



BARDA Industry Day Washington, DC

Contracting for Countermeasures

October 30, 2012



Where in the process...



- Based on identified requirements and market research capabilities that have been identified it was the decision of the organization to move forward with two distinct solicitations.
- A Request For Proposal (RFP) for a vaccine to be used in healthy adults, and that has been developed through the conclusion of a Phase 1 safety study, as outlined in the mandatory criteria of the example RFP.
- A Broad Agency Announcement (BAA) to utilize innovative approaches towards Advanced Research & Development (AR&D) efforts for the advancement of a BAEA vaccine suitable for use in special populations, as outlined in the special instructions of the example BAA.
- Based on the four fictitious company examples, the market capability/research indicates at least two companies are potentially qualified to respond to RFP and two to the BAA.



RFP Mandatory Criteria



SECTION M – EVALUATION FACTORS FOR AWARD

Mandatory Criteria for eligibility:

- FDA Licensure of a Biopharmaceutical Product within the Last Ten (10) Years
- U.S. Biopharmaceutical Manufacturing
- Surge Manufacturing Capacity of Vaccines for Pandemic Influenza Vaccine & Other Threats
- Completed Phase 1 clinical study with candidate vaccine
- The evaluation of the Mandatory Evaluation Criteria Eligibility will be done on a pass/fail basis. Failure to adequately document compliance for any of the above mandatory requirements will result in the elimination of the Offeror's proposal from further consideration. The proposal will be considered to be non-responsive, no further discussions held and the Offeror will be disqualified.
- All proposals that satisfy the mandatory eligibility criteria will be considered for a second phase (technical evaluation) where it will be evaluated based on technical merit and confidence ratings as well as evaluation of the business proposal.

Based on the information that was obtained through MR is there a possibility that any of the companies qualify for submission under the RFP?



Special Instructions – BAEA Vaccine



Special Instructions – BAEA Vaccine

- **Goal:** Development of easily administered and rapidly effective countermeasures that can be used by untrained persons and by first responders dealing with large numbers of exposed individuals. Ease of administration in mass casualty situations should take into account the practical limits of IV or injected medications versus inhaled, intranasal and sublingual administration (these alternative routes may fail if persons have profuse respiratory secretions). Autoinjector intramuscular injection may continue to be a preferred route of administration for many compounds during mass casualty situations.
- **Objectives:** As part of the proposed SOW, BARDA is interested in advanced development and eventual licensure/approval of medical countermeasures for injuries resulting from exposure to the named agents, both acute and delayed onset. BARDA is interested in research and development of rapidly effective medical countermeasures, including those that can be self-administered or used by untrained persons and by first-responders dealing with a large number of exposed individuals.
- BARDA is primarily interested and supportive of pharmacokinetic, pharmacodynamic, and clinical efficacy studies in pediatric population, geriatric populations, pregnant women, and immune compromised populations with a goal of specific use FDA labeling as may be needed for these populations. In alignment with the Public Health Emergency Medical Countermeasure Enterprise Implementation Plan for CBRN Threats, HHS will prioritize the development and acquisition of medical countermeasures that are associated with an effective concept of operations (CONOPs).
- This solicitation includes mature and advanced (TRL 4 or higher) therapeutic countermeasures that protect the civilian population from the acute and delayed health effects of biological exposure to any of the named threat agents.

General

- The purpose of these special instructions is to specifically solicit solutions for treating injuries resulting from exposure to the following agents or a combination of the following agents:
 - Anthrax
 - Smallpox
 - Botulism