



Broad Agency Announcements (BAA)

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Background and Regulatory Basis – FAR 6.102(d)(2) and 35.016

- The Broad Agency Announcement is a competitive announcement to obtain proposals for basic and applied research and that part of development not related to the development of a specific system or hardware procurement. Currently, there are two open BAAs, one for Chemical, Biologics, Radiological and Nuclear (CBRN), and one for Strategic Science and Technology (SST) that we will discuss in more detail.
- The BAA is described in FAR 6.102(d)(2), “ Use of Competitive Procedures,” and FAR 35.016, “ Broad Agency Announcements.” This vehicle fulfills requirements for scientific study and experimentation directed toward advancing state-of-the-art science, and/or increasing knowledge or understanding.
- The BAA technique shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated.



Elements of the BARDA BAAs

- Describes agency's research Areas Of Interest (AOI) for individual program requirements,
- Describes criteria for selecting the proposals, their relative importance and evaluation method,
- Specifies time periods for receipt of white papers/quad charts, process for accepting full proposals and,
- Contains instructions for preparation and submission of proposals.



Benefits

- Streamlines the procurement process.
- Greater transparency and open communication.
- Promotes the advancement of Medical Counter Measure (MCM) technology.
- Allows for competition of ideas/concepts throughout the established response period.
- Flexibility in amending the BAA to add or subtract information or requirements.
- Can remain open for up to a one year period of time.
- White paper stage serves as market research.



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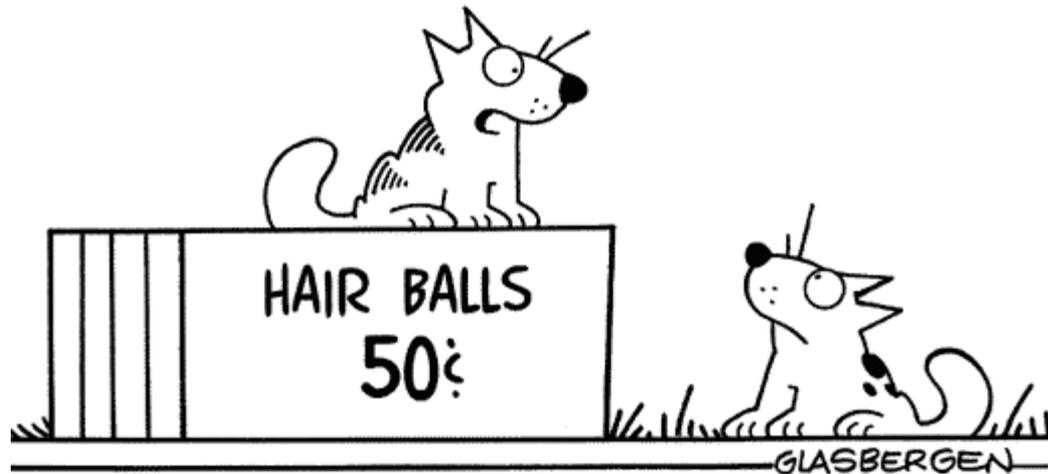
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Market Research

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“Business is lousy. Maybe I should have done more market research first.”



Restrictions of a BAA

- Limited to basic and applied research and advanced technology.
- Excludes non-research procurements (such as support services, even if technical support of research).
- Cannot be used for a specific requirement.
- Cannot be used for production.



BARDA BAA – Process

The two stage process

Stage I:

- White paper/quad chart submission stage directs offerors only to submit a brief technical paper (10 - 15 pages) rather than the full proposal.
- The white paper/quad chart will be reviewed for scientific and technical viability; then BARDA will provide feedback within 90 days of submission.
- Less of an investment of resources initially.
- Opportunity for interaction with BARDA prior to submission of white papers via email addresses published in the BAA and Tech Watch.



BARDA BAA – Highlights

- Full Proposal evaluation includes a category for proposals that are scientifically and technically sound that may require further development and/or may be recommended for award subject to availability of funds. (CAT II)
- Multiple awards of various values are anticipated and are dependent upon the proposals' scientific and technical merits, how well the proposals fit BARDA's areas of interest, and available funding.



