

## Request for Project Proposals



**Solicitation Number: MTEC 18-03-DTTBI**  
**“Drug Treatment for Traumatic Brain Injury (DTTBI)”**

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: March 26, 2018***

***Proposal Due Date: May 21, 2018***  
***Noon Eastern Time***

***White Papers Are NOT Required***

***Amendment No. 01 changes the Proposal due date to May 21, 2018 at Noon Eastern Time.***

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## **1 Executive Summary**

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### **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.

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” defense 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 proposal submission. Strategic oversight for the award(s) supported by this RPP will be provided by the Neurotrauma and Psychological Health (NPH) Program Management Office (PMO) at USAMMDA.

Treating traumatic brain injury (TBI) remains one of the top priorities for the Department of Defense (DoD). The DoD and the military services require solutions to fill the capability gap to treat TBI as close to point of injury as possible, to reduce primary and secondary brain damage. The current standard of care for TBI remains supportive in nature, based on management of symptoms, with no drug therapies that address the brain damage. Despite numerous clinical trials on potential therapies, there is no U.S. Food and Drug Administration (FDA) approved drug therapy for the treatment of TBI. TBI has been shown to increase long-term mortality and reduce life expectancy. Estimated economic costs of care for TBI are >\$75B per year according to the Centers for Disease Control (CDC). Therefore, it is important to develop a therapy that will decrease lost duty time and mitigate the life-long disability and rehabilitation costs associated with these post-injury conditions.

The intent of the DoD Drug Treatment for TBI (DTTBI) program is to improve the quality and quantity of candidate drugs entering Phase 3 trials for the treatment of moderate to severe TBI. The objective of this award is to leverage the capabilities of an existing clinical trial network with proven capability to recruit individuals with TBI, and to enable a TBI clinical consortium that can rapidly execute multiple FDA regulated Phase 2 clinical trials intended to fully characterize drug candidates prior to entering Phase 3 trials.

The deliverable at the end of the award is to demonstrate efficacy of at least one TBI candidate drug in Phase 2 clinical trials and recommend its continued development toward FDA regulatory clearance.

### **1.3. Award Governance Structure**

The intent of this program is for Awardees to work closely together with a DoD Advisory Board (AB) and subject matter experts in an actively coordinated, “mini-consortium-type” effort to address the objective described herein. This “mini-consortium-type” effort is referred to within this RPP as the TBI Clinical Consortium (TBI CC). Awardees under this RPP will be managed by the AB, which will be chaired by the NPH Product Manager Sponsor’s Office Technical Representative (SOTR). Awardees shall be prepared to communicate with the AB on a routine basis for meetings in-person or “virtually” through video conferences or teleconferences, to assure:

- continuing synchronization and integration of Awardee efforts,
- select TBI drug candidates to be evaluated in Phase 2 Clinical trials by the TBI CC,
- develop innovative study designs and Phase 2 clinical trial protocols that will rapidly identify drug candidates with the most potential for success in Phase 3 clinical trials
- develop a comprehensive TBI drug development strategy, and
- allocate funding based on progress of award Milestones and Deliverables.

Decision making if other funding partners participate in cost sharing or co-funding will be made by a mutual agreement developed by the DoD AB and those partners/stakeholders. However, the DoD AB will make the final determination of utilization of the DoD resources provided through the Award.

## **2 Administrative Overview**

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### **2.1 Request for Proposals**

Each MTEC proposal submitted must contain both a Technical and Cost Proposal Volume as described in Section 4 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](http://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 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 has available approximately \$25 Million (M) for Fiscal Years (FY) 18-22, with an expected start date of August 1, 2018 (subject to change). 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 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 and Deliverables.

It is expected that MTEC will make a single award to a qualified team to accomplish all tasks. The TBI CC shall be led by a centralized point of contact at the prime contracting organization. If a single proposal is unable to sufficiently address the entire scope of this RPP's objectives (outlined in Section 4), several Offerors may be asked to work together in a collaborative manner or MTEC may make multiple, individual awards to Awardee(s) to accomplish subset(s) of the key tasks. Therefore, it is highly recommended that only Offerors interested in the potential to collaborate with other Offerors submit proposals in response to this RPP.

