

## **APPLICATION "MTEC Prototype Acceleration Bridge Loans"**

Issued by the:
Medical Technology Enterprise Consortium (MTEC)
315 Sigma Drive
Summerville, SC 29486

Request Issue Date: November 12, 2024

Note: The BIDS system will open for submissions no later than November 22, 2024. Applications will be evaluated on a rolling basis. If all available funds are disbursed, the application submission portal will close and no further applications will be accepted.

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#### **1** Executive Summary

#### 1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Department of Defense U.S. Army Medical Research and Development Command 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 and follow-on production.

MTEC is 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 MTEC website (www.mtec-sc.org).

#### 1.2. Purpose

This application, issued by MTEC, represents a new MTEC Prototype Acceleration Funding mechanism to provide bridge loans:

- **Objective** To "de-risk" technology advancement toward a military application to a point that allows the MTEC member to secure follow-on funding
- **Funding Available** \$50,000 100,000 per loan (loan amount is negotiable on a case-by-case basis dependent on Applicant's need).
- Award Type Promissory Note (also referred to as a "Bridge Loan")
- Scope of Work Tasks technical and business in nature
- Process Stage 1: Application, Stage 2: Final Approval and Disbursement of Funds

#### 2 Administrative Overview

#### 2.1. Process

This MTEC Prototype Acceleration Bridge Loan process will be conducted using the following approach.

• Stage 1 [Application]: Current MTEC members are invited to submit applications according to the instructions outlined in Section 4.2. The MTEC staff will evaluate applications submitted and will select the applications that best meet the criteria in Section 5. Evaluations are expected to be conducted on a first-in, first-out basis.

Therefore, we highly encourage Applicants to submit as soon as possible during the open submission period. Bridge loans will be issued on a rolling basis. Evaluations will be conducted individually on a submission-by-submission basis. MTEC reserves the right to request additional information or a virtual meeting with select Applicants to inform a final decision.

• Stage 2 [Final Approval and Disbursement of Funds]: Applicants recommended for funding will advance into negotiations of the terms of the promissory note, final approval and disbursement of funds.

#### 2.2. Information Session

An Information Session will be conducted via virtual webinar format to provide potential Applicants the opportunity to interact directly with MTEC related to this specific funding opportunity. The flow of the Information Session will be as follows. First, MTEC will provide an overview of this opportunity. Then, all attendees are invited to anonymously type in questions into the webinar's chat function, which are answered verbally and live by the appropriate presenter from MTEC. We highly encourage anyone interested in this funding opportunity to listen in and/or ask questions. Please register for the MTEC Bridge Loans Information Session to be held December 1:00 PM ET on 2024 at: https://ati.zoomgov.com/webinar/register/WN O7Ob-LjtQPiMDIVcACpg3w

Applicants are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions responses.

#### 2.3. Funding Availability and Type of Funding Instrument Issued

It is suggested that the maximum request for each bridge loan not exceed \$50,000 - 100,000; however, MTEC is willing to negotiate higher amounts on a case-by-case basis based on the Applicant's need. MTEC anticipates that several bridge loans will be made to qualified Applicants. [NOTE: MTEC will be the sole funder of the bridge loans resulting from this application process. Therefore, bridge loans will be technically and financially managed by MTEC professional staff. The Government will <u>not</u> provide funding in support of this program.]

Bridge loans will be provided in the form of a promissory note. Refer to Section 9 for a full description of the terms of the promissory note. Below is a summary of the terms:

- All financing is advanced upon full execution of the promissory note
- Borrower is required to use capital in accordance with their proposed scope statement not to exceed a 12-month period, unless permission is granted by the MTEC Chief Science Officer
- Payback to MTEC is due no later than 24 months from receipt of the promissory note, but earlier re-payment is encouraged
- Annual interest rate of 4%
- Final negotiated scope statement for use of funds will be included with the promissory note as an attachment.

If selected for a bridge loan, Borrowers will be required to:

- Participate in monthly meetings with MTEC until full repayment of the bridge loan
- Provide a written report:
  - At the end of the proposed scope statement
  - 12 months after issuance of the bridge loan
  - Upon total repayment of the bridge loan

#### 2.4. Proprietary Information

MTEC will oversee submission of applications, 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 Applicant's application and the subsequent agreement administration if the application is selected for a bridge loan. Please mark all Confidential or Proprietary Information as such. An Applicant's submission of an application indicates concurrence for MTEC staff to evaluate all information included in the proposal submission. MTEC Officers and other staff granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest statements.

