Biomedical Advanced Research and Development Authority (BARDA) Request for Project Proposals (RPP) for

"NextGen Vaccines: Statistical Support, Correlates of Protection, and Meta-analysis"

RPP #: 24-04-NGVxStats

Issued: February 23, 2024

Amendment No. 01 Issue Date: March 15, 2024

Due: March 27, 2024, by 1pm Eastern

Biomedical Advanced Research Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
400 7th Street, SW, Washington, DC 20024

MedicalCountermeasures.gov

Amendment No. 01 does the following:

Extends the proposal due date from March 25, 2024, to March 27, 2024, at 1pm Eastern.

All other terms and conditions remain unchanged.

Contents

1 Executive Summary

Rapid Response Partnership Vehicle Consortium

The Rapid Response Partnership Vehicle (RRPV) Consortium is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Biomedical Advanced Research and Development Authority (BARDA).

The RRPV will help fortify national health security by developing medical countermeasures products prior to and during a pandemic or public health emergency. The RRPV will focus on the acceleration of products and technology development, regulatory approval, commercialization, and sustainment to address pandemic influenza, emerging infectious diseases, and other biological threats.

Advanced Technology International (ATI) has been awarded an Other Transaction Agreement (OTA) by BARDA to serve as the Consortium Management Firm (CMF) for the RRPV.

RRPV is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from all organizations who work within stated technical focus areas; for more information on the RRPV mission, refer to the RRPV website at RRPV.org. For entities interested in joining the RRPV Consortium and responding to this solicitation, please visit www.rrpv.org/how-to-join.

Purpose

Project NextGen aims to advance next-generation vaccines and enabling capabilities to improve our response against COVID-19 variants and prepare for future threats. As part of this, BARDA is supporting vaccine trials across a number of candidates and capabilities. Other clinical support services are also being provided to ensure harmonization across trials – for example, standardized clinical sample collection and immune assays. An important goal of this harmonization is to enable assessment of vaccine correlates of protection and meta-analysis across trials.

As the COVID-19 pandemic evolves, characterization of correlates of protection (CoPs) will be critical for ongoing vaccine development and optimization as variants and subvariants continue to emerge. BARDA intends to leverage immunogenicity data from multiple clinical trials of investigational next-generation COVID-19 vaccines and FDA licensed or authorized COVID-19 vaccines to inform a broader understanding of immunologic correlates of vaccine protection. In addition to interventional clinical trials of investigational products, establishing a paradigm that allows for the capture of real-world data on both immunologic and clinical endpoints is critical for a continual assessment of thresholds of protection in an immunologically heterogeneous and geographically diverse cross-section of the United States.

Therefore, this Request for Proposals (RPP) aims to provide statistical and data coordination support, including vaccine correlates of protection (CoP) analysis and meta-analysis, to support the advanced clinical development and assessment of next-generation COVID-19 vaccines and capabilities.

Offerors are encouraged to submit a proposal to at least one or both of the following specific areas of interest (referred to herein as “modules") of this RPP:

1) **Module 1 – NextGen Vaccine Study Statistical and Data Coordination Support (1 award with $16.5M ceiling):** Module 1 includes two base tasks and one optional task as follows: (Task 1-base) full statistical and data coordination support for one home-focus vaccine decentralized

clinical trial (DCT); (Task 2- base) statistical support for CoP and meta-analysis across up to 11 vaccine trials; (Task 3 – option) ad hoc, final statistical analysis, and project meeting support for one retail-focus DCT.

2) **Module 2 – Assessing Foundational CoP Data (1 Award with $500K ceiling):** Module 2 includes assessment of foundational CoP data from first-generation COVID-19 vaccine trials.

Strategic oversight for the Project Award(s) supported by this RPP will be provided by BARDA.

2 Administrative Overview

Request for Project Proposals (RPP)

Each response submitted to this RPP shall contain a Technical Proposal and a Cost Proposal, as well as additional documents described in Section 3 of this request. ***White papers are not required for this RPP.***

RPP Approach

It is expected that there will be a total of one qualified respondent to accomplish the statement of objectives for each module, although each module may (or may not) be awarded to a separate respondent.

Each proposal selected for award under this RPP will be executed as a Project Award under the RRPV by the RRPV CMF and be funded under the OTA Number 75A50123D00005. The same provisions will govern this Base Agreement as the OTA between the US Government (USG) and ATI, unless otherwise noted in the Project Award.

At the time of the submission, Offerors must certify on the cover page of their Proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the RRPV Base Agreement. Base Agreements are typically not executed until Offeror is selected for award.

Offerors are advised to check the RRPV website periodically during the proposal preparation period for any changes to the RRPV Base Agreement terms and conditions.

Period of Performance and Type of Funding Instrument Issued

The Period of Performance is estimated to be seven years for Module 1 and two years for Module 2. Performance of work activities required to execute objectives will begin immediately upon execution of this Task Order and conclude upon closeout of any subsequent Project Award or as otherwise described in the base Agreement. The Period of Performance may be revised for Project Award(s), as approved by the Government.

Expected Award Date

Offeror should plan on the period of performance beginning sometime in the third quarter of fiscal year 2024. Government reserves the right to change the proposed period of performance start date through negotiations via the RRPV CMF and prior to issuing a Project Award.

Anticipated Proposal Selection Notification

As the basis of selections is completed, the Government will forward their selections to the RRPV CMF to notify Offerors. Proposers will be notified of the decision via email from the RRPV CMF of the results of the evaluation. All Offerors will receive feedback on eligible submissions.

Proprietary Information

The RRPV CMF will oversee submission of proposals submitted in response to this RPP. The RRPV CMF shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than proposal evaluation and agreement administration. Please mark all Confidential or Proprietary Information as such. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CMF responsibilities.

Eligibility Criteria

Offerors submitting proposals must be RRPV members when the proposal is submitted. As mentioned above, prospective Offerors may join the consortium at www.rrpv.org/how-to-join.

Additionally, in order to respond to this RPP, Offerors must satisfy the following minimum eligibility criteria:

For Module 1:

- Demonstrate experience as an organization that provides clinical data management and statistical analysis to include trials for medical countermeasures as appropriate for and aligned with the project for a minimum of five years.
- Demonstrate experience performing clinical data management and statistical analysis in decentralized clinical trials within the past three years.

For Module 1 and 2:

- Demonstrate specialty expertise and experience in advanced statistical methodologies and data analyses of immunogenicity and correlates of protection.

Proposals found to not meet minimum eligibility criteria(s) as detailed above may be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

Intellectual Property and Data Rights

Intellectual Property (IP) rights for RRPV Project Awards will be defined in the terms of a Project Awardee's Base Agreement. The RRPV CMF reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the Project Awardees during the entire award period.

The Offeror shall comply with the terms and conditions defined in the RRPV Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered consistent with terms of the base OT as defined in the RRPV Base Agreement unless otherwise specified in the proposal and agreed to by the Government. All proposed data rights are subject to Government review and approval. Rights in technical data agreed to by the Government will be incorporated into the Project Award.

The Offeror shall indicate in its proposal submission its acceptance of the terms and conditions defined in the RRPV Base Agreement regarding intellectual property and data rights.

The Offeror shall complete the table provided in Section 6 of the SOW, for any items to be furnished to the Government with restrictions. An example is provided below.

Technical Data to be Furnished with Restrictions	**Basis for Assertion**	**Asserted Rights Category**	**Name of Organization Asserting Restrictions**	**Milestone # Affected**
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2

3 Proposals

Question and Answer Period

Date	**Event**
23 Feb 2024	RPP released
7 Mar 2024 COB	Questions due from proposers
13 Mar 2024 COB	Questions & Answers released (can be approx.)
27 Mar 2024 1PM ET	Proposals due

Please submit questions to rrpv-contracts@ati.org.

