Medical Countermeasures Clinical Studies Network (MCM CSN)

Solicitation 13-100-SOL-00008

Pre-Proposal Conference

BARDA/ASPR/OS/HHS

April 17, 2013

Agenda

Introduction	Jo Schweinle, MD; Director Division of Clinical Studies, BARDA/ASPR
RFP Review	Josh Speidel, PhD; Project Officer, BARDA/ASPR
Contracting Review	Matt McCord; Contracting Officer, AMCG/ASPR
Break	30 minutes
Question Review	Josh Speidel, PhD; Project Officer, BARDA/ASPR
Concluding Remarks	Jo Schweinle, MD; Director Division of Clinical Studies, BARDA/ASPR

Note

This presentation and verbal discussions that occur during this meeting are not intended to change the requirements of the RFP. Changes to the RFP must be documented in writing and posted to the Federal Business Opportunities website for this solicitation.

Questions may be submitted on the index cards for consideration during the break, or at MCM-CSN@hhs.gov.

All official solicitation documents are posted on www.FedBizOpps.gov.

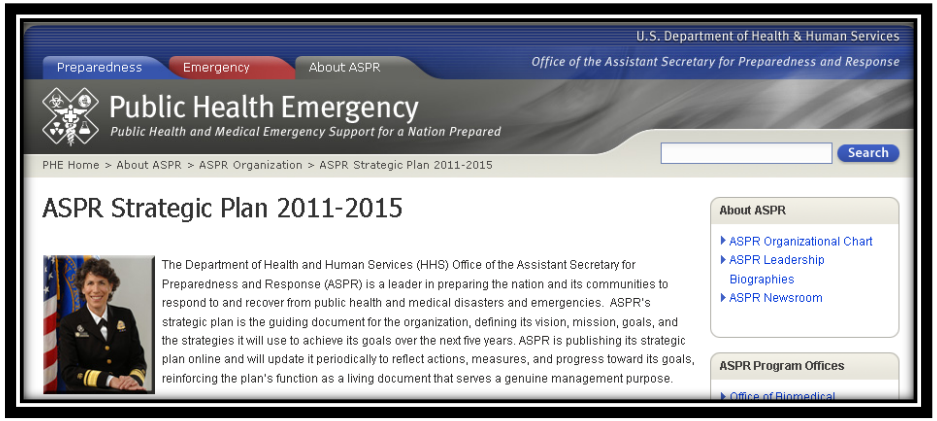
The solicitation and all amendments to the solicitation documents are posted on this website under the Solicitation number RFP-13-100-SOL-00008

Please take note of amendments to the RFP

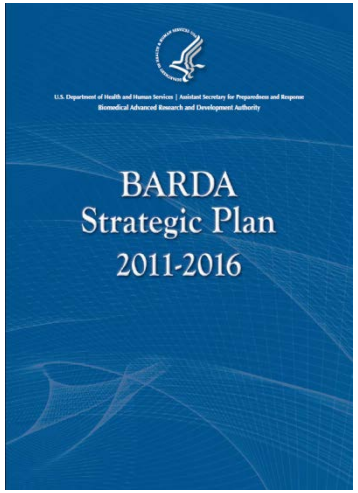
If you have questions or problems obtaining the Solicitation or Amendment documents, please contact us at MCM-CSN@hhs.gov.

Background

ASPR Goal 3: Provide core advanced development and manufacturing services to medical countermeasure innovators



BARDA Goal 2: Reduce regulatory barriers and clarify regulatory pathways by assisting private sector partners in the development of regulatory strategies and **design and execution of clinical studies** for needed medical countermeasures



RFP Review

Background

The MCM CSN Strategic Objectives:

- Provide a clinical study core service for use on a routine or emergency basis by BARDA and by BARDA's product development partners.
- Enhance BARDA's preparedness and response to CBRN, PI and EID threats.
- Promptly complete clinical activities supporting regulatory applications including but not limited to EUA.
- Conduct urgently needed clinical trials during a public health emergency.
- Improve financial management of clinical trials and potentially reduce the MCM clinical development costs to BARDA.
- Reduce the risk associated with less mature or repurposed products by expanding the available clinical data.

