Request for Project Information



Solicitation Number: MTEC-25-01-Platelet_SoT

"Platelet and Platelet-like Products State of the Technology Meeting Request for Information"

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 7, 2024

Project Information Paper Due Date: November 1, 2024

Noon Eastern Time

The Medical Technology Enterprise Consortium (MTEC) is excited to post this announcement for a Request for Project Information (RPI) focused on understanding the state of the technology of platelets and platelet-like products.

CLINICAL PROBLEM:

Blood-vascular injury is an underlying etiology for many types of injuries and disease, including trauma, radiation injury, select infectious diseases, sepsis, and many more.¹ The persistent blood supply issues and very limited surge capabilities in the U.S. limit both routine and disaster scenario medical care, where blood and blood components are a critical treatment for blood-vascular injury (e.g., hemorrhage, thrombocytopenia, etc.). In addition, the current sustainability issues with the U.S. blood supply will be exacerbated during mass casualty incidents. Some key knowledge and capability gaps include¹:

- Regular blood supply shortages in routine care that are predicted to worsen over time as demand for blood products increase, while donor numbers continue to decrease
- Severely limited capability of the blood system to surge to emergency-level needs
- Limited shelf life and portability of conventional blood components and whole blood
- Poor ability to stop life-threatening extremity, junctional, or internal hemorrhage
- Limited understanding of the implications of using component therapy versus whole blood versus fresh whole blood early resuscitative intervention
- Limited ability to optimize transfusion strategies with attention to setting, patient state, timing, and choice of blood product

In response to these gaps, the United States Government (USG) formed an interagency group to form a strategic plan. The interagency group was comprised of stakeholders from the Department of Defense (DoD); the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH); the Biomedical Advanced Research and Development Authority (BARDA); and the National Aeronautics and Space Administration (NASA), which are the primary agencies with major research and development (R&D) programs for micro- and macro-blood-vascular injury and blood product supply and safety. The U.S. Food and Drug Administration (FDA) and the Office of the Assistant Secretary for Health (OASH) share a role pertaining to blood supply safety and availability. Together, this interagency group identified a critical need for improved capabilities to understand, detect, prevent, mitigate, treat and recover from the pathophysiology that occur along the continuum from blood-vascular injury.¹ New technologies that are focused on preventing or addressing the underlying pathophysiological mechanisms of blood-vascular injury, and the resulting disorders of metabolism, are anticipated to enhance USG medical preparedness across various operational domains and threat spaces.

¹Reference: Interagency Strategic Plan for Research and Development to Understand, Prevent, Treat, and Recover from Injury to the Blood-Vascular System 2023

BACKGROUND ON UPCOMING STATE OF THE TECHNOLOGY MEETING:

Through MTEC, and in support of the Interagency Strategic Plan for Research and Development to Understand, Prevent, Treat, and Recover from Injury to the Blood-Vascular System 2023, the DoD Combat Casualty Care Research Program (CCCRP), the BARDA Radiation/Nuclear Medical Countermeasures Program, and the NHLBI Division of Blood and Blood Diseases intends to host a Platelet and Platelet-like Products State of the Technology Meeting in Bethesda, MD, on February 4-6, 2025. MTEC will notify the scientific community when registration information related to this State of the Technology meeting is available and it will also be posted on the MTEC website.

The purpose of this meeting is to inform the USG and the greater scientific community of innovative research focused on platelet and platelet-like products, in support of current and future military and civilian platelet needs for future large scale combat operations as well as domestic mass casualty and disaster response. Attendees of the State of Technology meeting are expected to bring an understanding of platelet and platelet-like products and their development. They will also gain exposure to government agencies, their respective portfolios, and potential funding opportunities relevant to platelet products. The meeting will give an opportunity for a dynamic exchange of ideas among all participants and provide support to identify and overcome challenges. The intended impact of the State of the Technology meeting is to better inform possible future investments within DoD and across the interagency enterprise to advance specific technologies poised to address unmet needs in the field of platelet products and enhance the standard of care for military and civilian populations. The meeting organizers will develop a State of the Technology Report with the intent for publication following the meeting.