Proposal General Instructions
Offerors who submit Proposals in response to this RPP must submit by the date on the cover page of this RPP. Proposals received after the time and date specified may not be evaluated.

The Proposal format provided in this RRPV RPP is mandatory and shall reference this RPP number. Offerors are encouraged to contact the Point of Contact (POC) identified herein up until the Proposal submission date/time to clarify requirements.

The Government will evaluate Proposals submitted and will select the Proposal(s) that best meets their current technology priorities using the criteria in Section 5.

All eligible Offerors shall submit Proposals for evaluation according to the criteria set forth in this RPP. Offerors are advised that only ATI, as the RRPV's CMF, with the approval of the Other Transaction Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

Proposal Submission
Proposals shall be submitted by the date and time specified on the cover page.

Do not submit any classified information in the proposal submission.

Offerors shall submit files in Microsoft Word, Microsoft Excel, or Adobe Acrobat (PDF – portable and searchable document format) formats as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension (.docx, .doc, .xlsx, or .pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters.

A receipt confirmation will be provided by email. Offerors may submit, or re-submit, in advance of the deadline**. Neither the Government nor the RRPV CMF will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror fails to submit the full submission prior to the deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

Proposal Preparation Cost
The cost of preparing Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

Submission Format
Proposals shall reference this RPP number. Each document below (e.g., Technical Proposal, Cost Proposal Narrative, Cost Proposal Format, and Statement of Work) is mandatory and must each be submitted as separate files and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact the RRPV CMF with any questions so that all aspects are clearly understood by both parties. The proposal should include the following:

- **Technical Proposal (30-page limit, unless noted*) – See Attachment 1:** One signed Technical Proposal (.pdf, .doc or .docx). The mandatory template is provided as Attachment 1, and includes mandatory sections for a cover page*, information sheet*, executive summary and minimum eligibility requirements, technical approach, current and pending support, data rights*, and key personnel resumes*.

- **Cost Proposal (no page limit) – See Attachment 2:** One Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative is required using the mandatory template. Separately, Section II: Cost Proposal Format is required in Excel (.xlsx) format, with working formulas to the maximum extent practicable. See Section 3.5 of this RPP for additional information.

- **Statement of Work/Milestone Payment Schedule (no page limit) – See Attachment 3**: One Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the mandatory template provided as Attachment 3.

Cost Proposal

The Cost Proposal must include two sections, Section I; Cost Proposal Narrative, and Section II: Cost Proposal Format. Offerors are encouraged to use their own cost formats for Section II such that the necessary detail is provided. The RRPV CMF will make optional cost proposal formats for Section II available on the Members-Only RRPV website. The cost proposal formats for Section II are **NOT** mandatory.

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

Restrictions on Animal and Human Subjects

Project Awardees must comply with restrictions and reporting requirements for the use of animal and human subjects, as addressed in further detail in the RRPV Base Agreement. It is anticipated that the Project Award(s) issued under this RPP will require the following:

- Effective July 17, 2023, BARDA will automatically issue a Certificate to all BARDA funded research commenced on or after July 17, 2023, that is within the scope of the BARDA Policy Notice No. BARDA-CoC-001-2023 – Issuing Certificates
- Support and maintain applicable regulatory submissions throughout life of the project.
- The Project Awardee shall cross-reference any applicable regulatory files, such as INDs, Master Files, and BLA prior to the conduct of the studies, and shall allow cross-referencing of these documents associated with this effort.

Additional information on the applicable regulatory terms is provided in the RRPV Base Agreement.

These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.

4 Technical Requirements (Attachment A)

4.1 Introduction

This RPP describes two modules that support the assessment of potential CoPs using humoral and cellular immunogenicity data correlated to symptomatic COVID-19 following vaccination with an FDA licensed/authorized COVID-19 vaccine or an investigational COVID-19 vaccine. Note that data to conduct the analysis work sought under this RPP will be provided by BARDA in coordination with partners that are conducting the associated clinical trials outside of this RPP; no clinical trials will be conducted by the Offerors under this RPP. BARDA will work with the Performer(s) for Module 1 and Module 2, along with the partners conducting the clinical trials outside of this RPP, to coordinate and establish any agreements necessary to conduct the work described herein (e.g., data transfer agreement; etc.).

For scheduling and pricing purposes, Offerors should assume that all activities may occur concurrently to support cost and schedule savings.

4.2 Solution Requirements

Project Objectives. Offerors may respond to either a single module (i.e., either Module 1 or Module 2) or to both modules; the awardee will be responsible for the work described in the Module(s) to which they respond. If responding to both modules, Offerors should describe work packages and cost each module individually.

Module 1 – NextGen Vaccine Study Statistical and Data Coordination Support (1 award with $16.5M ceiling- inclusive of optional task 3). The entity responding to this project is referred to in this document as the "Performer". This project will support the full range of routine statistics and data coordination for the three Module 1 tasks described in Table 1; each task must be priced. See Attachment D for Module 1 assumptions, constraints, and limitations.

Table 1 – Module 1 Tasks

Task	Description of Item
1 (Base task)	One COVID-19 vaccine clinical study – Home-Focus DCT. Please note that the implementation of this study will be outside of this RPP (See Attachment E for study synopsis) and the entity performing the trial is referred to in this RPP as the "Study Execution Partner". For reference, and in regards to the study described at Attachment E, see Attachment I and J for information on the specimen collection, processing, and testing for the study and attachment K for possible biometric devices that may be used in the study. Work will include program management and administration specific to Module 1; program management across the study described in Attachment E; protocol development and medical writing support; full-scope statistical and data management support from protocol development through analysis; pharmacovigilance and safety monitoring; central data analytical support; study

	portals for secure electronic document storage; regulatory services; quality assurance and audits; and clinicaltrials.gov registration and results reporting.
2 (Base task)	Statistical analysis to assess CoPs for up to 11 Project NextGen COVID-19 vaccine protocols following vaccination with investigational product(s) or an FDA licensed/authorized COVID-19 vaccine, both individually and in aggregate (within and across trials). Meta-analysis, ad hoc statistical analysis, statistical consult, reporting, and project meeting support. Please note that the implementation of the Project NextGen COVID-19 vaccine protocols will be outside of this RPP. The studies will include, but may not be limited to, those described in the following study synopses: (1) one home-focus DCT (Attachment E); (2) one retail-focus DCT (Attachment M); and (3) NextGen vaccines Phase 2b trials (Attachment E). For reference, and in regards to the studies described at Attachments E, F, and M, see Attachment I and J for information on the specimen collection, processing, and testing.
3 (Optional task)	One COVID-19 vaccine clinical study – Retail-Focus DCT (Option Task). Interim, ad hoc, final statistical analysis, and project meeting support. See Attachment M for study synopsis.

The Responsibilities of the Performer and Study Execution Partner may be found in Attachment G, which outlines the range of activities and execution responsibility. Assume the Study Execution Partner is expected to fulfill the Clinical Trial Planning and Execution (CTPE)-like roles as described in the BARDA Clinical Studies Network (CSN) Governance Plan (conducting the clinical trial planning and execution for the study at Attachment E), while the Performer is to fill the Statistical and Data Coordinating Center (SDCC)-like role. Both are expected to collaborate to achieve first subject first visit in the Fall of 2024 (by October 01, 2024). The Performer may propose additional changes to this Governance Plan with rationale. BARDA may determine that designations in the Governance Plan should change to provide the best result for the USG prior to or after the award.

