

BARDA Ventures: Request For Information (“RFI”)

October 14, 2019

Biomedical Advanced Research and Development Authority (“BARDA”)
Office of the Assistant Secretary for Preparedness and Response (“ASPR”)
U.S. Department of Health and Human Services (“HHS”)
200 Independence Avenue, S.W.
Washington, D.C. 20201

To: Prospective Partners & Interested Parties

Subject: RFI Overview & Response Instructions

The Division of Research, Innovation and Ventures (DRIVE) of the Biomedical Advanced Research and Development Authority (BARDA), the Office of the Assistant Secretary of Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) is issuing this Request for Information (“RFI”) in order to collect feedback on the attached draft solicitation document (see “Attachment 1: BARDA Ventures RFI: Draft Solicitation For Comment”).

Information collected from this RFI will serve as continued market research for the development of a possible program where BARDA would partner with a third party entity (“Venture Partner”) to strategically address gaps in preparedness and areas within the continuum of response which require innovative and entrepreneurial approaches. The Venture Partner could, as authorized by law, use venture capital practices and methods to foster and accelerate the development of innovative tools and technologies to enhance National Health Security preparedness and responses in ASPR’s mission to “Save Lives and Protect Americans from 21st Century Health Security Threats.” Further background information is described in the attached draft solicitation.

BARDA is seeking information and feedback on all components of the attached draft solicitation with comments and feedback sought on the pertinence and feasibility of each component of the draft document. This includes, but is not limited to, feedback in the form of questions/comments related to: restrictions; authorities; proposal instructions; evaluation criteria; and overall solicitation structure as detailed in the draft document. Interested parties are encouraged to provide feedback in the attached Excel spreadsheet (“Attachment 2: RFI - Draft Solicitation Feedback Form”) referencing the page and line numbers including any edits / comments. BARDA is also seeking general feedback on how venture capital practices can best be employed through this potential framework.

Important Note: Interested parties should not prepare or submit an actual proposal to the attached draft solicitation document in Attachment 1. The purpose of this RFI is only to collect information by receiving feedback/comments to the draft solicitation. Accordingly, BARDA will not be issuing any awards from responses received

BARDA Ventures: Request For Information (“RFI”)

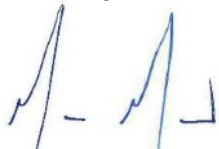
to this RFI. Responses will not be evaluated in any way, but may be used to further develop and refine the described requirement. BARDA will not return or provide feedback on any submissions, but BARDA does reserve the right to further engage with respondents to clarify understanding of submitted comments.

BARDA will treat any response to this RFI as source selection sensitive information and will protect confidentiality accordingly. By submitting a response to this RFI, you understand that review of those responses may include non-federal BARDA personnel serving in scientific, engineering, technical assistance (“SETA”) or similar support service roles.

Documents are to be submitted electronically via email to DRIVE.Contracting@hhs.gov by **November 18, 2019, 09:00 AM ET.** Questions should be sent directly to Matt McCord, Director of Partnering, DRIVE at matthew.mccord@hhs.gov.

Thank you in advance for any submission as we anticipate responses received to this RFI will be highly beneficial to BARDA.

Sincerely,



Matthew A. McCord
Director of Partnering, DRIVE
Biomedical Advanced Research & Development Authority (BARDA)



BARDA Ventures RFI: Draft Solicitation

October 14, 2019



I. BACKGROUND

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary of Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) serves the nation by partnering with industry to make available medical countermeasures against a wide range of major threats to our national health security. BARDA and our industry partners have been successful in delivering new therapeutics, vaccines, diagnostics and devices against serious health threats including chemical, biological, radiological, nuclear (CBRN) agents, pandemic influenza and emerging infectious diseases and their sequelae.

In 2010, HHS completed an extensive assessment of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), the national program responsible for developing, stockpiling, and providing medical countermeasures to the U.S. population in the event of a public health emergency. The 2010 medical countermeasures review¹ identified areas of enterprise risk that impeded the development of necessary medical countermeasures and products. The 2010 medical countermeasures review recommended the development of an independent strategic investment entity to foster the development of commercially viable medical countermeasures. Subsequently in 2016, Congress passed the “21st Century Cures Act” which authorized ASPR/BARDA to enter into an agreement with a “Medical Countermeasures Innovation Partner” (“MCIP”)², which among other directives (described below), authorizes the MCIP to utilize “strategic venture capital practices and methods.”

