

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE S	PAGE OF PAGES 1 40
2. AMENDMENT/MODIFICATION NO. 0001	3. EFFECTIVE DATE 26-Apr-2013	4. REQUISITION/PURCHASE REQ. NO.		5. PROJECT NO.(If applicable)
6. ISSUED BY NATICK CONTRACTING DIVISION US ARMY CONTRACTING COMMAND - APG NATICK CONTRACTING DIVISION ATTN: CCAP-SCN, KANSAS STREET NATICK MA 01760-5011	CODE W911QY	7. ADMINISTERED BY (If other than item 6) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		X	9A. AMENDMENT OF SOLICITATION NO. W911QY-13-R-0012	
		X	9B. DATED (SEE ITEM 11) 18-Apr-2013	
			10A. MOD. OF CONTRACT/ORDER NO.	
			10B. DATED (SEE ITEM 13)	
CODE	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input checked="" type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input checked="" type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Summary of Changes:				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)		
		TEL:	EMAIL:	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY _____ (Signature of Contracting Officer)		26-Apr-2013

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

The following items are applicable to this modification:

SUMMARY OF CHANGES

The purpose of this amendment is as follows:

- 1) Add ADM language to Section A.
- 2) Update the language in CLINs 0002AA, 0002AB, 0002AC, 0002AD, 0008, 0008AA, 0008AB, 0008AC, 008AD and CLIN 0009 as described below.
- 3) Update the Inspection/Acceptance terms of CLIN 0001.
- 4) Update Section J "List of Attachments" to reflect 2 attachments and 18 CDRLs.
- 5) Add Section L.2 for the Bidder's Library. This is where the VLP TDP can be attained.
- 6) Update the number of copies required under Section L.3.2.1.
- 7) Update Section L.3.4.1.3
- 8) Update Section 3.3.3 of Attachment C Statement Of Objectives.
- 9) Update the Quality Template Attachment under Section L Attachment D.
- 10) Add the VLP Non Disclosure Template to Section L Attachment D.

SECTION A - SOLICITATION/CONTRACT FORM

The required response date/time has changed from 02-June-2013 05:00 PM to 07-Jun-2013 05:00 PM.

SECTION A – SOLICITATION/CONTRACT FORM

The following has been added to Section A

The DoD recently awarded an Advanced Development and Manufacturing (ADM) contract (W911QY-13-C-0010) to Nanotherapeutics, Inc. Alachua, FL to establish a core manufacturing medical countermeasure (MCM) capability.

MCM contractors are encouraged to consider the ADM contractor for subcontracting opportunities under FAR 52.244-5 for the following MCM developmental core functions: Clinical Research Organization, Contract Manufacturing Organization, Test & Eval, & Fill/Finish.

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 0002AA

The CLIN extended description has changed from product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 1.6ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Final product per dosage concentration, with and without adjuvant 1.6ug of each antigen to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

SUBCLIN 0002AB

The CLIN extended description has changed from product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 5ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Final product per dosage concentration, with and without adjuvant 5ug of each antigen to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

SUBCLIN 0002AC

The CLIN extended description has changed from product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 16ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Final product per dosage concentration, with and without adjuvant 16ug of each antigen to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

SUBCLIN 0002AD

The CLIN extended description has changed from product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 50ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Final product per dosage concentration, with and without adjuvant 50ug of each antigen to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

CLIN 0008

The CLIN extended description has changed from Deliver cGMP bulk and final Marburg vaccine product suitable for Phase 1 clinical trial including all labor and materials related thereto, release testing, and 24-month stability testing. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). Excludes all work performed to deliver CLIN 0007. One lot consists of a final Marburg vaccine product per dosage concentration, with and without adjuvant (for four concentrations of each bulk antigen concentration produced, 1.6ug, 5ug, 16ug and 50ug) to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Deliver cGMP bulk and final Marburg vaccine product suitable for Phase 1 clinical trial including all labor and materials related thereto, release testing, and 24-month stability testing. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award). Excludes all work performed to deliver

CLIN 0007.

SUBCLIN 0008AA

The CLIN description has changed from Final trivalent vaccine to Final Marburg vaccine.

The CLIN extended description has changed from product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 1.6ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Final product per dosage concentration, with and without adjuvant 1.6ug of Marburg antigen to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

SUBCLIN 0008AB

The CLIN description has changed from Final trivalent vaccine to Final Marburg vaccine.

The CLIN extended description has changed from product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 5ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Final product per dosage concentration, with and without adjuvant 5ug of Marburg antigen to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

SUBCLIN 0008AC

The CLIN description has changed from Final trivalent vaccine to Final Marburg vaccine.

The CLIN extended description has changed from product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 16ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Final product per dosage concentration, with and without adjuvant 16ug of Marburg antigen to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

SUBCLIN 0008AD

The CLIN description has changed from Final trivalent vaccine to Final Marburg vaccine.

The CLIN extended description has changed from product per dosage concentration, with and without adjuvant bulk antigen concentration produced, 50ug to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

to

Final product per dosage concentration, with and without adjuvant 50ug of Marburg antigen to support clinical dose escalation studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

CLIN 0009

The CLIN extended description has changed from Conduct expanded stability testing (for an additional three years beyond CLIN 0002 requirement) on cGMP Marburg bulk and final products produced under CLIN 0008. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award).

to

Conduct expanded stability testing (for an additional three years beyond CLIN 0008 requirement) on cGMP Marburg bulk and final products produced under CLIN 0008. All efforts shall be in accordance with the contractor's Statement of Work (SOW) dated (to be inserted upon award).

SECTION D - PACKAGING AND MARKING

The following have been modified:

Packaging and Marking shall be in accordance with the Contractor's Statement of Work dated (insert upon award), Attachment 1 in Section J.

All packaging, handling, storage, and transportation shall be in strict accordance with FDA or in accordance with Government specifications. At a minimum, all deliveries shall be marked with the Contract number and Contractor name. The Contractor shall guarantee that all required materials/deliverables shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

The Acceptance/Inspection Schedule for CLIN 0001 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Destination	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

LIST OF ATTACHMENTS

Attachment	Description	Date	No. of
------------	-------------	------	--------

No			Pages
1	Contractor's Statement of Work	To be inserted upon award	
2	VLP Technical Data Package: To include list of Government Furnished Information and manufacturing process	March 2013	353

Contract Data Requirements List (CDRL) DD Form 1423

Data Item #	Description
A001	Integrated Product Team Meeting Minutes
A002	Contractor's Progress, Status, and Management Report
A003	Integrated Master Schedule (IMS)
A004	Scientific and technical Reports Summary
A005	Quarterly Program Review
A006	Contract Work Breakdown Structure
A007	Quality Agreement
A008	Technical Data Package
A009	EVMS - Integrated Baseline Review (IBR)
A010	EVMS – Integrated Program Management Report(IPMR)
A011	EVMS – Contract Funds Status Report
A012	Report, Production, or Delivery Problems
A013	Risk Management Plan
A014	Master Production Batch records
A015	Production Batch Records
A016	Regulatory Submissions and Communications
A017	Risk Management Status Report
A018	Stability Test Plan

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO BIDDERS

GENERAL INFORMATION

L.1 GENERAL INFORMATION

L.1.1 PROPOSAL SUBMISSION

Proposals shall be delivered no later than 5:00 p.m. Eastern Time (ET) on 02 June 2013 to the address below:

Solicitation W911QY-13-R-0012

ATTN: Nathan Jordan

ACC-APG Natick Contracting Division

110 Thomas Johnson Drive

Frederick, MD 21702

Each box shall be marked with the volume and copy number(s) contained in each box. See section L.3 for formatting and submission details.

L.1.2 PRE-AWARD SURVEY

The Government may conduct a Pre-Award Survey prior to any contract award. The pre-award survey may examine the Offeror's and/or Key Subcontractor's records of integrity and business ethics (which includes satisfactory compliance with the law including tax, labor and employment, environmental, antitrust, and consumer protection laws), technical ability, production capacity, management structure, financial capability, accounting systems, security controls/clearances, labor resources, performance record, and ability to meet required schedules.

L.1.3 DISCLOSURE OF PROPOSAL

a. Information contained in the successful or unsuccessful Offeror's technical/management or price proposal must be released under the Freedom of Information Act (5 U.S.C. 552) upon request from the public after contract award except to the extent it contains trade secrets and privileged or confidential commercial or financial information. If the Offeror's proposal contains material meeting this description which is customarily maintained in confidence in the course of the Offeror's business and is not otherwise publicly available, and if the Offeror does and is not otherwise publicly available, and if the Offeror does not want it disclosed to the public, he shall mark the title page with the legend that follows.

"This proposal, furnished in response to Solicitation No. W911QY-13-R-0012 contains trade secrets and/or privileged or confidential commercial or financial information. This information is maintained in confidence in the course of the Offeror's business and is not otherwise publicly available. The Offeror submits this information to the Government in confidence and understands that it is received with that intent. This information shall not be released or disclosed outside the Government under the Freedom of Information Act (5 U.S.C. 552) or under any other circumstances."

b. Proposals so marked will be accepted by the Government in confidence and will not be released provided that the Offeror and/or the Government can show, upon request under the Freedom of Information Act, that disclosure would either (1) impair the Government's ability to obtain necessary information in the future or (2) cause substantial harm to the competitive position of the Offeror.

L.2 BIDDERS LIBRARY

The Government candidate is the Virus Like particle containing the filovirus glycoprotein and the matrix protein (VP40) produced in mammalian cells as described in the Government Candidate Data Package provided in the bidder's library. Offerors are to propose to deliver, after limited advanced development, a current Good Manufacturing Practices (cGMP) trivalent filovirus vaccine using the Virus-Like Particle (VLP) system that will be suitable/acceptable for release for use in humans by the Government to support non-clinical and Phase 1 clinical studies under an Investigational New Drug (IND) application. The bidder's library will be internet accessible. In

order for all Offerors to have ample opportunity to gain access, the library will be accessible upon release of the RFP, and remain open for 60 days. Please see below for instructions to access the bidder's library. Please contact Nate Jordan for an appointment via e-mail to Nathan.C.Jordan.civ@mail.mil.

The ACC-APG Natick Contracting Division/JPEO-CBMS will establish an online reading room to allow access to previously undisclosed information. The purpose of the online reading room is to allow access to information that may include documents available to the general public, as well as documents with restricted access. Although no classified material will be made available, online access will be strictly controlled. If you wish access to this online reading room, the following conditions shall apply and be agreed upon in a request memorandum:

1. The interested parties shall identify one POC for online access and submit necessary credentials by email to the Contract Specialist identified below– which will be forwarded to the Contracting Officer and Edgewood Chemical Biological Center Security Office.
2. All requests for access will be decided by the Contracting Officer and ECBC Security Office on a case-by-case basis. Respondents shall submit proof of credentials from a SAM-registered organization with a CAGE Code and DUNS number on company letterhead, signed by your Facility Security Officer or Executive Management Personnel with printed name and position title.
3. Upon approval, respondents granted access will be sent the online reading room access information.
4. Viewers shall have read-only privileges; Respondents may not upload, delete, nor edit reading room documents.
5. Respondent's identities shall only be known to Government personnel related to this online reading room who have signed non-disclosure agreements.
6. Online access may be revoked at any time without explanation.