Module 1 Performance Objectives. The Performer must meet the performance objectives described herein. Each task (Table 1) is inclusive of all resources necessary to implement all aspects of the support described.

- Program Management and Administration
    - Perform all aspects of project management as per the Project Management Plan and as specified in other contractor plans. This includes: program coordination; implementation; Quality Assurance/Quality Control (QA/QC) oversight for entire program; risk management and mitigation.

- Provide administrative support to coordinate meetings, prepare presentation materials, draft minutes, and action items.
- Perform program management for the project.
- Develop a Project Management Plan (PMP) that describes the relationships, accountabilities, communications, and oversight of coordination of the collaborative activities.
- Provide protocol development and medical writing support. Protocol development should take into consideration:
  - Diversity of the clinical study population, taking into account applicable principles outlined in "Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry" https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial
  - Other FDA Guidance Documents including and not limited to:
    - Draft "Decentralized Clinical Trials for Drugs, Biological Products and Devices" https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices
    - Draft "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations" https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations

- Statistical and Data Management Services
  - Provide full-scope statistical support ranging from development of the study protocol and study related documents such as statistical analysis plan (SAP) and clinical study report (CSR) to providing analysis and study result reports for regulatory submission and publishing purposes.
  - Provide full-scope statistical programming support for generating Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) datasets (including supporting documents such as annotated Case Report Form (CRF), define.xml, Pinnacle 21) validation, and reviewer's study guide), and Tables, Listings, Figures (TLFs) for the study.
  - Provide full-scope data management support, ensure processes in place for data integrity, use validated systems in compliance with 21 CFR part 11 (e.g., clinical database development and support, safety database development and support, Interactive Web Response System (IWRS)/Interactive Voice Response System (IVRS) development and support, data cleaning review, data listings, data status metrics, preparation of study-related materials and instructions, medical and drug coding, Serious Adverse Event (SAE) reporting, database training and the assessment of clinical site capabilities for data collection and management, etc.)
  - Provide SAE reconciliation Standard Operating Procedures (SOP) if safety database is separate from clinical database.

- Meta-analysis, ad hoc statistical analysis, statistical consult, reporting, and project meeting support.
    - Conduct meta-analysis, ad hoc statistical analysis, statistical consulting, reporting.
    - Provide associated plans and reports for meta-analysis and ad-hoc analysis.
    - Provide statistical consult as needed.
    - Plan to lead, facilitate, administer BARDA Project Coordination Team (PCT) and other similar meetings (including BARDA external partners) on a biweekly basis.
    - Plan to provide ad hoc, interim, and final statistical analysis reports and data packages to BARDA and, as directed by BARDA, to BARDA partner(s).
- Statistical analysis to assess CoPs for NextGen COVID protocols following vaccination with investigational product(s) or an licensed/authorized COVID-19 vaccine, both individually and in aggregate (within and across trials).
    - Conduct CoP analyses, including SAP development, selection of immune markers, data cleaning and harmonization, exploratory and final analyses, data visualization, reports, and manuscript writing.
    - Generate a list of samples based on sampling plan for correlates of protection. BARDA or BARDA partners will provide the clinical data and all associated document for Performer to generate this list.
    - Work with BARDA and BARDA partners on data standardization and integration across multiple trials.
    - Either consult on or lead the development of SAPs. For planning purposes, assume that Performer will lead this effort.
    - Plan to lead, facilitate, and administer BARDA Project Coordination Team (PCT) and other similar meetings to discuss plans for analyzing data for correlates of protection (including BARDA external partners) on a biweekly basis.
    - Plan to provide ad hoc, interim, and final statistical analysis reports and data packages to BARDA and, as directed by BARDA, to BARDA partner(s).
- For one retail-focus DCT (optional task), provide interim, ad hoc, and final statistical analysis, and project meeting support. See Attachment M for the study synopsis that will be performed outside this RPP and will provide the data for analysis.

- Regulatory Services
    - Maintain Performer related content for electronic trial master file (eTMF) during active study and coordinate and collaborate with the partners that are conducting the associated clinical trials outside of this RPP to transfer all applicable files to the eTMF.
    - As directed by BARDA, register and/or provide information for the clinical study to ClinicalTrials.gov Protocol Registration and Results System (PRS).
- Pharmacovigilance and Safety Monitoring
    - Provide Pharmacovigilance and Safety Monitoring as per Attachment G Governance Plan.

- Central Data Analytical Support
    - Provide centralized data analytical support for regulatory, site monitoring and medical/safety monitoring. This includes and is not limited to: real time reports on subject accrual, AE/SAE, protocol deviations, and subject visit compliance.
    - Provide data visualization dashboards within the web-based document/content management system and study portals including and not limited to: site specific screening and enrollment as well as aggregation of data over time; population trends and subgroups.
        - Reports from the data visualizations/dashboards must also be by electronic transfer, e.g., from Contractor EDC/IVRS/CTMS to a USG database or dashboard and/or provided to BARDA (outside of the Contractor access-controlled web-based document/content management system). The Offeror and USG to discuss and agree on format. Please refer to Attachment H Example Data Visualization (Enrollment).
    - Administer and maintain a web-based document/content management system and study portals for secure electronic communications of study data and reports.
    - Administer and maintain a web-based study portal for secure electronic access to safety and laboratory data.
- Quality Assurance and Audits
    - Development and implementation of an effective internal project specific Quality Assurance and Quality Control Plan ensuring compliance with federal and local regulations and approved protocol.
    - Maintain inspection readiness state.
    - The Performer shall undergo independent quality audits initiated at the discretion of the USG for review of Performer processes, procedures, and operations at the Contractor's site to ensure regulatory compliance.
        - The Performer shall ensure that designated staff and all necessary information/documents are available.
        - For cause audits may also be performed at any time and without advance notice to the Performer, in instances of non-performance and/or suspected non-compliance with federal and/or local regulatory requirements.

Module 2 – Assessing Foundational CoP Data.

Module 2 will advance our understanding of COVID-19 vaccine CoP by leveraging data from two completed vaccine studies: Study 1 (NCT04505722), which will address new immune CoP question in the blinded phase; and Study 2 (NCT04904549), which will assess immune correlates of protection in the blinded and post-unblinding phases. Offerors must price both studies; Module 2 includes a total ceiling of $500,000 and will use a firm-fixed price contract mechanism. See Attachment L for Module 2 assumptions, constraints, and limitations.

Module 2 Performance Objectives. The Performer must meet the performance objectives described herein, inclusive of all resources necessary to implement all aspects.

- Program Management and Administration

- Perform all aspects of project management specific to Module 2 as per the Project Management Plan and as specified in other performer plans. This includes: program coordination; implementation; QA/QC oversight for entire program; risk management and mitigation.
- Provide administrative support to coordinate meetings, prepare presentation materials, draft minutes, and action items.
- Develop a Project Management Plan that describes the relationships, accountabilities, communications, and oversight of coordination of the collaborative activities.

