Request for Project Information (RPI)



RPI Number: MTEC-24-03-Dental

"Military Dental Research - Seeking New Technologies and Development Partners"

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: October 25, 2023

Project Information Paper Due Date: November 30, 2023

Noon Eastern Time

The Medical Technology Enterprise Consortium (MTEC), in support of the Naval Medical Research Command (NMRC) Naval Advanced Medical Development (NAMD) program, is excited to post this Request for Project Information (RPI) focused on surveying the current state of engineering and medical prototypes, knowledge products, and manufacturing capacity related to military dental research.

PURPOSE OF THE PROJECT INFORMATION PAPER:

This Request for Project Information (RPI) contains background material and guidance for the preparation of project information papers to the MTEC. Project information papers will be reviewed by the Sponsor and used in a manner that shapes NAMD efforts in this technology space. The results of the project information paper submission will serve as a means to assess the development landscape and potentially focus efforts that will follow.

As a note: This RPI is issued solely for information and planning purposes and does not constitute a solicitation. Neither unsolicited proposals nor any other kind of offers will be considered in response to this RPI. Responses to this notice are not offers and will not be accepted by the government to form a binding contract or agreement. Responders are solely responsible for all expenses associated with responding to this RPI. All information received in response to this RPI that is marked "Proprietary" will be handled accordingly.

FOCUS AREAS OF INTEREST:

Due to the Navy and Marine Corps' diverse warfighting capabilities, Sailors and Marines (and Joint Service members) operate in a vast array of challenging and austere environments. Their missions often require the suspension of regular oral hygiene and routine dental care which can result in the development of dental diseases and emergencies. Routine clinical dental care is necessary to maintain the resilience and readiness of the warfighter, and next generation biomedical products and solutions are required to maintain proper dental health and to treat, predict, and prevent dental diseases in challenging environments. Furthermore, combat injuries frequently result in significant damage to the oral maxillofacial region, leading to distinct consequences such as cosmetic alterations, functional impairments, and chronic orofacial pain. There is a pressing need for novel biomedical, engineering, and clinical devices and products that can effectively address these multifaceted consequences, while prioritizing long-term comprehensive care, to restore both physical and cosmetic aspects of the face and maxillofacial region. The specific focus areas of interest are as follows (not listed in order of importance):

Focus Area 1 - Evaluation of Technologies for Dental Care, Diseases, and Emergencies:
 The government is interested in technologies, devices, and methods for the prevention and treatment of dental and maxillofacial injuries and infections and orofacial pain

occurring in a military population that often operates for extended periods of time in austere/extreme environments. This includes methods to provide routine clinical dental care, predict and prevent dental diseases (though molecular and computational methods), and treat dental diseases and emergencies in operational environments. This focus area also includes products or devices to treat injuries to the oral cavity, face, and facial bones sustained during combat (e.g., mandibular fractures, stabilizing facial burns, restoring functional aspects of the face and mouth, long-term post-trauma care, etc.). Proposed technologies should be at least at a Technology Readiness Level (TRL) of 5. Interested parties are encouraged to submit information papers using the template included in **Addendum 1 of this RPI**.

- Focus Area 2 Capabilities Areas of Expertise: The government is interested in building relationships with partners to accomplish strategizing, planning, and prototype development activities for technologies that address dental care, diseases, and emergencies. These relationships would aim to translate new biomedical prototypes out of the laboratory (military or academic) setting and through the regulatory approval process, with ultimate applications for use by military dental clinicians and maxillofacial surgeons (especially the Navy and Marine Corps). Specific capabilities of interest include (but are not limited to):
 - Customization of dental care and maxillofacial surgical devices or adaptations for military use;
 - Ruggedization of maxillofacial surgical and dental care devices;
 - Manufacturing of dental care devices or materials (scale-up, initial production runs, etc.) that may include novel components such as micro- or nanoparticles and micro- or nanocapsules;
 - Investigational Device Exemption/Investigational New Drug (IDE/IND)-enabling studies required by the U.S. Food and Drug Administration (FDA) with specific indications for dental care and oral or maxillofacial surgery;
 - Conduct of clinical studies using prototypes in the areas of dental, oral, or maxillofacial restoration; or
 - Activities related to securing regulatory approval by the FDA with indications for dental care and/or maxillofacial surgery.