Instructions for Access to the Bidder's Library:

1. Visit <http://www3.natick.army.mil/filo.html>
2. Click on the red "Register" link
3. Fill out the online form and DO NOT press register yet.
4. Before pressing register, click on the FILO Bidder's Library Non-Disclosure Agreement link and follow the directions (print, sign, scan and email to Nate Jordan: nathan.c.jordan.civ@mail.mil).
5. Click on Register.
6. The online form and non-disclosure agreement email will be reviewed together by Mr. Jordan.
7. Once you are awarded access, you will receive a confirmation email from him with a password for the internet link and a second password to open the document.

L.3 INFORMATION TO OFFERORS AND INSTRUCTIONS FOR PROPOSAL PREPARATION

L.3.1 General Instructions

L.3.1.1 This section provides general guidance for preparation of proposals as well as specific instructions on the format and content of the proposal. The Offeror's proposal must include all data and information requested and must be submitted in accordance with these instructions. The proposal shall be compliant with requirements as stated in the Statement of Objectives (SOO), Attachment C and Contract Data Requirements List (CDRL) in Section J. The Offeror shall include evidence (e.g., statement of intent to enter into a teaming agreement) of Subcontractor relationships. **Non-conformance with these instructions may result in an unfavorable proposal evaluation. Any Offeror who submits an incomplete package may be considered unacceptable and could be eliminated from further competition.**

L.3.1.2 The proposal shall be clear, concise, and with sufficient detail for effective evaluation and for substantiating the validity of stated claims. The proposal should not simply rephrase or restate the Government's requirements, but rather shall provide convincing rationale to address how the Offeror intends to meet these requirements. The Offeror shall assume that the Government has no prior knowledge of the Offeror's facilities and experience and will base its evaluation on the information presented in the Offeror's proposal.

L.3.1.3 Each Offeror shall submit a proposal for the optimization and manufacture of a trivalent filovirus vaccine candidate using the Virus Like Particle (VLP) system for which the license to the Intellectual property is owned by the Government. The List of Government Furnished Material is provided in Section J.

L.3.1.4 Elaborate brochures or documentation, binding, detailed art work, or other embellishments are unnecessary and not desired.

L.3.1.5 The proposal acceptance period shall be specified in block 12 of the Standard Form 33 (at least 180 days minimum).

L.3.1.6 Questions regarding this Request for Proposal (RFP) must be made in writing within 15 calendar days after issuance of amendment 0001 and directed to the sole point of contact for this acquisition, Contract Specialist, Nathan Jordan at cbms.filorfp@amedd.army.mil. The Government reserves the right to decline addressing questions received more than 15 calendar days after final RFP issuance. Telephonic questions will not be accepted.

L.3.1.7 If an Offeror believes that the requirements in these instructions contain an error, omission, or are otherwise unsound, the Offeror shall immediately notify the Contract Specialist listed above in writing with supporting rationale. Offerors are reminded that the Government reserves the right to award this effort based on the initial proposal, as received, without discussion.

L.3.1.8 In accordance with (IAW) Federal Acquisition Regulation (FAR) Subpart 4.8 (Government Contract Files), the Government will retain one copy of all unsuccessful proposals. Unless the Offeror requests otherwise, the Government will destroy extra copies of such unsuccessful proposals.

L.3.1.9 In the event that revised proposals are authorized, any changed pages shall be annotated in the footer with a revision date, and changed text shall be highlighted to identify changes made from original proposals.

L.3.1.10 Debriefings. The Offeror may request debriefing by providing a written request to the Contracting Officer. If the Government elects to establish a competitive range, the Contracting Officer will promptly notify the Offeror of any decision to exclude an offer from the competitive range. Upon written request, an Offeror may receive a debriefing IAW FAR 15.505. The Offeror desiring a debriefing must make a request in writing within three (3) calendar days after receiving the Contracting Officer's notification. To the maximum extent practicable, debriefings will be conducted within five (5) working days after receipt of the Offeror's written request.

L.3.2 Organization of Proposals

L.3.2.1 The Offeror shall prepare the proposal and include the number of copies set forth as shown in the table below. Each volume shall be clearly labeled. The Offeror shall clearly mark one hardcopy of each volume as "ORIGINAL" and additional hardcopies shall be clearly marked as "COPY".

VOLUME	VOLUME TITLE	COPIES	PAGE LIMIT
I	Executive Summary	5 Hard 1 CD/DVD ROMs	5

II	Technical	9 Hard 1 CD/DVD ROMs	75
III	Program Management	9 Hard 1 CD/DVD ROMs	25
IV	Past Performance	5 Hard 1 CD/DVD ROMs	No limit
V	Cost/Price and Contract Documentation NOTE: This section V shall be submitted in binders separate from the binder(s) in which sections I through IV are submitted.	3 Hard 3 CD/DVD ROMs	30

L.3.2.2 Electronic Submission – The technical and program management volumes shall be submitted on separate CD-ROMs in PDF format except for the Cost Section, which shall be submitted as a “Read Only” Microsoft Excel file, showing all formulas and links, including:

- Offeror’s total costs including Subcontractor costs
- Offeror’s costs separate from Subcontractor costs
- Total costs of all Subcontractors, and
- Total costs of each Subcontractor individually.

The electronic submission shall be compatible with Microsoft Windows XP, Microsoft Excel 2007 and Adobe Acrobat 8.0. For the Integrated Master Schedule (IMS), in addition to a high level presentation in PDF format as part of the Program Management submission, the Offeror shall submit an electronic copy with schedule data in “Read Only” Microsoft Project file that shows all formulas and links. The files shall be virus and malware free. All passwords shall be removed.

L.3.2.3 Page Limitations - Page limitations shall be treated as maximums. If exceeded, the excess pages will not be read nor considered in the evaluation of the proposal and will be returned to the Offeror as soon as practicable. Documents referenced in the proposal but not included in the proposal will not be reviewed or considered. Page limitations exclude FDA form 483s, FDA establishment inspection report, pre-approval inspection report; Curriculum Vitae and bibliographic data for the Program Manager, Consultants, Key Personnel, Key Subcontractor Personnel, Quality Management Plan, Quality Agreement, Risk Management Plan and Subcontractor Proposals. Each subcontractor proposal cannot exceed 10 pages and the total of all subcontractor proposals cannot exceed 50 pages. The IMS to be included in Volume III, Program Management, has no page or line limit and should provide sufficient detail to facilitate Government assessment of schedule realism.

L.3.2.4 Page Size and Format - A page is defined as each face of a sheet of paper containing information. When both sides of a sheet display printed material, it shall be counted as two pages. Page size shall be 8.5 by 11 inches, not including foldouts. Pages shall be single-spaced. Except for the reproduced sections of the solicitation document, the text size shall be no less than 12 point. Tracking, kerning, and leading values shall not be changed from the default values of the word processing or page layout software. Use at least 1 inch margins on the top and bottom and ¾ -inch side margins. Pages shall be numbered sequentially by volume. These page format restrictions shall apply to responses to both electronic and hard copy proposals.

L.3.2.5 Tables, Charts, Graphs and Figures - Legible tables, charts, graphs and figures shall be used wherever practical to depict organizations, systems and layout, implementation schedules, plans, technical data, etc. These displays shall be uncomplicated, legible, and shall not exceed 11 by 17 inches in size. Foldout pages shall fold entirely within the volume, and count as a single page. Foldout pages may only be used for large tables, charts, graphs, diagrams and schematics, not for pages of text. For tables, charts, graphs and figures, the text shall be no smaller than 10 point. These limitations shall apply to both electronic and hard copy proposals.

L.3.2.6 Cross-Referencing - To the greatest extent possible, each volume shall be written on a stand-alone basis so that its contents may be evaluated with minimum cross referencing to other volumes of the proposal. Information required for proposal evaluation which is not found in its designated volume will be assumed to have been omitted from the proposal. Cross referencing within a proposal volume is not permitted.

L.3.2.7 Indexing - Each volume shall contain a more detailed table of contents to delineate the subparagraphs within that volume. Tab indexing shall be used to identify sections. Indices do not count against the page limitations for their respective volumes.

L.3.2.8 Glossary of Abbreviations or Acronyms - Each volume shall contain a glossary of all abbreviations and acronyms used. Glossaries do not count against the page limitations for their respective volumes.

L.3.2.9 Binding and Labeling – Each volume of the proposal should be separately bound in a three-ring, loose leaf binder permitting the volume to lie flat when open. Staples shall not be used. A cover page shall be bound in each book, clearly marked as to volume number, title, copy number, solicitation number, and Offeror. Be sure to apply all appropriate markings including those prescribed IAW FAR 52.215-1(e), Restriction on Disclosure and Use of Data, and FAR 3.104-4, Disclosure, Protection and Marking of Contractor Bid or Proposal Information and Source Selection Information.

L.3.2.10 Cost Information – All cost or pricing information shall be addressed ONLY in Cost/Price Proposal and Contract Documentation, Volume V (also referred to herein as Cost/Price Proposal). Labor hour estimates and material types and quantities may be used in other volumes only as appropriate for presenting rationale for alternatives or design decisions.

L.3.2.11 The information in each volume should be specific and complete. Legibility, clarity, and coherence are very important. Your responses will be evaluated against the factors, subfactors, and elements defined in Section M; Evaluation Factors for Award. Using the instructions below, provide as specifically as possible the actual methodology you would use for accomplishing/satisfying these subfactors. All the requirements specified in the solicitation are mandatory. By your proposal submission, you are representing that your firm will be responsible for meeting the requirements specified in the solicitation performed. It is not necessary or desirable for you to tell us so in your proposal. Do not merely reiterate the objectives or reformulate the requirements specified in the solicitation.

L.3.2.12 Proposal Evaluation by Non-U.S. Government Personnel - Offerors are advised that support contractor personnel from Goldbelt-Raven, LLC may assist the Government during the evaluation of proposals. Goldbelt-Raven, LLC personnel will be authorized to access only those portions of proposal data that are necessary to enable them to provide specific technical advice on specialized matters or particular problems. All support contractor personnel will be expressly prohibited from scoring, ranking, rating, or recommending the selection of a source. The exclusive responsibility for source selection remains with the U.S. Government. All will function under a nondisclosure statement.

L.3.3 Volume I - Executive Summary

L.3.3.1 Narrative Summary: The Offeror shall provide a concise narrative summary of the entire proposal, including significant risks, and a highlight of any key or unique features, excluding cost/price. The salient features should tie in with Section M Evaluation Factors/Subfactors. Any summary material presented here shall not be considered as meeting the requirements for any portions of other the volumes of the proposal.

L.3.3.2 Table of Contents: The Offeror shall provide a master table of contents of the entire proposal.

L.3.3.3 Cross-reference Matrix: The Offeror shall provide a crosswalk (Compliance Matrix) of their proposal to link the requirements of sections SOO, L, and M of this RFP.

