MTEC-20-12-COVID-19_Diagnostics
"Wearable Diagnostic for Detection of COVID-19 Infection"

The Medical Technology Enterprise Consortium (MTEC) is excited to post this summary announcement for a Request for Project Proposals (RPP) to develop a wearable diagnostic capability for the pre- / very early-symptomatic detection of COVID-19 infection.

PROGRAM BACKGROUND:

The pandemic COVID-19, a disease caused by a novel coronavirus, continues to spread worldwide. There is a dire and urgent need for development of rapid, accurate wearable diagnostics to identify and isolate pre-symptomatic COVID-19 cases and track/prevent the spread of the virus.

SOLUTION REQUIREMENTS:

Offerors should only propose technology solutions that meet the following two criteria as the following specifications define the minimum prototype requirements that all proposals must demonstrate:

1. Currently be at a Technology Readiness Level (TRL) of 3/4 or above [definition of TRL – https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf], and
2. Currently be in development or commercially available.

An ideal solution would meet the following capabilities or specifications (not listed in order of importance).

- Platform must be designed for pre-detection (e.g., physiological monitoring of readiness) and early detection of infection and pathogenic response that can be utilized pre-clinically leading to use at Point-of-Need role of care (ROC) 1/2, local doctor's office, emergency departments, urgent care centers and immediate care clinics.

- The capability should be "wearable", non- or minimally-invasive and be able to assess physiological markers to monitor the health state of the user. A single device is preferred, but a combination of technologies is acceptable.

- Device(s) should be designed to be worn for continuous physiological monitoring in a non-obtrusive manner and should not affect the daily activity of the wearer. Physiological markers indicative of health state that are of interest to this RPP include, but are not limited to, physiological markers of early COVID symptomology (elevated temperature /

fever, respiratory difficulty / cough, etc.), antibodies against COVID 19, and molecular biomarkers indicative of COVID 19 exposure (not all markers are necessary but sufficient markers to provide evidence of COVID exposure are required). Sampling of physiological markers/antibodies/biomarkers can occur "on demand" to conserve power. Device should be worn until exposure has been verified or until a medical professional has deemed the device is no longer needed.

- Results should be easy to interpret by non-laboratory personnel and results should be collected and able to be saved and shared in a standard and secure (maintain HIPPA) format.

- The device must be able to be stored and operated between 4°C to 45°C.

- Physiologic surveillance for COVID-19 positive individuals that do not yet show clear medical symptoms is an ultimate goal. Physiological signatures therefore must produce predictive algorithms that can be tied into validated and relevant antibody/molecular measurements.

- Offeror must have an established manufacturing capability for the platform and assay kits on a large-scale.

SCOPE OF WORK:

- During the Period of Performance (PoP), the Awardee(s) will be expected to develop a working prototype and perform testing on clinically relevant human samples (known positive and negative) and compared to current gold standard. Specificity to detect COVID-19 infection or markers of current infection from asymptomatic or symptomatic patients should be demonstrated.

- Current Institutional Review Board (IRB) approval is preferred at the time of enhanced white paper submission. Awardee(s) will be required to obtain protocol approval from USAMRDC's Human Research Protections Office (HRPO) at the start of the PoP. Offerors are required to bring forth access to data sets of utility to prediction of infection.

- Offerors shall have a plan to obtain an Emergency Use Authorization (EUA) status from the U.S. Food and Drug Administration (FDA) within the first 45 days of the PoP if the product will be an FDA-regulated COVID diagnostic.

- During the PoP, the Offeror is expected to file for clearance/approval by the U.S. FDA along the appropriate regulatory pathway (i.e., 510(k), de novo, etc.).

The deliverable at the end of the PoP is to have an EUA for the new wearable capability and be ready to distribute the device and test kits within 15 days of receiving the EUA.

POTENTIAL FUNDING:

The U.S. Government (USG) Department of Defense (DoD) currently has available approximately $25 Million (M) FY20 funds for this program.

MTEC expects to make up to ten (10) awards.

The anticipated PoP is up to 9 months.

ACQUISITION APPROACH:

The MTEC will implement the "Enhanced White Paper" contracting methodology for this RPP, which will be an accelerated approach to award. Because of the nature and urgency of the program's requirements, this streamlined approach is anticipated to be a better means to highlight company methodologies and skills required to address the technical and transition requirements. The Enhanced White Paper process requires extremely quick turnaround times by Offerors. MTEC anticipates that awards will be issued within 4 weeks of the RPP release date. **For more information regarding the requirements of the Enhanced White Paper process and template, refer to the RPP.**

MTEC MEMBER TEAMING:

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to proposal submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government. MTEC members are encouraged to use the MTEC Database Collaboration Tool to help identify potential teaming partners among other MTEC members. The Database Collaboration Tool provides a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, R&D highlights/projects, and technical expertise. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

The Collaboration Database Tool can be accessed via the "MTEC Profiles Site" tab on the MTEC members-only website.

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.

ADMINISTRATIVE INFORMATION:

Enhanced White Papers are due no later than May 13 at 12:00pm Eastern Time. Due to the critical and urgent nature of the technical topic area, MTEC membership is **NOT** required for the submission of an Enhanced White Paper in response to this MTEC RPP. However, membership will be required for Offerors recommended for award. For information on how to join MTEC, please visit http://mtec-sc.org/how-to-join/

The full RPP is posted to the MTEC website https://www.mtec-sc.org/solicitations/

POINTS OF CONTACT:

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

- Technical and membership questions – Dr. Lauren Palestrini, MTEC Director of Research, lauren.palestrini@officer.mtec-sc.org
- Programmatic 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

MTEC
Medical Technology Enterprise Consortium