BARDA will coordinate the activities of the MCM CSN with the clinical resources of our interagency partners – including those of the National Institute of Allergy and Infectious Diseases (NIAID).

MCM CSN Solicitation Key Elements

- Proposals are due May 16th, 2013
- Full and open competition
- Teaming and subcontracting arrangements are permitted
- Period of Performance = 2 year base with three 1 year options
- Minimum ordering amount: $400,000 during the base period
- MCM CSN will be an Indefinite Delivery Indefinite Quantity (IDIQ) Contract with the possibility for both Cost Reimbursable and Firm Fixed Price (FFP) Task Orders
- USG may issue multiple awards
- All updates, amendments, etc. will be available online at www.fedbizopps.gov

MCM CSN Mandatory Criteria for Eligibility

SECTION M – Evaluation Factors For Award

M.1. Technical Evaluation

M.1.2. Mandatory Criteria for Eligibility

Offerors shall have completed at least one infectious disease or chemical, biological, radiological or nuclear clinical study under a FDA Investigational New Drug (IND) application in the last 5 years. A clinical study is deemed "complete" for purposes of this criterion when a final clinical study report is produced.

SECTION L – Instructions, Conditions and Notices to Offerors:

L.2.1.1.(3) Section 3: Mandatory Evaluation Criteria

Offerors must show completion of at least one infectious disease or chemical, biological, radiological or nuclear clinical study under a FDA Investigational New Drug (IND) application in the last 5 years in order to be considered for award. A clinical study is deemed "complete" for purposes of this criterion when a final clinical study report is produced. Offerors shall submit the title of the clinical study, ~~the identity of the sponsor~~, the IND number as documentation.

C.3.1. Objective 1: Clinical Studies

Offeror shall provide clinical research services and study execution as a service to BARDA. These studies will clinically evaluate CBRN, PI and/or EID MCMs. These studies may be Phase 1, 2, 3, or 4 (as defined by the FDA) or combinations of these phases.

Clinical research services may include the following components:

- Planning and pre-study activities
- Safety Monitoring
- Document creation and management
- Clinical Trial Execution
- Identification and contractual agreements with clinical research vendors to support studies
- Data management and biostatistics
- Quality Metrics
- Clinical Site management
- Provide documented product delivery, storage and pharmaceutical product accountability procedures[1]

1.This will be added to this list of potential services for Objective 1 in the next amendment to the RFP.

C.3.2. Objective 2: Clinical Trial Response Readiness

Successful Offerors shall provide clinical study execution services, as described in Objective 1, for CBRN, PI and EID MCMs. RTORs will be divided into two components – preparedness and response.

C.3.2.1. Preparedness: Offerors may be required to perform the following activities to prepare for a clinical trial during a public health emergency:

- Provide a plan that is ready to execute for the trial to include but not limited to personnel, documentation, regulatory approvals, material and management plans as appropriate
- Test the plan
- Provide Clinical Protocol (CPs)
- Provide Case Report Forms (CRFs)
- Provide Informed Consent forms (ICFs)
- Develop a clinical and safety database in preparation for Clinical database readiness
- Pre-identify clinical research sites including study budget and contracts in place
- Pre-qualify central laboratories for validated assays
- ~~Provide documented product delivery, storage and pharmaceutical product accountability procedures~~ [1]
- Obtain Institutional Review Board (IRB) approval of the clinical protocols, annotated CRFs and ICFs. (National IRB if available/appropriate)
- Establish an identified project team. The project team may include a clinical research associate, safety monitor, data manager, regulatory specialist, medical writer, project manager and pharmacovigilance specialist
- Document data flow and sample handling processes (lab manual)
- **Operational strategy to gather clinical data**
- Annual review and renewal of the plan

1.To be removed from this list of potential services for Objective 2 in the next amendment to the RFP.