Project Information Papers should clearly describe expertise in each of the aforementioned areas as it relates to the dental research and combat injuries involving the maxillofacial region. Interested parties are encouraged to submit project information papers using the template included in **Addendum 2 of this RPI**.

REQUIREMENTS OF THE PROJECT INFORMATION PAPER:

The intent of this RPI is to understand respondents' interest and technology capabilities within the abovementioned focus area. MTEC is seeking input from both MTEC members and non-members via a project information paper to be considered by the government. Project information papers will be shared with the reviewers under non-disclosure agreements.

Project Information Papers may be submitted at any time during the submission period but no later than the due date and time specified on the first page of this RPI using BIDS: https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. See Addendum 3 of this RPI for further information regarding BIDS registration. MTEC membership is NOT required for submission of Project Information Paper.

MTEC:

The MTEC mission is to assist the U.S. Army Medical Research and Development Command (USAMRDC) and other government sponsors by providing cutting-edge technologies and effective materiel life cycle management to transition medical solutions to industry that protect, treat, and optimize Warfighters' health and performance across the full spectrum of military operations. MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement (OTA), Agreement No. W81XWH-15-9-0001, with the U.S. Army Medical Research Acquisition Activity (USAMRAA). MTEC is currently recruiting a broad and diverse membership that includes representatives from large businesses, small businesses, "non-traditional" government contractors, academic research institutions and not-for- profit organizations.

POINTS OF CONTACT:

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

- Technical and membership questions should be directed to the MTEC Chief Science Officer, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@ati.org
- All other questions should be directed to the MTEC Program Manager, Mr. Evan Kellinger, mtec-sc@ati.org

Addendum 1 – Focus Area 1 Project Information Template

[3-page limit. Times New Roman 11 point (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. These project information submissions will be shared with the Sponsor; therefore, all information must be **nonproprietary**. Project Information Paper should be submitted as a Word (*.doc or *.docx) document using the template provided in this RPI.]

Date: [Insert Date of Submission]

Title: [Insert descriptive title of project]

Point of Contact: [Insert name, organization, email address, phone number]

Technology: [Provide a clear description of why and how the proposed technology or project fits into the described focus area of this RPI. Describe how the technology addresses an unmet need in both military and civilian markets.]

Technology/Knowledge Readiness Level (TRL/KRL): [Please indicate the TRL/KRL stage in which the project will start as well as anticipated TRL/KRL level at project completion. NOTE: Full definitions of TRLs can be found here. More information regarding KRLs can be found <a href=here. Readiness Level at Project Start: Readiness Level at Project End:

Preliminary Data: [Summarize the preliminary data that supports the current TRL designation.]

Next Steps: [Outline development goals and objectives for the proposed technology in sufficient detail to show a clear course of action. Provide a proposed period of performance. List milestones and deliverables from the proposed work.]

Anticipated Regulatory and Commercialization Strategy: [Provide a brief description of the anticipated regulatory pathway and commercialization plans, as applicable. Include information on any previous interactions with the FDA.]

Anticipated Outcomes: [Provide a description of anticipated outcomes from the proposed work.]

Personnel: [Briefly state the qualifications of the key personnel to perform the work.]

Estimated Funding Required to Advance Project: [Please estimate the required funding needed for each major task that advances the project into its next stage of development/milestone dependent upon its current maturity. Examples of tasks include, but are not limited to:

- late animal testing and regulatory filing;
- the next clinical trial;
- device manufacturing; etc.