Examples of areas of interest to be addressed at the State of Technology meeting include, but are not limited to, the following items. These areas of interest are **not** listed in order of importance:

- The Biology of Platelets
- Novel platelet and platelet-like products in the settings of trauma, surgical hemorrhage, medical bleeding, traumatic brain injury, non-traumatic extreme vascular dysfunction, etc.
- Role of extracellular vesicles and synthetic nanoparticles
- Ex vivo manufacturing of platelet and platelet-like products
- Clinical trial capabilities including platform capabilities applicable to platelets
- Potency assays or new tools needed to measure the function and efficacy of the platelets or platelet-like product
- Updates on recent clinical trials involving platelets and platelet-like products

PURPOSE OF THE PROJECT INFORMATION PAPER:

MTEC is seeking input from both MTEC members and the general public (non-member companies) that are working in the field of platelet biology and technology development. We seek input to gauge interest in attendance/technology presentations and to frame the agenda on areas of concerns, unmet needs, products/technology advancements and limitations, and regulatory challenges from all interested

parties, including but not limited to, healthcare providers, scientists, product developers, regulatory experts, and reimbursement strategists.

This RPI contains background material and guidance for the preparation of Project Information Papers to be submitted to MTEC. **MTEC membership is not required for submission of Project Information Paper.**

REQUIREMENTS OF THE PROJECT INFORMATION PAPER:

The intent of this RPI is to understand respondents' interest and technology capabilities in support of the State of the Technology Meeting's area of interest. MTEC is seeking input from both MTEC members and non-members via a project information paper to be considered by the panel. Project information papers will be shared with the reviewers under non-disclosure agreements. The MTEC may invite one or more of those who submit project information papers to participate in, or present to, the organizing panel during their convening.

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://submissions2.ati.org/ATI2/Portal.nsf/Start?ReadForm. See Addendum 2 of this RPI for further information regarding BIDS registration.

Project Information Papers should NOT include proprietary or classified information. Information obtained through this RPI may be used to develop the State of the Technology meeting's agenda as well as be included as a component of the final State of the Technology report.

Submission Document(s): Submitted via BIDS (5MB or lower per document)

- [Required] Project Information Paper: one Word document (See Addendum 1 of this RPI)
- [Optional] Quad Chart: one Word document (See Appendix A of this RPI)

MTEC:

The MTEC mission is to assist the USAMRDC 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.

POINT OF CONTACT:

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

- All technical questions should be directed to the MTEC Biomedical Research Associate, Dr. Chuck Hutti, Ph.D., chuck.hutti@ati.org
- All other questions, should be directed to MTEC Program Manager, Evan Kellinger, mtec-sc@ati.org

Addendum 1 – Information Paper Template

Project Information Template Military Technology Enterprise Consortium (MTEC) Platelet and Platelet-like Product State of Technology Meeting

[2-page limit. 12-point Arial font, smaller font may be used in figures and tables, but must be clearly legible. Single-spaced, single-sided, 8.5 inches x 11 inches. 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 Meeting Government Sponsors; 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.]

	nment Sponsors; therefore, all information must be nonproprietary. Project Information Paper be submitted as a Word (*.doc or *.docx) document using the template provided in this RPI.]
Date:	[Insert Date of Submission]
Point (of Contact: [Insert name, role, organization, email address, phone number]
	ers to the following questions are required: Are you interested in attending the State of Technology meeting [Dates: February 4-6, 2025]?
±,	Yes or No
2)	Describe any suggestions on specific areas of interest to incorporate into the meeting agendathat align with the overall topic of this State of the Technology meeting.
3)	If you have a specific technology or expertise on a knowledge area that you would like us to consider for presentation at the meeting, please indicate what type of presentation you wish to be considered for:
	Poster Presentation? Yes or No
	Oral Presentation? Yes or No
	Check the topic area that is most relevant
	☐ Novel platelet and platelet-like products in the settings of trauma, surgical hemorrhage, medical bleeding, traumatic brain injury, non-traumatic extreme vascular
	dysfunction, etc.
	Role of extracellular vesicles and synthetic nanoparticles
	\square Ex vivo manufacturing of platelet and platelet-like products
	\square Clinical trial capabilities including platform capabilities applicable to platelets
	\square Potency assays or new tools needed to measure the function and efficacy of the \square
	platelets or platelet-like product

☐ Updates on recent clinical trials involving platelets and platelet-like products

Provide <u>a brief narrative</u> on your expertise on a knowledge area or your technology, its state of

development, and how it aligns to the objectives.

