“Development and Evaluation of a Cryopreserved Platelet Product (CPP) for the U.S. Military”

The Medical Technology Enterprise Consortium (MTEC) is excited to post this pre-announcement for a Request for Project Proposals (RPP) focused on the development of a dimethyl sulfoxide (DMSO) cryopreserved platelet (CPP) product that has an extended shelf life (minimum of 2 years) compared to liquid stored platelets (LSP). The overall end goal of the program is a commercial product that is approved by the U.S. Food and Drug Administration (FDA) to enhance the battlefield management of severe hemorrhage resulting from combat trauma.

**Technology Focus Areas**
The leading candidate for a long-term stored platelet product, by virtue of technological maturity and risk, is DMSO CPP. DMSO CPP is a frozen platelet product (regulated as a biologic) composed of γ-irradiated [2500 centi-gray (cGy)] leukocyte reduced apheresis platelets stored in plasma and anticoagulant citrate dextrose solution A (for up to 57 hours after apheresis), concentrated, and frozen in approximately 6% DMSO at -80°C ± 15°C and stored at ≤ 65°C.

This program intends to support the development and evaluation of a DMSO CPP prototype through the processes required for U.S. Food and Drug Administration (FDA) approval. As such, Offerors will be expected to conduct all manner of development, test and evaluation activities (as necessary) to achieve an FDA-licensed DMSO CPP product that is suitable for use by the U.S. Military. Anticipated activities include (but are not limited to):

1) Design and development of a current good manufacturing practice (cGMP) compliant process for the manufacture of DMSO CPP.
2) Performance of necessary non-clinical activities and clinical trials.
3) Execution of all regulatory activities, including submissions, commensurate with serving as the regulatory sponsor in accordance with 21CFR132 subpart D.
4) Design, development, and validation of analytical processes and procedures to enable storage and shipment of CPP for U.S. Military use.
Potential Funding Availability
The U.S. Department of Defense (DoD) currently has available approximately $36 Million (M) for this effort. A period of performance no greater than 7 years is expected, and faster timelines are acceptable.

It is expected that MTEC will make a single award to a qualified team to accomplish all tasks. The program shall be led by a centralized point of contact at the prime contracting organization. If a single proposal is unable to sufficiently address the entire scope of this RPP’s objectives, several Offerors may be asked to work together in a collaborative manner.

Other Information
The MTEC mission is to assist the U.S. Army Medical Research and Materiel Command (USAMRMC) 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, “nontraditional” government contractors, academic research institutions and not-for-profit organizations.

The RPP will be posted to the MTEC website and a notice will be posted on FedBizOpps.gov to notify interested parties. MTEC membership is required for the submission of a full proposal in response to this upcoming MTEC RPP. To join MTEC, please visit http://mtec-sc.org/how-to-join/.

For inquiries regarding this pre-announcement, please direct your correspondence to the following contacts:

- Technical questions – Dr. Lauren Palestrini, MTEC Director of Research, lauren.palestrini@officer.mtec-sc.org
- Administrative questions - Ms. Kathy Zolman, MTEC Program Manager, kathy.zolman@ati.org
- Membership questions - Ms. Stacey Lindbergh, MTEC Executive Director, execdirect@mtec-sc.org