- Statistical and Data Management Services
  - **Study 1 (NCT04505722)**. The new immune correlates research for Study 1 (including SAP development, statistical methods, data analyses, computer code, dissemination of results) is summarized below. (Please note that the first paper assessing antibody markers as immune correlates of protection was published, based on the subset of the blinded phase data used for the Emergency Use Authorization application (Fong et al., 2022, Nature Microbiology). The three markers MSD anti-Spike IgG, MSD anti-RBD IgG, and pseudovirus neutralizing antibody 50% titer were studied, all with the Reference/Ancestral strain. In addition, a manuscript on the sieve analysis of the SARS-CoV-2 spike sequences from the final blinded data set for Janssen ENSEMBLE (Sadoff et al., 2022, NEJM) is submitted. The new immune correlates research for Project 1 (including SAP development, statistical methods, data analyses, computer code, dissemination of results) is summarized as follows:
    - Conduct the immune correlates analysis based on the final blinded data set, including the analysis of immune markers measured from four immunoassays conducted on blood samples collected at the Day 29 visit post-vaccination: the three antibody markers noted above plus antibody dependent phagocytosis (ADCP) score.
    - The data analysis includes all four immune markers measured against the Reference/Ancestral strain and of the first three immune markers (excluding ADCP score) measured against the Beta and Delta variants for South Africa case-cohort participants and against the Lambda, Gamma, Mu, and Zeta variants for Latin America case-cohort participants. (The 10-plex MSD assay is used to obtain the IgG data against the variants.) In addition, the data analysis accounts for time since vaccination by geographic region.
    - The data analysis accounts for SARS-CoV-2 lineage as well as for SARS-CoV-2 Spike amino acid sequence features, in order to understand how immune correlates of protection depend on lineage and how they depend on Spike amino acid sequence features, especially neutralization-relevant amino acid sequence features. The analyses account for SARS-CoV-2 viral load at virologic confirmation of COVID-19, as these data are needed to account for the fact that some participants with a COVID-19 primary endpoint have

missing data on lineage and Spike sequence. In addition, the data analysis accounts for time since vaccination and geographic region.

- Elements of the project to complete the data analyses entail:
  - completing the SAP;
  - completing the extension of the statistical methods for assessing immune correlates of protection to incorporate data on variants and Spike amino acid sequence features and accounting for the missing data on these viral features;
  - completing the development of the R computer code with documentation and open-source sharing on a Github repository that implements that statistical methods noted in the above two bullets.
- Drafting and publishing at least 2 peer-reviewed papers:
  - a brief-communication manuscript about the Day 29 anti-Reference strain IgG and neutralization immune markers as correlates of protection against severe-critical COVID-19, the first correlates paper on severe-critical COVID-19 from the US Government COVID-19 Vaccine CoP Program;
  - a more expansive paper on the Day 29 anti-variant strain IgG and neutralization immune markers as correlates of protection against variant-specific and Spike amino acid feature specific COVID-19, which includes characterization of how well the variant-invariant CoP model holds, informing models for predicting vaccine efficacy against future variants.
- Exploratory statistical analyses will be conducted of the Day 29 ADCP marker measured against the Reference strain, in the context of the Day 29 neutralization marker data and the variant and amino acid sequence feature data, to understand how the ADCP and neutralization markers jointly associate with COVID-19 and may operate as correlates of protection or enhancement under certain circumstances. This manuscript would only be pursued if ADCP enhancement assays were performed on relevant samples.
- Study 1 data set to be obtained and shared by BARDA or designee with the Performer. Study 1 data sets include:
  - Final blinded-phase P3003 Janssen ENSEMBLE clinical data set used to assess vaccine efficacy
  - Day 29 immune marker data set from case-cohort participants and from breakthrough COVID-19 endpoint cases
  - Lineages and Spike amino acid sequences from COVID-19 primary endpoint cases, plus data on viral load at COVID-19 illness onset and indicators of whether lineage/sequence data are missing

- **Study 2 (NCT04904549)**. In NCT04904549, a study consists of two phase 3 COVID-19 vaccine efficacy trials, includes the so-called Stage 1 trial comparing a

monovalent vaccine vs. placebo and the Stage 2 trial comparing bivalent vaccine vs. placebo. The new immune correlates research for Study 2 (including SAP development, statistical methods, data analyses, computer code, dissemination of results) is summarized as follows:

- Conduct the immune correlates analysis of each of the Stage 1 and Stage 2 trials, based on the final blinded data sets (Dayan et al., submitted), including the analysis of immune markers measured from three immunoassays conducted on blood samples collected at the Day 1, Day 22, and Day 43 visits: 10-plex MSD anti-Spike IgG, 10-plex MSD anti-RBD IgG, and pseudovirus neutralizing antibody 50% titer. These three immunoassays are applied to measure responses against the Reference/Ancestral strain as well as against Omicron sub-variants (BA.1, BA.2, BA.4/BA.5) and Delta (for the Stage 1 trial) that circulated during the trials.
- The data analysis accounts for whether participants are baseline SARS-CoV-2 negative or baseline SARS-CoV-2 positive, assessing correlates of protection for each baseline status group separately (if enough statistical power) as well as pooled, with evaluation for modification of the correlates of protection by baseline status.
- The data analysis accounts for variant and SARS-CoV-2 Spike amino acid sequence features as well as for missing data on variant and viral sequences, and also accounts for time since vaccination and geographic region.
- Elements of the project to complete the data analyses entail:
  - completing the SAP;
  - completing the extension of the statistical methods developed in Project 1 to account for inclusion of baseline SARS-CoV-2 positive participants;
  - completing the R computer code with documentation and open-source sharing on a Github repository that implements statistical methods noted in the above two bullets.
- Drafting and publishing 1 or 2 peer-reviewed papers reporting the results (depending on the results, there may be separate papers for the Stage 1 and Stage 2 trials or a single paper combining results across the trials).
- In addition to the research described above based on the final blinded data sets and immune markers measured at Day 1, Day 22, Day 43, the immune markers are also being measured from a subset at five time points after Day 43 (at Day 78, Day 134, Day 202, Day 292, Day 387), to characterize binding and neutralizing antibody immunogenicity persistence over time, and to study these antibody profiles as exposure-proximal correlates of protection if the immune markers are measured from enough participants experiencing breakthrough COVID-19 infection.
- Study 2 data set to be obtained and shared by BARDA or designee with the Offeror. Study 2 data sets include:

- Final blinded-phase P3005 Sanofi Vat08 clinical data sets (Stage 1 trial, Stage 2 trial) used to assess vaccine efficacy
- Day 1, Day 22, Day 43 immune marker data set from case-cohort participants and from breakthrough COVID-19 endpoint cases as well as from baseline SARS-CoV-2 positive placebo arm COVID-19 endpoint cases
- Day 78, Day 134, Day 202, Day 292, Day 387 immune marker data set from case-cohort participants and from breakthrough COVID-19 endpoint cases as well as from baseline SARS- CoV-2 positive placebo arm COVID-19 endpoint cases
- Lineages and Spike amino acid sequences from COVID-19 primary endpoint cases, plus data on viral load at COVID-19 illness onset and indicators of whether lineage/sequence data are missing

- Quality Assurance and Audits
    - Development and implementation of an effective internal project specific Quality Assurance and Quality Control Plan ensuring compliance with federal and local regulations and approved protocol.
    - Maintain inspection readiness state.
    - The Performer shall undergo independent quality audits initiated at the discretion of the USG for review of Contractor processes, procedures, and operations at the Contractor's site to ensure regulatory compliance.
    - The Performer shall ensure that designated staff and all necessary information/documents are available.
    - For-cause audits may also be performed at any time and without advance notice to the Performer, in instances of non-performance and/or suspected non-compliance with federal and/or local regulatory requirements.

Regulatory Objectives

Support and maintain regulatory submissions throughout life of the project if applicable.

The performer must submit to the Government all regulatory and supporting documentation as appropriate for the work performed if applicable.