#### 2.5. Expected Bridge Loan Issuance Date

The timeline to bridge loan issuance will vary depending on the number and quality of applications. Applicants who are selected to advance into Stage 2 of the process can expect to receive final approval and disbursement of funds within 15 business days after execution of the promissory note and acceptance of related project terms.

#### 2.6. Anticipated Selection Notification

As the basis of selections is completed, MTEC staff will notify Applicants by email.

#### 3 Technical Requirements

#### 3.1. Background

MTEC is continuing the implementation of our prototype acceleration funding opportunity and commercialization grant programs under this new "Prototype Acceleration Bridge Loan" program. This provides an opportunity to de-risk medical technology development by MTEC members in order to advance their readiness to secure follow-on funding. In other words, the Prototype Acceleration program will provide MTEC funding to "bridge" the technology maturation to a point where the MTEC member is able to secure follow-on funding. Follow-on funding is broadly defined to include both private and public sources of funding received after initiation of the work funded by this Prototype Acceleration Bridge Loan. The Applicant is required to provide a well-defined strategy for obtaining follow-on funding to include repayment. The Applicant is encouraged to provide letters of support from potential follow-on funders.

Applications shall focus on providing medical solutions to support readiness and care in future battlefield scenarios in support of the areas listed at <a href="https://mtec-sc.org/whatwedo/">https://mtec-sc.org/whatwedo/</a>. It is encouraged that potential Applicants reach out to the Point of Contact listed in Section 6 to determine whether your proposed technology has military relevance, aligns with the mission of MTEC, and is within scope for this program.

#### 3.2. Eligibility Criterion

The Applicant must be an MTEC member of good standing at the time of proposal submission.

#### 3.3. Use of Funds

The use of funds should focus on tasks that advance the technology and/or commercial readiness of the organization to the next major milestone that helps secure follow-on funding and should be based on the maturity of the technology and/or organization at the time of submission. **Examples** include **but are not limited to**:

- Refine/mature prototype towards clinical product
- Conduct military-relevant testing (e.g., ruggedization for operation in military environments, prototype demonstrations in a relevant or operational environment (live or simulated))
- Conduct stability and shelf-life studies
- Conduct nonclinical and preclinical studies required for the technical data package for a regulatory application
- Establish Good Manufacturing Practices for clinical trials and for market release
- Prepare regulatory package (e.g., clinical trial protocol development, Investigational New Drug application, Investigational Device Exemption application), including regulatory consultant costs.
- Conduct clinical studies (as needed) to support regulatory approval/clearance
- Establish a robust quality system
- Improve the efficiency and reproducibility of manufacturing process for scale up
- Work towards clearance/approval by the U.S. Food and Drug Administration
- Integrate medical informatics system components, evaluate system in a simulated environment, and/or develop interfaces to supporting systems
- Conduct initial production runs; first article testing, etc.
- Execute a competitive landscape analysis/ market research
- Evaluate intellectual property protection and valuation
- Develop a regulatory and reimbursement strategy
- Develop a market access strategy

#### 3.5. Restrictions on Animal and Human Subjects

Applications must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Borrower shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, and continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually). IACUC and IRB approvals MUST be in place prior to the initiation of work using animal or human subjects.

#### 4 Application Preparation and Process

#### 4.1. Application Submission

Applications shall be submitted by the date and time specified on the cover page using BIDS: <a href="https://submissions2.ati.org/ATI2/Portal.nsf/Start?ReadForm">https://submissions2.ati.org/ATI2/Portal.nsf/Start?ReadForm</a>. Include the MTEC-BridgeLoans Solicitation Number on each application submitted. The BIDS system will open for submissions no later than November 22, 2025. Include the MTEC Solicitation Number (MTEC-BridgeLoans) on each Application submitted. See Section 10 for further information regarding BIDS registration and submission. An automated BIDS receipt confirmation will be provided by email.