Do not provide budget detail – only provide a total estimated budget for each major milestone. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project.

Addendum 2 – Focus Area 2 Project Information Template:

[3-page limit. Times New Roman 11 point (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. These project information submissions will be shared with the Sponsor; therefore, all information must be **nonproprietary**. Project Information Paper should be submitted as a Word (*.doc or *.docx) document using the template provided in this RPI.]

Expertise and Experience:

- For each capability area checked above, describe the organization's expertise, facilities, equipment, and other relevant resources as it relates to dental prototype development.
- Briefly describe the experience of the key personnel, partner organizations, and associated subject matters experts that have expertise in dental prototype development projects as it relates to the capability areas.

- Identify any work of a similar nature that could be used to enforce your organization's capabilities in support of dental prototype development and advancement through the regulatory process.
- Include relevant example prototypes that you have worked with specific to dental care, diseases, and emergencies.

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Addendum 3 – BIDS instructions:
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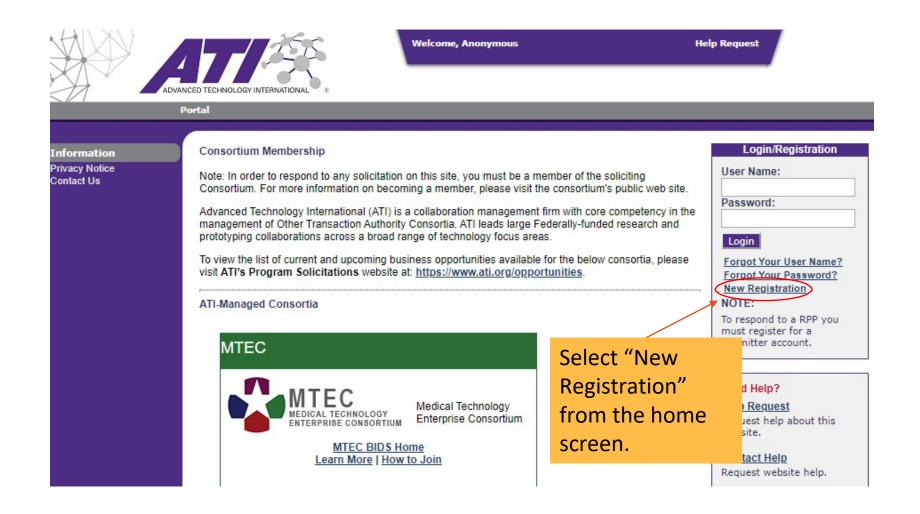
MTEC BIDS REGISTRATION

MTEC BIDS URL:

<u>HTTPS://ATI2.ACQCENTER.COM/ATI2/PORTAL.NSF/START?READFORM</u>



BIDS New Registration





BIDS New Registration



Welcome, Anonymous

Help Request

Portal

Select "Submitter".

Please select the type of account you are registering for:

Government

. Government Requirement Submitter#Evaluator/AOR - Select this in order to submit requirements, evaluate whitepapers and proposals, and/or make an award. Please note you must be approved before you will be able to access the system.

Industry

Submitter - Select this in order to submit responses to solicitations.

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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BIDS New Registration

BIDS Registration: 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	lactor autheritication.
* Email Address. * Email Confirmation. * Contractor Status. Cell Number.	
Preferred Code Delivery Method	selecting either when logging in.
Website * Programs Requested	mpsi
	MTEC
Submit Registration	Select "Submit Registration" to complete BIDS registration.



Medical Technology Enterprise Consortium

BIDS registration is instantaneous. It does not require any verification by the MTEC team. After successfully registering, you can submit proposals to any open MTEC RPP.

- MTEC Membership will be verified once a proposal is received and after the proposal deadline.
- Updates to submitted documents can be made anytime prior to the due date and time.
- MTEC RPP links will be opened, within BIDS, at least two weeks prior to the submission deadline.