The DoD-selected Research Project Awards will be funded under the 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 NPH 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 U.S. Government (USG) and MTEC. Subsequently, any proposal 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](http://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 Proposal 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.

### **2.3 Proprietary Information**

The MTEC CM will oversee submission of 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 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.

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 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 and Directors access to your Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Directors who are granted Proposal 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 Proposals 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) and RPP (Section 5), 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-Awardee collaboration.

### **Cash Contribution**

Cash Contribution means the Consortium and/or the Offeror's (or Offerors' lower tier subawards) financial resources expended to complete the SOW. The cash contribution may be derived from the Consortium's or Offeror's (or Offeror' 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 Statement of Work (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 that the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), Offerors' 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, 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 Proposal 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 Government and the individual Awardees 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. Offerors 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**

Government-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 Government 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 Government 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 Government purpose data rights or unlimited data rights. If this is not the intent, then the Proposal should discuss data rights associated with each item,** and possible approaches for the DoD to gain Government 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.

If applicable, complete the below table for any items to be furnished to the DoD with restrictions. An example is provided.

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	Government Purpose Rights	Organization XYZ	Milestone 2

### **2.12 Expected Award Date**

Offeror should plan on a period of performance (POP)/delivery schedule that commences on June 15, 2018. The delivery schedule is estimated as 5 years, or until the delivery of the recommended **TBI drug(s) candidate prototype that has been fully characterized and has the best chance for success in a Phase 3 trial(s)**. The DoD reserves the right to change the start date through negotiations via the CM and prior to issuing an Award.

### **2.13 Anticipated Proposal Selection Notification**

After the evaluations are completed, the DoD will forward its selections to the MTEC CM to notify Offerors of the overall proposal rating and its potential recommendation for award.

## **3 Proposal**

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### **3.1 Proposal**

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 questioners' proprietary data) on the Members-Only MTEC website. The DoD will evaluate Proposals submitted and will select the Proposal(s) that best meet its current technology priorities using the criteria in Section 5.

### **3.2 Proposal Submission**

Found on the MTEC Members Only Site.

### **3.3 Submission Format**

Found on the MTEC Members Only Site.

## 4 Proposal Preparation Instructions

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### 4.1 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 this MTEC RPP is mandatory and shall reference this RPP number (MTEC 18-03-DTTBI). Offerors are encouraged to contact the POC identified herein up until the proposal submission date/time to clarify requirements. Offerors shall propose a Milestone Payment/Delivery Schedule which should include all significant accomplishments/events 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/events 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 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/Delivery 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 DoD Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Awards as result of this RPP.

### 4.2 Technical Requirements

#### 4.2.1 Statement of Objective

The goal of the DTTBI program is to improve the quality and quantity of candidate drugs entering Phase 3 trials for the treatment TBI. **The intent is to leverage the combined expertise of the DoD, industry and academia to identify at least one promising drug candidate to enter Phase 3 clinical trials for the treatment of moderate to severe TBI.**

The objective of this award is to leverage the capabilities of an existing clinical trial network with proven capability to recruit individuals with moderate to severe TBI, and to enable a consortium that can rapidly execute multiple FDA regulated Phase 2 clinical trials to fully characterize drug candidates prior to entering Phase 3 trials.

The DoD seeks proposals from an already established and experienced clinical trial network with proven capability to recruit individuals with moderate to severe TBI. **This program is NOT intended to develop a new clinical trial network or establish new clinical trial sites.** The TBI CC will be expected to conduct Phase 2 clinical trials on several TBI drug candidates. The desire is to

enhance the quality of Phase 2 clinical trial data set and reduce the overall risk of future investment into Phase 3 by fully characterizing TBI drug candidates in thorough Phase 2 testing that simultaneously optimizes time and cost through innovative methods such as but not limited to adaptive or platform trial designs.