L.3.4 Volume II - Technical Volume

The Technical Section shall not contain any reference to cost or price; however, information concerning labor hours and categories, Consultant services, travel requirements, materials and equipment needed, and, if applicable, Subcontractor(s), shall be contained in the Technical Volume in sufficient detail so that the Government may adequately evaluate the Offeror's understanding of the requirements.

L.3.4.1 Manufacturing Approach

L.3.4.1.1 Offerors shall provide a manufacturing advanced development plan in sufficient detail to allow the Government to assess the fulfillment of the SOO. The formulation studies, assay development, and process development plan shall be described in sufficient detail, including go-no-go decision points complete with rationale, so that the Government may assess technical and schedule risks. The Offeror shall also discuss the potential for the scalability of the manufacturing process.

L.3.4.1.2 Offerors shall describe in sufficient detail the approach to developing a scalable manufacturing process that will meet the requirements defined in the Statement of Objectives (SOO). The manufacturing plan shall include a process development flow diagram. The manufacturing plan should include elements/approaches or philosophy of ICH Guidance Pharmaceutical Development Q8(R2)" in its application of scientific approaches and quality risk management for the development and or scale up process of the product and its manufacturing process.

L.3.4.1.3 Describe the approach to assay development. Describe in sufficient detail the proposed in-process and release testing for the bulk products and release testing of the final product. Offeror shall describe an approach to developing a potency assay for the bulk and final product.

L.3.4.1.4 Describe the approach to the development and selection of a trivalent final vaccine formulation that meets the requirements defined in the SOO.

L.3.4.1.5 Describe an International Conference on Harmonization (ICH)-compliant stability test plan for each of the products defined in the SOO. At a minimum the stability test plan shall include a rationale of testing periodicity and the number of units to test.

L.3.4.1.6 The SOO defines the cGMP Trivalent Filovirus Vaccine lots required. Describe the specific activities required to manufacture those lots.

L.3.4.1.7 Describe the approach to the development and selection of a thermo stable trivalent final vaccine formulation that meets the requirements defined in the SOO.

L.3.4.2 Manufacturing Facility

L.3.4.2.1 Describe in sufficient detail the Offeror's personnel, facility, and equipment that will be used to meet the manufacturing requirements outlined in the SOO.

L.3.4.2.2 Describe provisions to insure facility systems supporting production are appropriate for product integrity (e.g., air handling, waste, automated monitoring systems, security, etc.) and include documentation to demonstrate implementation of these facility systems supporting production.

L.3.4.2.3 Describe provisions to insure systems supporting storage, packaging, handling, and distribution, are appropriate to maintain product integrity during these efforts. The Offeror shall provide documentation to demonstrate implementation of these systems.

L.3.4.2.4 Describe in sufficient detail the Offeror's safety program, including personnel and procedures, to demonstrate its success and compliance with federal, state, and local safety and environmental laws.

L.3.4.2.5 The Government reserves the right to conduct a pre-award site visit of facilities to include, subcontractor facilities to fully evaluate this Subfactor. The scope of the visit will be based on the questions after evaluation of proposals. Offerors will receive advance notification of the visit and a list of items to be reviewed.

L.3.4.3 Regulatory Compliance/Approach

L.3.4.3.1 The Offeror shall describe its regulatory approach for accomplishing requirements in the SOO and other sections of the RFP, including adherence to FDA regulations, guidance, the requirements related to manufacturing and testing, and preparation for regulatory submissions (i.e., CMC).

L.3.4.3.2 The Offeror shall provide an overview of its quality and regulatory systems with examples that demonstrate those systems are implemented (i.e. RA/QA roles and responsibilities). The Offeror shall provide cGMP compliance evidence for applicable Subcontractor(s).

L.3.4.3.3 The Offeror shall provide credible evidence of a FDA cGMP-compliant facility to support process development and manufacture of all clinical material (e.g., manufacture of Phase 1 material, FDA Form 483's received within the past three years, response to FDA Form 483, FDA Establishment Inspection Report, and Pre-Approval Facility Inspection). The Offeror's cGMP facility must be in good standing with the FDA at the time of proposal and award.

L.3.4.4 Quality Management Plan (QMP)

L.3.4.4.1 The Offeror's proposal shall include a QMP describing in sufficient detail the approach to Quality Assurance and Quality Control (QA/QC) and all Major Subcontractors, as defined in L.3.7, QA/QC to demonstrate the understanding of a sound Quality Management System. The Offeror shall demonstrate compliance with FDA quality requirements and guidance's. The Offeror shall describe in sufficient detail the components of the Offeror's QMP and its integration into the manufacturing approach. The QMP shall include, but is not limited to, quality systems in the following areas: facilities, equipment, utilities, personnel, storage, procedures for establishing quality agreements with subcontractors, vendor qualifications and technology transfer.

L.3.4.4.2 The Offeror's proposal shall include a Draft Quality Agreement that outlines the responsibilities of the Government and the Offeror with respect to quality assurance of the manufacture, testing, and release of Product in accordance with the ICH Q7 and ICH Q10 guidelines, reference to US FDA 21 CFR 210/211/600 and other regulations as applicable. The final mutually agreed upon Quality Agreement will become contractually binding and will be updated IAW CDRL A007. If the Offeror does not have a Quality Agreement template examples may be accessed at the following websites: <http://www.socma.com/assets/File/socma1/PDFfiles/bptf/Quality-Agreement-Template-4.28.10.pdf>

http://www.apic.cefic.org/pub/Quality%20Agreement%20Guideline_final_December%202009_clean.pdf

L.3.4.4.3 The Government reserves the right to conduct a quality audit to fully evaluate this Subfactor.

L.3.4.5 Statement of Work (SOW)

The Offeror shall propose a complete SOW which meets the requirements stated in the Government's SOO and the requirements of the RFP. The SOW shall be submitted using MIL-HDBK-245 as guidance (<https://www.acquisition.gov/sevensteps/library/DODhandbook.pdf>).

L.3.4.5.1 Information Required. The Offeror's proposed SOW shall define the tasks required for filovirus vaccine advanced development ensuring all minimum requirements of the Government provided SOO and preliminary Work Breakdown Structure (WBS) have been addressed, including Program Management. A list of Government

required data deliverables is contained in this document as Contract Data Requirements Lists (CDRLs), however the Offeror shall tailor that list to reflect contractor unique data deliverables demonstrating understanding of manufacturing development efforts to meet first in human requirements for conduct of a Phase 1 study, identify related Data Item Descriptions (DIDs), and reference the related paragraph(s) in the SOW.

L.3.4.5.2 Organization. All SOW activities must be organized by the SOO format in a Contract Work Breakdown Structure (CWBS) and segregated by performance schedule for all tasks to be performed. The SOW shall correlate and use the same numbering system as the CWBS and Integrated Master Schedule (IMS).

L.3.4.5.3 SOW Program Management Activities and Requirements. The SOW must include the program management activities required to accomplish SOO objectives and to comply with requirements specified in the RFP. The SOW must contain every program management activity and task to be accomplished.

L.3.4.6 Process/Item Data Architecture

Offerors are instructed to mark their proposals in accordance with the data rights clauses included in this solicitation based on the Offeror's proposed Data Architecture which may or may not accord the Government greater data rights than otherwise applicable based upon facts and circumstances.

L.3.5 Volume III – Program Management Volume

L.3.5.1 Contract Work Breakdown Structure (CWBS)

The Offeror shall submit a CWBS and CWBS Dictionary using the MIL-STD-881, (http://www.acq.osd.mil/pm/currentpolicy/wbs/MIL_HDBK-881A/MILHDBK881A/WebHelp3/MILHDBK881A.htm). The minimum CWBS expected is Level 5. However, the Offeror shall extend CWBS elements as needed to obtain the depth and breadth required to define the contract

scope and to accurately describe the proposed effort. The CWBS shall correlate with the SOW, CLINs, and IMS. The CWBS shall not include dollar values. A template CWBS is provided in Section L, Attachment D.

L.3.5.2 Integrated Master Schedule (IMS)

The Offeror shall propose an IMS which documents the critical path, major milestones (including subcontractor identification and award), delivery dates, tasks/activities, duration, and schedule relationships. Details of the Offeror's integrated processes shall be addressed in the IMS. The IMS shall be directly traceable to the Offeror's SOW, CLINs, and the CWBS. The IMS is intended to be used as a tool for daily progress tracking of the program/project. Tasks/activities should roll-up to increasingly higher summary levels. All tasks/activities in the IMS shall be logically linked together showing predecessor/successor relationships. The tasks/activities shall be sufficient to account for the entire program under contract. In addition to a high level presentation in PDF format as part of the Program Management submission, the Offeror shall utilize an electronic copy of the schedule for submission (Microsoft Project) of schedule data in "Read Only" format that shows all formulas and links for review. Dates delineated in the IMS and Section F of this solicitation shall become contractually binding and will be adjusted accordingly based on actual contract award date. The IMS will reflect the proposed delivery date for the intended product. Refer to the Integrated Master Plan and Integrated Master Schedule Preparation and Use Guide (http://www.acq.osd.mil/sse/docs/IMP_IMS_Guide_v9.pdf) for development of the IMS. The final IMS will become contractually binding and will be updated IAW CDRL A003.

L.3.5.3 Risk Management System

The Offeror shall submit a Risk Management Plan that details the Offeror's integrated methods for identifying, analyzing, prioritizing, mitigating, and tracking risk drivers and includes plans for adequate resources for risk mitigation strategies to demonstrate the understanding of a sound risk management system. The Offeror shall describe tools or methodologies used in the integrated risk management and risk assessment processes. The Offeror shall identify at a minimum the top ten potential technical and quality risks, the root cause for each, the potential program impact for each, and describe the proposed risk mitigation strategies.

L.3.5.4 Key Personnel Qualifications

The proposal shall include a Curriculum Vitae (CV) and bibliographic data for the Program Manager and other Key Personnel such as Directors (or equivalent) of Regulatory Affairs, Quality Assurance/Quality Control (QA/QC), Manufacturing, and Risk Management detailing their qualifications to perform the work. In the case of subcontractor key personnel, the subcontract agreement shall flow down the Government Key Personnel Clause as incorporated into the awarded contract. If the Offeror does not presently employ Personnel in the positions identified as Key, the Offeror must present a description of the terms of the commitment(s). The Offeror shall provide technical, regulatory, and management staffing plans, specifically addressing vacancies and maintaining Key Personnel. The Offeror shall also provide the CVs and/or resumes and list proposed duties of key subcontractor personnel and consultants (if any) who are proposed for this effort. The Offeror shall provide specific details of all assigned personnel explaining their appropriateness, scientific qualifications, depth and breadth of expertise and credentials relative to the projects. The Offeror shall describe the proposed labor hours and labor categories relating to the performance of the SOW of Key Personnel.

