

Combating Antibiotic Resistant Bacteria (CARB) - Request for Project Information



Request for Project Information (RPI) Subject: Combating Antibiotic-Resistant Bacteria (CARB)

The Government is interested in receiving project information in support of the National Strategy for combating antibiotic-resistant bacteria (see Technology Focus Areas below).

Background:

The Medical Technology Enterprise Consortium (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, "non-traditional" government contractors, academic research institutions and not-for-profit organizations.

This Request for Project Information (RPI) contains background material and guidance for the preparation of project information papers to the MTEC. Project information papers will be reviewed by the Sponsor and used in a manner that shapes a future MTEC solicitation that requests full project proposals. The results of the project information paper submission will serve as a means to assess the development landscape and potentially focus the proposal effort that will follow.

Project information submissions should describe projects that are based on logical reasoning and sound scientific rationale. They should not be exploratory in nature and do require a foundation of preliminary data. Please note that MTEC-sponsored projects must result in "prototype" research deliverables that transition medical solutions to industry. At a minimum, these projects must be at a stage to conduct studies required for a regulatory filing to the Food and Drug Administration (FDA), which suggests that the prototype design is near frozen, proof-of-concept has been demonstrated in a large animal model (if applicable), and a committed industrial partner is involved.

The use of antibiotics saves millions of lives each year around the world. Unfortunately indiscriminant use and lack of compliance with treatment guidelines have led to conditions for accumulation of mutations in bacteria that have caused drug resistance, resulting in a significant decrease in the number of available drugs effective to treat both rare and common bacterial infections. The rise in antibiotic resistance threatens various aspects of life, including both human and animal health, the agriculture industry, the economy, and the treatment of post-surgical infection from elective and life-saving medical procedures. Therefore, there is a critical need to develop novel antibiotics, other therapeutics, and, vaccines to combat infection by antibiotic-resistant bacteria and improve medical surveillance and diagnostic tests for the identification and characterization of antibiotic-resistant bacteria. Advancement in these areas will hopefully make a major impact by strengthening national and international healthcare for humans and animals, public health, agriculture practices, food safety, and research, development and manufacturing.

Combating Antibiotic Resistant Bacteria (CARB) - Request for Project Information

TECHNOLOGY FOCUS AREAS

This **MTEC Request for Project Information** is generally focused on the development of technologies (i.e., biosurveillance, diagnostic tests, antibiotics, vaccines, and other therapeutics) that combat antibiotic-resistance. The use of interdisciplinary approaches including systems biology and synthetic biology to advance prototype development efforts to combat antibiotic resistance are encouraged but not required. Examples of specific areas of interest include, but are not limited to:

1. *Disease surveillance to detect and control antibiotic-resistance*
 - National and global approaches to coordinate and integrate data across established medical surveillance systems, including laboratory response networks
 - Robust laboratory platforms for testing resistance and genetic characterization of antibiotic-resistant bacteria
 - Improved methods or approaches to monitor and control the spread of antibiotic-resistant bacteria in theaters of operation
 - Technologies or approaches tailored to leverage overseas laboratory assets and capabilities for medical surveillance of antibiotic-resistant bacteria
 - Enhance ongoing U.S. Department of Defense efforts to maintain a repository of resistant bacteria strains by developing novel advances in specimen collection, storage, and data analysis
 - Agile new technical or logistical approaches to augment the whole-genome sequencing methods of existing U.S. Department of Defense surveillance efforts, (e.g., the Multidrug-resistant organism Repository and Surveillance Network at Walter Reed Army Institute of Research and the Global Emerging Infectious Disease Surveillance and Response programs)
2. *Improved, affordable diagnostics that rapidly detect and/or characterize antibiotic-resistant bacteria*
 - Point-of-need, rapid diagnostic methods that rapidly differentiate between bacterial and viral infections
 - Point-of-need, rapid diagnostic tests that identify patterns and/or mechanisms of antibiotic resistance to limit the use of antibiotics
 - Utilization of genetic material (e.g., whole genome sequencing or metagenomics) and/or bioinformatics to develop new diagnostics tests with an open-system architecture compatible with the widest possible range of military-relevant settings from austere point-of-use and mobile, deployed hospitals in theaters of operation through clinical use in fixed-facility military and civilian hospitals worldwide
 - Novel, culture-based methods that profile and characterize antibiotic resistance
3. *Development of novel antibiotic drugs or other non-traditional therapeutics for the treatment of infections caused by antibiotic-resistant bacteria*
 - Novel antibiotics or therapeutic approaches include those that combat carbapenem resistance that is based on impermeability, efflux pump mechanisms, overexpression of broad-spectrum β -lactamases, and/or expression of β -lactamases and other carbapenemase enzymes
4. *Development of novel vaccines to prevent the spread of resistant bacteria*
5. *Advancement of innovative therapeutic approaches to combat or circumvent antibiotic-resistance*