II. OBJECTIVES

BARDA Division of Research Innovation and Ventures (DRIVE) seeks to partner with a third party entity (Venture Partner) that will address gaps in preparedness and areas within the continuum of response which require innovative and entrepreneurial approaches that would not be considered under traditional medical countermeasure (“MCM”)³ development.

¹ Section V. A. 4. - The Public Health Emergency Medical Countermeasures Enterprise Review, August 2010

² PUBLIC LAW 114–255 “21st Century Cures Act” —DEC. 13, 2016

³ Per 42 U.S. Code § 247d–6a a “Qualified countermeasure” is defined as a drug (as that term is defined by section

BARDA envisions establishing a sustained and ongoing bilateral partnership utilizing venture capital practices to address the following objectives/tasks:

- i. Foster, promote, and accelerate the development and innovation of medical countermeasures and related tools, technologies, data, and techniques to meet strategic response needs,
- ii. Address unmet health security needs that are directly related to saving and protecting American lives from 21st Century health security threats,
- iii. Provide expert consultation and advice to foster innovators and commercially viable medical technologies..

BARDA will educate and advise the Venture Partner on the BARDA mission space and the potential applicability of technologies to the mission. In turn, the Venture Partner will independently implement an investment strategy with the ultimate goal of impacting the rapid development of tools and technologies to improve the United States' preparedness posture against known and unknown threats. The Venture Partner will be solely responsible for all investment activities and decisions.

It is anticipated the Venture Partner will employ a variety of investment mechanisms commonly used in venture capital, including innovative financing options and pro-rata rights, as necessary. When appropriate to improve the financial and/or strategic standing of the investment, it is anticipated the Venture Partner will ensure oversight of investments such as board membership, personnel management of portfolio companies, subject matter expertise and guidance, and use other practices common to the venture capital community.

Page 3 of 18

321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21), that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6)—

- (i) to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security;
- (ii) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph; or
- (iii) is a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii)

BARDA has identified the following areas as illustrative of its mission. It is encouraged that the Venture Partner takes this framework to spark ideas and expand upon the areas through an iterative process of diligence, market research and dialogue with the BARDA programs and community at large.

1. **Situational Awareness, Recognition, and Reporting** – Develop tools, products, technologies, data, and techniques that can detect, recognize, and report on potential agents and threats in as close to real time as possible.
2. **Identification and Characterization** – Rapidly identify and characterize known and unknown agents and threats causing disease in people.
3. **Prevention Design** – Develop and implement tools, products, technologies, data, and techniques to prevent or reduce the spread of disease and threats.
4. **Validation** – Implement innovative evaluation methods to increase the speed with which effectiveness and safety of technologies can be demonstrated.
5. **Production** – Transform methods, processes, and capacity to overcome constraints in the manufacturing of products.
6. **Distribution** – Enhance ways to manage the supply chain and distribute health products quickly and widely to reach all communities across the United States in response to threats.
7. **Administration** – Improve the delivery and administration of pharmaceutical products to individuals in need.

III. ELIGIBILITY CRITERIA

All responsible sources capable of satisfying the U.S. Government's needs may submit a proposal that would be considered by BARDA.

- (a) This section provides the mandatory criteria, as outlined in the 21st Century Cures Act, for eligibility to enter into a partnership with BARDA⁴ as the Venture Partner:

⁴ Qualifications are governed by authorizing language contained in section 319L of the Public Health Service Act (42 U.S.C. 247d-7e) as amended by the "21st Century Cures Act" PUBLIC LAW 114-255—DEC. 13, 2016

- i. Be an independent, non-profit entity⁵ not within the Department of Health and Human Services;
- ii. have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the U.S. Government;
- iii. Have experience in promoting novel technology innovations;
- iv. “Be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under 42 U.S.C. 247d-7e(c) (4) (E) (IV);
- v. Demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products; and
- vi. Demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures.