#### 4.2. Instructions for the Preparation of the Stage 1 Application

Applicants submitting applications will be required to submit using the following steps outlined below:

#### Stage 1: Applications

#### Required Submission Documents (7): Submitted via BIDS

- Pitch Deck: One PDF document 5 MB or lower. Applicants are strongly encouraged to follow the 11-slide format of the pitch deck. [Suggested template can be found here: <u>Solicitations - MTEC | Medical Technology Enterprise Consortium</u>] Please feel free to use your own template and style but follow the 11-slide format. Additional Back-up slides, labeled as such, containing relevant information can be included in your Pitch Deck.]
- 2. **Pitch Deck Supplement:** One PDF document 5MB or lower [Required template is provided in Section 8.]
- 3. Letter(s) of Support: One Word or PDF document 5MB or lower. If submitting multiple letters of support, then please consolidate all into one document. Letters of support from potential follow-on funders are highly encouraged. If you have no letters of support, please upload a document that states, "We are not including letters of support with our proposal."
- 4. **Scope Statement and Milestone Summary:** One PDF document 5 MB or lower. [Required template can be found here: <u>Solicitations MTEC | Medical Technology Enterprise Consortium</u>]

- Borrower Responsibility Questionnaire: One PDF document 5 MB or lower. [Required template can be found here: <u>Solicitations MTEC | Medical Technology Enterprise Consortium</u>]
- 6. **Financial Statements (Actuals):** One document 5 MB or lower that includes the Applicant's most recent 3-year actual financial statements (i.e., 2021, 2022, 2023).
- 7. **Financial Statements (Pro forma):** One excel document 5 MB or lower that contains the estimated financial statements for 2024 and the financial plan/budget for the next two years (2025 and 2026).

Applicants should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated above. 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.

At the conclusion of the Stage 1 evaluation, Applicants who are favorably evaluated will be approved for the loan and invited into Stage 2, which includes negotiations, final approval of the promissory note, and disbursement of funds.

#### 5 Selection

#### 5.1. General Information

Evaluations at all stages of this process shall be based on an independent, comprehensive review and assessment of the application against stated evaluation factors. The process may involve the use of contractors as subject matter expert consultants or reviewers. Where appropriate, MTEC will employ NDAs to protect information contained in submissions. MTEC reserves the right to negotiate with Applicants.

#### 5.2. Application (Stage 1) - Selection and Evaluation Process

MTEC will conduct a preliminary screening of submitted applications to ensure compliance with the requirements of this program. As part of the preliminary screening process, applications that do not meet the following mandatory requirements may be eliminated from the competition or additional information may be requested. The following will be assessed as part of the Preliminary Screening process:

- <u>MTEC Membership Status:</u> The Applicant must be a MTEC member of good standing at the time of proposal submission.
- <u>Formatting:</u> The application submission documents follow the required formatting and page limitations.

Qualified applications will then be evaluated by an MTEC evaluation panel, who will make recommendations regarding invitation to Stage 2. Feedback will NOT be provided to the Applicants.

#### **Stage 1 - Evaluation Factors (of descending importance):**

- 1. Financial Maturity
- 2. Technical Merit and Commercial Readiness

**Evaluation Factor 1 – Financial Maturity:** The Applicant's application will be assessed for the:

- Degree to which the Applicant will be able to repay the funds according to the terms described within this RPP.
- Alignment of the proposed use of funds with this RPP.
- Ability of the Applicant to demonstrate funding to-date, describe their current funding challenges, and demonstrate fundability going forward, particularly likelihood of receiving funding from follow-on funders if milestones proposed are achieved.
- Financial viability as determined by a risk assessment and stability review (questionnaire available upon request)

**Evaluation Factor 2 – Technical Merit and Commercial Readiness:** The Applicant's application will be assessed for the extent at which the following are satisfied:

- The degree to which the Applicant presents a medical technology in alignment with MTEC's mission to improve military readiness and health.
- The degree to which the Applicant presents a proprietary medical technology with strong supporting preliminary data and a competitive advantage.
- Likelihood of achieving and advancing through the development milestones identified in its proposal, thus advancing the Applicant's commercialization readiness. Information that will be assessed includes team, intellectual property, market opportunity, reimbursement, regulatory strategies, etc.

#### 5.3. Final Approval and Disbursement of Funds (Stage 2)

Applicants invited to Stage 2 will then be invited to engage in negotiations with MTEC for final approval of the promissory note's terms and disbursement of funds.

