appropriate controls for administration of cellular therapy (placebo control, potential confounding treatments (e.g. inclusion/exclusion, hemostasis and blood transfusion) and outcomes assessment (blinding as to treatment)). Relevant outcomes may include inflammation and/inflammatory complications, organ function/injury scores, and mortality. In addition, all safety data and indications need to be identified for capture and review.
3. Document sufficient patient population (number, severity, availability in the acute post injury phase, and ability to conduct exemption from informed consent) to ensure assessment of prototype cellular therapy is conducted in a timely manner.
4. Consider capacity for future assessment of cellular therapies from a variety of sources (e.g. industry, academic labs, and international partners) in a well described clinical population as a reimbursable service.

The Offeror's plan should cover all necessary activities to complete clinical evaluation, including all responsibilities commensurate with regulatory sponsorship including (but not limited to) safety reporting, clinical monitoring, data management, regulatory writing and submissions, stability reporting, and the Data Safety Monitoring Board (DSMB).

Clinical Plans should provide adequate technical details of proposed clinical protocol design(s), key personnel, clinical facilities, proposed clinical procedures, supporting laboratory studies, and post-characterization data analysis including but not limited to the following:

i. Clinical Protocols

Describe the clinical protocol to be used to evaluate the proposed cellular therapy.

ii. Clinical Capabilities and Clinical Support Setting

Clinical Plans should describe capabilities including key regulatory personnel (for example, a senior Regulatory Affairs Advisor, Principal Investigator (PI) and Associate Investigator(s)).

iii. Data Management Plan

Describe the data management plan.

iv. Clinical Monitoring

Offerors should describe a risk-based approach to clinical monitoring to ensure the protocol(s) are conducted in accordance with the principles of ICH E6, FDA GCPs, and requisite portions of 21CFR. Deliverables anticipated from the successful Awardee for this activity include a clinical monitoring plan(s), clinical monitoring visit reports for each study, and corrective action tracking/reports adequately demonstrating management and resolution of any observed protocol non-conformance. Additionally, the clinical Monitors are expected to conduct site-initiation visits (SIV), for cause visits, and closeout visits.

Clinical Plans also should include appropriate details of the relevant support staff qualifications, capabilities and outpatient facilities for the proposed clinical trial site(s), ancillary out-patient clinical support settings, and any relevant biomedical laboratories or related facilities.

v. Sample Collection and Analysis

Offerors should describe any specific clinical- and post-characterization plans to collect, analyze, store, maintain and otherwise exploit ex vivo clinical samples from the clinical studies.

vi. Data Safety Monitoring Board

Offerors should describe, in general, a proposed DSMB structure and time points at which the DSMB will meet to review trial data.

3.2.2 Management, Schedule, Resources and Personnel

The successful Offeror will provide a description of a sound management plan that demonstrates an ability to perform the proposed project in an orderly, timely manner. The project team proposed will include a description of the expertise of all key personnel, to include the corporate experience that demonstrates the ability to accomplish the technology objectives. All facilities and resources to be leveraged should be sufficiently identified and their availability described for executing the research project. Any cost share resources that will be applied beyond the required statutory minimum should have clearly identified tangible technical benefits that will result from these resources. The successful Offeror will include a detailed schedule with cost risks, and potential mitigation strategies identified.

3.2.3 Commercialization Plan and Regulatory Pathway

The successful Offeror will provide a description and justification of the anticipated regulatory pathway and commercialization plan. The Commercialization Plan should describe the strategy the Offeror will employ to move a technology to the military and civilian market. The plan provides a roadmap to convey how the Offeror may ultimately generate revenue and profits from the innovation, either from partnering to license and/or co-develop the technology, or continuing to develop internally with additional funds identified in conjunction with MTEC funding. The quality of the analysis within the Commercialization Plan is a critical element of the MTEC proposal review. Assumptions within the plan should be clearly stated, and evidence of validation should be provided. Include pertinent information about intellectual property. Describe the planned indication for the product label, if appropriate, and include an outline of the development plan required to support that indication. The application should describe a transition plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of this award. The PPG offers key questions to answer in completing the plan. The Commercialization Plan must concisely convey:

- A description and justification of the anticipated regulatory pathway
- The business opportunity enabled by the innovation
- The compelling value proposition for the intended customer

- The key points of a plan appropriate for the Offeror's stage of development
- The status of the effort to date
- The current as well as the anticipated commercial landscape
- Pertinent information about Intellectual Property
- The planned indication for the product label, if appropriate
- Transition plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of this award
- The vision for the enterprise and how the proposed innovation fits into the future market.