(b) Potential Organizational Conflicts of Interest.

- a. Without prior approval, a contractor cannot simultaneously provide scientific, engineering, technical assistance (SETA), advisory and assistance services (A&AS), or similar support to any part of the U.S. Government and also be eligible to participate on the Venture Partner team. Any individual who has provided SETA or A&AS services previously to ASPR/BARDA within one year is ineligible to respond. Additionally, any individual who has provided SETA or A&AS services previously to BARDA on this specific solicitation is ineligible to respond. As part of the proposal submission, all members of the proposed team (including any potential subawardees or consultants) must affirm if they (their organizations and individual team members) have provided any SETA or similar support to any U.S. Government Agency. All facts relevant to any potentially disqualifying factors must be disclosed.

⁵An Offeror is deemed to be an eligible “Independent non-profit entity” is independently recognized by the Internal Revenue Code exempt from federal income tax. Further, the entity must be recognized in the state of incorporation as a non-profit entity pursuant to applicable law and regulation.

- b. If SETA, or similar support was provided to any U.S. Government program(s) by a member of the Offeror, the proposal must include:
- o The name of the U.S. Government program office receiving the support;
 - o The prime contract number;
 - o Identification of proposed team member (subawardee, consultant) providing the support; and
 - o An OCI mitigation plan.

(c) Salary Rate Limitation. HHS is constrained in its use of funds by the appropriations law⁶ set by the U.S. Congress which states:

None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.

Accordingly, U.S. Government funds appropriated to HHS and received by the Venture Partner cannot be used to pay salaries in excess of the federal Executive Level II salary. Note that this does not limit the amount of salary an entity may compensate an individual, rather it would limit the amount of salary that could be paid to an individual using those HHS funds. The Venture Partner will have to comply with this guideline or cannot be considered for award.

IV. ACCESS TO RECORDS & FOREIGN OWNED INTERESTS

1. Access to Records.

The U.S. Government, at its discretion, will have access to and the right to examine records of the Venture Partner per normal course (pre, during, and post-execution) of Other Transaction Authority, as granted to the U.S. government. This only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law.

2. Foreign Owned Interests

The Venture Partner shall ensure that no foreign investment capital or interests from U.S. Government prohibited sources list of Embargoed and Sanctioned countries, as defined by U.S. Departments of Treasury and Commerce, are used by the Venture Partner to co-invest with U.S.

⁶ 2018: PUBLIC LAW 115-245

Government funds.

V. RIGHTS RESERVED

BARDA reserves specific rights, in addition to rights by law or regulation, including:

- The right to request any additional, necessary documentation upon initial review. Such additional information may include, but is not limited to, a further detailed proposal, budgets, and representations and certifications.
- The right not to select a partner.
- The right to remove a partner from consideration should the parties fail to reach agreement on terms, conditions, and cost within a reasonable time, the partner fails to provide requested additional information in a timely manner, or BARDA believes it in the best interest of the U.S. Government.
- The right to provide capital to the Venture Partner in phases, with options for continued work at the end of one or more of the phases.

VI. SUBMISSION OVERVIEW

The solicitation process will be conducted in two stages. Stage 1 proposals will be reviewed pursuant to the criteria established below and will be due 15 calendar days following notice. BARDA reserves the right to engage with any Offeror, as necessary, to clarify information submitted in the Stage 1 proposal. Following this evaluation, those Stage 1 proposal Offerors whose proposals receive the highest ratings will receive notification that they are eligible to advance to the next phase of evaluation. Those Offerors who are not amongst the most highly rated will also be notified they have not been selected to proceed to Stage 2.

Those successful Stage 1 Offerors will be invited to submit more detailed Stage 2 proposal, which will be due 45 calendar days following notice. During Stage 2 proposal evaluations, BARDA may request to meet with Offerors (in-person or via telecom), as necessary, as part of the evaluation process.

