BARDA Ventures Solicitation

November 6, 2020

Saving Lives. Protecting Americans.

ASPR

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. Since its creation in 2006, BARDA, through these public-private partnerships, has successfully delivered 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 Review[1] identified areas of enterprise risk that impeded the development of necessary medical countermeasures and products. The 2010 review recommended the development of an independent strategic investment entity to support the development of commercially viable medical countermeasures. Subsequently in 2016, Congress passed the 21st Century Cures Act which authorized BARDA to enter into an agreement with a Medical Countermeasures Innovation Partner (MCIP)[2] to accelerate development and innovation of medical countermeasures and technologies through the use of "strategic venture capital practices and methods."

The emergence and spread of infectious disease has always and will continue to pose serious threats to humanity. The recent emergence of a highly infectious novel coronavirus, SARS-CoV-2, in Wuhan, China in December 2019 has led to a global pandemic. As this pandemic continues to spread and cause economic devastation and loss of lives, COVID-19 has made clear the need for sustained long-term investment in technologies that can prepare the United

[1] Section V. A. 4. - The Public Health Emergency Medical Countermeasures Enterprise Review, August 2010 https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf

[2] PUBLIC LAW 114–255 "21st Century Cures Act" —DEC. 13, 2016, amending section 319L of the Public Health Service Act (42 U.S.C. 247d-7e).

States and the world for new emerging infectious diseases and a wide variety of health security threats including nuclear, chemical, and biological attacks. The establishment of a MCIP will provide a new tool for BARDA, HHS, and the United States Government (USG) to stimulate sustained investment in health security and increase the speed and expand the capability to which the United States can respond to COVID-19, future outbreaks, and other health security threats.

II. OBJECTIVES

BARDA's Division of Research, Innovation, and Ventures (DRIVe) seeks to partner with a single nonprofit entity (Managing Entity) that will address gaps in pandemic preparedness and areas within the continuum of response for national health security threats which require innovative and entrepreneurial approaches that would not otherwise be considered under traditional medical countermeasure (MCM)[3] advanced research and development. BARDA envisions establishing a sustained and ongoing bilateral partnership to address the following objectives (as outlined in section 319L of the PHS Act, as amended by the 21st Century Cures Act, 42 USC 247d-7e):

i. Foster and accelerate the development and innovation of MCM and technologies that may assist advanced research and the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;
ii. Promote the development of new and promising technologies that address urgent MCM needs, as identified by the Secretary;
iii. Address unmet public health needs that are directly related to MCM requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and
iv. Provide expert consultation and advice to foster viable MCM innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure

[3] See Appendix E: Definitions

products.

To carry out these objectives, BARDA will educate and advise the Managing Entity on the BARDA mission and the potential applicability of technologies to the mission. In turn, the Managing Entity will carry out the objectives by implementing management, investment, development, and commercialization strategies with the ultimate goal of rapidly advancing development of treatments, tools, and technologies to enhance and fortify the United States' preparedness posture against known and unknown threats, including SARS-CoV-2 and future emerging infectious diseases.

It is anticipated that the Managing Entity will employ methods commonly used in venture capital, including equity financing, to carry out the objectives and address unmet needs in the BARDA mission. In addition, the Managing Entity will participate in oversight of its portfolio such as governance, board membership, fiscal oversight, personnel management of portfolio companies, subject matter expertise and guidance, and use other practices common to the venture capital community.