L.3.5.5 Subcontractor Management

The Offeror shall propose a subcontracting management approach to include analysis of subcontractor selection (i.e. list selection criteria), choice of subcontract types, and the plan for incentivizing contractors and assuring subcontractors meet cost, schedule, and performance requirements. The Offeror shall describe how subcontract competition will be sought, promoted, and sustained throughout the course of the cost reimbursement component of the acquisition, identify any known barriers to increasing subcontract competition and how to overcome any such barriers. The Offeror shall propose an approach to managing subcontractors, which defines the mechanisms for interactions/communications/data access. Furthermore, the Offeror shall explain its method for avoiding Subcontractors in financial distress and how the Offeror would rectify a situation where a Subcontractor's financial situation became problematic while under contract. The Offeror shall present mechanisms for managing and interfacing key Subcontractors/Consultants and the Government to include discussion of its techniques for communicating with its subcontractors/consultants, its plan for ensuring that performance is at the level required to ensure timely and effective contract execution. Steps planned for compliance with the Competition in Subcontracting clause (FAR 52.244-5) to be performed by any entity or group of entities under a subcontract shall be addressed in Volume V, the Cost Volume.

L.3.5.6 Earned Value Management (EVM)

Unless the total dollar value of cost type CLINs proposed is under \$15M, the Offeror shall provide a plan for adequate integration of technical performance with cost and schedule objectives via EVM System (EVMS), not to include Firm-Fixed Price efforts of the proposal. The EVM report shall include implementation plans for monitoring/reporting technical performance, cost, and schedule. The report shall address the identification of key processes and risk-planning activities related to frequency, intensity, and schedule. Key processes related to EVMS may include organizing, scheduling, work/budget authorization, accounting, indirect management, management analysis, change incorporation, material management, and Subcontractor management. The Offeror's EVMS shall be in accordance with the American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) standard 748, as well as FAR 52.234-4 and the policy letter, "Revision to DoD Earned Value Management Policy" dated march 7, 2005, provides additional guidance. The Government will consider reasonable plans and costs for establishing or improving an existing EVMS. For those Offerors requiring an upgrade to an existing management system to become fully compliant with this effort, an additional CLIN would be added to Section B for the upgrade of the system. In the event that total dollar value of the anticipated cost type CLINs is below the \$20M EVMS threshold, this requirement may be excluded or tailored at award.

L.3.6 Volume IV - Past Performance

L.3.6.1 Attachment A is to be completed and submitted by the Offeror. Attachment B is to be completed by each of the Offeror's Reference(s) provided in Attachment A.

L.3.6.2 The Offeror shall describe relevant on-going and previous (preceding three years only) Government contracts. This shall include a detailed discussion of relevant corporate experience manufacturing vaccines. The Offeror shall include the following information:

- a. Experience in assay development

- b. Experience in process development
- c. Experience in developing cGMP manufacturing processes and cGMP production of vaccines;
- d. Experience in manufacturing multivalent vaccines;
- e. Experience in producing vaccines based on virus particles, or like technology;
- f. Previous FDA submissions, inclusive of FDA response/non-response to submissions
- g. Corporate experience in timely identifying and solving challenging development efforts similar to those that may arise during the proposed effort with outcomes.
- h. Subcontract management team experience and the skill of those individuals in proposal evaluation, negotiation, and success in avoiding cost overruns.

L.3.6.3 If the Offeror, or any of its proposed Major Subcontractors, have limited Government contracting experience, a description of similar contracts with commercial entities, local and/or state governments should be included, if relevant. Information furnished concerning these efforts shall be similar to that requested of Government contracts.

L.3.6.4. The Offeror shall send Past Performance questionnaires (Attachment B) to Reference(s), who must submit the completed Past Performance questionnaire to the Government Contract Specialist listed above to be received no later than the proposal due date. It is the Offeror's responsibility to ensure that each Reference submits Attachment B to the Government by the required date.

L.3.7 Volume V – Cost Volume

L.3.7.1. General Information

L.3.7.1.1 Certified cost or pricing data are not required as a result of this solicitation. ("Cost or pricing data" are data requiring certification IAW [15.406-2](#). "Cost or pricing data" are factual, not judgmental, and are verifiable). These instructions are to assist you in submitting information other than cost or pricing data that is required to evaluate the reasonableness of your proposed cost/price. Compliance with these instructions is mandatory and failure to comply may result in rejection of your proposal. Note that unrealistically low or high proposed costs or prices, initially or subsequently, may be grounds for eliminating a proposal from competition either on the basis that the Offeror does not understand the requirement or has made an unrealistic proposal. Offers should be sufficiently detailed to demonstrate their reasonableness. The burden of proof for credibility of proposed costs/prices rests with the Offeror.

IAW FAR 15.403-1(b) and 15.403-3(a), information other than cost or pricing data is required to support price reasonableness. Information shall be provided IAW FAR 15.403-5. If, after receipt of proposals, the Contracting Officer determines that there is insufficient information available to determine price reasonableness and none of the exceptions in FAR 15.403-1 apply, the Offeror shall be required to submit cost or pricing data.

L.3.7.1.2 The Cost/Price Proposal shall be an integrated and comprehensive estimate with descriptions of estimating techniques and allocation methods that correlate in sufficient depth with the SOO, SOW, CWBS, IMS, and CLINs when applicable. Estimating technique(s) used to create the proposal shall be clearly identified. When responding to the Cost/Price Proposal requirements in the solicitation, the Offeror and associated Subcontractors may use any generally accepted estimating technique, including contemporary estimating methods, commercially available parametric cost models, in-house developed parametric cost models, etc., to develop their estimates. If necessary, reasonable and supportable allocation techniques may be used to spread hours and/or costs to lower levels of the CWBS.

L.3.7.1.3 The Cost/Price Proposal shall be prepared using the Excel workbooks provided in Section L, Attachment D. Failure to use the provided workbooks may result in rejection of the Offeror's proposal. The workbooks shall be submitted in "read only" format; however, calculations, formulas, links between spreadsheets shall be clear and accessible.

L.3.7.1.4 The Cost/Price Proposal shall show proposed dollar value for each of the Milestones identified in the SOW and IMS for each CLIN and Option CLIN.

L.3.7.1.5 The Cost/Price Proposal shall include any necessary equipment to be purchased/leased or minor facility modifications necessary to execute the proposed efforts.

L.3.7.2 Cost Breakdown

L.3.7.2.1 The Cost/Price Proposal shall include a cost breakdown by Government Fiscal Year (1 Oct-30 Sep). Offeror's shall utilize the Microsoft Excel workbook templates provided in Section L, Attachment D for submission of cost and pricing information. The Offeror shall submit a separate workbook for each CLIN. Cost/price information shall be submitted in "Read Only" format that shows all the calculations, formulas, and links for review. Option CLIN and Subcontractor efforts shall be reflected separately, but will include at a minimum, the information requested in the spreadsheet. Totals from detailed spreadsheets should track to the summary spreadsheet.

L.3.7.2.2 The Offeror shall submit an estimate by CWBS, by Government Fiscal Year (1 Oct – 30 Sep). Data for this spreadsheet will be provided at a minimum of CWBS Level 5 with subtotals provided at level 2. Add columns for additional years as required.

L.3.7.2.3 The Offeror shall address the following cost elements in sufficient detail to demonstrate reasonableness of the proposed costs.

L.3.7.2.3.1 Direct Labor. Provide estimated hours by CWBS (minimum Level 5), labor category and Government fiscal year. Explain the method used to determine the estimated hours necessary for each effort. Indicate if the proposed loaded rates are based on actual or projected rates for current employees. Indicate the escalation factor used and first month(s) for each Government fiscal year that the escalation factor is applied. Level of effort activities shall be expressed in man-hours. Define the number of man-hours that equal a man-year. Total labor costs/hours should track to summary spreadsheet. Add columns for additional years as required.

L.3.7.2.3.2 Subcontractor Costs. "Subcontractor" means any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a prime contractor or another subcontractor. Provide a complete description of all Subcontractor costs, including any Teaming Arrangements/Agreements by CWBS (minimum Level 5). Submit proposals for major Subcontractors, which are those with subcontract values exceeding \$250,000 ("Major Subcontractors"). Total subcontractor costs should track to the summary spreadsheet. The Offeror shall provide the basis of selection of the subcontractor and their analysis conducted to determine price reasonableness and the steps planned for compliance with the Competition in Subcontracting clause (FAR 52.244-5) to be performed by any entity or group of entities under a subcontract. Numerous sources of these potential subcontract functions are or may become available for competition. Offerors shall include Subcontractor letters of commitment.

L.3.7.2.3.3 Consultants. Justify the requirement for consultant services. List proposed Consultants by name, if known. For each Consultant, describe: (1) nature of services, (2) CWBS supported (minimum Level 5), (3) fee rate, and (4) total Consultant fee and any other allowable related costs (e.g., travel, per diem). The Offeror shall provide the basis of selection of each Consultant and their analysis conducted to determine price reasonableness. Total consultant costs should track to the summary spreadsheet.

L.3.7.2.3.4 Materials and Supplies. Provide a detailed listing of materials and supplies by CWBS (minimum Level 5), quantity, unit cost, and basis of estimate (e.g., vendor quotes, catalog pricing, subcontracting estimates). Competitive historical price information of prior purchases is adequate. For all sole-sourced materials and supplies, provide a consolidated cost summary of individual material quantities included in the CWBS being proposed and the basis of estimate. Total materials and supplies costs should track to the summary spreadsheet.

L.3.7.2.3.5 Travel. Provide the purpose, origin, destination, and duration of travel. Offerors are encouraged to read FAR 31.205-46 regarding allowability of travel costs. Total travel costs should track to the summary spreadsheet.

L.3.7.2.3.6 Equipment. Contractors are ordinarily required to furnish all property necessary to perform Government contracts. The Government shall provide property to contractors or authorize contractors to purchase property under the contract only when it is clearly demonstrated-

- (1) To be in the Government's best interest;
- (2) That the overall benefit to the acquisition significantly outweighs the increased cost of administration, including ultimate property disposal;
- (3) The provision of the property does not substantially increase the Government's assumption of risk; and
- (4) The Government requirements cannot otherwise be met.

The contractor's inability or unwillingness to supply its own resources is not sufficient reason for the furnishing or acquisition of property.

Provide a list of all proposed equipment to be purchased under the appropriate CLINs in support of the contract by CWBS (minimum Level 5). The list shall include equipment description, manufacturer, manufacturer's address, model and stock number, and estimated unit cost. Total equipment costs should track to the summary spreadsheet. Equipment shall be handled as a pass through cost and not have profit applied against it.

L.3.7.2.3.7 Other Costs. List direct costs not included in the above categories (i.e., special tooling, computer services, preservation, and packaging) and provide the basis of estimate.

L.3.7.2.3.8 Indirect Cost. Provide current rates for Overhead, Material Handling, General and Administrative (G&A), Facility Capital Cost of Money and any other indirect costs for all effort proposed. Provide forward pricing agreements if applicable. If forward pricing agreements are not in place, include historical trend for the last three-year period to assist in evaluating proposed rates.

L.3.7.3 Incentive Fee. The Offeror shall propose a target fee, minimum fee, and maximum, and a fee adjustment formula for base CLIN and each option CLIN separately. The Offeror shall propose milestones and incentive fees associated with each milestone.

L.3.7.4 Facilities Capital Cost of Money (FCCM). If FCCM is proposed, the Offeror must submit Form CASB-CMF and show the calculations of the proposed amount (see FAR 31.205-10).

