

Pre-Announcement, May 2019

Announcement for Request for Project Proposals - MTEC-20-11-PTSD-DT
Number W81XWH-15-9-0001



MTEC-20-11-PTSD-DT

“Post-traumatic Stress Disorder-Drug Treatment (PTSD-DT) Adaptive Platform Trial (APT)”

The Medical Technology Enterprise Consortium (MTEC) is excited to post this **announcement for a Request for Project Proposals (RPP)** to support the development and maintenance of clinical trial infrastructure for the simultaneous and sequential testing of drug interventions to treat post-traumatic stress disorder (PTSD) in an adaptive platform trial (APT) design.

Scope of Work:

The DOD has identified three focus areas for funding under this RPP. To meet the intent of this RPP, each proposal ***MUST*** specifically indicate which of the three Focus Areas described below are addressed. Offerors are not limited to a single proposal submission. If proposals include teaming across focus areas, Offerors are allowed to submit a single proposal that addresses more than one Focus Area, otherwise one proposal per focus area is preferred. Projects not aligned to at least one of these Focus Areas will not be considered for funding. It is expected that MTEC will make up to 3 awards - a single award for each focus area. It is possible that a single Offeror could receive an award for more than one Focus Area.

- **Focus Area #1 (Statistical Modeling):** Trial design, simulation, initiation, and execution, including drafting of key documents (e.g., statistical sections of Master Protocol, Statistical Analysis Plan, Operational Plan).
- **Focus Area #2 (Drug Selection):** Operationalization and execution of a drug selection process for initial and continual selection of interventions to be tested in the APT.
- **Focus Area #3 (Clinical and Clinical Operations):** Completion of the APT design, development of clinical trial infrastructure, and execution of the APT.

*NOTE: Refer to the full RPP for details related to each focus area’s scope of work.

Focus Area End Goals:

- **Focus Area #1 (Statistical Modeling):** The end goal for each step of focus area #1 is as follows:
 - STEP #1 (Trial design): A platform trial structure that will include patient subgroups, multiple arms, outcomes, etc. that will meet the goals of the DOD.

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- STEP #2 (Trial simulation): A detailed trial design software that will allow simulation of the trial skeleton design created above.
- STEP #3 (Trial initiation): Documents and meetings for trial initiation.
- STEP #4 (Trial execution): Execution of the adaptive analyses needed during the course of the trial including interim and final analyses.

- **Focus Area #2 (Drug Selection):** The end goal is a prioritized list of drugs recommended for inclusion in the APT. **NOTE: Focus Area #2 is for the drug selection process only. Focus Area #2 is not seeking proposals from Offerors that bring forth PTSD drugs for evaluation.*

- **Focus Area #3 (Clinical and Clinical Operations):** The end goal is a functioning adaptive platform trial built to DOD specifications allowing for efficient testing of a minimum of two interventions simultaneously to treat military-related PTSD, including discovery and validation of biological markers to identify patients with highest likelihood to respond to specific treatments.

Potential Funding Availability and Period of Performance:

The U.S. Government (USG) Department of Defense (DOD) anticipates funding the focus areas with Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) funds.

The anticipated Period of Performance (PoP) and estimated funding available for each focus area is as follows:

- Focus Area #1 (Statistical Modeling): 5 years (FY2021 – FY2025) \$630K
- Focus Area #2 (Drug Selection): 6 months (FY2021), and should not exceed \$250K
- Focus Area #3 (Clinical and Clinical Operations): 5 years (FY2021 – FY2025) \$25.5M

It is expected that MTEC will make up to 3 awards (a single award for each focus area) to qualified Offerors to accomplish the statement of work. It is possible that a single Offeror could receive an award for more than one Focus Area.

Pending successful completion of the total effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 USC 2371b section f.

Acquisition Approach:

Full proposals are required in response to this RPP thus reflecting a single stage acquisition approach. **Full proposals are due no later than May 21, 2020 at 12:00pm Eastern Time.**

MTEC membership is required for the submission of a proposal in response to this MTEC RPP. Offerors submitting proposals as the prime contractor must be MTEC members of good standing by **May 18, 2020**. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>

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A Proposers Conference via webinar will be held for interested parties to have their questions answered by the USG after the RPP is posted. MTEC Members will be notified when the Proposers Conference is scheduled.

MTEC:

The MTEC mission is to assist the U.S. Army Medical Research and Development Command (USAMRDC) by providing cutting-edge technologies and supporting 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, "nontraditional" defense contractors, academic research institutions and not-for-profit organizations.

Points of Contact:

Please direct your inquiries and correspondence to the following contacts:

- Technical and membership questions – Dr. Lauren Palestrini, MTEC Director of Research, lauren.palestrini@officer.mtec-sc.org
- Administrative questions – Ms. Kathy Zolman, MTEC Director of Program Operations, kathy.zolman@ati.org
- MTEC Member Collaboration Database Tool – Ms. Melissa Sanchez, MTEC Executive Assistant, melissa.sanchez@ati.org

To view this solicitation, click [here](#).

Sincerely,

MTEC Project Team