C.3.2. Objective 2: Clinical Trial Response Readiness

C.3.2.2. Response: Offerors may be required to perform the following activities to prepare for a clinical trial during a public health emergency:

Offerors shall commit upon Task Order (TO) award to start the study within defined timelines. The protocols for these studies may be established prior to the public health emergency, or created at the time of the public health emergency.

During an event, the Contractor shall provide a dedicated project team to handle the site/patient management, enrollment, data capture and pharmacovigilance responsibilities for the protocols. Once the initial protocols are fully enrolled and the data cleaned and locked, the Contractor will provide draft clinical study reports within the defined timelines. After BARDA review of the draft documents, the Contractor will provide a completed CSR for BARDA's approval and issuance within the defined timeline.

Requests for Proposals Comments

- Be certain to read the entire RFP
- Ask questions on anything that is unclear or requires further clarification
- Direct written questions to the appropriate individuals.
  - Contracting Officer (CO) and Contract Specialist (CS) at MCM-CSN@hhs.gov
- Two (2) separate required volumes
  - Technical Proposal
  - Business Proposal

Post-Submission Activities

- Mandatory Criteria Evaluation
- Technical and Business Evaluation Panels
- Contracting Officer Competitive Range Determination
- Pre-award Debriefing for Offerors not in the competitive range
- Discussions/Negotiations (if necessary)
- Site Visits (if necessary)
- Request and Receive Final Proposal Revisions
- Evaluation of Final Proposal Revisions
- Brief Source Selection Authority
- Award Determination
- Draft Contracts
- Contract Award
- Post-Award Debriefing

Contracting Review

Contractual and Administrative Information

All official solicitation documents are posted on www.FedBizOpps.gov.
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Matt McCord, Contract Specialist (202.260.0689)
Nat Cohen, Contract Specialist (202.205.8968)
Jason Bell, Contracting Officer (202.260.1457)

Base Contract Structure

CLIN #	Description	Period of Performance	Minimum Ordering Amount
001	**Base Period** – Clinical Study Services and Technical Reports on Task Orders.	24 Months	$400,000
002	**Option Period One** – Clinical Study Services and Technical Reports on Task Orders.	12 Months	$200,000
003	**Option Period Two** – Clinical Study Services and Technical Reports on Task Orders.	12 Months	$200,000
004	**Option Period Three** – Clinical Study Services and Technical Reports on Task Orders.	12 Months	$200,000

Business Proposal Format

- Three primary sections of the Business Proposal:

  1) Introduction/Overview/Background/Misc (Cover Sheet, Labor Rates, etc.)
  2) Sample RTOR 001
  3) Sample RTOR 002

  ➢ Submit all three as part of the "Business Proposal"

- Business Proposal Page Limits: **50 pages aggregate****

  15 pages (RTOR 001)
  15 pages (RTOR 002)
  20 pages (misc. base period)
  50 PAGES

- Font: 11 point (Tables/Charts = 8 point)

**Attachments required to be included from Section J of the RFP are NOT counted against the page limit nor are cover page and table of contents

Business Proposal Clarifications

- Earned Value Management System (EVMS)
  - No specific tool is necessarily required at the time of base contract award. However, task orders may require EVMS.

- Past Performance: provide 5 contracts completed in the past three years (Government or private)
  - Note: Offeror must disclose ALL current Government contracts for services similar to those sought in this RFP
  - Attachment #10 & #11: Informational purposes

- Sample RTOR's: Cost-reimbursement
  - Presentation of budget
  - EVMS

Business Proposal Clarifications

- Costs unallowable unless authorized by Contracting Officer (B.5.6):
  - Certain types of subcontracts;
  - Foreign travel costs;

- Number of Awards
  - Anticipating one or more
  - Based on quality of responsive proposals received

- Small Business Plan:
  - Required for contracts (task orders) in excess of $650K
  - Not required for small businesses (defined by NAICS code)

- Attachment #13 Payment Enrollment Form

RFP Questions

Please submit questions 10 calendar days prior to solicitation closing date (*i.e.* May 6). However, we will make our best effort to answer questions received after this date until the solicitation closes (*i.e.* May 16).