#### 6 Point-of-Contact

For inquiries, please direct your correspondence to the MTEC Chief Science Officer, Dr. Lauren Palestrini, Ph.D., <a href="mailto:lauren.palestrini@mtec-sc.org">lauren.palestrini@mtec-sc.org</a>

#### 7 Acronyms/Abbreviations

BIDS System for Submission of the Proposal IACUC Institutional Animal Care and Use Committee

IRB Institutional Review Board

MTEC Medical Technology Enterprise Consortium

NDA Nondisclosure Agreement

OCI Organizational Conflict of Interest

POC Point-of-Contact

PPG Proposal Preparation Guide

#### **8** Pitch Deck Supplement Template

#### [NOTE: 3-page limit]

#### **Contact Information**

- Organization Name
- Organization website
- In what city and state is your organization headquartered?
- POC: first and last name
- POC: email address
- POC: LinkedIn url, professional website, or other link with bio

#### **Problem and Solution**

- Briefly describe the clinical need.
- Describe the value proposition of your product and clearly articulate your competitive advantage over already existing solutions and other solutions in development by others in the field.
- What stage is your product [early concept, pre-clinical, clinical, approval, or sales]?
- Describe the product including relevant data and milestones/deliverables accomplished to date.
- Share a link to a demo of your product (if available).
- Include an image of your current prototype.

#### Market and Business Model:

 Clearly articulate the market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.

#### Financial Maturity

- Describe your current funding challenges and your need for this "bridge" funding.
- How much non-dilutive funding have you raised to date? Include the sources of funding.
- How much dilutive funding have you raised to date? Include the sources of funding.
- Demonstrate fundability going forward and plans for repayment of the loan.

- If available and highly encouraged, provide a letter(s) of support for potential follow-on funding by a third party
- Identify which investors you have spoken with. Include what those investors provided as feedback, in other words, briefly describe what they recommended should be done next.

#### The Ask

- Total funding requested [maximum allowable request is \$100,000].
- Describe your proposed use of the requested funds.

#### 9 Terms of the MTEC Promissory Note

#### **PROMISSORY NOTE**

or before		, 2026, with	out notice	·.]					
[All Principal	and accru	ued interest o	n this Pron	nissory N	ote shall be	due and	payable	in full o	n
principal bala	ince herei	under, at an ar	inual intere	est rate of	f 4%.				
	(th	ne "Principal") <i>,</i>	together v	with inter	est compute	ed daily o	n the ou	tstandir	ιg
Consortium	(MTEC)	(hereinafter	referred	to as	"Holder") <i>,</i>	the pi	rincipal	sum (	of
referred to	as "Make	r"), promises	to pay to	the ord	ler of Medi	cal Tech	nology E	nterpris	se
FOR VALUE F	RECEIVED,	[RECIPIENT NA	AME], a [D	elaware]	[limited liab	ility com	pany] (he	ereinaft	er
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Maker may pre-pay the Principal on this Promissory Note, together with accrued interest, if any, as set forth herein. Payment of Principal on this Promissory Note, together with accrued interest, if any, shall be made to Holder at 315 Sigma Drive, Summerville, SC 29486 or at such other place as Holder may from time to time designate in writing.

If Maker shall default on a payment required hereunder on the date when due, and shall fail to cure such default within five (5) business days after receipt of written demand for cure by Holder, or if Maker shall file a voluntary petition in bankruptcy, be adjudicated as a bankrupt or insolvent, file any petition or answer seeking or acquiescing in any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief for Maker under any United States, state or other statute relating to bankruptcy, insolvency or other similar relief for debtors, or shall seek, consent to or acquiesce in the appointment of any trustee, receiver or liquidator of Maker or of all or any substantial part of the assets of Maker, or shall make a general assignment for the benefit of creditors, or shall admit in writing the inability to pay debts generally as they become due, and Maker shall fail to negate the effect of any such action or proceeding not initiated by Maker (whether by dismissal of proceedings, discharge of trustees or receiver or otherwise) within thirty (30) days from and after the occurrence thereof, then Holder, at Holder's option, shall be entitled to accelerate any and all of the indebtedness evidenced by this

Promissory Note and the same shall become immediately due and payable, and to exercise cumulatively all other rights and privileges provided by law.