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Innovations

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**“My team has created a very innovative solution,
but we’re still looking for a problem to go with it.”**



Overview of CBRN BAA 11-00009

- Identifies innovative and promising technologies for advanced development across CBRN Research Areas of Interest, focusing on Technology Readiness Level (TRL) of 5 or greater with exceptions for Proof of Concept proposals of 3 or greater.
 - Vaccines
 - Antitoxins and Therapeutics
 - Antimicrobial Drugs
 - Radiological/Nuclear Threat Countermeasures
 - Chemical Threat Countermeasures
 - Diagnostic



Overview of SST BAA 11-100-00001

- Designed to promote science and technology advancements of platforms applied to MCM development for the Strategic Science and Technology Division (SST) of BARDA.

Areas Of Interest (AOI)

- Technologies to accelerate evaluation of candidate vaccines and therapeutics
- Formulation chemistry, protein stabilization, and vaccine delivery technologies



Overview of SST BAA 11-100-00001 (cont.)

- Innovation methods in bioprocess development and manufacturing
- Methods and technologies to advance development of tests for rapid diagnosis of human injury and infections



Differences Between a BAA and a Competitive RFP

- The Type of Research and Development:
 - RFP – focuses on a specific system or hardware solution.
 - BAA – Scientific study and experimentation directed toward advancement of the art, and/or increasing knowledge or understanding.
- The Statement of Work
 - RFP – The Government drafts a common SOW to which all offerors propose.
 - BAA – The government drafts a statement of general research interest or a statement of the problem. The Offerors draft their own statement of work and technical approach.



Differences Between a BAA and a Competitive RFP (cont.)

- Proposal Comparison
 - RFP – All proposals are intended to accomplish the same outcome and the awardee is selected by comparing each proposal to the evaluation criteria factor.
 - BAA- Proposals contain stand-alone unique solutions. They are not compared to one another.



Differences Between a BAA and a Competitive RFP (cont.)

- Nature of the Competition
 - RFP- Proposals address common SOW and compete, one against another to the evaluation criteria factor. Cost, price, past performance, or best value, is often the deciding factor.
 - BAA- Each proposal presents a separate approach to solving the problem. There is technical competition in the “marketplace of ideas.” Cost or price is rarely the deciding factor on the winning proposal.



Differences Between a BAA and a Competitive RFP (cont.)

- Evaluation Process
 - RFP- An RFP closely follows a predetermined source selection plan. (In BARDA traditionally point scored)
 - BAA- Proposals undergo a scientific review process. A proposal that is otherwise weak could be selected if it shows significant technical promise or relevance to the BARDA mission, such as a risky but perhaps revolutionary approach. (BAAs use adjectival ratings)
 - Two stages of review. White paper review results in an Invite or Do Not Invite decision.



TEP Evaluation

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search ID: jkon674

"A and C are a bit on the gritty side... B seems to have a bitter aftertaste... C has a good taste but a bit too mushy..."



Differences Between a BAA and a Competitive RFP (cont.)

- TEP Process (Full Proposals)
 - Many similarities between BAA and RFP TEPs
 - Most important distinction is that proposals are not ranked against each other.
 - A TEP review of multiple proposals may recommend multiple or no proposals move forward into negotiations.
 - Formal TEP of all full proposals conducted on evaluation factors in BAA.
 - A CAT II revised proposal will have a second TEP conducted.



Communication During Evaluation Process

- Communication
 - A significant difference is the degree of communication during the review process. We *like* to talk to you.
 - Therefore, if proposal moves through process, you have multiple opportunities to interact with the CO and the PO.
 - Letter inviting a full proposal encourages a meeting either by telecon or in person.
 - A CAT II rating gives you another chance to have a meeting to discuss the rating and/or concern



Feedback During Evaluation Process

- Our Do Not Invite letters and Decision Not to Proceed into Negotiations letters contain feedback to assist with future submissions.
- The Decision Not to Proceed is a letter debriefing without you having to request the debriefing.
- We understand how expensive and time consuming submitting a proposal is. The goals are to mitigate some of the risk for you by providing guidance as well as improving the proposals submitted.