**Constraints and Boundaries:**

Several factors should be considered for preparation of a proposal in response to this RPP:

- **TBI drug candidates:** To accelerate the timeline to finding a DTTBI, **this RPP is limited to drugs that have completed at least Phase 1 human clinical studies (at a minimum) and that are focused on a TBI global endpoint of improvement of outcomes (such as Glasgow Outcome Scale Extended).** Drugs in clinical development for other conditions or diseases (such as seizure treatments, stroke treatments, Alzheimer’s treatments etc.) that may provide an improvement for TBI outcomes may also be considered. The DoD aims to fund the evaluation of specific drug candidates (potentially in collaboration with non-DoD sources of funding) in multiple Phase 2 clinical trials that are jointly selected between the DoD AB, TBI CC, and associated subject matter experts.

All controlling and/or applicable rules, regulations, and statutes as they relate to drug development shall apply. The Government requires that clinical trials are carried out in compliance with all applicable Federal, State, DoD, US Army, and FDA regulations and Good Clinical Practice Guidelines.

- **TBI Patient Population:** It is expected that Offerors will have access to resources that can help overcome the challenges of TBI clinical trials. Difficulties in conducting regulated studies in trauma patients include the lack of consent in severely injured patients, significant variability in the nature and severity of TBIs, and the overall health status of patients. TBI patient stratification, comparison to imaging, interim analysis, and population enrichment shall be integral parts of trial design, and Offerors shall demonstrate expertise in these areas.
- **Military Relevance:** This award must be relevant to the health care needs of the DoD.. TBI drug candidate prototypes must be for an adult population for administration at far forward echelons of medical care as well as fixed medical care settings. Proposals should focus on developing a TBI drug product that can be used to treat moderate to severe TBI patient population during the first 24 hours after injury (acute administration).
- **Commercial Partners:** The DoD expects Offerors to include partnerships with commercial entities/industry partner(s) committed to bringing the product to market. At a minimum, it is expected that any industry partners have already had formal communication with the FDA (e.g., pre- Investigational New Drug (IND) meeting) and have data sufficient to file an IND. It is the DoD’s desire that industry partners will manufacture and procure their TBI drugs (provide in-kind cost share, with sufficient

clinical safety data to support Phase 2 clinical trials) in sufficient volumes to support rigorous Phase 2 testing. The DoD will not exclude industry partners that are unable to manufacture and procure their TBI drugs.

- **Comprehensive and Integrated Consortium with a Centralized Point of Contact (POC):** DTTBI MTEC resources shall not be used to stand up clinical trial sites; rather, the DoD expects to leverage capabilities already existing in the TBI research and development landscape. Agreements among TBI CC members shall be handled by the TBI CC to the greatest extent possible. A centralized POC for the TBI CC shall be named and will be ultimately responsible for official communication and deliverables. Offerors are expected to propose a TBI CC comprised of the necessary qualified personnel, facilities, equipment, supplies, services, and subcontractors and related administrative and information technology support to accomplish the objectives.
- **Award Governance Structure:** The Awardee(s) under this RPP will be managed by the DoD AB, which will be chaired by the DoD Product Manager/SOTR. The successful Offeror(s) shall be prepared to communicate with the AB on a routine basis for meetings in-person, or “virtually” through video conferences or teleconferences, to assure continuing synchronization and integration of Awardee efforts, select TBI drug candidate prototypes to be evaluated in Phase 2 Clinical trials by the TBI CC, develop a comprehensive TBI drug development strategy, and make recommendations for funding allocations based on progress of award Milestones and Deliverables. If other funding partners participate in cost sharing or co-funding, the DoD AB will make the final determination on the utilization of the DoD resources provided through this RPP.

**Additional Expectations of Awardee(s):**

- Provide Summary Report(s) within three (3) working days of events that will cause more than a four (4) week delay in schedule or an increase in cost.
- Provide the DoD with advanced notification of all meetings with the FDA to enable the DoD to participate as observers. Provide copies of all communications with the FDA, pertaining to the performance of the clinical trial(s) funded by this program including, but not limited to, annual and periodic reports, IND submissions, pre-meeting packages, and other correspondence including that which was initiated by the FDA shall be provided to the DoD within ten (10) days. Provide official minutes of each FDA meeting to the DoD within three (3) days of receipt of the official minutes.