L.3.7.5 Defense Contract Management Agency (DCMA) or the Defense Contract Audit Agency (DCAA). If the Offeror is currently under administration or audit cognizance of the DCMA or the DCAA; the name, address, and telephone number of the Government Agency's Point of Contact shall be furnished.

L.3.7.6 Estimating System. Provide a description of the estimating system or methods used. Indicate if there has been a Government review or audit of the estimating system. If the government has reviewed the estimating systems of the Offeror and the proposed Subcontractors, provide results of the review/audit (including date of review and contact numbers) or documentation of the results.

L.3.7.7 Purchasing System. Provide a summary description of the purchasing system or methods (how sources are selected, what provision is made to ensure quantity and other discounts) used. Identify any deviations from these standard procedures in preparing this cost proposal. Indicate if there has been a Government review or audit of the purchasing system. If the government has reviewed the purchasing systems of the Offeror and the proposed Subcontractors, provide results of the review/audit (including date of review and contact numbers) or documentation of the results.

L.3.7.8 Accounting System. Indicate if there has been a Government audit of the accounting system and if so, provide evidence of the accounting system's acceptability, as per DCAAP 7641.90, Section 2-301.1.a. Identify any deviations from these standard procedures in preparing this cost proposal. IAW FAR 16.301-3(a)(i), a cost reimbursement contract may only be used when the contractor's accounting system is adequate for determining cost applicable to a Government contract. The Pre-Award Survey attached at ## shall be submitted with the proposal of any Offeror that does not have an approved cost accounting system at the time of proposal submission.

L.3.7.9 Company Financial Statements. Offerors shall provide copies of their annual financial statements for the last three years.

L.3.8 Other Information Required

L.3.8.1. PROVIDE THE NAME, TITLE, AND TELEPHONE NUMBER OF THE COMPANY/DIVISION POINT OF CONTACT REGARDING DECISIONS MADE WITH RESPECT TO YOUR PROPOSAL AND WHO CAN OBLIGATE YOUR COMPANY CONTRACTUALLY. ALSO, IDENTIFY THOSE INDIVIDUALS AUTHORIZED TO NEGOTIATE WITH THE GOVERNMENT.

ATTACHMENT A: PAST PERFORMANCE INFORMATION

WHEN FILLED IN THIS DOCUMENT IS SOURCE SELECTION SENSITIVE INFORMATION

IAW FAR 3.104

Provide the information requested in this form for each contract/program being described. Provide frank, concise comments regarding your performance on the contracts you identify. Provide a separate completed form for each contract/program submitted. The number of past efforts shall be limited to six for the prime contractor and three for each subcontractor. Relevancy shall demonstrate your ability to perform the proposed effort.

A. Offeror Name (Company/Division): _____

CAGE Code: _____

DUNS Number: _____

(NOTE: If the company or division performing this effort is different than the Offeror or the relevance of this effort, or the instant acquisition is impacted by any company/corporate organizational change, note those changes. Refer to the "Organizational Structure Change History" you provided as part of your Past Performance volume.)

B. Program Title: _____

C. Contract Title: _____

1. Contract Agency or Customer: _____

2. Contract Number: _____

3. Contract Type: _____

4. Period of Performance: _____

5. Original Contract \$ Value: _____ (Do not include unexercised options)

6. Current Contract \$ Value: _____ (Do not include unexercised options)

7. If Amounts for 5 and 6 above are different, provide a brief description of the reason:

(c) Brief Description of Effort as ____Prime or ____Subcontractor
(Please indicate whether it was development and/or production, or other acquisition phase and highlight portions considered most relevant to current acquisition.)

(d) Completion Date:

D. Original date: _____
E. Current Schedule: _____
F. Estimate at Completion: _____
G. How Many Times Changed: _____
H. Primary Causes of Change: _____

(e) Primary Customer Points of Contact: (For Government contracts, provide current information on all three individuals. For commercial contracts, provide points of contact fulfilling these same roles.)

(f) **Program Manager: Name** _____
Office _____
Address _____

Telephone _____
Email _____

(g) **Contracting Officer: Name** _____
Office _____
Address _____

Telephone _____
Email _____

(h) **Administrative Contracting Officer:**
Name _____
Office _____

Address _____

Telephone _____

Email _____

- (i) Address any technical (or other) area about this contract/program considered unique.
- (j) Illustrate how your experience on this program applies for each of the applicable factors, subfactors, and elements in Section M.
- (k) Include relevant information concerning your compliance with FAR 52.219-8, Utilization of Small Business Concerns, on the contract you are submitting.
- (l) Identify whether a subcontracting plan was required by the contract you are submitting. If one was required, identify in percentage terms, the planned versus achieved goals during contract performance. If goals were not met, please explain.
- (m) Describe the nature or portion of the work on the proposed effort to be performed by the business entity being reported here. Also, estimate the percentage of the total proposed effort to be performed by this entity and whether this entity will be performing as the prime, subcontractor, or a corporate division related to the prime (define relationship).

SECTION L: ATTACHMENT B
ATTACHMENT B: PAST PERFORMANCE QUESTIONNAIRE

SOLICITATION NUMBER:

WHEN FILLED IN THIS DOCUMENT IS SOURCE SELECTION SENSITIVE INFORMATION

IAW FAR 3.104

- (n) Please complete this questionnaire. Handwritten responses are sufficient. If you need more space than that provided, please attach additional pages or write on the back. Responses will be treated as source selection sensitive information. Scan and email or fax the completed questionnaire to:

NAME:	Mr. Nathan Jordan
Office	ATTN: ACC-APG NATICK CONTRACTING DIVISION
Address	110 Thomas Johnson Drive Frederick, MD 21702, USA
Telephone	301-619-9813 (FAX); 301-619-5069
Email	Nathan.C.Jordan.civ@mail.mil

Explanation of codes:

CODE PERFORMANCE LEVEL

E EXCEPTIONAL – Performance meets contractual requirements and exceeds many requirements to the Government's benefit. The contractual performance of the elements being assessed was accomplished with few minor problems for which corrective actions taken by the contractor were highly effective.

V VERY GOOD – Performance meets contractual requirements and exceeds some requirements to the Government's benefit. The contractual performance of the element being assessed was accomplished with some minor problems for which corrective actions taken by the contractor were effective.

S SATISFACTORY – Performance meets contractual requirements. The contractual performance of the element being assessed contains some minor problems for which corrective actions taken by the contractor appear or were satisfactory.

M MARGINAL – Performance does not meet some contractual requirements. The contractual performance of the element being assessed reflects a serious problem for which the contractor has not yet identified corrective actions or the contractor’s proposed actions appear only marginally effective or were not fully implemented.

U UNSATISFACTORY – Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element being assessed contains serious problem(s) for which the contractor’s corrective actions were ineffective.

N NOT APPLICABLE – Unable to provide a score. Performance in this area is not applicable to effort assessed.

(o) Please complete the following identifying information and past performance assessment:

A. Contractor: _____

B. Contract number: _____

C. Period of Performance: _____

D. Negotiated price or cost at award: _____

E. Current estimated contract dollar amount: _____

F. Describe product acquired: _____

When Completed – Source Selection Information – See FAR 3.104

(p) Circle the appropriate letter for each item on the questionnaire and provide supporting narrative.

ASSESSMENT ELEMENTS

(1) Contractor’s record of process development.

E V S M U N

(2) Contractor’s record of pilot scale cGMP manufacturing .

E V S M U N

(3) Did the contractor deliver according to the agreed-to schedule? What were the causes of any schedule variances? Did the contractor require assistance to resolve any schedule problems?

E V S M U N

(4) How well did the contractor proactively manage schedule/performance/cost and risks?

E V S M U N

(5) What is your overall rating of the contractor's performance?

E V S M U N

(6) Contractor's cost control. Did the contractor deliver at the agreed-to cost/price? Describe the reasons for changes to contract value (e.g., scope changes, overrun/underrun, customer-imposed schedule changes, etc.)

E V S M U N

When Completed – Source Selection Information – See FAR 3.104

(7) Identify the contractor's overall strengths and weaknesses.

(8) Given the choice, would you award to this contractor again? Explain.

(9) Are you aware of any other contracted efforts performed by this contractor similar in nature to this contract? Please identify contract/program and point of contact.

(10) Is there anyone else we should send this questionnaire to? Please identify by name, organization, and phone number.

(If more comment space is needed, write on back, or attach pages.)

(11) Please provide organization, name, title, address, email, and phone number of the person completing this questionnaire.

Email

Phone

 FAX

SECTION L: ATTACHMENT C STATEMENT OF OBJECTIVES

STATEMENT OF OBJECTIVES

Virus-Like Particle Trivalent Filovirus Vaccine process Development, Formulation, and Manufacturing efforts

Statement of Objectives (SOO)

1. Introduction and Background:

The requirement for a vaccine to protect against filovirus exposure is described in the Department of Defense (DoD) Joint Requirements Oversight Council (JROC) approved Joint Medical Biological Warfare Agents Prophylaxes Initial Capabilities Document (ICD), dated September 14, 2004. The ICD calls for a medical prophylaxis that will provide broad spectrum protection against a range of biological warfare agents and a range of exposure routes. The Joint Vaccine Acquisition Program Joint Product Management Office (JVAP JPMO), a subordinate organization to Chemical Biological Medical Systems Joint Project Management Office (CBMS JPMO), is responsible for the development, production, and stockpiling of Food and Drug Administration (FDA)-licensed vaccine products to protect the Warfighter against Biological Warfare agents.

A filovirus vaccine must protect against *Marburgvirus* and *Ebolavirus* (Sudan and Zaire). A vaccine(s) against the filoviruses would counter the threat of illness and death, and maintain Warfighter performance in a biological-warfare environment. To accomplish this goal, the Chemical Biological Medical Systems – Joint Vaccine Acquisition Program (CBMS-JVAP) will serve as the integrator for the Technology Development Phase by managing and coordinating the various vaccine development contracts and intergovernmental efforts through a Phase 1 clinical trial. The Office of the Surgeon General, Department of the Army will serve as the FDA regulatory sponsor through a Phase 1 clinical trial. All required efforts shall be in accordance with (IAW) FDA guidelines and requirements leading to the eventual licensure of a new filovirus vaccine.