Submit questions to: MCM-CSN@hhs.gov.

Question Review

Submitted Questions/Answers

- Mandatory criteria – ‘completion’
- Attachments to the RFP and the page count
  - Attachments 3, 4, 9,10 and 12
  - Gantt charts
- Attachments to the Sample Task Orders - numbering
- Due date extension

General Questions Continued

- The RFP notes that HHSAR 352.228-7 is applicable. Does BARDA request Offerors to carry Clinical Trial Insurance and if so, shall Offerors include this cost in their Sample Task Order 0001 and Sample Task Order 0002?
  ANSWER: The requirement to carry Clinical Trial Insurance will be defined on a case-by-case basis. For purposes of this RFP response, the cost of Clinical Trial insurance should be included in Sample RTOR 0001 and 0002 proposal responses.
- Per the RFP, QA support will be needed throughout both of the objective/task orders but what about Investigator Site Audits? Does BARDA plan to conduct those themselves or do they intend for the contractor to do so?
  ANSWER: As appropriate the contractor is expected to conduct site audits. BARDA reserves the right to attend, initiate or conduct site audits independently or in concert with the contractor. BARDA RQA does have the expertise to conduct an ISA but can also have a contractor conduct the ISA. In the latter case BARDA may be an observer.
- Will this contract execute Emergency Use Authorization expanded access trials only in the Continental United States?
  ANSWER: This contract anticipates the potential to execute Emergency Use Authorized trials only in the United States (including expanded access trials).
- Please confirm if the page counts for the sample task order technical (20 page limit per) and business proposal (15 page limit per) are included in the total page count limit of 75 pages for the technical proposal and 50 pages for the business proposal.
  ANSWER: Yes

General Questions Continued

- To what extent do activities as described in section C.3.1 (Objective 1) have to be completed in a single protocol or single IND, and does each individual service need to be the sole responsibility of the Offeror, or are previous teaming experiences acceptable?
  ANSWER: Activities described in section C.3.1. (Objective 1) do not need to be completed in a single protocol or single IND. Previous teaming experiences are unacceptable.
- Will the successful bidder be responsible for establishing subcontracts (per Section C.3.1 8a, page 12) with the clinical sites, or will they be responsible for establishing a site selection process?
  ANSWER: A successful Offeror is responsible for establishing subcontracts with clinical sites and for establishing a site selection process.
- What is the estimated number of non-emergency trials, by phase and by year, that are expected to be competed on this contract?
  ANSWER: BARDA may conduct two (2) to five (5) non-emergency trials per year. The Phase of the studies will be specified in the RTOR. BARDA does not commit to conducting any studies, however B.5.1. specifies the Minimum Ordering Amount of $400,000 for the base period, and $200,000 for each subsequent option period.

General Questions Continued

- Are academic medical centers permitted to be part of the MCM network if the CRO routinely uses these types of sites?
  ANSWER: Academic medical centers that meet the requirements established in the RFP would be acceptable.
  - Assuming the answer is yes, is BARDA interested in utilizing a site consortium with commercial and academic sites managed by a CRO for this effort? For example, for ROTR 001, is it acceptable to include 1 academic site and 5 commercial sites that met all requirements?
    ANSWER: This would be acceptable.
- Will the Contractor be required to submit the CSR electronically or via paper?
  ANSWER: All reports to the government will be electronic.
- What % of projected trials would not be conducted under an IND?
  ANSWER: No response.
- Does the Government have a preferred vendor for safety database services?
  ANSWER: No
- What National IRBs would likely be utilized?

  ANSWER: This will be defined in any future task order requiring the use of a National IRB.