Maker acknowledges that Holder is extending this Promissory Note to finance its prototype development in [INSERT TECHNOLOGY OR PROJECT DESCRIPTION]. The objective of Holder's financing is to "de-risk" medical technology development in order to advance readiness for commercialization and follow-on investment. Maker has submitted a Prototype Acceleration proposal that defines the technology development to be financed by this Promissory Note. The Scope Statement and Milestone Summary for the financed Prototype Acceleration effort is herein incorporated as Attachment A. In the event that Maker fails to meet technical objectives outlined in the Scope Statement and Milestone Summary, as determined solely by Holder's Chief Science Officer, then Holder, at Holder's option, shall be entitled to accelerate any and all of the indebtedness evidenced by this Promissory Note and the same shall become immediately due and payable, and to exercise cumulatively all other rights and privileges provided by law.

Time is of the essence with respect to this Promissory Note, and except as otherwise provided herein, demand, protest, notice of demand and non-payment and all other notices whatsoever, are hereby waived by Maker. Should this Promissory Note be collected by or through an attorney-at-law, Holder shall be entitled to collect reasonable attorneys' fees and all other reasonable costs and expenses of collection from Maker.

If delivered personally, the date on which a notice or demand hereunder is delivered shall be the date of receipt or delivery, and if delivered by mail, such notice or demand shall be sent by registered or certified mail, return receipt requested, postage prepaid, and the date on which such notice or demand is received (as evidenced by the registered or certified mail receipt) shall be the date of delivery. In the event any notice or demand is mailed to a party in accordance with this paragraph and is returned to the sender as undeliverable, then such notice or demand shall be deemed to have been delivered or received on the fifth day following the deposit of such notice or demand in the United States mail. Notices and demands made hereunder shall be addressed to Holder at its address set forth hereinabove (or at such other address as Holder may time to time designate in writing) and to Maker . If delivered electronically, the date on which a notice or demand hereunder is sent shall be the date of receipt or delivery. The electronic notice or demand must be sent via electronic mail, delivered to the Maker's representative as evidenced by prior electronic communications.

This Promissory Note shall be governed by and construed in accordance with the laws of South Carolina. This Note shall not be assigned by either party without the consent of the other party.

IN WITNESS WHEREOF, Maker has executed this Promissory Note on the day and year first above written.

[NAME]	
Ву:	
Name:	
Title:	

10 BIDS Registration and Application Submission Instructions

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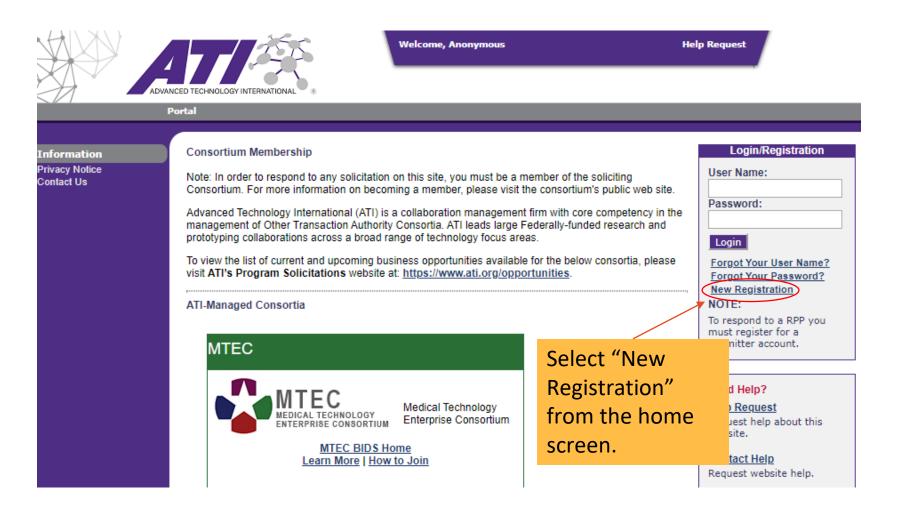
# MTEC BIDS REGISTRATION

**MTEC BIDS URL:** 

HTTPS://ATI2.ACQCENTER.COM

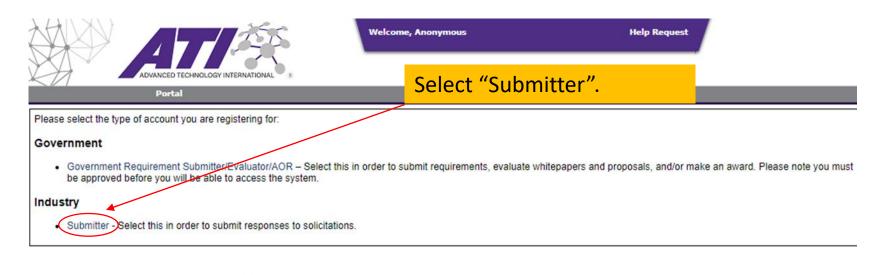


#### Navigate to the MTEC BIDS website and select "New Registration"





#### Select "Submitter"



SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.