Please note: For RPPs that are two stages (i.e. White Paper to Full Proposal) only the account that submitted the stage 1 proposal (the White Paper) will be allowed to submit for stage 2 (the Full Proposal), if selected.

ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.





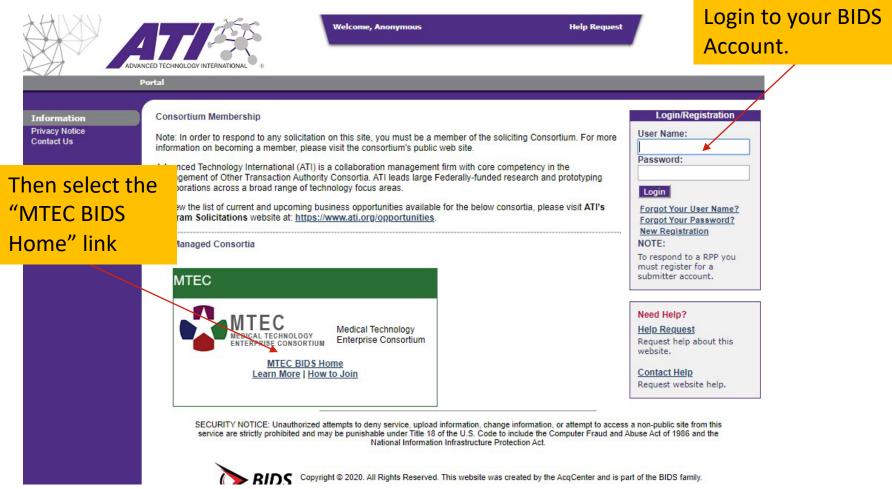
MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:

<u>HTTPS://ATI2.ACQCENTER.COM/ATI2/PORTAL.NSF/START?REA</u> DFORM

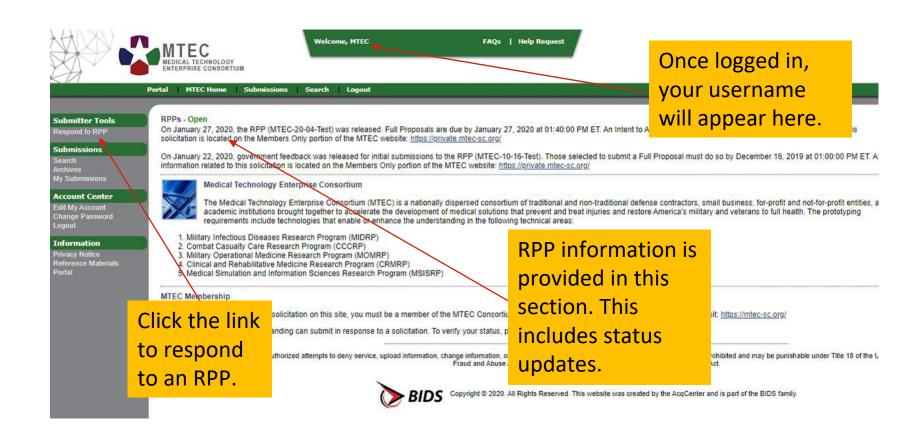


Navigate to the MTEC BIDS site and login. After login select the "MTEC BIDS Home" link.