In addition to traditional venture capital practices and portfolio management activities, the Managing Entity, on an ad ho basis, will provide services to help rapidly advance mission relevant technologies to address unmet needs and priorities from both the USG and entrepreneurial communities. These activities, to carry out the objectives outlined above, serve as a catalyst to accelerate solutions to national health security needs that are directly related to MCM development and not tied to investments by the Managing Entity. This will benefit product developers and entrepreneurs as a means to provide expert consultation and advice while fostering viable medical innovation. The Managing Entity will strive to make available portions of personnel time and consultation available whether through the BARDA Accelerator Network as a subject matter expert on commercialization or other education programming and guidance to entrepreneurs in the US. The Managing Entity will be requested to serve on entrepreneur or investor in residence programs on behalf of BARDA and the USG, and identify and consult with the USG on product development and business and/or commercialization consideration activities. Other services may include stakeholder engagement activities through

facilitation of workshops, industry days, developing market intelligence, and portfolio tracking activities that support MCM development, and market research reviews conducted separately from venture capital activities and partnership operations. The above is a representation of activities that could foster viable medical innovation but is not comprehensive. Final activities will be subject to availability of funding and mutual agreement of the Managing Entity and BARDA.

BARDA has identified the areas in Figure 1 below as illustrative of its mission. It is encouraged that the Managing Entity 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 the community at large. The Managing Entity will place a particular focus on technologies to aid in long term pandemic preparedness efforts and response to emerging infectious diseases, such as SARS-CoV-2 and other novel pathogens with pandemic potential. These known and unknown threats could fall under the continuum of response activities below. It is critical that investments made in these areas are agnostic to the threat in consideration for new and emerging pathogens and agents. Technologies, such as but not limited to diagnostics, therapeutics, vaccines, and supply chain resilience should address related threats to include COVID-19 and other emerging infectious diseases and pathogens.

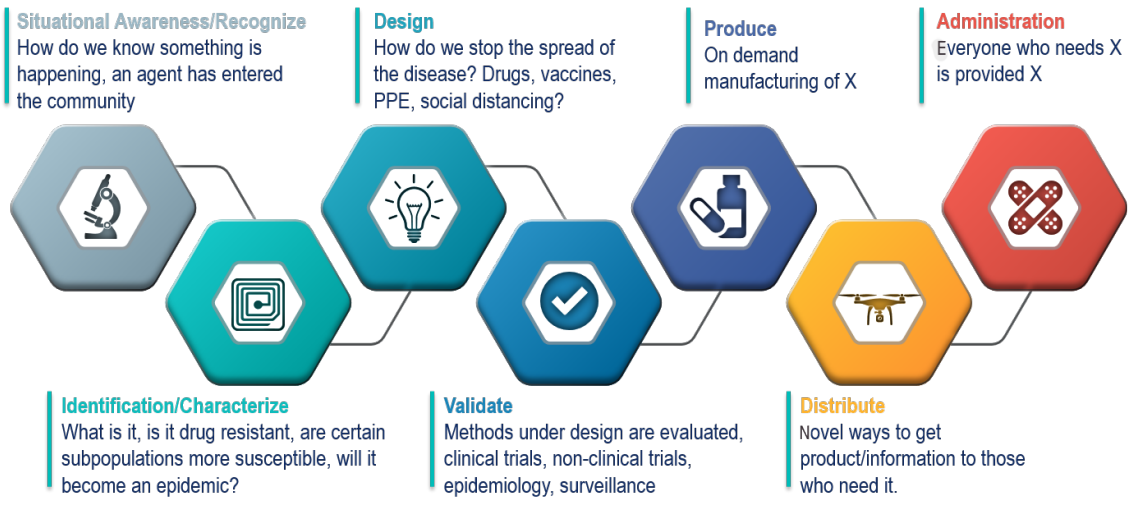

Figure 1 - BARDA Mission of Addressing End to End Health Security Solutions

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** – Technologies and platforms to 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 tested and demonstrated.
5. **Production** – Transform methods, processes, and capacity to overcome constraints in the manufacturing of products in the US.
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 medical/biological products and technologies to individuals in need.

III. JOINT OVERSIGHT COMMITTEE

During the course of the partnership between BARDA and the Managing Entity, the envisioned plan will be to set mission priorities at regular meetings of a Joint Oversight Committee (JOC). The JOC will be comprised of the Managing Entity and BARDA personnel. BARDA will establish program priorities and the Managing Entity will be responsible for executing the strategic objectives. The JOC will mutually agree on the strategic objectives of the program and ensure actions align with BARDA mission. (e.g., focus upcoming deals and investments on SARS-CoV-2 related technologies). Illustrated in Figure 2 below is the framework and process by which the JOC will agree upon technology areas to pursue that are within the BARDA mission.