General Questions Continued

- Regarding Attachment 2, does the Government expect site costs such as recruitment, enrollment, remuneration, visit fees, supplies, etc to be included? If so, where would those costs fit in Attachment 2?
  ANSWER: The government expects site costs such as recruitment, enrollment, remuneration, visit fees, and supplies to be included in Attachment 2B under 14. Site Initiation.
- On page 95 of 156 (Number 1 of Exclusion Criteria) in the RFP, a description of the vaccine composition is included. However, the adjuvant is simply described as squalene-based. Since squalene itself is not an adjuvant, can you be more specific about the composition of the actual adjuvant or give its designation such as MF59 or AS03?
  ANSWER: Assume the adjuvant is a generic oil in water emulsion, however Offerors are not anticipated to be responsible for activities requiring information on the composition of the adjuvant.

General Questions Continued

- Can the Government clarify whether the RFP requires that the pricing provided for Sample Tasks 1 and 2 should (or should not) include per patient reimbursement to the site(s).
  ANSWER: Yes.
  - Appendix A, page 96. If the answer above is that the pricing should include per patient reimbursement costs as part of this proposal response, can the Government define the type of safety labs and antibody assays required for Sample Task 1?
    ANSWER: For Sample RTOR 0001, safety labs are general chemistry and hematology: Electrolytes, SGPT, SGOT, albumin, total protein, Creatinine, BUN. WBC with differential, RBC, platelets, HgB, HCT, PT, PTT. Antibody assays include Hemagglutination Inhibition Assay and microneutralization. Page 96 is hereby modified to include this list of safety labs and antibody assays.
- If the service listed in C.3.1 on page 11 is not listed in either of the sample Task Order pricing schedules on page 87 or 114, should the Offeror assume that the service will not be provided for the Sample Task?
  ANSWER: Offerors are expected to provide the ensemble of services required to complete the objectives of the Sample Task Orders given the information provided, even when they are not explicitly identified.
- What are the potential circumstances where remote data entry may be relevant?
  ANSWER: No additional information on this topic will be provided.

General Questions Continued

- Page 12, Section 8a. The RFP states that the Offeror must have current access to a network of sites available to perform clinical studies. Does the Government require a description of the site network?
  - If so, can the Government define the specific information/capabilities/ experience it is interested in to understand the Offeror's site network capabilities?

  ANSWER: The government requires a description of the site network. The description should include the therapeutic areas and the Phase of studies the sites have conducted as well as the site personnel available to work on the studies.
- Section C7, page 16. Can the Government confirm whether or not it would like the template for the QC/QA monitoring plan submitted with the RFP response?
  ANSWER: Yes.
- For the purposes of defining the approach and price for clinical monitoring, is the Government willing to consider Risk Based Monitoring Approach or does it require 100% source verification?
  ANSWER: The government is willing to consider less than 100% source verification. Please provide a plan for a Risk Based Monitoring Approach.
- Section M 1.3.2 d page 72. Can the Government confirm that it would like the actual quality management metrics from the Offeror's experience or is it the defined targeted metrics that the Government is interested in?
  ANSWER: BARDA would like to review the actual quality management metrics from the Offeror's experience.

General Questions Continued

- Section M 1.3.5 page 73. Can the Government provide a more specific definition of the request for "quantitative details" requested to be included in the Technical Approach for Sample Tasks?
  ANSWER: No further information will be provided for this topic.
- Attachment 1B, page 86. When providing pricing information, should the Offeror assume that the protocol is already developed, as on page 80 the RFP states that the design has already been discussed with the FDA?
  ANSWER: Yes.
- Attachment 1B page 86. Is this table a complete list of all activities to be performed for the trial or is this a tool to assess comparative pricing?
  ANSWER: The table is a guide for pricing.
- Attachment 1B page 87. Does management of investigator payments include contracting with investigators?
  ANSWER: Yes.