For research involving human subjects, HHS human subject protection regulations and policies require that any institution engaged in non-exempt human subjects research conducted or supported by HHS must submit a written assurance of compliance to the Office for Human Research Protections (OHRP). Under a Federal Wide Assurance, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

Section 301(d) of the Public Health Service (PHS) Act (42 U.S.C. 241) provides authority to the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research by issuing Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected. Effective July 17, 2023, BARDA will automatically issue a Certificate to all BARDA funded research

commenced on or after July 17, 2023, that is within the scope of the BARDA Policy Notice No. BARDA-CoC-001-2023 – Issuing Certificates of Confidentiality (CoC). The Contractor shall protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the PHS Act as a term and condition of the contract. The certificate will not be issued as a separate document.

Project Management Objectives

It is anticipated that the performer will be required to submit the following documents to capture the progression of the project, post-award. Offerors shall provide deliverables as included in Attachment 3, Statement of Work. Requirements may include, but are not limited to, the following:

Reporting

1. The performer shall deliver monthly technical and financial reports and progress reports, to including a master schedule. Quarterly and annual reports shall also be provided. At the end of the effort, the performer shall provide a detailed clinical study report, and a final technical and business report.
2. Additional deliverables will include:
    1. Draft and final nonclinical and clinical study reports.
    2. Inclusion of the U.S. Government in FDA meetings.
    3. Submission of all read-ahead packages for FDA meetings ahead of time.
    4. Records of any and all communications with the FDA.

Meetings

1. The performer shall schedule regular, recurring progress meetings with the Government.
2. The meeting agenda shall be submitted to the Government in advance and meeting minutes will be submitted following meetings.

Logistics Objectives

1. The performer shall be responsible for (sub) contracting or executing all intellectual property, material, and sample shipments and maintenance of all associated records and permits.

Performance Requirements

1. Submission and maintenance of non-clinical and clinical documentation for regulatory filings (pre-IND/IND) that support a regulatory strategy to achieve FDA licensure.

5 Selection/Evaluation

Compliance Screening

The RRPV CMF will conduct a preliminary screening of submitted Proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, Proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be

requested by the RRPV CMF. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

Proposal Evaluation Process

Following the preliminary screening, the Government sponsor will perform source selection using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified Proposals.

Qualified Proposals will be evaluated by a panel of subject matter experts (SMEs) who will make recommendations to a Source Selection Authority.

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each proposal against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) as discussed below. The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable, unless specifically stated otherwise.

The evaluation factors and evaluation criteria are described below.

For each evaluated proposal, the non-cost/price factors will each be assigned one of the following adjectival merit ratings:

- Outstanding
- Good
- Acceptable
- Marginal
- Unacceptable

Once an Offeror has submitted a Proposal, the Government and the RRPV CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

Evaluation Factors

The Government will evaluate the information provided in each Offeror's Proposal to determine which Proposal(s) provide(s) the best value to the Government. Such a determination will be based on the following criteria:

Factor 1 - Technical Approach: This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.

Factor 2 – Relevant Experience: This factor evaluates the offeror's demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems.

Factor 3 – Cost/Price: (See Section 5.4 below)

Evaluation factors are listed in descending order of importance.

Following the evaluation, the Source Selection Authority may:

1. *Select the proposal (or some portion of the proposal) for award*
2. *Place the proposal in the Basket if funding currently is unavailable; or*
3. *Reject the proposal (will not be considered for award and will not be placed in the Basket)*

Cost/Price Evaluation
The Cost Proposal will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

If a proposal is selected for award, the RRPV CMF will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP. Evaluation will include analysis of the proposed cost together with all supporting information. The RRPV CMF will request additional information or clarification as necessary. The RRPV CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the project value is fair and reasonable, subject to final Government negotiations.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

a) Realism. Proposals will be evaluated to determine if 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.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each phase of the proposed project when compared to the total proposed cost.

The RRPV CMF will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. 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 reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized, and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down in the Cost Proposal Format. An optional template is located on the Members-Only RRPV website.

c) Completeness. The RRPV CMF will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The RRPV CMF will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The RRPV CMF will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal may not be selected for award.

Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Funding recommendations depend on various factors and programmatic relevance. Based on the evaluation of the Technical Approach, Relevant Experience, and Cost/Price, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offerors will have the opportunity to concur with the requested changes, propose further changes and revise cost proposals, as necessary.

Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately selected for award, may be placed in the Basket (at the Government's sole discretion) for 2 years and eligible for award during that time. Proposals rated as Unacceptable will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal best meets its needs.

6 Points of Contact

- Questions related to this RPP should be directed to rrpv-contracts@ati.org.

Once an Offeror has submitted a Proposal, the Government and the RRPV CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

ATTACHMENT 1 – TECHNICAL PROPOSAL TEMPLATE

General Instructions

The Technical Proposal must address the technical requirements described in the RPP in sufficient detail to permit evaluation from a technical perspective in accordance with the evaluation factors set forth in the RPP. The Technical Proposal shall be single-spaced, single-sided, and 8.5 x 11 inches, and 12-point font. Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc.

The Technical Proposal shall be limited to 30 pages (unless otherwise noted below). Pages in excess of this limitation may not be considered**.** Offerors are advised that the number of pages should be commensurate with the degree of complexity of the proposed effort. It is expected, and encouraged, that less complex, less expensive proposals will be significantly less than 30 pages in length.

To ensure Technical Proposals receive proper consideration, **the Technical Proposal format shown below is mandatory**. If there are any items which are not applicable to a specific proposal, include the section topic in the proposal with a short explanation as to why it is not applicable.

1. Cover Page*
2. RRPV Member Organization Information Sheet*
3. Executive Summary & Minimum Eligibility Criteria
4. Technical Approach
5. Current & Pending Support
6. Resumes of Key Personnel*

***Excluded from page limitation**

1. Technical Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[Module 1, Module 2, Module 1 & 2]

[Proposal Title]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the RRPV Base Agreement.

[Offeror] certifies that this Proposal is valid for 180 days from the close of the applicable RPP, unless otherwise stated.

[As detailed in Section 2.6 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample:
This Proposal includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

_____ _____
Signature of responsible party for the Offeror DATE

2. Member Information Sheet

If an item is not applicable, then that section should be listed as "not applicable."

OFFEROR NAME:	
ALL PLACES OF PERFORMANCE:	
TITLE OF PROPOSED EFFORT:	
UEI # (if applicable):	
CAGE CODE (if applicable):	
SMALL BUSINESS (YES/NO):	
SMALL/ DISADVANTAGED BUSINESS (YES/NO): SOCIOECONOMIC CATEGORY?	
CONFLICT OF INTEREST (YES/NO):	
TOTAL COST OF PROPOSAL:	
PROPOSED PERIOD OF PERFORMANCE IN MONTHS:	
PREFERRED PAYMENT METHOD (FFP, CPFF, Cost Reimbursable (CR), CR/COST SHARE):	
REQUESTED USE OF GOVERNMENT RESOURCES, PROPERTY, LABS, ETC. (YES/NO):	
PROPOSED USE OF ANIMAL SUBJECTS (YES/NO):	
PROPOSED USE OF HUMAN SUBJECT (YES/NO):	
PROPOSED USE OF HUMAN SPECIMEN MATERIAL (YES/NO):	
PROPOSED USE OF HUMAN FETAL TISSUE (YES/NO):	
PROPOSED USE OF LIVE VERTABRATE ANIMALS (YES/NO):	
PROPOSED USE OF SELECT BIOLOGICAL AGENTS OR TOXINS (YES/NO):	
CONTRACT/NEGOTIATION CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
TECHNICAL/PRINCIPAL INVESTIGATOR CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
COGNIZANT RATE AUDIT AGENCY OFFICE (IF KNOWN, INCLUDE POC, ADDRESS, PHONE #, E-MAIL):	

3. Executive Summary & Minimum Eligibility Requirements

[The Executive Summary allows Offerors to briefly and concisely present the important aspects of their proposals to evaluators. The summary should present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core concepts of the proposed project.]