VII. STAGE 1 PROPOSAL PREPARATION & SUBMISSION

INSTRUCTIONS

1. Eligibility Requirements

Offeror provides details and/or representations to satisfy eligibility criteria described above (*see* Section III. “ELIGIBILITY CRITERIA,”);

2. Prospectus of Relevant Experience

Offeror, including its essential collaborators and key personnel, should provide detailed examples of relevant experience.

- a. Experience partnering with the U.S. Government to meet identified strategic needs.
- b. Experience managing a venture capital fund focused on healthcare and life science companies including identifying, investing, bringing products to market, and producing a financial proceeds for its investors.
- c. Experience and examples of promotion and generation of additional investment into portfolio companies from outside sources.
- d. Number of deals in the last 36 months including size and stage of syndicate, size of investment by Offeror in each deal.
- e. Demonstrated performance of current and previous managed fund(s) including at minimum total capital distributed, total capital returned, multiple of money, annualized Internal Rate of Return (IRR).

3. Vision and Proposed Venture Partner Model

Offeror should provide a high level overview of their vision of the partnership between BARDA and Venture Partner. As this is an unique private-public partnership, the Offeror should clearly define how the relationship between Venture Partner and BARDA will operate while satisfying the BARDA mission and simultaneously meeting all requirements of the law.

Stage 1 Proposals should be submitted to the BARDA Division of Research Innovation and Venture (DRIVe) Director of Partnering via email to (matthew.mccord@hhs.gov) by XX:XX ET on XX/XX/XXXX.

VIII. STAGE 2 PROPOSAL PREPARATION & SUBMISSION INSTRUCTIONS

For Stage 2 Proposals, the Offeror should submit a proposal consisting of a narrative (including

figures, schematics, diagrams, graphics, etc. which must be labeled) that describes the organization's capabilities, and approach, for performing the tasks and responsibilities outlined in sections 1 – 7 below.

1. Overview

Describe why the Offeror is interested in partnering with BARDA, and how the Offeror can help advance ASPR and BARDA's mission to Save Lives and Protect Americans from 21st Century Health Security Threats as the Venture Partner.

2. Organizational Capabilities

Offeror should provide an overview of capabilities the organization possesses to source, invest, and manage companies regionally, nationally, and internationally. If the Offeror does not currently have all necessary capabilities, describe how the Offeror plans to scale operations to support national and international investment activities and management.

- a. Provide an overview of the entire organization including ownership structure, the number of funds under management, total capital managed, demographics of sources of capital, and describe any plans (if there are any) to change or expand the organization.
- b. Ability to maintain daily operations and high performance of organization should managers or key personnel leave the organization through effective governance and management structures.
- c. Indicate if the organization/fund/personnel/portfolio companies have been involved in any legal litigations directly or indirectly.
- d. Provide operational processes including governance, cash flow management, method of accounting, tax, audit, valuation.
 - i. Provide specific details on how Offeror plans to account for portion of capital created with U.S. Government funds. Additionally provide the allocation of capital deployed and returned given the assumption that BARDA will make annual capital contributions to the Venture Partner and all proceeds from exits specifically from U.S. Government capital will be recycled into the Venture Partner.
- e. Provide the facilities and locations to support the Venture Partner.

3. Key Personnel

Provide the following of each key personnel that will be responsible for the management and

operations of the Venture Partner. Provide the following for each of the proposed Key Personnel:

- a. Name
- b. Description of role/contribution to the Venture Partner
- c. Relevant experience
- d. CV/Resume (attached as appendix)

Additional support staff, sub-contractors, consultants, or partnerships that will be relevant to the operations of the Venture Partner. Provide specific roles, duties and the proposed level of effort (as a percentage of full time employment, as necessary) provided by this personnel.

4. Investment Strategy and Approach

Outline the specific investment thesis and types of investment that will lead to successful financial proceeds and strategic impact in the areas as described in Section II, Objectives. The proposed investment strategy should be grounded in supporting information and data. Where applicable, provide real world examples of investments that fit within the BARDA mission. Provide the criteria (stage of technology development, market or sub-market segmentation, management activity, size of investment, etc.) for investment in technologies that align with the proposed thesis. BARDA and the Venture Partner will agree upon a technology area's applicability to support the BARDA mission; however, it is expected that the Venture Partner will operate and invest in companies independently.