General Questions Continued

- In Section G9 regarding Key Personnel on page 29, should the key personnel identified for this contract include the program director, project manager, medical monitor, data management project manager, and biostatistician as defined on page 80 of the RFP related to Sample Task Order 01, or is the list on page 80 just related to Sample Task Order 01 and not necessarily tied to the overall contract Key personnel?
  ANSWER: For the technical proposal to the base contract, top level management positions are sufficient. It is anticipated that responses to the Sample RTOR will require additional highly qualified personnel who should be identified as key to those responses. Key personnel for Task Orders are anticipated to include the program director, project manager, medical monitor, data management project manager and biostatistician.
- For both Sample Tasks Orders 1 and 2, the RFP states that the Offeror is to provide 24 hour medical monitoring and there is no pricing requested for development and management of either an SMC or DSMB. Does this mean that the Government does not intend to use either an SMC or DSMB in the sample tasks?
  ANSWER: The government will stipulate whether a SMC or DSMB is required for a study in the task order. Sample RTOR 0001 does require a DSMB. Sample RTOR 0002 does not require a DSMB.

General Questions Continued

- The RFP uses the phrase "key personnel" in many locations without specifying the positions of interest, and the RFP also makes clear that the qualifications of key personnel should be provided. Since highly qualified personnel working on each task order will change based on the nature of the task order, can an Offeror assume that the identification of top level management positions for the technical and business sides of the proposal is sufficient for key personnel? If not, could more guidance be provided by BARDA on the nature of key personnel.
  ANSWER: For the technical proposal to the base contract, top level management positions are sufficient. It is anticipated that responses to the sample Task Orders will require additional highly qualified personnel who should be identified as key to those responses. Key personnel for Task orders are anticipated to include the program director, project manager, medical monitor, data management project manager, and biostatistician.

Sample Request for Task Order 0001 (sRTOR1) Questions

- Attachment 1 clearly outlines the study design as a randomized, placebo controlled trial, please confirm if study vaccines and adjuvant will be administered in a double blind manner.
  ANSWER: Yes
- Please confirm if secondary packaging and labeling into kits will be required by the CRO.
  ANSWER: For sample RTOR0001, secondary packaging and labeling into kits will be required of the CRO.
- The deliverables schedule on page 96 outlines final IND submission package in Dec 2013, please confirm if CRO will be expected to prepare an IND as this task is not included in regulatory activity (Attachment 1B, Section 2, Table 1).
  ANSWER: For sample RTOR 0001, HHS will prepare and submit the IND package.

sRTOR1 Questions Continued

- In RTOR 1, how is the vaccine + adjuvant packaged – pre-filled syringe containing antigen & adjuvant; separate single-use antigen & adjuvant components that must be combined prior to administration; multi-use pre-mixed vials containing antigen + adjuvant; or multi-use separate vials of antigen & adjuvant that must be combined prior to administration? What are the dimensions of the smallest unit package of vaccine and how many vaccine doses does this represent?
  ANWSER: For sample RTOR 0001, separate, multi-dose vials of antigen & adjuvant that must be combined prior to administration are required. Each vial will contain 5 antigen doses or 5 adjuvant doses. The smallest unit package of vaccine will be twelve (12) five (5) mL vials. Package dimensions are as follows:

Components	Dimensions	Contents	Comment
Package	2.5" x 1.125" x 1.125"	10 doses	Providers receive increments of 10 packages
Master Carton	12.5"x 6.5" x 5.625"	100 packages (1,000 doses)	Provider can store as master carton or as packages

sRTOR1 Questions Continued

- In Attachment 1, Attachment 1B – Pricing Schedule/CLIN Structure, page 86 of 156, there is no mention of DSMB or Safety Review Committee (SRC). Is either the DSMB or SRC to be included in the costs for Objective 1 Clinical Studies? If yes, which committee?
  ANSWER: For sample RTOR0001, Yes. Pricing Schedule/CLIN Structure, item 7 on Pharmacovigilence on page 88 is hereby amended to add a line item for Data Safety Monitoring Board. This item is the responsibility of the Offeror and should be included in the business and technical proposals.