[Additionally, this section must address how the Offeror currently satisfies the following minimum eligibility requirement:]

For Module 1:

- Demonstrate experience as an organization that provides clinical data management and statistical analysis to include trials for medical countermeasures as appropriate for and aligned with the project for a minimum of five years.
- Demonstrate experience performing clinical data management and statistical analysis in decentralized clinical trials within the past three years.

For Module 1 and 2:

- Demonstrate specialty expertise and experiences in advanced statistical methodologies and data analyses of immunogenicity and correlates of protection.

4. Technical Approach

[Provide sufficient technical detail and analysis to support the technical solution being proposed for the project. Clearly identify the core of the intended approach. It is not effective simply to address a variety of possible solutions to the technology problems. Include citation to each Deliverable identified in the Statement of Work throughout the Technical Approach (e.g. (1.1)). Provide the following information:]

1. **Background:** [Describe the problem that the proposal is addressing.]
2. **Approach:** [Describe your overarching approach and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform or solution and listing the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Past Experience:** [Describe relative past experience, as well as the technical and management experience of the proposed team, to perform the proposed work]
5. **Technical Strategy**: [Provide a detailed and stepwise approach on how your organization intends to address the requirements set forth in the RPP and show a clear course of action.]
6. **Anticipated Outcomes**: [Provide a description of the anticipated outcomes from the proposed work.]
7. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur when an individual or an entity is unable, or potentially unable, to provide impartial advice or service to

the Government or separate entity because of other business activities or relationships. Disclose any potential conflict of interest pertaining to this opportunity. If none, state as such.]

8. **Key Personnel:** [Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified].

Key Personnel	**Organization**	**Role and Key Contribution**	**Level of Effort**
Name (Principal Investigator)			%
Name			%
Name			%
Name			%
Name			%

[Address the qualifications, capabilities, and experience of the proposed personnel who will be assigned to carry out the project. Ensure resumes of key personnel are provided in the "Resumes of Key Personnel" section. Resumes are excluded from page count limit]

9. **Schedule:** [Identify key technical, schedule, and cost risks, their potential impact and mitigation.]
10. **Offeror Resources**: [Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.]
11. **Government Resources**: [Identify any key Government facilities, Government equipment, Government property, etc. that your organization requests to use for the effort.]
12. **Cost Realism:** [This section provides technical evaluators with high-level cost data in order for the evaluators to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by cost element.]

Cost Realism Form EXAMPLE This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as samples only. Offeror must complete table with the applicable information.		
Cost Element	**Total Proposed Cost**	**Description/Explanation**
Labor	*$1,475,000*	

Labor Hours	*$14,750*	*5000 hrs of senior scientist; 3000 hours of program management; 3000 of hours of contracts management; 3750 hours of scientist*
Subcontractors	*$300,000*	*Sub A - $150,000; 1500 legal advisor hours Sub B - $150,000; 1500 hours of Testing*
Subcontractor Hours	*$3,000*	
Consultants	*$60,000*	*Financial consultant supporting all phases*
Consultant Hours	*$600*	
Material/Equipment	*$500,000*	*pipettes, gloves, computer software*
Other Direct Costs	*$12,000*	*ship testing materials to lab*
Travel	*$30,000*	*12 trips for 2 people for 2 days to Washington, DC from Charleston, SC for program meetings*
Indirect Costs	*$475,400*	*approved by DHHS 30 Sept 23*
Fee	*$0*	*Not applicable if cost share proposed*
Total Cost to Government	*$2,852,400*	
Cost Share	*$1,740,000*	*30,000 hours of lab assistant*
Total Project Value	***$4,592,400***	

5. Current & Pending Support

Current
Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

Pending
Title of Proposal:
Funding Agency/Requiring Activity:
Estimated Dates of Funding:
Proposed Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Title of Proposal:
Funding Agency/Requiring Activity:
Estimated Dates of Funding:
Proposed Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

[Add additional fields, if needed, to report all pending support]

6. Resumes of Key Personnel

Include the resumes of key personnel from the Offeror's organization, as well as subcontractors or consultants, who will work on this project if selected. The Principal Investigator must be identified.

ATTACHMENT 2 – COST PROPOSAL TEMPLATE

General Instructions

The objective of the Cost Proposal is to provide sufficient cost information to substantiate that the proposed cost is realistic, reasonable, and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the Technical Proposal (i.e., costs, cost share, dates, etc.). Proposals that deviate substantially from these guidelines or that omit substantial parts or sections may be found non-responsive and may be eliminated from further review and funding consideration.

To ensure Cost Proposals receive proper consideration, it is mandatory that the Cost Proposal include the information below.

Section I: Cost Proposal Narrative

a. Cover Page
b. Overview
c. Cost Information

Section II: Cost Proposal Format

The Cost Proposal Narrative is used to assess various criteria. This section will be used to determine reasonableness, allowability, and allocability of costs. The Cost Proposal Narrative section should provide a more detailed breakdown of the figures that are contained in the Cost Proposal Format. The Cost Proposal Narrative section also should give substantiation and written explanation of proposed costs. Breakdowns should be as accurate and specific as possible. Ensure that any figures presented in this part are consistent with the figures in the Cost Proposal Format.

Separately, the Cost Proposal Format must be provided in Excel, with working formulas to the maximum extent practicable. Optional formats are available on the Members Only website. However, Offerors are encouraged to use their own formats so long as the required level of detail is provided.

1. Cost Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[Module 1, Module 2, Module 1 & 2]

[Proposal Title]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the RRPV Base Agreement.

[Offeror] certifies that this Proposal is valid for 180 days from the close of the applicable RPP, unless otherwise stated.

[As detailed in Section 2.6 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample:
This Proposal includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

_____ _____
Signature of responsible party for the Offeror DATE

2. Cost Proposal Section I: Cost Proposal Narrative Template

1. Cost Proposal Narrative Overview

[The Cost Proposal Narrative must include sufficient information to evaluate the proposed value through cost information. This information is required to properly perform the cost and/or price analysis of a proposal. Proposals without this information cannot be properly evaluated and may be eliminated from selection for award. All Proposals must provide the following information as part of the Cost Proposal Narrative Overview:]

1. **Overall Approach.** [Provide an overall and succinct explanation of how this Proposal is justified.]
2. **Assumptions.** [Provide any assumptions. Note that assumptions should be limited to cost or pricing. Technical assumptions are better captured in the Statement of Work.]
3. **Preferred Payment Method.** [Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones (with ceiling), (2) Cost Reimbursable/Cost Sharing Milestones (with ceiling), (3) Cost Plus Fixed Fee Milestones (with ceiling) and (4) Fixed Price Milestones (with ceiling).]
4. **Total Cost by Phase Cost Elements.** [Include a list of each phase that is stated in the Statement of Work and its associated total cost by year. The sum of the phases must equal the total listed in the Cost Proposal Formats.]
5. **Cost Share.** [Cost Share includes any costs a reasonable person would incur to carry out (necessary to) proposed project's Statement of Work not directly paid for by the Government.] If a proposal includes cost share, then it cannot include fee. Cost Share may be proposed only on cost type agreements. There are two types of cost sharing: Cash Contribution and In-Kind Contribution.

