

1 STATEMENT OF OBJECTIVES (SOO)

2 **C.1. Background**

3 The requirement for medical countermeasures against the effects of chemical warfare agent
4 threats is under the purview of the Department of Defense (DoD) Joint Requirements Oversight
5 Council (JROC) draft Chemical Warfare Agent Prophylaxis and Pretreatment Pharmaceuticals,
6 Advanced Nerve Agent Increment 1 Capability Development Document (CDD), dated August 1,
7 2011. This CDD calls for a broad spectrum nerve agent medical countermeasure to prevent
8 Service Members from experiencing the effects of organophosphorus (OP) nerve agents, and thus
9 fulfills a critical need for force protection. The Medical Identification and Treatment Systems
10 Joint Product Management Office (MITS JPMO), a subordinate organization to Chemical
11 Biological Medical Systems Joint Project Management Office (CBMS JPMO), is responsible for
12 the Advanced Development of a prophylactic nerve agent countermeasure against OP nerve agent
13 threats (i.e. a Bioscavenger). The countermeasure must be safe, efficacious, quick acting, free
14 from performance-decrementing side effects, relatively non-invasive, approved by the U.S. Food
15 and Drug Administration (FDA), compatible with current military CBRN countermeasures, and
16 usable in contemporary operational environments. A countermeasure carrying logistical burdens
17 (e.g., special handling, storage conditions of -20 degrees Celsius, and multiple administrations)
18 may be acceptable, but are much less desirable. The ultimate goal of the Bioscavenger project is
19 to select, develop, and manufacture a FDA approved drug or biologic to decrease incapacitation
20 such that forces can maintain operational effectiveness within a contaminated area following
21 nerve agent exposure, irrespective of nerve agent type.

22 The hallmark of nerve agent exposure is acetylcholinesterase (AChE) inhibition. Symptoms occur
23 when nerve agent enters the peripheral or central nervous system, binds to AChE, and interferes
24 with the acetylcholine pathway. The collective effects of AChE inhibition are clinically
25 recognizable as cholinergic crisis, and include a multitude of symptoms to include increased
26 mucosal and salivary secretions, miosis, loss of bodily functions, vomiting and convulsions. This
27 may lead to death via complete respiratory depression due to excessive muscle contraction of the
28 diaphragm.

29 **C.2. Objectives**

30 The Government seeks an FDA approved countermeasure that will increase the likelihood that a
31 Warfighter will maintain operational effectiveness following nerve agent exposure, **specifically a**
32 **drug or biologic intended for use prior to an exposure to nerve agent, i.e., a prophylactic**
33 **countermeasure.** It is anticipated that the countermeasure, when administered prior to nerve
34 agent exposure, shall decrease incapacitation and death associated with nerve agent poisoning.
35 Specifically, when administered prior to nerve agent exposure, the countermeasure should
36 prevent injury by binding and sequestering or degrading nerve agent in the circulatory system
37 before it can reach the nervous system.

38 The Government seeks a countermeasure that exerts its effects **directly** on the toxic agent in that
39 it must bind and inactivate nerve agent molecules before they reach their target.

40 Government anticipates, for this contract, delivery of the FDA approved countermeasure within 6
41 years after contract award.

42 The Government also requires these objectives at a minimum:

43

44 C.2.1 Provide a prophylactic nerve agent countermeasure that is supportable throughout the
45 contemporary operating environment. The countermeasure should have, at a minimum, the key
46 system attributes listed below.

47

48 C.2.1.1 The prophylactic nerve agent countermeasure shall prevent the onset of
49 cholinergic crisis when administered a maximum of 24 hours prior to a supralethal
50 exposure to a broad spectrum of nerve agents and remain effective for a minimum of 10
51 days.

52

53 C.2.1.2 The prophylactic nerve agent countermeasure shall be operational across a wide
54 range of temperatures. It is required to have a minimum stability of 2 years at a storage
55 temperature of 0-35 degrees Celsius.

56

57 C.2.1.3 The final prophylactic product formulation suitable for administration in humans
58 and a delivery system suitable for military use. Ease of administration in an operational
59 military environment is a necessary attribute.

60

61 C.2.2 Delivery of 1,500 Troup Equivalent Doses (TEDs) of a FDA Approved prophylactic nerve
62 agent countermeasure.

63 C.2.3. The product label shall be in compliance with FDA requirements.

64 C.2.4 Provide a Drug Master File (DMF).

65 C.2.5 Provide a Technical Data Package (TDP) that includes all necessary documentation and
66 technical data for the Government, or its designee, to continue the development or production of
67 the product.

68 C.2.6 If at any time the product ceases to be marketed and is retired or in the event the Contractor
69 defaults and fails to remedy said default before or after approval, the Contractor shall transfer the
70 TDP to the Government or its designee. The Contractor shall also assist in the technical transfer.

71 C.2.7 Option: If exercised by the Government, produce 3,000 TEDs of the nerve agent
72 prophylactic countermeasure and deliver the product to the Government as directed (TED is
73 defined as the total number of doses required to affect the appropriate therapeutic endpoint). The
74 Government may require the delivery of this numbered line item, identified in Schedule B as an
75 Option item, in the quantity and at the cost stated in the Schedule. The Contracting Officer may
76 exercise the Option by written notice to the Contractor within 60 calendar days after the DoD
77 Milestone Decision Authority approval for the Full Operational Capability phase of acquisition
78 after the achievement of FDA approval or licensure of the product. Delivery of added items shall
79 be completed no later than 2 years after exercising this Option.