The investment thesis should be based on the assumption that \$50M of capital will be provided to the Venture Partner over a 5 year period (\$10M per year) for investment. However, the investment thesis must be adaptable and scalable to effectively deploy larger amounts of capital should BARDA decide to provide more capital to the Venture Partner or should successful proceeds significantly grow the size of the capital under management. BARDA's goal is for the Venture Partner investments to become self-sustaining within a realistic period. Accordingly the Venture Partner should be structured to reinvest all recycled proceeds specifically from U.S. Government capital in accordance with the terms of the ultimate agreement.

In addition to the overall investment strategy the Offeror should at minimum address the

following:

- a. Describe how the Offeror will manage a unique partnership with BARDA. The Offeror should outline all aspects of the partnership throughout the investment life cycle (pre-investment, post-investment, and exits). Describe Offeror's vision of how BARDA and the Offeror will agree on which technologies fall within the BARDA Mission and how feedback and advice from BARDA can effectively be addressed during the investment life cycle.
- b. Sourcing, evaluation, due diligence process, and investment timelines
 - i. Sourcing – Describe how deals will be sourced and any unique processes the Offeror will utilize to find deals relevant to BARDA's mission/impact areas.
 - ii. Evaluation, Due Diligence - Please outline the due diligence process and specific criteria for investment (i.e. stage of technology development, market or sub-market segmentation, management activity, size of investment, treatment modality) that the Offeror will utilize to meet the Venture Partner fund's overarching investment thesis. These should include, but not be limited to the unique processes as well as specific evaluation indicators (negative or positive) that the Offeror utilizes in the investment evaluation process.
 - iii. Timeline/Decision Tree - Offerors should outline and provide the envisioned investment evaluation timeline and decision tree including mapping out evaluation criteria that need to be met at each step of the process, the role of each team member in the process, the composition and function of any committee(s). This decision tree should outline when to proceed for further diligence as well as delineating steps at which BARDA may be asked to educate and advise regarding applicability to the BARDA Mission. Provide the envisioned cadence (ad hoc, monthly, quarterly) and volume (number of deals under review) of the deal flow process.
- c. Describe/provide a portfolio management strategy including any non-monetary resources provided to portfolio companies in order to minimize risks and maximize impact and financial proceeds.
- d. Outline the criteria in which follow-on investments will be deployed.

- e. Outline and identify parameters which would be used for gauging strategic and financial success and key performance indicators.
- f. Provide a comprehensive risk analysis for the portfolio and a plan for mitigation of the portfolio's financial and strategic risks.
- g. Offeror should describe how they plan to source and manage syndication partners.
- h. Offeror should describe how it will manage capital that may not be distributed at the same time each fiscal year or guaranteed year to year, as Venture Partner funding will be subject to Congressional authorization and be subject to annual appropriations.

5. Financial Projections & Operational Costs

The Offeror is requested to provide financial modeling and projections based upon the amount of capital distributed by BARDA.

- a. Financial model(s) consisting of but not limited to capital deployed, capital held in reserve, and exited capital (returned to investor and paid to bonus/profit share pool) as well as associated operating cost for the first 10 years of the fund's life based on the following scenarios:
 - i. \$10M annual capital distribution from BARDA to Offeror for years 1-5 (total of \$50M capital distribution).
 - ii. \$10M capital distribution from BARDA to Offeror in year 1 and \$40M annual capital distribution from BARDA to Offeror for years 2-5 (total of \$170M capital distribution).
- b. Describe the key variables and assumptions used for each financial model and the basis of those assumptions.
- c. Operational/management cost break down (salaries, benefits, rent, equipment, travel, professional service fees, etc) for years 1-5. Indicate what costs will exclusively paid by federal funds and any costs that would be cost-shared.
 - i. Indicate how these costs may change based on annual capital distributions of \$10M to \$40M and how estimates are determined.
- d. Propose a model by which a portion of proceeds will cover part or all of operational costs based on the assumption that BARDA intends to recycle

proceeds.

