REQUEST FOR INFORMATION

Smart Pills

Objective: This is a Request for Information (RFI) for planning purposes only. It is not to be construed as a commitment by the Government nor will the Government pay for the information solicited. No solicitation document exists or is guaranteed to be issued as a result of this RFI. The Joint Program Executive Office for Chemical and Biological Defense (Medical Countermeasures Systems) and the Joint Science and Technology Office are seeking information on the capabilities and willingness of private entities (non-profit and commercial) in the areas listed below.

Background:
Warfighters may fall ill to pathogens and infect others for days before symptoms present. Once symptoms appear, treatment may fail to save the warfighter. Unit effectiveness may also be compromised as other members of the unit fall ill. Diseases of particular concern arise from the Class A and B biological warfare pathogens (Ebola Virus, Marburg Virus, smallpox virus, *Yersinia pestis*, *Bacillus anthracis*, *Brucella spp.*, *Burkholderia pseudomallei*, *Burkholderia mallei*, *Francisella tularensis*). A diagnostic that will alert warfighters as soon after infection before symptoms appear as possible can save warfighter lives and protect unit effectiveness. A “smart pill” could be taken once a day in the morning and the warfighter could then forget about it unless it raised an alarm.

Requirements:
This topic seeks proposals to develop commercially available off-the-shelf (COTS) “smart pills” (ingestible diagnostics) that have already received FDA clearance for human diagnostic use or that are in the process of FDA clearance. Intended development may involve determining appropriate smart pills capable of signaling exposure to or oncoming disease from pathogens of interest in appropriate animal models. Smart pill signals should be detectable by smartphone for real-time diagnosis and then relayed to healthcare providers. Proposed work shall support submission for FDA clearance in support of the Joint Program Executive Office (JPEO) Joint Program Management Office for Medical Systems (JPM MCS) Diagnostic program.

Scope:
The goal is to discover COTS solutions if they are available or modification of COTS smart pills as necessary. Likely gastrointestinal conditions that may signal pre-symptomatic disease include changes in temperature, pH, pressure, gases, or molecules (biomarkers) in the GI tract. Proof-of-concept studies may focus on only one pathogen of interest, but priority will be given to studies considering multiple pathogens, especially hemorrhagic fever viruses.

Performance Objectives: The Government requests that potential performers provide up to 5 pages response containing the following information (if applicable):

- Specific analyte/target information including pathogen of interest
- Method or methods of detection
- Diagnostic window post exposure
- Software and hardware (e.g., smart phone) requirements for detection and reporting
- Time to result (estimated or actual)
- Time to elimination or dissolution information
• Sensitivity and Specificity
• Results of animal model or human trial testing
• FDA clearance status
• Current indications/contraindications

• Any reported adverse events during post-market surveillance
• Patient/subject restrictions

Administration: The Government will retain comments and information received in response to this RFI. Proprietary information should be identified as Company Proprietary. Do not use Government security classification markings. All written responses must be received by COB on **29 September 2017**. Responses should be sent by e-mail to: contracts.mcde@ati.org, with Subject Line of Responding Organization and RFI Title. Material that is advertisement only in nature is not desired.