**\*\*\*Offerors should focus their Technical Proposals on the following requested information. The Technical Proposal should tightly align with the Statement of Work and corresponding Cost Proposal.**

**The TBI Clinical Consortium:**

The DoD is requesting Offeror proposals for a TBI CC that: 1) consists of an existing clinical trial network with a demonstrated capability to recruit and retain individuals with moderate to severe TBI into clinical trials; and 2) is composed of a team of subject matter experts with the necessary expertise to evaluate potential TBI drug candidates, design high quality standardized protocols for FDA regulated Phase 2 clinical trials, execute partnerships that bring resources to the TBI CC, and navigate regulatory, manufacturing and commercialization requirements, and 3) has the necessary infrastructure to execute multiple Phase 2 clinical trials including but not limited to adequate qualified personnel, facilities, equipment, supplies, services, and subcontractors and related administrative and information technology support.

**Technical Proposals must include the following requested information:**

- **Clinical Trial Execution Sites:** The Proposal shall provide a description of the existing TBI clinical consortium. Description should include the clinical trial sites to be used to meet the requirements, including facility locations and associated required resources. Describe the proven history of TBI patient enrollment and FDA compliance capabilities. Provide details on the types of TBI trials conducted, how many TBI patients were enrolled overall and by site, and the time period it took to enroll those patients. Please indicate your experience with Exemption from Informed Consent (EFIC).
- **Experience:** The Proposal shall describe the experience of the key personnel of the TBI CC, its management team, the lead Point of Contact, Clinical Research Organization (CRO), and associated subject matters experts to meet the DTTBI objective and requirements. Describe the experience of each key person and subject matter expert with regard to research and development of TBI drug therapies, TBI patient population, design and execution of standardized Phase 2 clinical trials, regulatory expertise, data management and record of FDA interactions and subsequent drug approval. Specifically address how their skills and expertise directly inform TBI clinical trial design (adaptive or other methods) and/or FDA approval strategy. Describe and provide examples of the proven history of the CRO and FDA compliance capabilities.
- **Cost Sharing:** The Proposal shall describe any current and past partnerships that maximize funding dollars from non-government entities (via agreement structure, cost sharing with industry or other partners) for TBI drug clinical trials and how these reduce risk for stakeholders. Detail past projects with cost sharing (from non-government entities) and the types and amounts of additional funding that supported previous projects.
- **TBI Drug Candidates Selection Criteria:** The Proposal shall describe proposed drug evaluation criteria for TBI drug candidate selection for rapid development and testing in

Phase 2 trials. [Note, do NOT spend a significant portion of your technical proposal on defending your recommendations of TBI drug candidates.]

- **Clinical Trial Protocol Development:** The Proposal shall describe strategies and concepts for Phase 2 clinical trial design to rapidly advance development of TBI drug candidates. It is expected that Offerors will demonstrate expertise in and propose innovative approaches to clinical trial design and conduct which address prior shortcomings in clinical trials for TBI such as: (1) accounting for the heterogeneity in the nature and severity of TBIs using patient stratification or population enrichment, (2) use of imaging modalities for stratification or intermediate outcomes, and (3) full pharmacokinetic and pharmacodynamic characterization of drug candidates in injured brain and cerebrospinal fluid to identify therapeutic doses and dosing regimens. It is expected that Offerors will have established processes and demonstrated experience in overcoming challenges in regulated clinical trials of moderate to severe TBI such as obtaining informed consent in severely brain injured participants, recruitment and retention of severely injured participants.
- **Product Development Strategy:** The Proposal shall recommend an overall TBI drug product development strategy that includes regulatory, clinical development, manufacturing and commercialization plan.
- **Project Management Plan (PMP):** The Proposal shall provide a comprehensive cost and schedule PMP including, but not limited to: a TBI drug product developmental timeline, risk mitigation strategies for schedule and cost deviations, roles and responsibilities of the TBI CC management team members, describe the roles and responsibilities of the CRO, and methods to ensure proper quality oversight of subcontractors and industry partners to ensure reaching the Milestones and Deliverables. Since the specific TBI drugs have not been selected for evaluation by the TBI CC at the time of proposal submission, describe the strategies and rationale from a high-level perspective. Describe how the PMP documents will be updated throughout the DTTBI MTEC award delivery schedule.
- **Restrictions on Human Subjects:** The Technical Proposals shall comply with restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data. The TBI CC shall ensure local Institutional Review Board (IRB) approval, continuing review (in the intervals specified by the local IRB, but at a minimum, annually), and approval by the U.S. Army Human Research Protections Office (HRPO). Offerors shall include IRB and HRPO review and approval in the SOW/Milestones Table submitted with the technical proposal.
- **Data Sharing:** The DoD will provide oversight and negotiate for the DoD interests for maximal data sharing in the spirit of sharing lessons learned across the breadth of the award. In other words, the Awardee(s) will be expected to share data for subsequent