3.2.4 Past Performance Documentation

Offeror shall submit no more than 3 Past Performance References of relevant contracts within the past 3 years for its own performance. The Offeror shall also submit no more than 1 reference for each Subcontractor proposed. The contracts may be past or current as long as the performance did not end more than 3 years prior to the due date for the submission of the proposal, and the contracts may have been with Federal, State and/or City agencies and commercial customers. These references should be included in the fields provided with the MTEC Member Information Sheet.

(a) Reference Content: It is the Offeror's responsibility to provide valid, current and verifiable references. References must include:

Name of the Organization that will be providing the reference,
Name of the Point-of-Contact(s) (POC),
POC Telephone Number,
POC Email address,
Contract Number,
Total Contract Value,
Period of Performance, and
Scope of Work.

(b) Point-of-Contact(s): The above POCs must be either Government personnel (civil service or military) or employees of private sector clients (such as public or private sector medical facilities) with whom you have provided services. Information provided by or for POCs who work directly for your company, or indirectly (i.e. in a prime or subcontractor relationship), will NOT be considered relevant. Offerors shall ensure that contact information for designated references is accurate and up-to-date.

(c) Information from Other Sources: The Government may consider information obtained through other sources, including but not limited to the Past Performance Information System (PPIRS).

3.3 Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use

Technical proposals must comply with important restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, human cadavers, or laboratory animals. For a complete description of these mandatory requirements and restrictions and others, Offerors must refer to the accompanying MTEC PPG, Section 6.11 Additional Requirements.

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 30 days in their schedule for the ORP review and authorization process.

3.4 Cost Proposal

MTEC will make cost proposal formats available on the Members-Only MTEC website. **The proposal formats provided in the MTEC PPG is 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.

3.4.1 Proposal Preparation Cost

The cost of preparing proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

4 Selection

As described in Section 3.3.2 of the Proposal Preparation Guide, the CM will conduct a preliminary screening of received proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested. One of the primary reasons for non-compliance and elimination during this initial screening is that the proposal does not offer significant Nontraditional defense contractor participation or cost share (see RPP Section 1.6). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

| TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS | |
|---|---|
| RATING | DESCRIPTION |
| PASS | Offeror proposing an MTEC research project meets at least ONE of the following: <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor • Offeror's proposal has at least one Nontraditional Defense Contractor participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share |
| FAIL | Offeror proposing an MTEC research project does NOT meet any of the following: <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor • Offeror's proposal has at least one Nontraditional Defense Contractor participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share |

Following the preliminary screening, the Government sponsor will undertake proposal source selection. The proposal source selection will be conducted in accordance with the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

- a) *Select the proposal (or some portion of the proposal) for award*
- b) *Place the proposal in the Basket if funding currently is unavailable; or*
- c) *Reject the proposal (will not be placed in the Basket)*

4.1. Proposal Evaluation Process

Qualified applications will be evaluated by a panel of subject matter experts that will make recommendations for funding to the Source Selection Authority appointed by the Commanding General, USAMRMC based on Factors, Sub-factors and criteria described below.

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

Evaluation of proposals offered in response to this RPP shall be based on an independent, comprehensive review and assessment against all source selection criteria and evaluation factors, as further described. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined

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in this RPP. The Offeror shall clearly state how it intends to meet the requirements. Mere acknowledgement or restatement of a requirement or task is not acceptable.

Offerors submitting the best value proposals that meet the following Factors and evaluation criteria will be selected for award negotiations:

1. Technical Approach
2. Management, Schedule, Resources and Personnel
3. Potential for Transition and Commercialization
4. Past Performance
5. Cost/Price

Factors are listed in descending order of importance. The Technical Approach factor, Management, Schedule, Resources and Personnel factor, Potential for Transition and Commercialization factor, and Past Performance when combined, are significantly more important than the Cost/Price factor; however, Cost/Price will contribute substantially to the selection decision. As the collective non-cost factors begin to reach equality in the technical evaluation ratings, cost becomes a more important factor in the trade off analysis.