Summary of Government/Contractor Interaction with the Long Range BAA

- Under a BAA, both procurement contracts and non-procurement instruments, including grants, cooperative agreements and Other Transactions, may be awarded.
- AMCG is focused on using Other Transaction Authority (OTA) granted to HHS; however, at present we do not have this capability. We are working with leadership to finalize this process.



Summary

- BAAs allow for greater flexibility in both the proposal submission and selection phases.
- BAAs have the potential to be highly effective in BARDA's ability to respond quickly to emerging threats.
- Please Remember to...
- Contact the contracting officer with questions or concerns.
- **Note: The BAAs are an ongoing process where we welcome your feedback on how we can improve!**



Product Development & Technology Readiness Levels

Ron Manning, Ph.D.
Chief, Chemical, Radiological and Nuclear
Division of CBRN Countermeasures

June 8, 2011



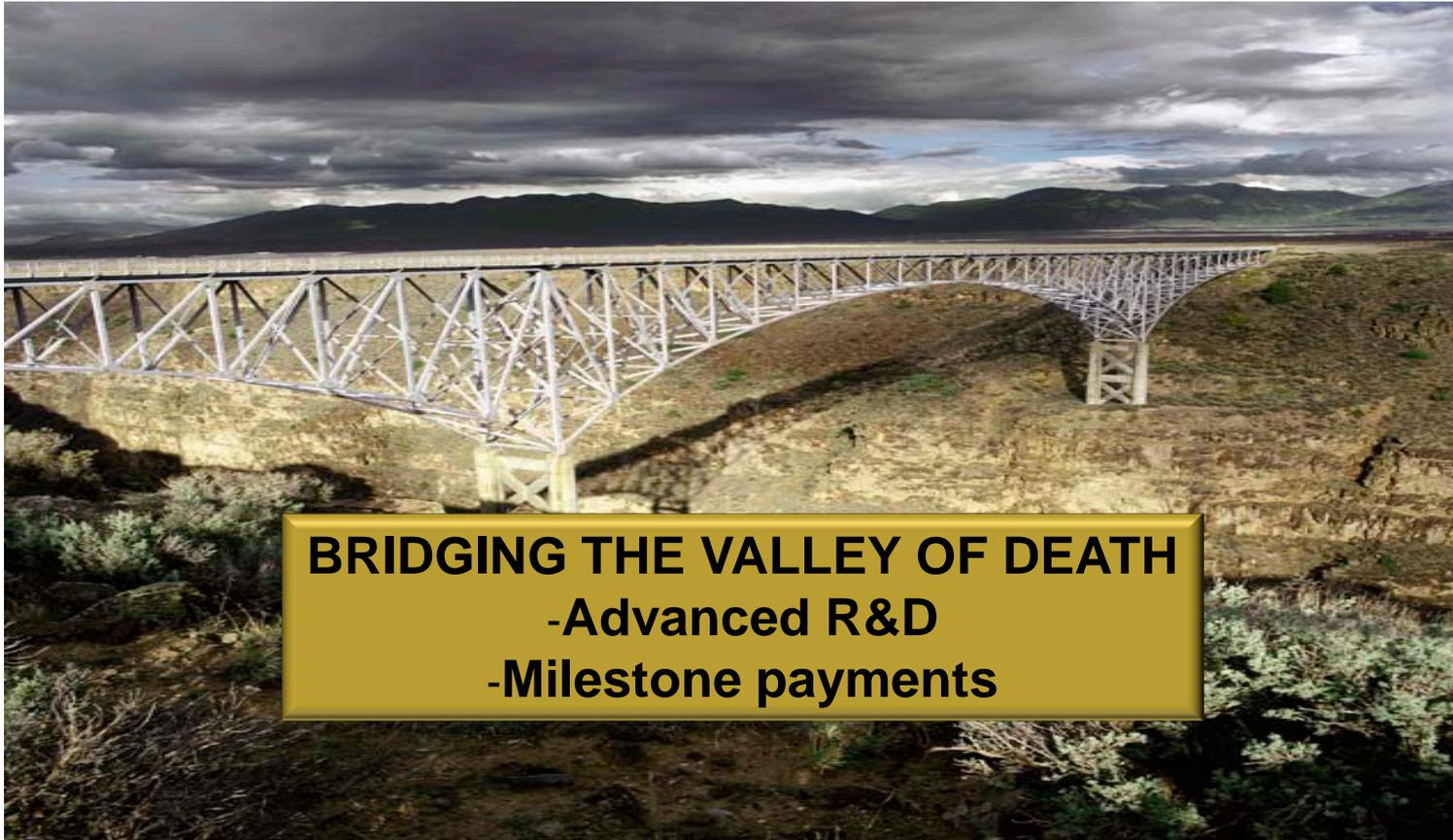
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BARDA'S Role in Product Development