analysis and follow on questions with the DoD in a manner that helps enable a successful outcome at the end of the award's delivery schedule. The proposal shall describe the necessary relationships with industry partners, including non-disclosure agreements, intellectual property agreements, and data rights and standardized informed consent for the intent of maximizing biospecimens and data use throughout the life cycle of the DTTBI award. Describe the data curation methods, policies and associated framework that will be used to manage data and maximize use among DTTBI and TBI stakeholders (such as FITBIR and InTBIR policy and guidelines).

#### **4.3 Preparation of the Proposal**

The proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (MTEC-18-03-DTTBI). 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. Offerors are encouraged to contact the MTEC POC identified herein with any questions so that all aspects are clearly understood by both parties. The full proposal shall include the following:

- **Technical Proposal submission:** one signed Technical Proposal (.pdf, .doc or .docx). The Technical Proposal must include the requested information in the format provided in the PPG and any additional information outlined in Section 4.2.
- **Statement of Work/Milestone Payment/Delivery Schedule:** one Word file (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone based Delivery/Payment Schedule to achieve the objectives and deliverables using the format provided herein (Attachment A). The DoD reserves the right to negotiate and revise any or all parts of SOW/Milestone Delivery/Payment Schedule. Offerors will have the opportunity to concur with revised SOW/Milestone Delivery/Payment Schedule, as necessary.
- **Cost Proposal submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (see Attachment 1 of the PPG) required. Separately, Section II: Cost Proposal Formats either in Excel (.xlsx or .xls) or PDF format is required.
- **Warranties and Representations:** One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.
- **Royalty Payment Agreement or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Research Project Award Assessment Fee **or** the Royalty Payment Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.



*Evaluation:* The DoD will evaluate and determine which proposal(s) to award based on the criteria described in **Section 5, "Selection"** of this RPP. The DoD reserves the right to negotiate with Offerors.

#### **4.4 Cost Proposal**

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

The Cost Proposal should reflect the approach described in the Technical Proposal including the Milestones and Deliverables outlined in the SOW.

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.

#### **4.5 Proposal Preparation Costs**

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

#### **4.6 Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use**

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 DoD 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.

## **5 Selection**

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The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. Proposals 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"> <li>• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>• Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent</li> <li>• Offeror provides at least one third of the total project cost as acceptable cost share</li> </ul>
FAIL	<p>Offeror proposing an MTEC research project does <b>NOT</b> meet any of the following:</p> <ul style="list-style-type: none"> <li>• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>• Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent</li> <li>• Offeror provides at least one third of the total project cost as acceptable cost share</li> </ul>

Following the preliminary screening, the DoD sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed below. The DoD will conduct an evaluation of all qualified proposals. The DoD Evaluation Panel may:

1. *Select the proposal (or some portion of the proposal) for award*
2. *Place the proposal in the Basket if funding currently is unavailable; or*
3. *Reject the proposal (will not be placed in the Basket)*

### 5.1 Proposal Evaluation Process

Qualified applications will be evaluated by a panel of subject matter experts who will make recommendations to a Source Selection Authority appointed by DoD.

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the DoD will employ non-disclosure-agreements to protect information contained in the RPP as outlined in Section 2.3.

Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. 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 in this RPP. The Offeror shall clearly state how it intends to meet the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The evaluation factors and evaluation criteria are described below.