2. Overall Objectives

The objective of this procurement is to deliver, after limited advanced development, a current Good Manufacturing Practices (cGMP) trivalent filovirus vaccine using the Virus-Like Particle (VLP) system that will be suitable/acceptable for release for use in humans by the Government to support non-clinical and Phase 1 clinical studies under an Investigational New Drug (IND) application. The manufacturer shall use the VLP system described in Section J, Attachment 2. The manufacturer shall develop, abide by and document cGMP and processes consistent with the International Conference on Harmonisation (ICH) Q7 and ICH Q5A- Q5E, FDA regulation 21 CFR Part 211 21 CFR Part 600, Guidance for Industry- CGMP for Phase 1 Investigational Drugs and Guidance for Industry- Characterization and Qualification of cell substrates and Other Biological Materials Used in Production of Viral vaccines for Infectious Disease Indications (February 2010). The contractor shall, pursuant to a documented scalable bulk and fill/finish manufacturing processes, develop, manufacture, test and deliver a cGMP VLP trivalent filovirus vaccine developmental candidate suitable for release for Phase 1 clinical trial use under an Investigational New Drug (IND) application. The Contractor shall, under documented scalable bulk and fill/finish manufacturing processes, develop each of the three filovirus vaccine components as monovalent bulk products; Marburg, Ebola Sudan, and Ebola Zaire so as to formulate these antigens into a single vial formation (trivalent vaccine). In so doing, the viral glycoprotein and VP40 genes from each strain, shall be co-transfected into a GMP compliant mammalian cell line, resulting in a fully assembled Virus-Like Particle (VLP) suitable for use in Phase 1 clinical trial under an Investigational New Drug (IND) application. In addition to draft Master Product Batch Record, the Contractor will provide and the Government will test product from various stages of process development and engineering runs to assess the extent by which the product meets the 80% goal for animal efficacy threshold stipulated in the draft CDD.

The intended product is a subunit, vector-free, trivalent vaccine consisting of multiple monovalent VLPs each expressing two antigens, glycoprotein (GP) and a matrix protein (VP40) of the filovirus strains. The VLPs are spontaneously produced in cells when the two genes encoding GP and VP40 are expressed ectopically. These VLPs have a morphology that is strikingly similar to the authentic filovirus with the GP expressed on the surface, traversing the envelope and a layer of matrix protein (VP40) underneath the envelope. It is anticipated that the final product will be a trivalent vaccine consisting of separate VLPs for Marburg virus, Ebola Zaire Virus and Ebola Sudan Virus however the Offeror can propose alternate formulations to meet the requirement. Each VLP will be produced separately in mammalian cells using optimized production and purification processes and mixed before vialing in a ratio that ensures similar immunogenicity of the individual components. It is anticipated that an adjuvant will be required to elicit the desired onset and duration of protection. The final vaccine formulation will provide immunity against variants of the Zaire and Sudan species of Ebola virus (EBOV) and variants of Marburg virus (MARV). The VLP product has the potential to be used as a prophylactic and/or a post exposure vaccine.

The Contractor shall, incident to the development of a filovirus vaccine, conduct formulation studies that include exploration of adjuvants as well as analytical assay development, including in-process and release assays of cGMP bulk(s) and final product, and International Conference on Harmonization (ICH)-compliant stability testing. The small-scale manufacturing process developed must be scalable and transferrable to another facility, if necessary.

3. Contract Objectives

The Contractor shall, in the development of a filovirus vaccine:

3.1 Provide and integrate all qualified and trained personnel, facilities, equipment, supplies, materials, services, quality oversight, and related administrative and information technology necessary to accomplish all the objectives and requirements of this SOO.

3.2 The cell line referenced in attachment J will be evaluated, as well as other proposed cell lines, in consideration of providing acceptable yields and meeting regulatory requirements. Establish and maintain cGMP Master and working cell banks to support human clinical trials.

3.3 Develop a bulk process and bulk assays

3.3.1 Optimize plasmid constructs and the process as needed to generate cGMP production quantities as described in Section 3.3.2 below. The Contractor shall provide a process that maximizes the level of GP expression and yield, both in the upstream and downstream processes. The developed process shall address scale up, safety, regulatory, and cost considerations. The Government will provide plasmid sequences, including the filovirus glycoprotein and VP40 sequences, as defined in Section J: List of Government Furnished Information.

3.3.2 Develop and optimize bulk processes (Marburg, Ebola Sudan, and Ebola Zaire) for the production and purification of VLP to be used with the VLP system described in Section J, Attachment 2. The developed process must be capable of producing 2000-2500 doses for each lot produced with the clinical dose anticipated to be, equal to or less than, 50ug per virus specific GP antigen, or 150ug total GP content. The manufacturing process must be robust, reproducible and scalable.

3.3.3 Complete at least two engineering runs at the same scale to be used for cGMP production of the vaccines. The engineering runs will be conducted at the same scale as cGMP production with draft Master Production Batch records that are executed under cGMP conditions inclusive of deviations/OOS/investigation procedures.

3.3.4 Conduct two year stability testing using Government approved specifications on products generated from engineering runs.

3.3.5 Develop and optimize in-process and release analytical assays for all bulk products to include but not limited to purity, identity, and characterization, such as absolute concentration of GP, host protein content, and

bioburden. Assays shall be compliant with cGMP or current Good Laboratory Practices (cGLP) standards as applicable. In addition the Contractor shall develop an immunogenicity test or potency assay, looking at antibody levels to ensure consistency over time and across lots. The contractor's potency assay development should involve product degradation and manipulation studies capable of detecting a 50% reduction in vaccine integrity.

3.4 Develop a trivalent final vaccine formulation.

3.4.1 Develop and provide a trivalent final vaccine formulation based on the monovalent bulk substances in accordance with CLIN 0002.

3.4.2 Formulation development efforts shall include investigation of adjuvanted products that have been previously licensed in the United States or tested in clinical trials which could boost the immune response and reduce the required vaccine concentration.

3.5 Develop final drug product release assays.

3.5.1 Develop, optimize, and provide analytical assays required for release testing of final drug product. Assays shall be compliant with ICH, cGMP and/or cGLP standards as applicable.

3.6 Option: Manufacture cGMP final trivalent vaccine product and placebo/control article suitable for non-clinical toxicology studies and a Phase 1 clinical trial.

3.6.1 The contractor shall produce 2000-2500 doses per lot with the clinical dose anticipated to be, equal to or less than, 50ug per virus specific GP antigen, or 150ug total GP content. The contractor shall use a manufacturing capability sufficient to produce material of each bulk antigen (Marburg, Ebola Sudan, and Ebola Zaire) to support non-clinical and clinical studies.

3.6.2 Manufacture and provide one (1) lot of a final trivalent vaccine product per dosage concentration, with and without adjuvant (for four concentrations of each bulk antigen concentration produced, 1.6ug, 5ug, 16ug and 50ug) to support clinical dose escalation and nonclinical studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

3.6.3 The contractor shall QA approve and evaluate all lots manufactured pending results from a contractor developed potency assay, and ensure sufficient material is set aside for the potential purpose of supporting a Government developed challenge based potency assay. The Government will review contractor approved batch records to determine acceptance of bulk and final product release.

3.6.4 Perform stability testing on the bulk and final drug product(s). Pursuant to contract options, Contractor shall conduct stability testing for a minimum of 2 years with the potential for 5 years at the Government's discretion.

3.6.5 Manufacture and provide 1000 doses of saline placebo/control article packaged in one (1) dose vials of a volume equal to the volume used for the vaccine.

3.7 Option: Provide the written/approved documents necessary to prepare the Chemistry, Manufacturing, and Controls (CMC) portion of the IND application submission in eCTD format (eCTD Module 2 and 3). The Contractor shall assist the Government with preparation for, and participation in meeting with the FDA or other regulatory agencies as requested by the Government, IAW CDRL A016.

3.7.1 If the contractor or subcontractor has a Master File with the FDA, the Contractor shall allow the Government to review and cross-reference it during preparation of the CMC section.

3.8 Option: Develop a thermo-stable trivalent final vaccine formulation suitable for non-clinical studies and Phase 1 clinical trials.

3.8.1 Develop and provide a thermo-stable trivalent final vaccine formulation that is stable for a minimum of 2 years (optimal stability 5 years) when stored at temperatures greater than or equal to -20°C, as requested by the Government.

3.9 Option: Manufacture cGMP final Marburg vaccine suitable for non-clinical toxicology studies and a Phase 1 clinical trial.

3.9.1 The contractor shall produce 2000-2500 doses per lot with the clinical dose anticipated to be, equal to or less than, 50ug per virus specific GP antigen using a manufacturing capability sufficient to produce material of requested marburg bulk antigen to support non-clinical and clinical studies.

3.9.2 Manufacture and provide one (1) lot of a final Marburg vaccine product per dosage concentration, with and without adjuvant (for four concentrations produced, 1.6ug, 5ug, 16ug and 50ug) to support clinical dose escalation and nonclinical studies. The minimum acceptable number of vials for each concentration is 2000 with adjuvant and 2000 without adjuvant. Each vial shall contain one (1) dose and sufficient overfill to enable extraction of the dose.

3.9.3 The contractor shall QA approve and evaluate all lots manufactured pending results from the contractor developed potency assay, and ensure sufficient material is set aside for the potential purpose of supporting a Government developed challenge based potency assay. The Government will review contractor approved batch records to determine acceptance of bulk and final product release.

3.9.4 Perform stability testing on the bulk and final drug product(s). Pursuant to contract options, Contractor shall conduct stability testing for a minimum of 2 years with the potential for 5 years at the Government's discretion.

3.9.5 Manufacture and provide 1000 doses of saline placebo/control article packaged in one (1) dose vials of a volume equal to the volume used for the vaccine.

3.10 General Objectives

3.10.1 Provide access and/or a copy of records, files, and other data derived or supporting the generation of data derived from this work for the purposes of audit by the FDA and/or other DoD entities. Such information is inclusive of all activities that assure compliance with FDA guidance and regulations, which may include Standard Operating Procedures (Standard Operating Procedures (SOPs), protocol amendments, meeting minutes, audits inspections schedules, equipment logs, reagent preparation logs, and laboratory notebooks related to this effort.

3.10.2 The Government reserves the right and the Contractor shall accommodate a Person-in-the Plant (PIP) during all critical processes of manufacturing, including but not limited to: non-GMP process development, cGMP manufacturing runs, tech transfer, cell and virus banking, culture seeding, electroporation, bulk harvest, concentration, purification, formulation, and filling efforts. The Contractor shall provide at a minimum 30 days advanced notification to ensure Government representation is present during the conduct of identified critical processes.

3.10.3 Contractors shall certify they are registered in accordance with Federal, State, and local laws and regulations, including safety and environmental requirements.

3.10.4 Deliver product to Government specified non-clinical and clinical destinations as requested by the Government. The Contractor shall provide sufficient material from the process development, engineering, and cGMP lots to support nonclinical efficacy and safety testing. Efficacy studies need to be planned at least 12 months in advance, therefore the Contractor shall provide the Government with a delivery schedule for each lot of material requiring testing. Delivery may include Outside the Continental United States (OCONUS) shipping and distribution. All packaging, labeling, handling, storage, and transportation of the product in shall be in compliance with U.S. Pharmacopeia 1079 (Good Storage and Shipping Practices) and in accordance with FDA cGMP regulations.

3.10.5 Option: The Contractor shall be required to utilize an Earned Value Management System (EVMS) recognized by the cognizant Administrative Contracting Officer (ACO) as complying with the criteria provided in American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) EVMS standard (ANSI/EIA-748), FAR 52.234-4, as well as the policy letter, "Revision to DoD Earned Value Management Policy" dated March 7, 2005. Defense Contract Management Agency (DCMA) has the responsibility of validating the Contractor's EVMS. The Contractor is required to hold an Integrated Baseline Review (IBR) at their facility to assess the realism and accuracy of the integrated performance measurement baseline IAW with CDRL A009. The IBR will be initiated no later than six months from the contract award, the exercise of significant contract Options, the incorporation of major modifications or as otherwise agreed upon, per FAR 52-234-3. The Government reserves the right to require utilization of a tailored EVMS if the cost type CLIN's are less than \$20M.