Table 2 explains the adjectival merit ratings that will be used for the non-cost factors (excluding past performance).

| 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. |

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|--------------|---|
| UNACCEPTABLE | Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable. |
|--------------|---|

Table 3 explains the adjectival merit ratings that will be used for the Past Performance Relevancy Rating.

| Table 3 Past Performance Relevancy Rating Standards | |
|--|---|
| Rating | Definition |
| Very Relevant | Present/past performance effort involved essentially the same scope and magnitude of effort and complexities this solicitation requires. |
| Relevant | Present/past performance effort involved similar scope and magnitude of effort and complexities this solicitation requires. |
| Somewhat Relevant | Present/past performance effort involved some of the scope and magnitude of effort and complexities this solicitation requires. |
| Not Relevant | Present/past performance effort involved little or none of the scope and magnitude of effort and complexities this solicitation requires. |

Table 4 explains the adjectival merit ratings that will be used for the Past Performance Confidence Assessments Rating.

| Table 4 Past Performance Confidence Assessments Rating | |
|---|---|
| Rating | Description |
| Substantial Confidence | Based on the offeror's recent/relevant performance record, the Government has a high expectation that the offeror will successfully perform the required effort. |
| Satisfactory Confidence | Based on the offeror's recent/relevant performance record, the Government has a reasonable expectation that the offeror will successfully perform the required effort. |
| Limited Confidence | Based on the offeror's recent/relevant performance record, the Government has a low expectation that the offeror will successfully perform the required effort. |
| No Confidence | Based on the offeror's recent/relevant performance record, the Government has no expectation that the offeror will be able to successfully perform the required effort. |
| Unknown Confidence (Neutral) | No recent/relevant performance record is available or the offeror's performance record is so sparse |

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| that no meaningful confidence assessment rating can be reasonably assigned. |
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4.1.1 Factor 1. Technical Approach

(1) Ratings. The Technical Approach factor will be evaluated using the merit rating as shown in Table 2.

(2) The overall Merit Rating will be based on an integrated assessment of the criteria described below.

The Offeror's proposed technical approach will be evaluated to the degree to which it meets the technology objectives described in Section 3.2 and details a clear understanding of the technical and necessary activities to conduct the clinical study.

Additional consideration will be given to:

- The degree to which any preliminary existing data supports the proposed objectives. .
- The clinical research capabilities communicated in the proposal including both intramural and/or proposed CRO support
- The qualifications of the clinical personnel, such as education, clinical training, experience, qualifications and availability for the proposed effort. Clinical personnel includes the PI, the co- or Associate PIs, lead program managers, key clinical support staff, and Contractors or Sub-Contractors.
- The degree to which the Offeror demonstrates a clear understanding of the necessary regulatory affairs, regulatory submissions, and regulatory compliance tasks and activities required to adequately and efficiently execute sponsor responsibilities across the proposed clinical and technical methods to accomplish the SOW and other sections of the RPP. This will include an assessment of project adherence to FDA regulations, other appropriate guidance, and requirements related to development and testing of biologics including, but not limited to, applicable portions of Title 21 of the US Code of Federal Regulations (CFR) Parts 11, 50, 54, 56, the Health Insurance Portability and Accountability Act (HIPPA) of 1996 (Pub.L. 104-191, 110 Stat. 1936, enacted August 21, 1996), and International Conference on Harmonisation Guidelines for Good Clinical Practices (GCPs) (ICH Guidelines for Good Clinical Practice (E6), Published May 9, 1997), ICH M9, and ICH M2.

The overall Regulatory Strategy and Regulatory Plan will be evaluated as part of Factor 3.

4.1.2 Factor 2. Management, Schedule, Resources and Personnel.

(1) Ratings. The Management, Schedule, Resources and Personnel factor will be evaluated using the merit rating as shown in Table 2.

(2) The overall Merit Rating will be based on an integrated assessment of the criteria described below.