4) The meeting organizers intend to attach an addendum to their final post-meeting report that includes quad charts of technologies related to the topics in this Request for Project Information. If you have a specific technology that you would like us to consider for inclusion in a final report detailing the breadth of technologies available within this focus area, then please use the attached quad chart template. Quad charts should be marked as either public release or confidential. Confidential submissions will be included in a separate addendum for government use only and will not be published publicly. See **Appendix A of this RPI** for template.

Appendix A: Quad Chart Template	Chart Template		
PRODUCT OR TECHNOLOGY:		Please check one box only: Confidential information for government use only	
COMPANY NAME & ADDRESS			
TECHNICAL/ADMINISTRATIVE POINT OF CONTACT (NAME, EMAIL	, PHONE)	Publicly release information	
Description of technology : A bullet list (2-3) of the primary scientific challenges being addressed, suggested use for technology and mechanism of action.	Picture or Graphic that Illustrates the research or concept (e.g., data figures, molecule illustrations or processes)		
or action.			
Benefits of proposed technology:	Timeline of previous accomplishments and future anticipated major		
Any significant technology development challenges:	goals/milestones		
Anticipated storage or cold chain requirements:			
Current maturity of Technology (TRL):			

Addendum 2 BIDS Instructions

THIS PAGE IS INTENTIONALLY LEFT BLANK. PLEASE SEE THE PRESENTATION BELOW.



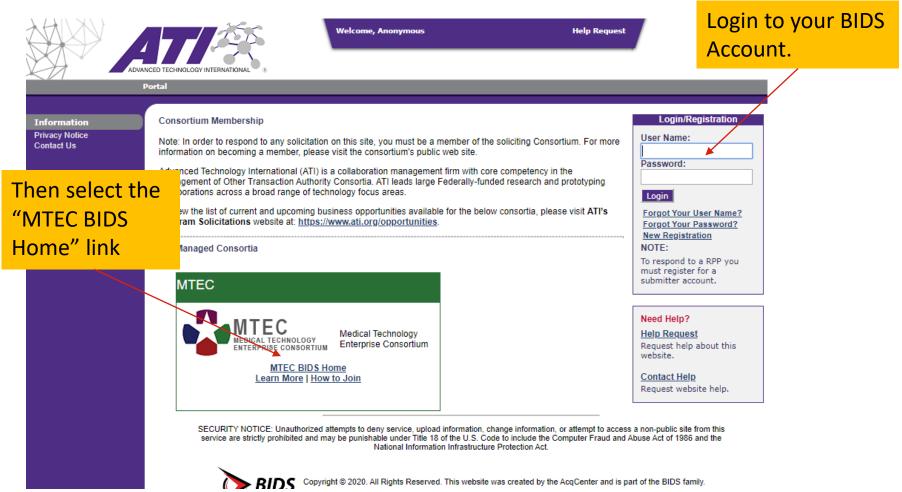
MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:

HTTPS://ATI2.ACQCENTER.COM

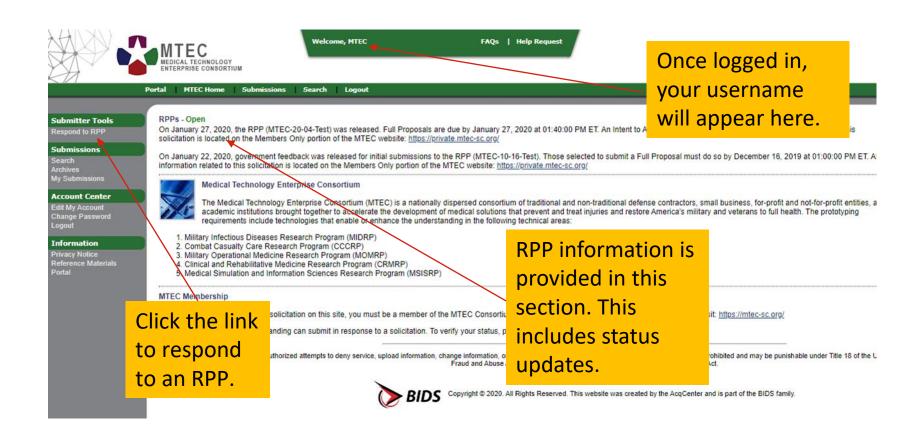


Navigate to the MTEC BIDS site and login. After login select the "MTEC BIDS Home" link.