6. Fundraising and Cost Sharing Plan

The Offeror should outline the strategy and timeline to independently recruit non-U.S. governmental co-investors (e.g. limited partners) into a fund established by the Venture Partner. This strategy would allow the limited partners to share the costs of operations, risks, and benefits of investments. Should any exit or proceed opportunities occur, the non-U.S. governmental limited partners are free to recycle the funds or take their proceeds. The plan should also convey structures and terms that satisfy the limited partners' investment goals and at the same time, meet the goals of BARDA's mission. The Venture Partner must ensure U.S. Government funds and private funds are independently tracked for proper capital accounting to maintain clear pro rata assignment of any investment made by the Venture Partner.

7. Relevant Case Studies

- a. Case studies – Provide examples with references or evidence of managing and exiting prior investments.
 - i. Provide at least one example of an exit with negative proceeds, what went wrong, actions taken, and lessons learned.
 - ii. Examples of the growth and maturation over 5 year period of healthcare technology portfolios under management (e.g. successful clinical trials, lab tests, FDA approvals, revenue, out licensure).
- b. Demonstrated investment experience (if applicable) in products/technologies/companies in BARDA's mission space.

Stage 2 Proposals should be submitted to the BARDA Division of Research Innovation and Venture (DRIVE) Director of Partnering via email to (matthew.mccord@hhs.gov) 45 days after notice inviting Offeror to submit a Stage 2 Proposal.

IX. EVALUATION PROCESS & CRITERIA

The proposal will initially be reviewed against the eligibility criteria established by legislation

and defined in Section III, of this solicitation. If it is determined Offeror does not satisfy the eligibility criteria, the proposal will not be evaluated. If it is determined the Offeror does satisfy the edibility requirement, the proposal will be evaluated against the following criteria.

Stage 1 Evaluation Criteria:

Stage 1 Proposal will be evaluated and ranked based on the following evaluation criteria listed in order of importance.

1. Prospectus of Relevant Experience

Relevant experience will be evaluated favorably if it addresses all of the outlined points in Section VII, 2, of this document and provides supporting references and/or backup documentation.

2. Vision and Proposed Venture Partner Model

The vision and proposed venture partnering model will be evaluated favorably if it uniquely demonstrates the ability to address BARDA's mission while maximizing returns through venture capital practices and methods. A favorable proposal will clearly outline the Offeror's proposed model under this unique partnership.

Those Offerors who submit the most highly ranked Stage 1 proposals may be invited to proceed to Stage 2.

Stage 2 Evaluation Criteria:

Stage 2 proposals will be evaluated and ranked on the following factors, which are listed in descending order of importance.

1. Soundness of Proposed Approach

The proposed approach will be evaluated as to whether it is a viable, realistic and nimble to satisfy the Venture Partner objectives. A sound proposal will clearly define all activities, identify and address all major risks, and propose planned mitigation efforts, such that a final outcome which achieves the goal can be expected as a result of this partnership. The Offeror demonstrates a clear understanding and commitment to the BARDA mission and its objectives.

2. Investment and Management Team

The Offeror will be evaluated based on the proposed team's potential to make a meaningful impact in the relevant space. A strong team will have key personnel that bring unique and demonstrated expertise to add value and maximize the ability of the organization to effectively to invest and manage companies and technologies in the healthcare sector.

3. Financial Models & Operational Costs

Proposed financial models will be evaluated for value of forecasted financial proceeds / impact of investments and reasonableness of assumptions. Proposed operational costs will be evaluated for whether they represent realistic costs necessary to execute Venture Partner objectives and overall value to BARDA. Any proposed cost-share through co-investments will be also be evaluated.

4. Relevant Case Studies

Case studies will be evaluated for demonstrated ability to problem solve and financial acumen as relevant to Venture Partner objectives. Any case studies submitted without supporting references and evidence will not be reviewed.

X. RANKING

Submissions will be evaluated against the above listed criteria and will be assigned ranks, per the following:

Stage I Ranking:

Each Stage I evaluation criterion will be evaluated and assigned one of the following rankings. Then, per the relative weights of the criteria, an overall score for the Stage I submission will be determined.

Stage II Ranking:

Each Stage II evaluation criterion will be evaluated and assigned one of the following rankings. Then, per the relative weights of the criteria, an overall score for the Stage I submission will be determined.