   Cash Contribution:
   Cash Contribution means the Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Project Award. The cash contribution may be derived from the Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

   An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Project Award or specific tasks identified within the SOW of a Project Award. Prior IR&D funds will not be considered as part of the Offeror's Cost Share.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Project Award, and restocking the parts and material consumed.

In-Kind Contribution:
In Kind Contribution means the Offeror's non-financial resources expended to perform a Project Award such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Project Award, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Project Award.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on cost share.

If cost share is proposed, the following must be provided:

- A description of each cost share item proposed;
- Proposed dollar value of each cost share item proposed; and
- The valuation technique used to derive the cost share amounts (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).]

2. Cost Proposal Narrative Cost Data

[The Cost Proposal Narrative must include the following cost categories and details, at a minimum.]

1. **Labor Rates**. [Portions of labor information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the position title of all personnel, the labor category description, the hourly rate for each individual, and show estimated hours for each labor category proposed. If an approved organizational estimating procedure use average labor rates for specific labor categories, this would be acceptable.

   It is recognized that an organization may not be able to identify all of the personnel to be assigned to the project several years in advance. Where this cannot be done, use generic position titles such as "scientist." If direct labor costs include allocated direct costs or other direct costs in accordance with established accounting and estimating practices and systems, identify these costs separately and provide an explanation and basis for proposed costs.

   Provide an explanation for any proposed labor escalation.

Offerors are expected to avoid overtime as much as practicable, except when lower overall costs to the Government will result or when it is necessary to meet urgent program needs. If overtime is proposed, provide an explanation as to why.]

2. **Salary Rate Limitation.** [Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level is an unallowable cost under the RRPV OTA and shall be addressed in accordance the RRPV Base Agreement.

   For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary." An individual's direct salary is the annual compensation that the entity pays for an individual's direct effort (costs). Direct salary excludes any income that an individual may be permitted to earn outside of duties to the entity. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

   The salary rate limitation does not restrict the salary that an entity may pay an individual, it merely limits the portion of that salary that may be paid with Federal funds.

   See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current period. See the RRPV Base Agreement for further details.]

3. **Fringe Benefits.** [Identify whether or not the proposed labor rates include fringe costs. If so, then identify the percentage rate. If not, then provide a statement to that effect and include the fringe costs in the indirect section instead.]

4. **Travel.** [Portions of travel information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the total travel amount proposed. Provide an estimate of the cost per trip; number of trips; number of days; number of persons; departure city, destination city; approximate travel time frames; and the purpose of the travel. The key is to apply best estimating techniques that are auditable. Include a brief explanation of the methodology used to estimate travel costs. If exact destination is unknown at time of proposal, for pricing purposes use a potential location using best known information. Note that RRPV project awardees are expected to be cost-conscious regarding travel (e.g., using coach rather than first class accommodations and, whenever possible, using Government per diem, or similar regulations, as a guideline for lodging and subsistence costs). If travel is estimated based on an approved methodology, then state as such.]

5. **Subcontractors/Consultants.** [Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical.

Provide a list of all subcontractor/consultant and a total cost for each. If a cost and/or price analysis has been performed, provide a copy or summary of results.

Support is required for each subcontractor/consultant as follows:

- If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalogue pricing, etc.)
- For a subcontractor/consultant less than $250,000, provide a brief explanation of the work to be performed.
- For a subcontractor/consultant greater than $250,000 and less than or equal to $2,000,000, provide a supporting quote and confirmation of compliance with the Salary Rate Limitation.
- If a subcontractor/consultant over $2,000,000 was competitively solicited, provide the price analysis showing how the price was determined reasonable, summary of competition, and copies of the competitive quotes.
- Absent any of the above, if relying on cost data for a subcontractor/consultant greater than $2,000,000, a cost-by-cost element breakout must be provided to the same level of detail as the Offeror.]

6. **Material/Equipment/Other Direct Costs.** [Portions of the material/equipment/other direct cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an itemized list of the material/equipment/other direct costs, including the itemized unit cost and quantity. Identify the supplier/manufacturer and basis of cost (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) for each item, if known. Additionally, a copy of the basis of cost documentation for each piece of proposed material/equipment/other direct cost with a unit cost greater than or equal to $25,000; or total cost greater than or equal to $150,000; must be provided. If material/equipment/other direct cost is estimated based on an approved methodology, then state as such.

   If any sort of usage cost is determined by a rate, identify the basis and rational used to derive the rate.

   Only in extraordinary circumstances will government funds be used to purchase equipment. Examples of acceptable equipment might include special test equipment, special tooling, or other specialized equipment specific to the research effort. This award is not an assistance agreement/instrument and Offerors should normally have the required equipment to perform. The value of equipment should be prorated according to the share of total use dedicated to carrying out the proposed work. Include a brief explanation of the prorating methodology used.]

7. **Indirect Costs.** [Portions of the indirect cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an estimate of the total indirect costs, identify each rate used in the proposal, and provide documentation to support the indirect cost rates by one of the below methods.
    a. Provide a copy of certification from a Federal agency indicating these indirect rates are approved by the Federal agency; or
    b. Provide a letter from the Offeror's Administrative Contracting Officer, in lieu of a rate certificate, stating these indirect rates are approved by a Federal agency;
    c. Copy of current forward pricing rate proposal with date proposal was submitted to the Administrative Contracting Officer; or
    d. Absent Government approved rates, provide detailed supporting data to include (1) indirect rates and all pricing factors that were used; (2) methodology used for determining the rates (e.g., current experience in the organization or the history base used); and (3) all factors, by year, applied to derive the proposed rates.

    Alternately, in lieu of providing indirect rates, if the Offeror can obtain appropriate Government assistance, it may provide a letter from the cognizant Federal audit agency stating that, based upon their review of the Offeror's proposal, the indirect rates used in the proposal are approved by a Federal agency and were applied correctly in this specific proposal. If the Offeror elects to rely on these Government inputs, it is responsible for ensuring any Government agency cooperation is obtained so that the proposal is complete when submitted.]

8. **Cost of Money.** [If applicable, Cost of Money should be proposed separately from indirect costs.]

9. **Fee/Profit.** [State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted when cost share is not being contributed. The fees shall be specific to the individual RRPV project and negotiated on a project-by-project basis.]

3. Cost Proposal Section II: Cost Proposal Format

[The Cost Proposal Format must be provided as a separate Excel document. Offerors are encouraged to use their own Excel cost formats so long as the necessary cost detail is provided. Working formulas should be included to the maximum extent possible. The Cost Proposal Formats provided on the RRPV Members Only Site are ***NOT*** mandatory.

The Cost Proposal Format section must include a breakout of the total cost proposed by cost element for each year of the program. If required by the RPP, costs must also be broken out by Phase stated in the Statement of Work. The sum of the Phases must equal the total.

Supporting data and justification for labor, equipment/material, team member/subcontractor, consultants, travel, other direct costs, indirect costs, and profit used in developing the cost breakdown also must be included. The Offeror must provide sufficient details to allow a full

understanding of and justification for the proposed costs. Offerors must refer to the RPP for a start date for cost estimating purposes.]

ATTACHMENT 3 – STATEMENT OF WORK (SOW) TEMPLATE

[The SOW developed by the Lead RRPV member organization and included in the proposal (also submitted as a separate document) is intended to be incorporated into a binding agreement if the proposal is selected for award. If no SOW is submitted with the proposal, there may be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. The following is the required format for the SOW.]