- An adjuvant is mentioned in the synopses along with A/H5N1 vaccine. Will cross- reporting to other sites for other studies be necessary for expedited reports?
  ANSWER: For sample RTOR0001, all reports involving the safety and immunogenicity will be submitted to BARDA. BARDA will be responsible for optioning any clinical trial agreements with manufacturing which include cross-reporting. In sample RTOR 0001, cross-reporting is not required.
- Page 81 states:

  Site Visit

  Site visits by HHS personnel are required post-award. See —Table 1: Scope of work and costs for each study activity in Attachment 2 for details.

  Please clarify the reference to Attachment 2, Table 1 as well as the role and responsibility of HHS personnel in the site visits.
  ANSWER: BARDA representative(s) will visit (with or without a representative of the CRO) one or more clinical site(s) to assess the quality of the site(s) and observe CRO site start-up activities, or other currently unspecified reasons.

sRTOR1 Questions Continued

- What is the duration of the contract for task order #1? In Table 1 (page 81) the total program duration is stated to be 24 months. On pages 79 and 81, the anticipated period of performance/contract duration are stated to be 26 months from date of task order award. Please clarify.
  ANSWER: Table 1 on Page 81 is hereby amended to 26 months.
- Table 1 on page 86/156 lists BARDA as responsible for Investigator Brochure preparation, while the Deliverables & Schedule table on page 96 lists the Investigator Brochure as a contract deliverable. Please clarify whether the contractor will be responsible for preparation of the Investigator Brochure
  ANSWER: Page 96 is hereby amended to remove delivery of item 9, Investigator Brochure.
- On page 87, Table 1 indicates that both BARDA and the CRO will have responsibility for packaging, labeling, storage and distribution of IP and that BARDA will be responsible for authorization of initial IP shipment to sites. Please clarify the respective roles and responsibilities of BARDA and the CRO in this regard.
  ANSWER: For Sample RTOR0001, BARDA will provide the Investigational Product. The CRO will be responsible for the packaging, labeling, storage and distribution of the Investigational Product. Table 1 on Page 87 is hereby amended to remove the 'X' in the column demarking the responsibility of BARDA.

sRTOR1 Questions Continued

- Please confirm that Offeror's do not need to include the costs of any study drug or sponsor provided material related to Sample ROTR 0001.
  ANSWER: Offeror's do not need to include the costs of any study drug or sponsor provided material related to Sample RTOR 0001.
- It is typical for a DSMB to be comprised of an odd number of members (either 3 or 5 total members is most common). Please provide the number of members you intend to have serving on this committee.
  ANSWER: The Offeror's design/discussion of this issue will be a factor in the technical assessment of their experience and qualifications to conduct the type of studies BARDA may be interested in. For Sample RTOR 0001, a DSMB with 3 members is required for sample RTOR 0001. For Sample RTOR 0002, a DSMB is not required.
- How many data review meetings are anticipated during the study? How many of these meetings do you anticipate will be held face-to-face and how many via teleconference?
  ANSWER: For Sample RTOR 0001, three scheduled teleconferences are required. For Sample RTOR 0002, zero review meetings are anticipated.

Sample Request for Task Order 0002 (sRTOR2) Questions

- Is it anticipated that response period will only occur after the 24 month base period has elapsed or could these overlap if tasks for preparedness have completed to an extent that it was possible to activate a response if outbreak situation occurred?
  ANSWER: The response may occur at any time during the Task Order period of performance. The preparation and response components of Sample RTOR 0002 could overlap. If response is required during the preparation period, the timeline to response may be amended to suit the circumstance.
- Is 24-hour response expected to cover 100% of all regions/states/cites in the USA only?
  ANSWER: For Sample RTOR 0002, Yes. The 24 hours response is expected to fully cover all of the United States. There is no expectation of coverage for the rest of the world.
- For "manage IP distribution" activity (Attachment 2B, Section 16, Table 1) there are two crosses indicating responsibility for HHS/BARDA and CRO. Please confirm if CRO will be responsible for setting up drug storage central depots and shipping to sites within 24 hours.
  ANSWER: For Sample RTOR 0002, the storage, shipment and delivery of the product will be solely managed by HHS.
- Will HHS/BARDA ship supplies in advance to a CRO-managed depot if needed, or will 24-hour response come from BARDA managed depot?
  ANSWER: For Sample RTOR 0002, the storage, shipment and delivery of the product will be solely managed by HHS.
- What is the likely product expiration date?
  ANSWER: For Sample RTOR 0002, HHS will be accountable for the expiry of the investigational product delivered to the clinical site(s).

