Pre-Announcement, April 2025

PRE-ANNOUNCEMENT

"Pharmacogenomics (PGx) Testing for Military Readiness Pilot "

The Medical Technology Enterprise Consortium (MTEC) is excited to post this pre-announcement for a Request for Project Proposals (RPP) focused on establishing a pilot program to demonstrate the enhanced use of pharmacogenomics (PGx) in the Military Health System (MHS) to aid in the treatment for specific medical conditions and improve healthcare delivery and outcomes.

BACKGROUND:

DHA Research & Engineering Directorate is requesting proposals for a PGx pilot program to aid and improve military readiness and clinical care for military personnel in response to the FY24 DoD Appropriations Act. The pilot program will develop and demonstrate the standards and processes that will result in Military Health System (MHS) protocols for routine PGx testing in applicable military cohorts and report PGx testing results that can provide actionable information to MHS providers for medical treatment of the Active-Duty population. The pilot will leverage the Electronic Health Record (EHR) patient information and patient outcomes to determine and report optimal healthcare delivery.

Results from this program will demonstrate the feasibility of utilizing PGx as an impactful and cost-effective solution to improve the personalization, safety, and efficacy of medication for Active-Duty service members (ADSM).

The intent of the PGx pilot program is to demonstrate the impact PGx can have on the ADSMs by preventing adverse drug reactions, optimizing drug dosing, and reducing the use of non-effective medications, as well as demonstrating the cost benefit, quality, and outcomes of treatment.

The PGx pilot program scope will include development of appropriate PGx processes (e.g. enrollment) relevant to military populations at DoD site(s), tracking outcomes after medical treatment, and performing analyses to determine treatment efficacy based on PGx testing.

TECHNICAL OBJECTIVE:

Proposed solutions are expected to include (but are not limited to) the following characteristics and activities:

1. Collaborate with Military Treatment Facilities (MTFs) to maximize the use of precision medicine in clinical care for ADSMs.

2. Establish a process for the integration of PGx into clinical care. This will include development of an Application Programming Interface (API) within the MHS EHR within the DoD secured server under strict data and national security requirements in accordance with National Institute of Standards and Technology (NIST) 8582 and DFARS 239.7602-2(a).
3. Identify, establish, and execute programmatic tasks of the pilot program. These may include, but are not limited to:
    a. Document pilot processes for Clinical PGx and tele-PGx platform within the MHS through the EHR, for PGx consultation, education, and fluency across the MHS community.
    b. Conduct data collection, and data analysis, to include the measurement of effectiveness of PGx processes.
    c. Measure treatment efficacy with respect to:
        i. reductions in adverse drug reactions and use of non-effective medications;
        ii. treatment outcomes;
        iii. informing long-term medication management for improvements in clinical health conditions; and
        iv. cost related to testing, treatment, and ADSM return to duty
    d. Ensure the use of all appropriate Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines, where appropriate.
    e. Develop progress and final reports with recommendations based on data analysis

Requirements for the Proposed Team:

The following are anticipated requirements to consider when forming a team and are considered necessary to ensure the successful development of the project.

1. This pilot program would require the awardee team to include clinical pharmacists trained in PGx, especially those with practical experience in implementing PGx with therapeutic conditions in one or more of the following medical conditions prioritized in the MHS: behavioral health, pain management, cardiology, infectious diseases, gastrointestinal disorders, and sleep disorders, etc. Other clinical conditions may be proposed as appropriate.
2. Must satisfy requirements to receive access to government furnished equipment (i.e., computer) and obtain a government common access card (CAC) – to be determined by DHA data access approval authority. This is anticipated in order to access to electronic health records (de-identified) to determine the health outcomes from pharmacogenomics testing.
3. The vendor/contractor **MUST** be willing and able to partner with Defense Health Agency clinical subject matter experts (to be specified post award) to ensure timely approval and access to DoD populations and medical data, to fulfill data security requirements, and maximize translation of findings to the MHS.

POTENTIAL FUNDING AVAILABILITY AND PERIOD OF PERFORMANCE:

The U.S. Government (USG) currently has **up to $2.2M** available for the upcoming program. The USG may apply additional dollars for follow-on efforts via post award modification to any resultant award(s) after

the evaluation and acceptance of work and cost plan. Dependent on the results and deliverables, additional time may be added to the period of performance for non-competitive follow-on tasks.

MTEC expects to make a **single award in FY25** to a qualified Offeror to accomplish the scope of work. If a single proposal is unable to sufficiently address the entire scope of the RPP, several Offerors may be asked to work together in a collaborative manner. The period of performance should not exceed **36 months**.

ACQUISITION APPROACH:

The upcoming RPP will be conducted using the Enhanced White Paper approach. In Stage 1, Offerors are invited to submit Enhanced White Papers using the mandatory format contained in the upcoming RPP. The Government will evaluate Enhanced White Papers submitted and make a selection based on the solution(s) that best meet its current priorities using the evaluation criteria described in the upcoming RPP. The Offeror(s) whose proposed solution is selected for further consideration based on the Enhanced White Paper evaluation will be invited to submit a full cost proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements.

The upcoming RPP will be posted to the MTEC website (mtec-sc.org) and a summary version will be available on SAM.gov to notify interested parties. The RPP is expected to be released as soon as possible and will have a proposal preparation period of approximately 30 days. MTEC membership is required for the submission of an Enhanced White Paper in response to the upcoming MTEC RPP. To join MTEC, please visit http://mtec-sc.org/how-to-join/.

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.

POINT OF CONTACT:

For inquiries regarding this pre-announcement, please direct your correspondence to Dr. Lauren Palestrini, Chief Science Officer, lauren.palestrini@mtec-sc.org.

Sincerely,

MTEC Project Team

MTEC
Medical Technology
Enterprise Consortium