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Complete the registration form. Be sure to select how you want to receive the dual factor verification code (SMS text message is recommended).

Extn. Fax Number:	How to receive dual factor authentication.
* Email Address:  * Email Confirmation:  * Contractor Status:  Cell Number:	Enter a cell number in order to be able to receive passcodes via SMS. Enter exactly 10 digits without any punctuation.
Preferred Code Delivery Method:	Select your preferred method for receiving two-factor passcodes. If you select SMS, you must enter a cell number. You will still have the selecting either when logging in.
Website: * Programs Requested:	E-Mail     http://  What area do you belong to? Please select all that apply:
	■ MTEC
Submit Registration	Select "Submit Registration" to complete BIDS registration.



BIDS registration is instantaneous. It does not require any verification by the MTEC team. After successfully registering, you can submit an application to the MTEC Prototype Acceleration Bridge Loan program.

- MTEC Membership will be verified once an application is received.
- Updates to submitted documents can be made anytime prior to submitting your application.



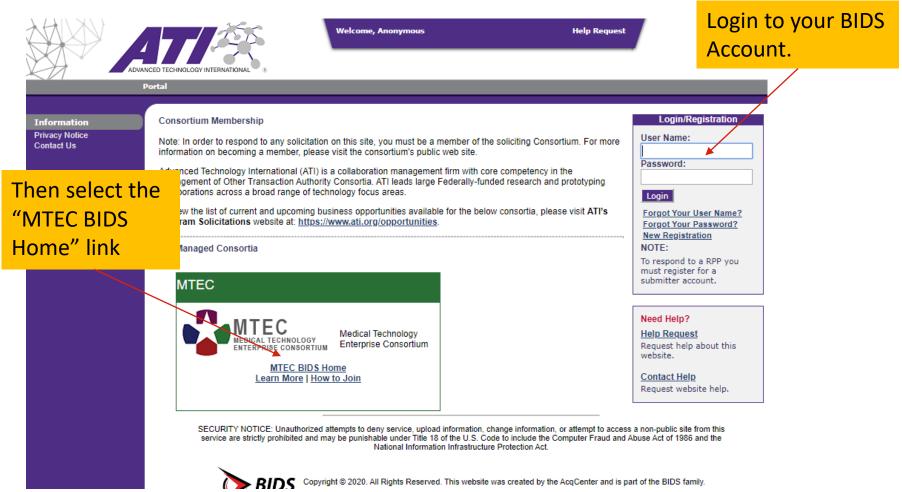
# MTEC BIDS Application Submission

MTEC BIDS URL:

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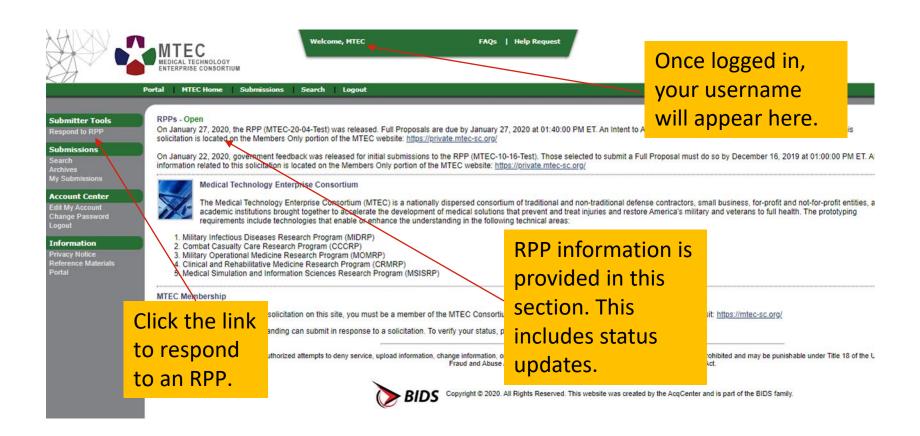


Navigate to the MTEC BIDS site and login. After login select the "MTEC BIDS Home" link.