80 C.3. Program Management

81 C.3.1. A SOW, Integrated Master Plan (IMP), Integrated Master Schedule (IMS), Contract Work
82 Breakdown Structure (CWBS), CWBS dictionary and Risk Management Plan for the proposal
83 that encompasses the entire scope of the contract based on this Government provided SOO. The

84 IMS shall be updated monthly to track progress. The CWBS elements shall be extended to define
85 the complete contract scope and shall be to a depth and breadth necessary to accurately describe
86 the proposed effort, to a minimum of Level 4. The IMS, CWBS, and SOW shall be structured to
87 correlate with each other. A final IMP shall be submitted 30 days post contract award. The IMS
88 will be incorporated into the contract upon award.

89 C.3.2. An Earned Value Management (EVM) System (EVMS) formally validated and accepted
90 by the cognizant Administrative Contracting Officer (ACO) as complying with the criteria
91 provided in American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA)
92 EVMS standard (ANSI/EIA-748), DoDI 5000.02 Operation of the Defense Acquisition System
93 Acquisition Programs as well as the policy letter, "Revision to DoD Earned Value Management
94 Policy" dated March 7, 2005. Defense Contract Management Agency (DCMA) has the
95 responsibility of validating the Contractor's EVMS. The Contractor is required to hold an
96 Integrated Baseline Review (IBR) to assess the realism and accuracy of the integrated
97 performance measurement baseline. The IBR will be initiated no later than six months from the
98 contract award, the exercise of significant contract Options, the incorporation of major
99 modifications or as otherwise agreed upon. The Contractor shall provide monthly EVM reports
100 and quarterly Contract Funds Status Reports using DD Form 1568. In the event that a contract is
101 awarded below the EVMS threshold, this requirement will be excluded at award.

102 C.3.3. Compliance with all Contract Data Requirements Lists (CDRLs) is shown as Attachment J
103 to the RFP (to be published at a future date).

104 C.3.4 Compliance with the DD254 and CRP Security Classification Guide (attachments 3 and 4
105 in Section J of the contract, to be published at a future date) to include obtaining and maintaining
106 a Secret level DoD facility clearance with appropriately cleared personnel, as necessary.

107 **C.4. General**

108 The Contractor shall:

109 C.4.1. Provide the necessary qualified personnel, facilities, equipment, supplies, services,
110 Subcontractors/Consultants and related administrative and information technology support to
111 accomplish the objectives.

112 C.4.2. Allow access to records, files, and other data derived from this work for the purposes of
113 audit by the FDA and/or other DoD entities.

114 C.4.3. Prepare a written Quality Plan that spells out the roles and responsibilities of the
115 Contractor/Subcontractors/Consultants. Under this Quality Plan, allow the Government or its
116 designee to audits and/or site visits of the Contractor and/or its Subcontractors/Consultants for
117 regulatory compliance and quality assurance purposes.

118 C.4.4. Provide copies of all communications with the FDA and include the Government in all
119 discussions with the FDA in accordance with the CDRL. In addition, the Contractor shall
120 provide copies of study reports and Target Product Profile in accordance with the CDRL.

- 121 C.4.5. Provide monthly Contractor's Progress, Status and Management Reports that describe
122 progress made within the period, summarize projected vs. actual progress, report costs, and
123 inform the Government of existing or potential problem areas and risk mitigation plans. Include
124 invoices submitted during the report month.
- 125 C.4.6. Participate in a periodic teleconference to include Integrated Product Team meetings in
126 accordance with the CDRL (to be published at a future date) or as needed. Contractor shall
127 provide minutes of teleconferences within one week.
- 128 C.4.7. Provide a Summary report within three working days, of events that will cause more than a
129 two week delay in schedule, or an increase in cost Estimate at Completion in accordance with
130 CDRL.
- 131 C.4.8. To ensure that the contractor is utilizing best business practices for clinical and nonclinical
132 study data collection and reporting, the Contractor shall employ an automated information system
133 (AIS) in accordance with electronic common technical document (eCTD) and ICH guidance
134 described at FDA website (<http://www.fda.gov/cder/regulatory/ersr/ectd.htm>) for electronic data
135 submissions to the FDA. MITS JPMO, following the Contractor's quality assurance review and
136 acceptance, also requires timely read only remote access via the Contractor's AIS to clinical and
137 nonclinical data. The latter requirement does not substitute for any other contract deliverable.
- 138 C.4.9. In the event the Government provides necessary starting materials and/or equipment, the
139 furnishing of such property will follow all established guidelines as outlined in FAR Part 45,
140 FARS Part 245 and DFARS 252.211.7007. It is anticipated that Defense Contract Management
141 Agency (DCMA) will serve as the property administrator for the contract and shall have access to
142 the facility/facilities to conduct periodic audits.
143
- 144 C.4.10. The Contractor shall support the submission of an Emergency Use Authorization (EUA)
145 by preparation of letter(s) that cross-reference the IND file and/or other regulatory
146 documentation. The Contractor shall cooperate and supply additional information as needed for
147 the Government to write the pre-EUA to include, but not limited to, information on efficacy,
148 safety, manufacturing and directions for use by health care provider.