SECTION L: ATTACHMENT D
PROPOSAL TEMPLATES

- 1) Proposal Template.



Proposal Template
Filovirus Vaccine.pdf

- 2) Cost Templates.



Filovirus



Filo VLP Cost

CostTemplateCLIN.xl: Template Summary.xl

- 3) RFP Cross Walk.



RFP SECTION
CROSS WALK.xlsx

- 4) CWBS Template.



V:\PD\Filovirus CWBS
Template.xls

- 5) Quality Agreement



V:\PD\QUALITY
AGREEMENT TEMPLA

- 6) Non Disclosure Agreement to Access TDP



V:\PD\TDP_NDA.pdf

SECTION M - EVALUATION FACTORS FOR AWARD

The following have been modified:

EVALUATION CRITERIA

M.1 EVALUATION CRITERIA

M.1.1 GENERAL BASIS FOR CONTRACT AWARD –

The Government intends to award a contract for the development and manufacturing of Marburg, Ebola Sudan and Ebola Zaire filovirus vaccine(s) that will support all activities necessary to successfully complete a FDA Phase I Clinical Trial.

Contract award will be based on government's proposal evaluation and subsequent exchanges with the Offerors utilizing Evaluation Factors, and Subfactors representing the "Best Value" as described in FAR Part 15.101-1. Offeror(s) deemed responsible under the FAR Part 9 guidelines shall submit proposals conforming to the solicitation requirements. The Government's Source Selection Authority (SSA) will decide which Offeror will be awarded a contract. The Government intends to select the source whose offer is overall most advantageous to the Government. The Government reserves the right to reject any or all proposals and to award no contract at all, depending on the quality of the proposal(s) submitted and the availability of funds. Offerors are cautioned that award may not necessarily be made to the lowest-priced Offeror.

The proposals shall be complete, shall arrive by the date and time indicated in the solicitation notice, and shall be compliant with all proposal preparation instructions. Offerors shall refer to Section L (Instructions, Conditions, and Notices to Offerors), the Statement of Objectives (SOO), and other sections of the RFP for proposal preparation.

Contract Award will be based on "Best Value" to the Government.

The Government considers the non-cost "Best Value" evaluation factors of Technical, Program Management, and Past Performance to be more important than cost. Proposals will be evaluated on Technical, Program Management, Past Performance, and Cost Factors.

It is anticipated that only one award will be made as a result of this Request for Proposal (RFP).

M.1.2 PROPOSAL EVALUATION –The Offeror's proposal shall be compliant with the requirements of the RFP as stated in Section L, the SOO, the Contract Data Requirements List (CDRL), and other parts of this solicitation. Non-conformance with the instructions in Section L may result in submission of a deficient proposal which may receive an unfavorable proposal evaluation and lead to expulsion from the competition/source selection. Any incomplete package submitted by any Offeror may be deemed unacceptable and not considered for award. Proposals judged unsuitable in terms of technical capability, commitments, or cost may be rejected as indicating a lack of understanding of the requirements.

M.1.3 AREAS OF EVALUATION – The Government will review and perform an assessment of the proposal using Evaluation Factors described in Section M.3.2, Proposal Risk and Performance Confidence when making the Source Selection Decision.

M.1.4 COMPETITIVE RANGE – If the Contracting Officer decides that discussions with Offerors are needed, a competitive range determination will be made, if applicable. The competitive range will be comprised of the most highly rated proposals, unless the range is further reduced for purposes of efficiency. The Contracting Officer will notify Offerors promptly in writing if and when their proposals are excluded from the competitive range or otherwise eliminated from the competition. That notice shall state the basis for the determination that a proposal revision will not be considered.

M.1.5 CLARIFICATIONS – In accordance with FAR 15.306, the Government may conduct limited exchanges with Offerors after receipt of proposals or award without discussions. Such exchanges shall not be used to cure proposal deficiencies or material omissions, materially alter the technical or cost elements of the proposal, and/or otherwise revise the proposal. Therefore, the Offeror's initial proposal shall contain the Offeror's best terms.

THE GOVERNMENT RESERVES THE RIGHT TO AWARD A CONTRACT(S) BASED ON INITIAL PROPOSAL SUBMISSION, WITHOUT EXCHANGES AND/OR DISCUSSIONS.

M.2 GENERAL CONSIDERATIONS

M.2.1 PROPOSAL RISK – Proposal risks are those associated with the likelihood that an Offeror's proposed approach will meet the requirements of the solicitation in the RFP SOO. Proposal risk will be evaluated according to M.3.3.2 and independent from Adjectival Ratings and Performance Confidence/Relevancy. The Government will assign a Proposal Risk after completing Technical and Cost proposal reviews. An overall risk ranking of Low (L), Moderate (M), or High (H) will be assessed and assigned.

The assessment of risk is not intended to be a product of a mechanical or mathematical analysis, but rather the product of subjective judgment by the Government after it considers relevant information.

M.3 EVALUATION FOR AWARD

M.3.1 GENERAL – The evaluation of proposals in response to this RFP shall be based on an independent comprehensive review and assessment of each proposal against all source selection criteria, Factors, Subfactors, Elements, Proposal Risk, and Performance Confidence as further described below. Ratings consistent with these evaluation Factors will be derived from (1) the ability of the Offeror, as demonstrated in the Technical, Program Management, and Past Performance Sections, to perform the work in accordance with all aspects of requirements outlined in this solicitation and (2) the realism of the Cost Section. Proposals that are unrealistic in terms of capability commitments in Technical, Program Management, or Cost will be deemed to reflect an inherent lack of technical competence and/or failure to comprehend the complexity and risks associated with contract requirements. Such failures, which bring into question the responsibility of the Offeror, may constitute grounds for proposal rejection.

M.3.2 FACTORS and SUBFACTORS – Four Factors will be used in this evaluation: Technical, Program Management, Past Performance, and Cost. The Technical and Program Management Factors are more important than the Past Performance Factor. In accordance with FAR 15.304 (e)(1), the non cost factors when combined are significantly more important than cost. The Subfactors within each Factor are of equal importance. The Elements within each Subfactor are of equal importance.

$$[(\text{Technical} = \text{Program Management}) > \text{Past Performance}] > \text{Cost}$$

M.3.2.1 FACTOR 1 – TECHNICAL

The Government will evaluate the completeness, feasibility, soundness, and practicality of the Offeror's proposed approach and plan for accomplishing the requirements of the SOO as proposed in the SOW. The evaluation will include analysis of the effort proposed to carry out each task, the explanations of the methods to be employed and the Offeror's regulatory compliance and approach. The Government will evaluate the Offeror's ability to meet the manufacturing requirements outlined in the SOO. The proposed technical capabilities will be evaluated using five (5) Subfactors as follows:

M.3.2.1.1 SUBFACTOR 1 – MANUFACTURING APPROACH

The Government will evaluate the feasibility of the Offeror's manufacturing advanced development plan including: process development for manufacturing clinical trial material; assay development; purification and yield; formulation development; scalability of the manufacturing process and stability testing. Analysis will also include whether the proposed manufacturing process, assay development (to include absolute quantitation of GP

concentration), and formulation studies, including adjuvant, are sufficiently defined as specified in the SOO. The Government will evaluate the proposed process development flow diagram for feasibility and completeness to include decision points and quality elements. The Government will evaluate the feasibility of the Offeror's approach and knowledge and use of practices to facilitate packaging, handling, storage, and distribution of product. (L.3.4.1)

M.3.2.1.2 SUBFACTOR 2- MANUFACTURING FACILITY

The Government will evaluate the proposed facility to ensure that it meets cGMP requirements to include the schedule when the facility will be available to the requirements of the contract. The Government will evaluate the proposed key facility systems to support production, to include but not limited to: personnel, environmental controls, cleaning, proper equipment, location, security monitoring system, backup power, and procedures to protect the product. The Government will evaluate the proposed facility to ensure that adequate space and product flow exists to conduct cGMP manufacturing operations as specified in SOO. The Government will evaluate the proposed storage, packaging, handling, and distribution systems are appropriate to meet the requirements of the contract and that the Offeror has implemented these processes. The Government will evaluate the proposed safety program, including personnel and procedures, to demonstrate its success and compliance with federal, state, and local safety and environmental laws. The Government reserves the right to conduct a pre-award site visit of facilities to include key subcontractor facilities to fully evaluate this Subfactor. (L.3.4.2).

M.3.2.1.3 SUBFACTOR 3 – QUALITY SYSTEM

The Government's evaluation will include an analysis of the following quality elements:

(a) REGULATORY COMPLIANCE/APPROACH

The Government will evaluate whether the Offeror's proposed manufacturing facilities are adequate and compliant with FDA current Good Manufacturing Practices (cGMP; 21 CFR 210, 211) regulations for manufacturing, and applicable storage and testing. The Government's evaluation will include an analysis of the Offeror's demonstrated knowledge of the FDA guidelines and regulations related to cGMP. The Government will evaluate the feasibility of the Offeror's regulatory approach to meet the requirements defined in the SOO to include but not limited to compliance with cGMP, ICH guidelines, and preparation of the Chemistry, Manufacturing, and Control (CMC) section of the Investigation New Drug submission (IND). The Government will evaluate that the Offeror's cGMP facility is in good standing with the FDA. (L.3.4.3)

(b) QUALITY MANAGEMENT PLAN (QMP)

The Government will evaluate the Offeror's and Major Subcontractor's QMP for quality standards in facilities, equipment, methods, practices, records, controls, documentation supporting implemented, comprehensive cGMP compliant system, comprehensive and adequately staffed Quality Assurance Unit, established quality agreements with Subcontractors, and the approach to technology transfers of processes and assays. Evaluation will include an analysis of whether the approach to Quality is integrated into the scope of work. The Government reserves the right to conduct a quality pre-award on site audit to fully evaluate this Subfactor. The Government will evaluate the Offeror's Quality Systems which will include processes for the receipt and inspection of manufacturing components; equipment preventive maintenance program; storage of components and manufactured products (materiel management); temperature monitoring; security; and training. The Government will evaluate the Offeror's proposed Quality Agreement for completeness (L.3.4.4)

M.3.2.1.4 SUBFACTOR 4 – STATEMENT OF WORK (SOW)

The Government's evaluation will include analysis of whether the proposed SOW captures all requirements in the SOO, organized in SOO format using the same numbering system as the CWBS and Integrated Master Schedule (IMS), in sufficient detail and organization to demonstrate that all tasks will be executed in full compliance with all relevant statutes and regulations for the effort being executed. The Government's evaluation will include an analysis of whether the proposed SOW demonstrates an understanding and completeness for each deliverable. (L.3.4.5)

M.3.2.1.5 SUBFACTOR 5 – Process/Item Data Architecture- Extent of Data Rights

This solicitation includes clauses that specify Government data rights and, based upon facts and circumstances relative to each proposal, may afford the Government varying degrees of rights to data. The Government will evaluate proposals to determine the extent of the Government's entitlement to data rights under these clauses based upon each proposal received. The Government assigns greater value to proposals that afford the Government greater rights in data inasmuch as greater rights in data allow the Government to foster competition and/or broaden industry participation in future program initiatives. The Government will evaluate the Offeror's proposal regarding this Subfactor. (L.3.4.6).