Efforts to reduce the incidence of drug-resistant infections due to the following bacteria are of particular interest, however, the submission of projects that target other drug-resistant bacteria with military relevance are also encouraged:

- Carbapenem-resistant *Enterobacteriaceae* (CRE)

Combating Antibiotic Resistant Bacteria (CARB) - Request for Project Information

- Carbapenem-resistant *Acinetobacter* spp.
- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Vancomycin-resistant *Enterococcus* (VRE)
- Other Multidrug-resistant (MDR)-Gram negative strains
- *Clostridium difficile*
- *Neisseria gonorrhoeae*
- Multidrug-resistant *Pseudomonas* spp.
- Multidrug-resistant non-typhoidal *Salmonella*
- Multidrug-resistant tuberculosis infections
- Antibiotic-resistant invasive pneumococcal disease

Project information papers must be submitted by 11:59 pm on May 12, 2017 via email to mtec-sc@ati.org. Project information papers may be submitted by both MTEC members and non-members. Please note that MTEC membership is required for the submission of a full proposal in response to a future MTEC Request for Project Proposals (RPPs) for CARB. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>

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

Technical questions - Dr. Lauren Palestrini, PhD, MTEC Director of Research:

lauren.palestrini@officer.mtec-sc.org

Administrative questions - Ms. Polly Graham, MTEC Program Manager:

polly.graham@ati.org

Membership questions - Ms. Stacey Lindbergh, MTEC Executive Director:

execdirect@mtec-sc.org

Combating Antibiotic Resistant Bacteria (CARB) - Request for Project Information

Military Technology Enterprise Consortium (MTEC) CARB Project Information Template

[2 page limit. Times New Roman 11 point (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. These project information submissions will be shared with the Sponsor; therefore, all information must be **nonproprietary**.]

Date: [Insert Date of Submission]

MTEC CARB Technology Objective: [Biosurveillance, Diagnostics, Antibiotics, Vaccines, Innovative Therapeutic Approaches]

Title: [Insert descriptive title of project]

PI: [Insert PI name, institution, email address, phone number]

Background: [Provide a clear description why and how the proposed project fits into the MTEC mission. Describe how the technology addresses an unmet need in both military and civilian markets.]

Objectives/Specific Aims/Hypotheses: [Provide a description of the purpose and objectives of the proposed studies with specific aims and/or study questions/hypotheses.]

Study Design: [Outline the proposed methodology in sufficient detail to show a clear course of action. Provide a proposed period of performance. List milestones and deliverables from the proposed work.]

Anticipated Regulatory and Commercialization Strategy: [Provide a brief description of the anticipated regulatory pathway and commercialization plans.]

Technology Readiness Level (TRL): [Please indicate the TRL stage in which the project will start as well as anticipated TRL level at project completion. A table with the description of TRLs is included below]

TRL at Project Start:

TRL at Project End:

Anticipated Outcomes: [Provide a description of anticipated outcomes from the proposed work.]

Personnel: [Briefly state the qualifications of the PI and key personnel to perform the work.]

Estimated Funding Required to Advance Project: [Please estimate the required funding needed for each major task that advances the project into its next stage of development/milestone dependent upon its current maturity. Examples of tasks include, but are not limited to:

- late animal testing and regulatory filing;
- the next clinical trial;
- device manufacturing; etc.

Do not provide budget detail – only provide a total estimated budget for each major milestone. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project.]

Combating Antibiotic Resistant Bacteria (CARB) - Request for Project Information

| Technology Readiness Level | Description |
|----------------------------|--|
| TRL 1. | basic principles observed |
| TRL 2. | technology concept formulated |
| TRL 3. | experimental proof of concept |
| TRL 4. | technology validated in lab |
| TRL 5. | technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies) |
| TRL 6. | technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies) |
| TRL 7. | system prototype demonstration in operational environment |
| TRL 8. | system complete and qualified |
| TRL 9. | actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies); |