## 5.2 Evaluation Factors

Evaluation factors are listed in descending order of importance:

Factor 1: Technical Approach

Factor 2: Management Approach

Factor 3: Potential for Transition and Commercialization

Factor 4: Cost/Price

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 Technical Approach, Management Approach, and Potential for Transition and Commercialization factors.

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.

### 5.3 Evaluation Factor 1. Technical Approach

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

The Offeror's proposed solution will be assessed for the likelihood of successfully achieving the objective of DTTBI as defined in Section 4.2 above. The likelihood of success will be determined by considering the soundness and clarity of the technical approach. The proposal should provide a succinct approach for achieving the project's objectives and will be evaluated for:

- a) A specific listing by site name of the TBI CC's clinical trial executions sites, facilities and resources, and historical data to meet the technical requirements and objective.
- b) Demonstrated experience of TBI CC and its centralized POC in a way that maximizes the DoD investment.
- c) The rationale and criteria used for TBI candidate drug selection that will be finalized with the DoD after award.
- d) Demonstrated CRO team of qualified, experienced and knowledgeable staff, with the unique technical and management expertise to carry out the SOW.
- e) Rationale and strategies of Clinical Trial protocols specific to the DTTBI objectives.

### Evaluation Factor 2. Management Approach

The Management Approach factor will be evaluated using the merit rating as shown in Table 2.

The Management Approach factor will be evaluated for the degree to which the Offeror's Proposal demonstrates:

- a) Clearly identified strategy and plan to execute the technical requirements to proposed milestone schedule.
- b) A project management plan that describes an explanation of the duties of the CRO, implementation of clinical monitoring, data collection, quality assurance.
- c) A comprehensive data sharing plan among partners of the TBI CC and DoD that will leverage lessons learned throughout the course of the award.

**Evaluation Factor 3: Potential for Transition and Commercialization.**

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:

- a) Offeror's ability to develop partnerships with drug product sponsors/industry partners.
- b) Offerors ability to create product development plan, including commercialization strategy.

**Evaluation Factor 4. Cost/Price**

The Cost/Price Factor will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

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 (including cost share and levels of effort of proposed personnel). The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. 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, 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 DoD. The DoD will then review this assessment and make the final determination that the negotiated project value is fair and reasonable. [Note, the DoD budget and expected delivery period is described in section 2 Administrative Overview above.]

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

- a) **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 SOW and Milestone Payment/Delivery Schedule proposal.

Estimates are considered "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 may 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.

- b) **Reasonableness.** The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be considered reasonable, it must represent a price to the DoD 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 and 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.

- c) **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.

The Offeror's 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 therefore rendering the proposal ineligible for award.

#### **5.4 Review and Selection**

Proposals that are in compliance with the requirements of the RPP will be evaluated in accordance with the merit based, competitive procedures based on the criteria stated above. The DoD reserves the right to negotiate and request changes to any or all parts of the SOW. Offerors will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

#### **5.5 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 DoD 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 DoD 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 DoD requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

## **6 Points-of-Contact**

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

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

## **7 Acronyms/Abbreviations**

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AB                      Advisory Board

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ATI	Advanced Technology International
CAS	Cost Accounting Standards
CC	Clinical Consortium
CDC	Centers for Disease Control and Prevention
CDD	Capability Development Document
CDP	Clinical Development Plan
cGMP	Current Good Manufacturing Practice
CM	Consortium Manager
CMA	Consortium Member Agreement
CRO	Clinical Research Organization
DoD	U.S. Department of Defense
DTTBI	Drug Treatment for Traumatic Brain Injury
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
HRPO	Human Research Protections Office
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
M	Millions
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NPH	Neurotrauma and Psychological Health
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
ORP	Office of Research Protections, USAMRMC
OV	Operational View
PDP	Product Development Plan
PK/PD	Pharmacokinetics/pharmacodynamics
PMO	Program Management Office
PMP	Program Management Plan
POC	Point of Contact
POP	Period of Performance/Delivery Schedule
pOTA	Prototype Other Transaction Agreement
PPG	Proposal Preparation Guide
QCP	Quality Control Plan
RPP	Request for Project Proposals
RMP	Risk Management Plan
SOTR	Sponsor's Office Technical Representative