sRTOR2 Questions Continued

- Is there a minimum or maximum patient number that would trigger study termination and/or reporting?
  ANSWER: For Sample RTOR 0002, No. Collection of data from 200 patients are sufficient to complete enrollment. The number of patients will be determined based on the size of the emergent event.
- In section H.2.2, page 31 of 156, expectation is that all Phase III studies will have a DSMB. Attachment 2B, starting on page 114 of 156, does not include Data Safety Monitoring Board (DSMB) in the Activities for the Phase III study. Should the contractor response include DSMB activities and associated costs?
  ANSWER: Sample RTOR 0002 is hereby amended to solely Cost Plus Fixed Fee.
- Please clarify the duration of the base award for task order 2 and the number and duration of option periods.
  ANSWER; The base award for Sample RTOR 0002 is 24 months. The duration of option periods in Sample RTOR 0002 is 12 months. The Option to Respond will only be executed in the case of a Public Health Medical Emergency. The Option to continue preparedness will be exercised at the end of the base period, as warranted by performance and/or BARDA program needs.

sRTOR2 Questions Continued

- Please clarify the scope of the table top exercise and subsequent gap analysis in terms of the scope of exercise inputs. For example, would this include modeling only those activities within the precise task 2 scope such as product delivery, patient eligibility, AE reporting, etc., or would it also include external impacts such as public response, media participation, coincident emergencies, etc.
  ANSWER: For Sample RTOR 0002, the contractor is expected to gap test the aspects of preparedness for which the contractor is responsible such as collection of clinical data, as defined in Sample Request for Task Order Response 2, from sites treating patients during an emergency.
- Please clarify the scope of the table top exercise participants. Would the exercise be limited to BARDA and the contractor(s), or would it also include distribution partners, site participants, the Food and Drug Administration and/or others?
  ANSWER: For Sample RTOR 0002, the table to exercise will include participants from the contractor and BARDA.
- On page 114, Table 1 indicates that both HHS/BARDA and the CRO will have responsibility for the clinical protocol and ICF template. Please clarify the respective roles and responsibilities of HHS/ BARDA and the CRO regarding the development of a final clinical protocol and ICF template.
  ANSWER: For Sample RTOR 0002, HHS will develop protocol and ICF template for use during an emergency. The CRO is expected to ensure IRB approval of the protocol during the period of performance for preparedness.

sRTOR2 Questions Continued

- On page 115, the table indicates that HHS/BARDA will be responsible for packaging, labeling, storage and distribution of investigational product as well as authorization of initial IP shipment to sites and that both HHS/ BARDA and the CRO will have responsibility for managing IP distribution and related documentation. Please clarify the respective roles and responsibilities of HHS/ BARDA and the CRO in this regard. For example, will HHS/BARDA or the CRO be responsible for shipping IP to the sites?
  ANSWER: For Sample RTOR 0002, HHS will be responsible for packaging, labeling, storage and distribution of investigational product including shipping IP to the sites.
- Will the contractor be responsible for conducting the hematology and chemistry laboratory analyses?
  ANSWER: For Sample RTOR 0002, the hematology and chemistry laboratory analysis for Sample RTOR 0002 is expected to be done by the clinical sites treating the patients.
- Do you anticipate 24/7 dosing?
  ANSWER: For Sample RTOR 0002, Yes.

Closing Remarks