BRIDGING THE VALLEY OF DEATH
-Advanced R&D
-Milestone payments



Technology Readiness Levels

1. Review of Scientific Knowledge Base
2. Development of Hypotheses and Experimental Designs
3. Target/Candidate Identification and Characterization of Preliminary Candidate(s)
4. Candidate Optimization and Non-GLP in Vivo Demonstration of Activity and Efficacy
5. Advanced Characterization of Candidate and Initiation of GMP Process Development
6. GMP Pilot Lot Production, IND Submission, and Phase I Clinical Trial(s)
7. Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trial(s)
8. Completion of GMP Validation and Consistency Lot Manufacturing, Pivotal Animal Efficacy Studies or Clinical Trials, and FDA Approval or Licensure
9. Post-Licensure and Post-Approval Activities



Science and Technology Platforms Applied to Medical Countermeasure Development

BARDA-BAA-11-100-SOL-00001

Brian Dattilo, Ph.D.

Project Officer

Strategic Science and Technology Division (SST)

June 8, 2011



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Innovation – What are the guidelines?



"I'll be happy to give you innovative thinking. What are the guidelines?"



Platform Technologies and Applications

CBRN Division

Product Specific Applications – e.g. Anthrax vaccine, etc.

SST Platform Technologies – Process Oriented

Ex vivo Immune System

Adjuvant/Delivery

Analytical Assays

Protein Stabilization

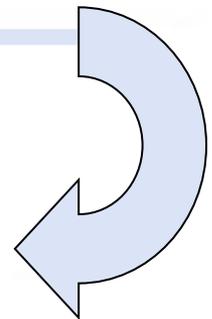
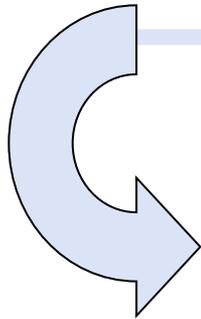
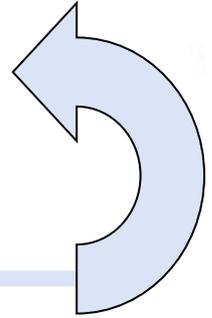
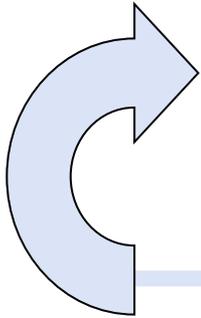
*Molecular Tools / Methods
for Diagnostic Tests*

Biomanufacturing

Applied to Late Stage Products – Integrated Development Activities

Product Specific Applications – e.g. H1N1 vaccine, etc.

Influenza & Emerging Diseases Divisions





SST BAA Areas of Interest

- SST Area of Interest #1: Technologies to accelerate evaluation of candidate vaccines and therapeutics
- SST Area of Interest #2: Formulation chemistry, protein stabilization, and vaccine delivery technologies
- SST Area of Interest #3: Innovative methods in bioprocess development and manufacturing
- SST Area of Interest #4: Methods and technologies to advance development of tests for rapid diagnosis of human injury and infections



Purpose of SST BAA

Innovations in Product Development and Analytical Technologies

- Support innovative applied science and technology platforms associated with product development, analytical characterization, evaluation, and biomanufacturing improvements relevant to MCM objectives
- Generate validated data for comparability analysis with candidate products in late stages of development and that have direct application to commercial-scale manufacturing and testing processes
- Development activities should be fully integrated with regulatory activities
- Complement and support CBRN, Flu, and EID portfolio efforts
- *Note that the BAA states “BARDA is open to evaluation of technologies at multiple stages of development.”*