Rankings/Definitions:

i. **Excellent: An “Outstanding” submission is characterized as follows:**

The proposed approach indicates an exceptionally thorough and comprehensive understanding of the program goals, resources, schedules, and other aspects essential to performance of the program. In terms of the specific factor (or significant sub- factor), the proposal contains major strengths, exceptional features, or innovations that should substantially benefit the program. There are no weaknesses or deficiencies. The risk of unsuccessful contract performance is extremely low.

ii. **Good: A “Good” submission is characterized as follows:**

The proposed approach indicates a thorough understanding of the program goals and the methods, resources, schedules, and other aspects essential to the performance of the program. The proposal has major strengths and/or minor strengths which indicate the proposed approach will benefit the program.) Weaknesses, if any, are minor and are more than offset by strengths. Risk of unsuccessful performance is very low.

iii. **Acceptable: A “Satisfactory” submission is characterized as follows:**

The proposed approach indicates an adequate understanding of the program goals and the methods, resources, schedules, and other aspects essential to the performance of the program. There are few, if any, exceptional features to benefit the program. The risk of unsuccessful performance is low. Weaknesses are generally offset by strengths.

iv. **Unacceptable: An “Unacceptable” submission is characterized as follows:**

The proposed approach indicates a lack of understanding of the program goals and the methods, resources, schedules, and other aspects essential to the performance of the program. Numerous weaknesses and deficiencies exist. The risk of unsuccessful performance is high.

XI. APPENDIX

A. Reporting Requirements

B. CV & Resumes of Key Personnel

C. Letters of Commitment

D. Conflict of Interest Plan

Appendix A: Reporting Requirement

BARDA expects to receive the following industry standard reports from the Venture Partner partner which may include:

Report	Contents	Due Date
Portfolio Companies Performance Report	Financial reports, Milestones, Personnel, IP, Fundraising, Valuation	Within 25 days after the end of each quarter
General Fund Performance Report	Change in value over past quarter and year-to-date, Portion of fund valued per company, Risk Register/plan, Fund comparison to similar funds and to broader market averages, Table of holdings, Current valuation, Transactions during quarter/year, Investments and proceeds per quarter/year, Total cash returned, Capital called/committed, Amount outstanding, Fees paid, Changes in portfolio.	Within 25 days after the end of each quarter and/or within 90 days of the year-end
Schedule of Investment	Type of investment vehicle, Term of vehicle, Amount invested in each vehicle, Any pertinent note	Within 25 days after the end of each quarter
Unaudited Financial Statements for the year-to-date	Full financial report – specifically on use of fund for operational support	Within 15 days after the end of each month
Independent Audited Financial Statements	Full financial report	Within 120 days of the year-end

Appendix B: CV & Resumes of Key Personnel

Please attach short curriculum vitae for key project staff only (no more than one page each).

Neither curriculum vitae nor an organizational chart will count towards the narrative page limit.

Also include information about any contractual organization(s) that will have a significant

role(s) in implementing the project and achieving project goals. Please ensure to include key personnel not only for the operations of the organization but also the key consultants with the technical expertise in the functional areas of drug or device development.

Appendix C: Letters of Commitment

Offeror should provide any letters of support and/or commitment from any partners and/or stakeholders that are relevant to the proposed partnership. Include confirmation of the commitments to the project (should it be funded) made by key collaborating organizations, agencies and Alliance Members in this part of the application. Any organization that is specifically named to have a significant role in carrying out the project should be considered an essential collaborator. If a partner proposes contributing towards your cost share, then this contribution is part of your proposal, the partners cost share must be included in the Letter of Commitment.

Appendix D: Conflict of Interest Plan

Offeror should propose a plan to address, identify, avoid and/or mitigate, any actual and/or perceived organizational Conflict of Interests (COI) associated with being a partner with BARDA as the Venture Partner. The Offeror shall propose necessary policies and procedures to ensure their role does not result in unequal access of information, impaired objectivity, or biased ground rules. BARDA DRIVE may require third party COI review and reports throughout the period of performance.