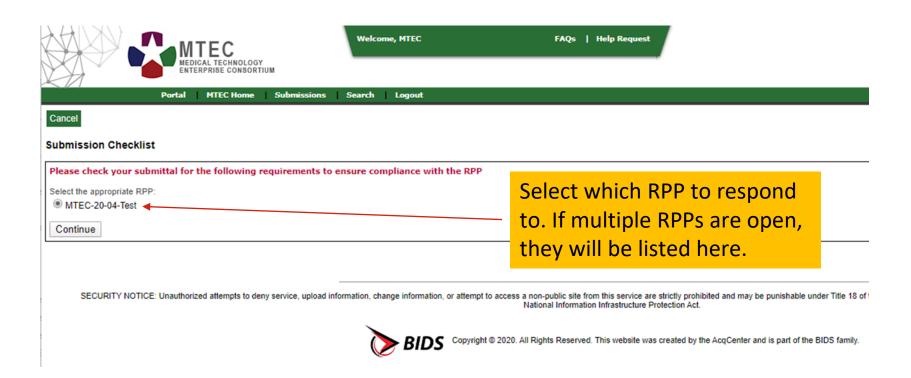


Select the "Respond to RPP" link under the submitter tools



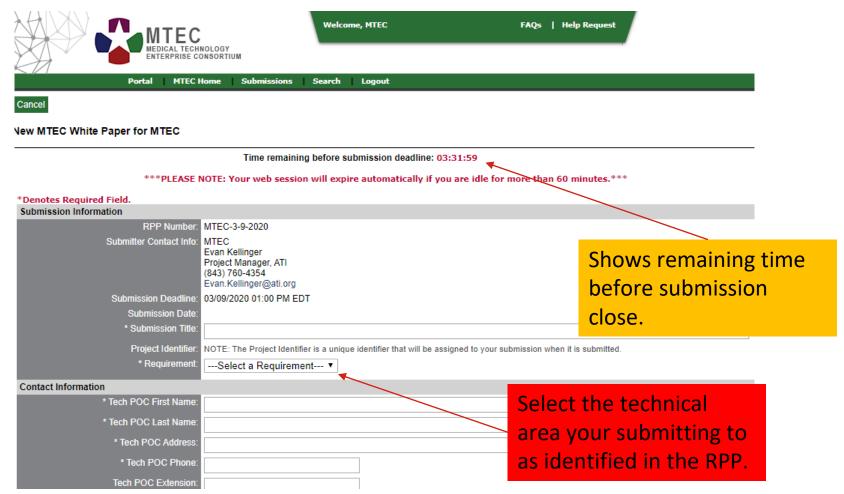


Select which RPP you will be responding to.



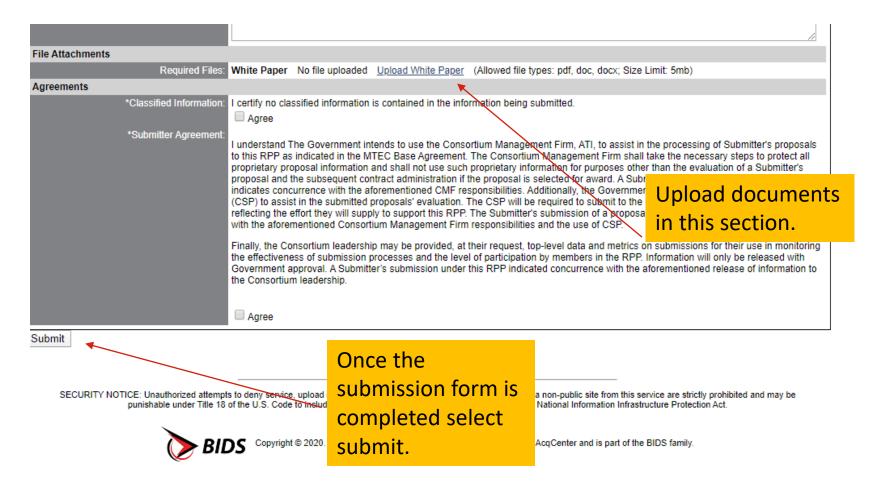


Complete the submission form.





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).

- 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.

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.