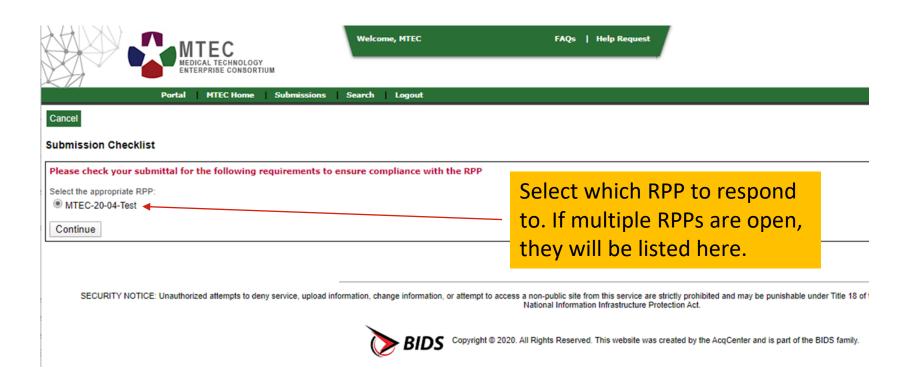


## Select the "Respond to RPP" link under the submitter tools



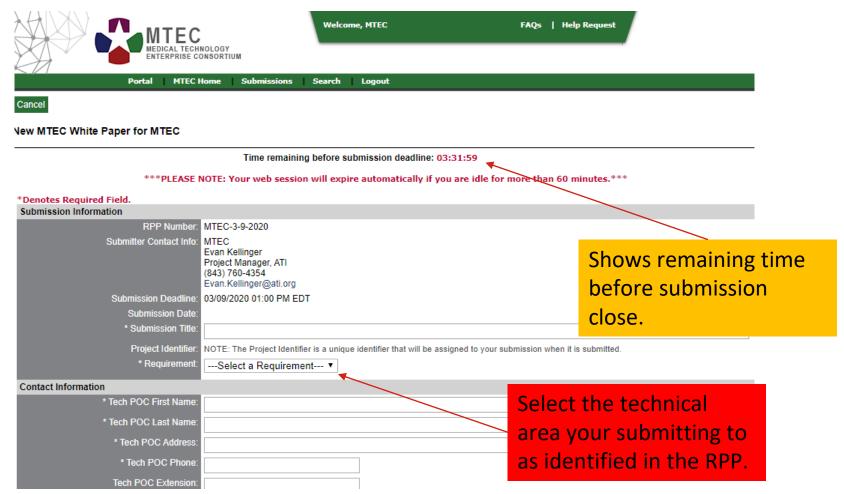


Select which RPP you will be responding to.



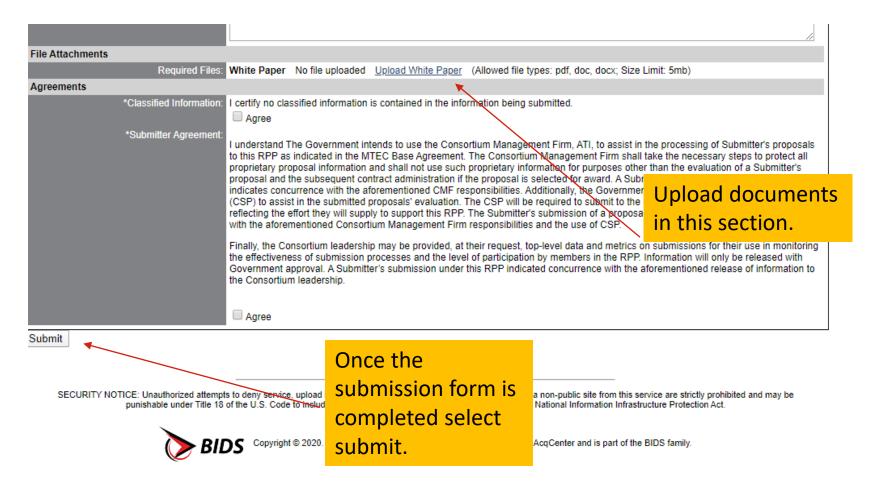


## Complete the submission form.





Complete the submission form by uploading the required documents and click submit.





Once you have successfully submitted an application, you will receive a notification with your submission number.

- Submission documents can be modified anytime prior to the due date and time from your BIDS account.
- To make changes to your submission, prior to the due date/time, select the submission link from the home page and navigate to your submission.