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SOW	Statement of Work
TBI	Traumatic Brain Injury
TBI CC	Traumatic Brain Injury Clinical Consortium
TRL	Technology Readiness Level
USAMRMC	U.S. Army Medical Research and Materiel Command
USAMMDA	U.S. Army Medical Materiel Development Activity
USG	U.S. Government, specifically the DoD

## **Attachment A: Statement of Work (SOW)**

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The SOW developed by the Lead MTEC member organization is intended to be incorporated into a binding agreement if the Proposal 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. **The content of the SOW should tightly align with and mirror the Technical Proposal, Milestone Payment/Delivery Schedule, and Cost Proposal.**

### **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 DoD 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 DoD 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.

**Applicable Documents** (*To be determined by the DoD based on negotiation of Scope/Project Objective*)

In the event only specific requirements of these documents must be included in the SOW then only these excerpts should be used and should be made into either a clear task statement (if required) or a clear reference statement (if for guidance only and not for contract compliance).

**Requirements** (*To be provided initially by the Offeror at the time of submission to be finalized by the DoD 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 DoD 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 DoD 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 DoD (to the SOTR designated in the SOTR appointment letter) 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.

**Shipping:** The Consortium shall use appropriate, cGMP-compliant refrigerated shipping carriers for drug product shipments (FedEx, World Courier, or similar, as agreed to by the SOTR), and appropriate shipping methods for all other materials, equipment, and hard copy documents. In the United States, the Consortium shall use the US Postal Service standard delivery for delivery of all such shipments.

**DoD Acceptance Period:** The SOTR and/or NPH shall review draft deliverables and make comments. The SOTR will have the right to reject or require correction of any deficiencies found in the deliverables that are contrary to the information contained in the Consortium's accepted proposal. In the event of a rejected deliverable, the Consortium will be notified in writing by the SOTR of the specific reasons for rejection. The Consortium shall have five (5) business days to correct the rejected deliverable and return it per delivery instructions.

The following deliverables/information is required:

- **Deliverable 1: Project Management Plan (PMP).** The TBI CC shall provide a revised PMP with a program schedule for DoD review with any changes to the PMP submitted with the proposal. The plan shall be used to manage, track and evaluate the Consortium's performance. The PMP shall consist of control policies and procedures in accordance with standard industry practices for project administration, execution and tracking. A Quality Control Plan (QCP) shall document how the TBI CC will meet and comply with the quality standards established in its proposal. The TBI CC shall develop and maintain a Risk Management Plan (RMP) that highlights potential risks that may arise during the life of the contract, their impact on cost, schedule and performance, and an appropriate mitigation plan. This plan should reference relevant Statement of Work sections, where appropriate. This PMP shall represent how the TBI CC plans to accomplish the entire work scope of this award.

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- Deliverable 2: Spend Plan. The Consortium shall provide a Spend Plan which details how they expect to incur and invoice for costs against the contract. The Spend Plan shall mirror the Milestone Payment/Delivery Schedule and in addition, include detailed costs to be incurred monthly by fiscal year (1 October – 30 September) through the Award Milestones and Deliverables, starting with the award date. The Spend Plan total shall match with the total costs proposed for the entire award in the Cost/Pricing Sheet. The Spend Plan shall be updated as necessary throughout the duration of the project/award. The TBI CC shall report actual progress against the Spend Plan in the Quarterly Progress Report (i.e., Quarterly Technical and Business Status Reports).
- Deliverable 3: Clinical Development Plan (CDP). The CDP describes the goals and objectives of the clinical program for Phase 2 studies to fully characterize chosen TBI drug candidates. This plan shall include, but is not limited to: background; scientific summary; target population; pharmacokinetics/pharmacodynamics (PK/PD); mechanism of action; side-effects; a list of any/all clinical studies planned or completed including any objectives/endpoints; statistical analysis plan; letters of reference; rights of reference; and a schedule of deadlines for milestones and decision making (go/no-go); and any associated risks.
- Deliverable 4: Regulatory Development Plan. The Consortium shall provide a plan that describes the specific steps and actions required to meet the regulatory objective defined in the target product profile or equivalent.
- Deliverable 5: FDA Interactions. The Consortium shall provide copies of the plan and processes that will ensure the DoD has visibility and input on all FDA communications regarding the pharmaceutical under development for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections and enforcement documentation, Data Safety Monitoring Board reports, and registration and listing. Refer to Data Item Description, DI-TCSP-82040.
- Deliverable 6: Product Development Plan (PDP). The Consortium shall provide a PDP that includes, but is not limited to: the manufacture, quality control testing, and cold chain management of the product under development, the commercial transition, marketing analysis, strategy, and plan to demonstrate commercial uses and viability of the product under development, and estimated cost to manufacture and unit price based on projected manufacturing quantities (e.g., 10,000, 100,000, 1,000,000, 10,000,000 units, etc.).
- Deliverable 7: Clinical Study Protocol. The Consortium shall provide the clinical study protocol(s) and related documents including, but not limited to, the statistical analysis plan, informed consent, Investigators Brochure, source documents, study procedures