Statement of Work

RPP#: RPP24-04-NGVxStats
Project Identifier: RRPV24-04-NGVxStats-XXX (obtain from selection notification)
Project Title:
Member Organization Name:

1.0 Introduction/Background [*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.]*

2.0 Scope/Project Objective [*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.]*

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

3.0 Requirements [*To be provided initially by the Offeror at the time of proposal submission to be finalized by the Government based on negotiation of Scope/Project Objective].*

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

4.0 Deliverables [*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.]*

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Minimum deliverables for Modules 1 and 2 are found in Attachment B and Attachment C, respectively.

5.0 Milestone Payment Schedule [*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture)]*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the RRPV member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the RRPV member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- Be commensurate in number to the size and duration of the project (i.e., a $5M multi-year project may have 20, while a $700K shorter term project may have only 6);
- Not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- Be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- Include at a minimum Monthly Reports which include both Technical Status and Business Status Reports (due the 25th of each month), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

RRPV Milestone Payment Schedule Example						
RRPV Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	$20,000		$20,000
2	N/A	Monthly Report (Technical and Business Reports)	1/25/2020	$ -		$ -
3	N/A	Monthly Report (Technical and Business Reports)	2/25/2020	$ -		$ -
4	1	Protocol Synopsis	2/28/2020	$21,075		$21,075
5	2	Submission for Program Office Approval	2/28/2020	$21,075		$21,075
6	N/A	Monthly Report (Technical and Business Reports)	3/25/2020	$ -		$ -
7	N/A	Monthly Report (Technical and Business Reports)	4/25/2020	$ -		$ -
8	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	$210,757	$187,457	$398,214
9	N/A	Monthly Report (Technical and Business Reports)	5/25/2020	$ -		$ -
10	N/A	Monthly Report (Technical and Business Reports)	6/25/2020	$ -		$ -
11	N/A	Monthly Report (Technical and Business Reports)	7/25/2020	$ -		$ -
12	N/A	Monthly Report (Technical and Business Reports)	8/25/2020	$ -		$ -
13	N/A	Monthly Report (Technical and Business Reports)	9/25/2020	$ -		$ -
14	4	Toxicity Studies	10/1/2020	$63,227		$63,227
15	N/A	Annual Report 1	10/25/2020	$ -		$ -

16	N/A	Monthly Report (Technical and Business Reports)	11/25/2020	$ -		$ -
17	5	FDA authorization trial	11/30/2020	$84,303		$84,303
18	6	Research staff trained	11/30/2020	$ -		$ -
19	7	Data Management system completed	11/30/2020	$ -		$ -
20	N/A	Monthly Report (Technical and Business Reports)	12/25/2020	$ -		$ -
21	8	1st subject screened, randomized, and enrolled in study	1/1/2021	$150,000	$187,457	$337,457
22	N/A	Monthly Report (Technical and Business Reports)	1/25/2021	$ -		$ -
23	N/A	Monthly Report (Technical and Business Reports)	2/25/2021	$ -		$ -
24	9	Completion of dip molding apparatus	3/1/2021	$ 157,829	$ 187,457	$ 345,286
25	N/A	Monthly Report (Technical and Business Reports)	3/25/2021	$ -		$ -
26	N/A	Monthly Report (Technical and Business Reports)	4/25/2021	$ -		$ -
27	N/A	Monthly Report (Technical and Business Reports)	5/25/2021	$ -		$ -
28	10	Assess potential toxicology	6/1/2021	$157,829		$157,829
29	N/A	Monthly Report (Technical and Business Reports)	6/25/2021	$ -		$ -
30	N/A	Monthly Report (Technical and Business Reports)	7/25/2021	$ -		$ -

31	N/A	Monthly Report (Technical and Business Reports)	8/25/2021	$ -		$ -
32	N/A	Monthly Report (Technical and Business Reports)	9/25/2021	$ -		$ -
33	11	Complete 50% patient enrollment	10/1/2021	$350,000	$187,457	$537,457
34	N/A	Annual Report 1	10/25/2021	$ -		$ -
35	N/A	Monthly Report (Technical and Business Reports)	11/25/2021	$ -		$ -
36	N/A	Monthly Report (Technical and Business Reports)	12/25/2021	$ -		$ -
37	N/A	Monthly Report (Technical and Business Reports)	1/25/2022	$ -		$ -
38	N/A	Monthly Report (Technical and Business Reports)	2/25/2022	$ -		$ -
39	12	Electronic Report Forms Developed	3/1/2022	$315,658	$187,457	$503,115
40	N/A	Monthly Report (Technical and Business Reports)	3/25/2022	$ -		$ -
41	N/A	Monthly Report (Technical and Business Reports)	4/25/2022	$ -		$ -
42	N/A	Monthly Report (Technical and Business Reports)	5/25/2022	$ -		$ -
43	N/A	Monthly Report (Technical and Business Reports)	6/25/2022	$ -		$ -
44	N/A	Monthly Report (Technical and Business Reports)	7/25/2022	$ -		$ -

45	13	Complete 100% patient enrollment	8/1/2022	$315,658	$187,457	$503,115
46	N/A	Monthly Report (Technical and Business Reports)	8/25/2022	$ -		$ -
47	N/A	Monthly Report (Technical and Business Reports)	9/25/2022	$ -		$ -
48	N/A	Annual Report 1	10/25/2022	$ -		$ -
49	14	Report results from data analysis	11/1/2022	$157,829		$157,829
50	N/A	Final Reports (POP End)	11/30/2022	$ -		$ -
			Total	$2,025,240	$1,124,742	$3,149,982
					Period of Performance (Months)	XX Months
					Contract Type	FFP/CPFF/CR

Please Note:

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.

2. Expenditure Based Contracts – You may invoice for actual costs incurred and providing a progress report on technical milestones.

3. Cannot receive payment for a report (i.e., Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)

4. Monthly, Quarterly, and Annual Reports include BOTH Technical and Business Reports (separate).

5. Final Report due date must be the POP end noted in Project Award.

6. RRPV Milestone Numbers are used for administrative purposes and should be sequential.

7. Task Numbers are used to reference the statement of work if they are different from the RRPV Milestone Number.

6.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

If the Offeror intends to provide technical data which existed prior to, or was produced outside of the proposed effort, to which the Offeror wishes to maintain additional rights, these rights should be asserted through the completion of the table below.

Note that this assertion is subject to negotiation prior to award.

Rights in such Data shall be as established under the terms of the Base Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The below table lists the Awardee's assertions.

Technical Data or Computer Software to be Furnished with Restrictions	**Basis for Assertion**	**Asserted Rights**	**Name of Organization Asserting Restrictions**	**Deliverables Affected**

ATTACHMENT SUMMARY

Attachment A - Statement of Objectives for Technical Activities, "Statistical Support, Correlates of Protection, and Meta-analysis"
Attachment B – Module 1 Deliverables Table
Attachment C – Module 2 Deliverables Table
Attachment D – Module 1 Assumptions, Constraints, and Limitations
Attachment E – Module Home-Focus DCT RPP_Protocol Synopsis_Final_16Jun23
Attachment F – Module 1 Protocol Synopsis Next Generation COVID-19 Vaccines_DRAFT_04Apr2023
Attachment G – Module 1 BARDA CSN Governance Plan v1.0_2021-09-02res
Attachment H – Module 1 Example data visualization (enrollment)
Attachment I – Module 1 NIAIDDMID SOP PBMC and Associated Plasma Collection
Attachment J – Module 1 Specimen Guidelines for Transfer of Specimens for Secondary use to CSN BSIP
Attachment K – Module 1 Possible Options for Biometric Devices, status FDA Cleared
Attachment L – Module 2 Assumptions, Constraints, and Limitations
Attachment M – Module 1 - Retail-Focus DCT Clinical Protocol Synopsis