M.3.2.2 FACTOR 2 – PROGRAM MANAGEMENT

The proposed program management capabilities will be evaluated using seven (7) Subfactors as follows:

M.3.2.2.1 SUBFACTOR 1 – CONTRACT WORK BREAKDOWN STRUCTURE (CWBS)

The Government's evaluation will include analysis of whether the Offeror's CWBS is extended in detail to accurately define the complete contract scope. The Government will evaluate the CWBS dictionary for completeness. The Government will evaluate whether the CWBS accurately depicts the Offeror's proposed effort and correlates with the SOW (which follows the SOO format), IMS, and Contract Line Item Numbers (CLINs). (L.3.5.1)

M.3.2.2.2 SUBFACTOR 2 – INTEGRATED MASTER SCHEDULE (IMS)

The Government's evaluation will include analysis of the manufacturing critical path, major tasks/activities, duration, delivery dates, schedule relationships, and schedule to assess if these IMS components are reasonable, realistic, and complete. The Government will evaluate the proposed delivery date for the intended product. The Government's evaluation will include analysis of whether the IMS is directly traceable to the SOW, CLINs and the CWBS. The Government will evaluate whether the tasks/activities in the IMS link together showing predecessor/successor relationships and are sufficient to account for the entire program/project under contract. The Government's evaluation will include analysis of whether the technical approach, associated risks, and the feasibility of accomplishing these within the proposed timeline are reflected in the IMS. (L.3.5.2)

M.3.2.2.3 SUBFACTOR 3 – RISK MANAGEMENT SYSTEM

The Government's evaluation will include analysis of the proposed risk management plan identifying the process for implementing proactive risk management in an integrated and timely manner as part of the overall effort. Evaluation will also include an analysis of the proposed tools to enable integrated methodologies for the risk management process, including risk assessment, mitigation, tracking, resolution and reporting. The Government will evaluate the Offeror's proposed risks, root cause, impacts, and recommended mitigation strategies to assess the Offeror's understanding of the risk management process. (L.3.5.3)

M.3.2.2.4 SUBFACTOR 4 – KEY PERSONNEL

The Government will evaluate the Offeror's proposed technical, regulatory, and management staffing plan and the plan for addressing vacancies, replacements, and maintaining Key Personnel. The Curriculum Vitae or resume of each proposed key person and consultant (if any) to be assigned to this effort will be evaluated for their appropriateness, depth and breadth of expertise, and credentials relative to the project. The Government's evaluation will include analysis of whether the proposed labor hours and categories are inadequate, sufficient, or excessive to successfully perform the SOW. (L.3.5.4)

M.3.2.2.5 SUBFACTOR 5- SUBCONTRACTOR MANAGEMENT

The Government will evaluate the Offeror's proposed subcontracting approach, including subcontractor selection, compliance with any requirement for competition and the approach for assuring that the Subcontractor(s) meet(s) cost(s), schedule(s), and performance requirements. Among other evaluation elements, the Government will review the Offeror's standard procedures for selecting subcontract types and proposed methods of incentivizing Subcontractors (incentive-fee/award fee contracts, etc.) and approach for dealing with/avoiding risk prone

subcontractors. The Government will evaluate the Offeror's proposed approach to managing subcontractors and the mechanisms for interactions/communications/data access. (L.3.5.5)

M.3.2.2.6 SUBFACTOR 6 – EARNED VALUE MANAGEMENT SYSTEM (EVMS)

The Government will evaluate the proposed EVMS for the full integration of the measurement of manufacturing performance with cost and schedule objectives. The Government will consider the Offeror's EVM understanding, and whether implementation for monitoring/reporting technical performance, accounting, cost and schedule is feasible. The Government's evaluation of the Offerors' EVMS will be measured against the American National Standards Institute (ANSI)/Electronic Industries Alliance (EIA) standard 748, FAR 52.234-4 as well as DFARS 252.234-7001 and DFARS 252.234-7002

(http://farsite.hill.af.mil/reghtml/regs/far2afmcfars/fardfars/dfars/dfars252_237.htm#P720_44177) and the policy letter, "Revision to DoD Earned Value Management Policy" dated March 7, 2005, provides additional guidance. (L.3.5.6).

M.3.2.3 FACTOR 3 - PAST PERFORMANCE

Past Performance will be evaluated by assessing Past Performance Relevancy and Performance Confidence. Past Performance Relevancy will address how relevant recent efforts accomplished by the Offeror are to the effort under the solicitation. Performance Confidence Assessment will evaluate how well the Offeror performed under previous contracts and assign a confidence level based on that performance. If no past performance history exists, the Confidence Assessment will be rated as unknown/neutral. Relevancy and Confidence definitions are shown below.

Past Performance Relevancy Ratings

- Very Relevant: Present/past performance effort involved essentially the same scope and magnitude of effort and complexities this solicitation requires.
- Relevant: Present/past performance effort involved similar scope and magnitude of effort and complexities this solicitation requires.
- Somewhat Relevant: Present/past performance effort involved some of the scope and magnitude of effort and complexities this solicitation requires.
- Not Relevant: Present/past performance effort involved little or none of the scope and magnitude of effort and complexities this solicitation requires.

Performance Confidence Assessments

- Substantial Confidence: Based on the offeror's recent/relevant performance record, the Government has a high expectation that the offeror will successfully perform the required effort.
- Satisfactory Confidence: Based on the offeror's recent/relevant performance record, the Government has a reasonable expectation that the offeror will successfully perform the required effort.
- Limited Confidence: Based on the offeror's recent/relevant performance record, the Government has a low expectation that the offeror will successfully perform the required effort.
- No Confidence: Based on the offeror's recent/relevant performance record, the Government has any expectation that the offeror will be able to successfully perform the required effort.
- Unknown Confidence (Neutral): No recent/relevant performance record is available or the offeror's performance record is so sparse that no meaningful confidence assessment rating can be reasonably assigned.

The Government's evaluation will include an analysis of the Offeror's description of relevant on-going and previous (preceding three years only) Government contracts and may include an analysis of similar contracts with commercial entities, local and/or state governments. The Government's evaluation will consider the Offeror's relevant experience:

- a) Experience in assay development;
- b) Experience in process development;
- c) Experience developing cGMP manufacturing processes and cGMP production of vaccines;
- d) Experience manufacturing vaccines, specifically multivalent vaccines;
- e) Experience producing vaccines based on virus particles, or like technology;
- f) Previous FDA submissions, inclusive of FDA response/non-response to submissions;
- g) Corporate experience solving challenging development efforts similar to those that may arise during the proposed effort with outcomes.
- h) Experience in subcontract management specifically in selecting, incentivizing contractors, and managing contractors effectively to avoid cost overruns.

The Government will also evaluate the Offeror's Past Performance Questionnaire(s) submitted to the Government by the Offeror's Reference(s). The Offeror is responsible for ensuring Reference(s) Questionnaire submission(s) are received within the stated timeline. Failure to receive these data from References will not impact past performance evaluation positively. (L.3.6.1 and L.3.6.4)

M.3.2.4. FACTOR 4 – COST

The Government will evaluate the estimated cost, incentive fee(s), and share ratios proposed by the Offeror for performing all requirements outlined in this RFP. Evaluation will include analysis of the proposed cost, incentive fee(s), and share ratios together with the supporting cost information. The Offeror's cost rationale will be evaluated for business judgment and protecting the taxpayers' investment. The Government will be the sole judge of validity/appropriateness of these determinations.

(a) Reasonableness: The Offeror's cost/price proposal will be evaluated using one or more of the techniques defined in FAR 15.404 to determine if it is reasonable and realistic. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price and cost reasonableness are established through cost and price analysis techniques as described in FAR 15.404.

When adequate price competition exists (see FAR 15.403-1(c)(1)), generally no additional information is necessary to determine the reasonableness of price. However, if there are unusual circumstances where it is concluded that additional information is necessary to determine the reasonableness of price, the contracting officer shall, to the maximum extent practicable, obtain the additional information from sources other than the Offeror. Offerors may provide the percentage of discounts obtained from suppliers and subcontractors to demonstrate their ability to manage costs. Awardees can reasonably anticipate receiving GSA Authorization letters, therefore, Offerors may want to leverage the use of GSA contracts and related pricing. Obtaining spot discounts and price locks for a period of time from subcontractors on supplies and services will be viewed favorably by the contracting officer. In addition, the contracting officer may request information to determine the cost realism of competing offers or to evaluate competing approaches.

(b) Realism: The Government will evaluate whether the proposed Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal that correlate with SOW, CWBS, IMS, and CLINs when applicable, as described in FAR 15.404-1.

The Government will develop a most probable Cost of Performance for each Offeror when evaluating the Contractor Total Procurement Price projections. The most probable cost may differ from the Contractor's bid price in the Offeror's proposal. The most probable cost is determined by adjusting (for evaluation purposes only) each Offeror's proposed cost, when appropriate, to reflect any changes (unnecessary additions or omissions by the Offeror) in cost elements to realistic levels based on the cost realism analysis.

(c) Completeness: The proposal should clearly and thoroughly document the cost/price information supporting the proposed Cost Model in sufficient detail and depth. The Government will evaluate whether the Offerors cost proposal used the provided workbook format to ensure completeness.

M.3.3 Scoring Criteria

M.3.3.1. Technical, Program Management, Past Performance Factors, Subfactors and Elements will be rated using a Color/Adjectival rating scheme. Subfactor ratings will be rolled up into their corresponding Factor rating.

General definitions of ratings:

OUTSTANDING=BLUE – The proposal meets requirements and indicates an exceptional approach and understanding of the requirements. The proposal contains multiple strengths and no deficiencies.

GOOD=PURPLE – The proposal meets requirements and indicates a thorough approach and understanding of the requirements. The proposal contains at least one strength and no deficiencies.

ACCEPTABLE=GREEN – The proposal meets requirements and indicates an adequate approach and understanding of the requirements. The proposal has no strengths or deficiencies.

MARGINAL=YELLOW – The proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements.

UNACCEPTABLE=RED – The proposal does not meet requirements and contains one or more deficiencies and is unawardable.

M.3.4 Proposal Risk

A single Proposal Risk will be assigned by assessing the Evaluation Factors for Technical, Program Management, and Cost according to the definitions below:

Low Risk	Has very little potential to cause disruption of contract effort or increase in cost or diminution in performance. Government monitoring through an effective IPT with the contractor will probably be able to overcome most difficulties.
Moderate Risk	Has some potential to cause minor disruption of contract effort or increase in cost or diminution in performance. In order to overcome disruption, more involved Government monitoring, in addition to the IPT, will be required.
High Risk	Likely to cause serious disruption of contract effort or increase in cost or diminution in performance even with special Contractor emphasis and close Government monitoring. The program may be jeopardized by excessive cost overruns.

(End of Summary of Changes)