manual, study specific procedures, pharmacy manual, FDA Form 1572, clinical trial agreement(s), and transfer of regulatory obligations documentation (FDA Form 1571 listing the obligations transferred). The Consortium shall also provide a Trial Master File structure before the initiation of clinical study. The Consortium shall provide the above documents in ICH eCTD format.

- Deliverable 8: Interim Analysis Report. The Consortium shall provide an interim analysis report for the Phase 2 clinical study that includes, but is not limited to information on the clinical study progress, results, analysis, and preliminary conclusions. The interim analysis period should be designed in the Phase 2 clinical study protocol.
- Deliverable 9: Clinical Study Report. The Consortium shall provide a clinical study report that includes, but is not limited to, the clinical study design, results, statistical analysis, discussions, and conclusions. The Consortium shall submit the report in ICH eCTD format as required.
- Deliverable 10: Recommendation Report shall submitted for each TBI drug candidate at the conclusion of its Phase 2 testing. Data analysis, lessons learned, and overall recommendation per drug shall be included. Further Phase 2 testing, recommendation for down select, and other regulatory and commercialization pros and cons shall be discussed within the Recommendation.
- Deliverable 11: Annual Product Review. The Consortium shall participate in an Annual Product Review in-person meeting with the US DoD either at Fort Detrick, MD or at the Consortium site to review progress and discuss technical issues.
- Deliverable 12: Non-Disclosure/Non-Use Agreement. The Consortium shall sign and submit Non-Disclosure Statement(s) among members and shall also ensure that all staff including all subcontractors and consultants performing on any task/delivery order execute and adhere to the terms of the non-disclosure statement, protecting the procurement sensitive information of the DoD and the proprietary information of other Consortium Awardees.

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

The Milestone 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 awards, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the

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milestone payment/delivery 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 costs incurred and will not have to match exactly to the amounts listed on the milestone payment/delivery 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 25th of Jan, Apr, Jul, and Oct (for prior quarter activity), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

Milestone/ Delivery No.	SOW Task Number	Significant Event/Accomplishments/ Deliverables	Due Date	Total Program Funds	Total Cost Share	Total Project
1						
2						
3						
N						
<b>Total</b>						

**Shipping Provisions** *(The following information, if applicable to the negotiated SOW, will be finalized by the DoD 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 DoD based on negotiation)*

- When applicable (see Additional Expectations of Awardees) the TBI CC shall provide Summary Report(s) within three (3) working days of events that will cause more than a four (4) week delay in schedule or an increase in
- Quarterly Reports – The MTEC research project awardee shall prepare 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. Quarterly

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Reports shall be submitted by the 25th calendar day following prior calendar quarter close based on the following schedule. (Required)

<b>Report Months</b>	<b>Due Date</b>
January – March	25 April
April - June	25 July
July - September	25 October
October - December	25 January

- Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose delivery schedules 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 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, the TBI CC will submit a Final Business Status Report, which will provide summarized details of the resource status of the Award, in accordance with the terms and conditions of the Base Agreement. (Required)
-