- Presentation of a sound management plan that demonstrates an ability to perform the proposed project in an orderly, timely manner.
- Degree to which the project team's expertise, key personnel, and corporate experience demonstrate ability to accomplish the SOW.
- Extent that facilities and resources are sufficiently identified and available to execute the effort as proposed.
- Clearly identified tangible technical benefits resulting from cost share resources above the required statutory minimum. This would include:
 - Any cost share proposed when it is not required by statute because your proposal includes a nontraditional defense contractor participating to a significant extent; or
 - Any cost share beyond the statutory 1/3 minimum requirement if your proposal does not include a nontraditional defense contractor.
- Detailed schedule with cost risks, and potential mitigation strategies identified.

The TEP reserves the right to conduct initial and periodic site visits of facilities to include intramural or CRO out-patient and in-patient clinical sites, as well as other key subcontractor facilities.

4.1.3 Factor 3. Potential for Transition and Commercialization

(1) Ratings. The Potential for Transition and Commercialization factor will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposal will be assessed for:

- How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of research, development, or clinical testing.
- How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for military Service members and or their beneficiaries.
- How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
- How well the proposal identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.
- How well the regulatory strategy is described, if applicable.

4.1.4 Factor 4. Past Performance

Ratings. The Past Performance factor will be evaluated using the merit rating as shown in Tables 3 and 4.

The Government will conduct a Past Performance evaluation of the Offeror's Past Performance as well as that of its subcontractors. Past Performance consists of two aspects for evaluation: past performance relevancy and performance confidence. The Government will evaluate the Offeror's past performance references to determine how relevant a recent effort accomplished by the Offeror is to the requirement to be acquired through this source selection. Common aspects of relevance include similarity of service/support, complexity, magnitude of effort, and dollar value. Second, the Government will evaluate the Offeror's past performance references to determine the quality of work performed and assess the level of expectation that the Offeror can successfully perform the required effort. Past performance that is found not to be within the past three years or relevant will not be evaluated.

4.1.5 Factor 5. Cost/Price

(1) Ratings. The Cost area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

(2) The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. The Government Technical Evaluators will assess cost realism as part of the source selection process. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter (PUL), if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

(i) Realism

Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

(ii) Reasonableness

The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website.

(iii) Completeness

The MTEC CM will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.

4.2. Best Value

The Government will conduct the source selection and MTEC CM will award the projects in Best Value sequence. If applicable, the Government will invoke a best value process to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. Based on the results of the Technical Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offeror's will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

4.3. Definition of General Terms Used in Evaluations:

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

Weakness - A flaw in the proposal that increases the risk of unsuccessful award performance.

Significant Strength - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful award performance.

Deficiency - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

5 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, lisa.fisher@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. Polly Graham, MTEC Program Manager, polly.graham@ati.org

Once an Offeror has submitted a proposal, neither the Government nor the MTEC CM will discuss evaluation/proposal status until the source selection process is complete.

6 Acronyms/Abbreviations

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| AKI | Acute Kidney Injury |
| ARDS | Acute Respiratory Distress Syndrome |
| ATI | Advanced Technology International |
| CM | Consortium Manager |
| CMA | Consortium Member Agreement |
| DSMB | Data Safety Monitoring Board |
| FAQ | Frequently Asked Questions |
| F&A | Facilities and Administrative Costs |
| FDA | Food and Drug Administration |
| FY | Fiscal Year |
| G&A | General and Administrative Expenses |
| IP | Intellectual Property (e.g., patents, copyrights, licensing, etc.) |
| M | Millions |
| MOF | Multiple Organ Failure |
| NDA | Nondisclosure Agreement |
| OCI | Organizational Conflict of Interest |
| ODC | Other Direct Charges |
| ORP | Office of Research Protections, USAMRMC |
| OTA | Other Transaction Agreement |
| POC | Point-of-Contact |
| PPG | Proposal Preparation Guide |
| RPP | Request for Project Proposals |
| SOW | Statement of Work |
| TBI | Traumatic Brain Injury |
| TRL | Technology Readiness Level |
| USAMRMC | U.S. Army Medical Research and Materiel Command |
| USG | U.S. Government |
| VTE | Venous Thromboembolic Disease |