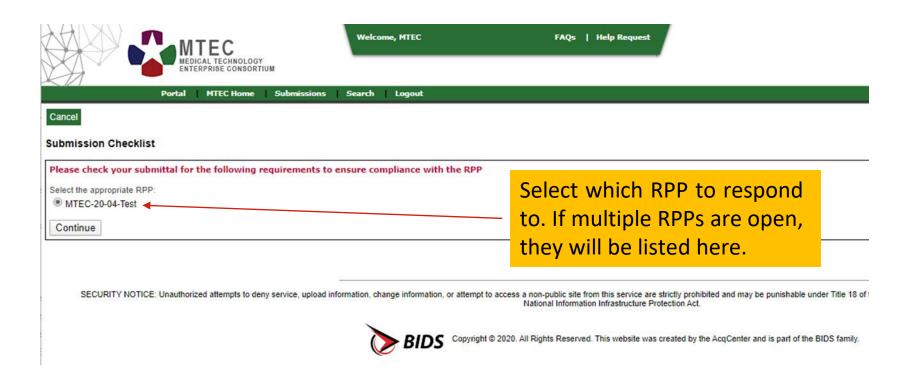


Select the "Respond to RPP" link under the submitter tools



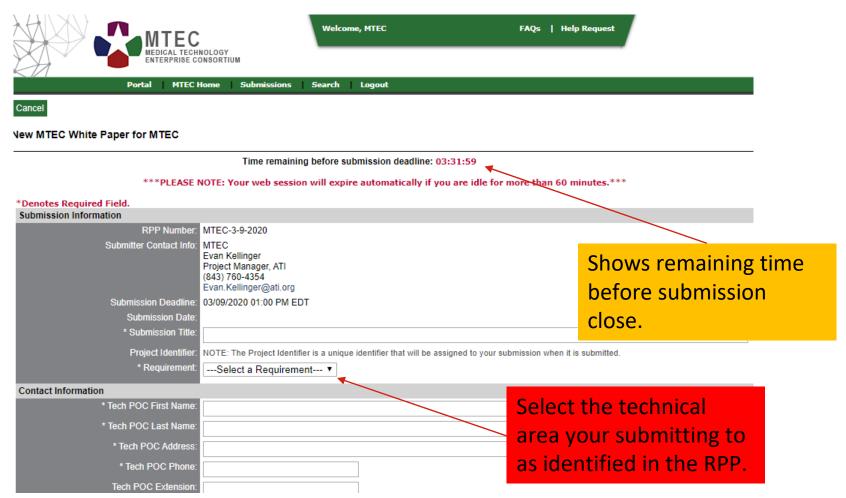


Select which RPP you will be responding to.



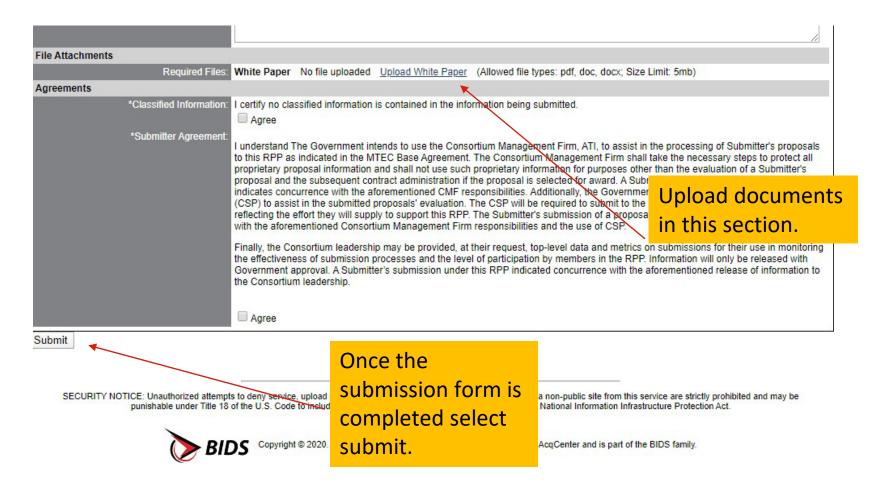


Complete the submission form.





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





Once you have successfully submitted a proposal, you will receive a notification with your submission number (ex. MTEC-23-24-Everest- 045).

Please note: For RPPs that are <u>two stages</u> (i.e. White Paper to Full Proposal) <u>only the account that submitted the stage 1 proposal</u> (the White Paper) <u>will be allowed to submit for stage 2</u> (the Full Proposal), if selected.

ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.