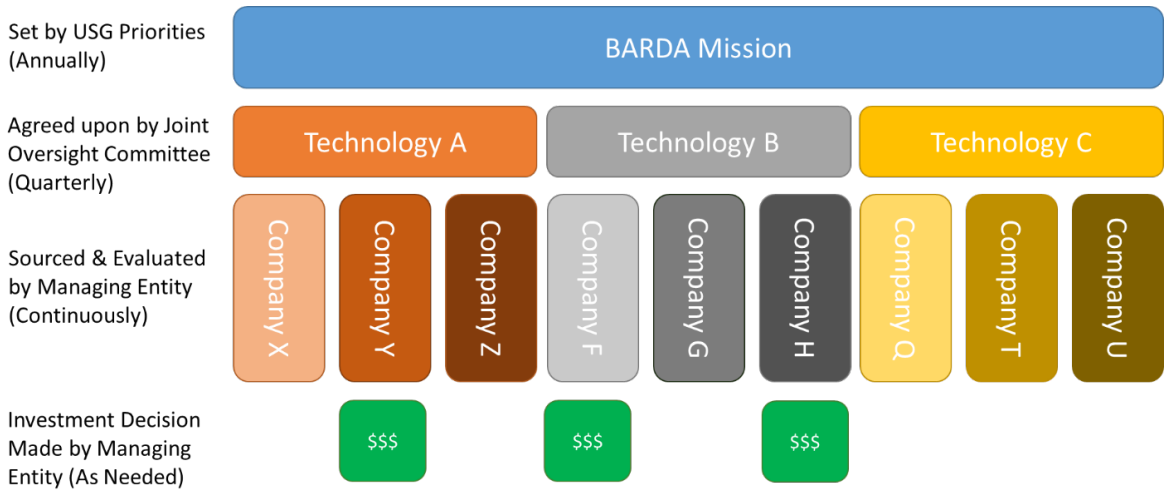

Figure 2 - Mission Alignment Framework

As the Managing Entity identifies prospective deals, they would be brought to BARDA Ventures team for concurrence to ensure compliance with BARDA mission prior to proceeding to any in-depth diligence phase. It is possible a prospective deal might involve a technology for which the USG would be interested in obtaining rights beyond those offered in a traditional venture capital arrangement. In these exceptional circumstances, the Other Transaction Agreement Officer (OTAO) may request the Managing Entity seek special terms as part of a deal. If a scenario such as this occurs but the Managing Entity determines the requested special terms would not be economically viable or feasible, the Managing Entity may decide to not pursue the deal, as a major part of the work carried out by the Managing Entity will be to use their expertise to deploy venture capital methods only when prudent.

IV. ELIGIBILITY CRITERIA

All responsible sources capable of satisfying the USG's needs may submit a proposal.

(a) This section provides the mandatory criteria, as outlined in the PHS Act, for eligibility to enter into a partnership with BARDA[4] as the Managing Entity, an entity must:

i. Be an independent, non-profit entity not within HHS;

ii. Have a demonstrated record of being able to create linkages between

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

innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the USG;

iii. Have experience in promoting novel technology innovation;

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 MCM.

(b) Independent Nonprofit Entity:

For purposes of this solicitation, an "independent nonprofit entity" is defined as a legal entity that (i) is already qualified for tax-exempt status under the Internal Revenue Code and (ii) is controlled by an independent board of directors and maintains accounting independent from any other organization, (iii) is not "fiscally sponsored" or otherwise controlled by any other entity (for profit or non-profit).

Further, the entity must be capable of maintaining this tax-exempt status while successfully performing all tasks envisioned under any potential BARDA partnership. Respondents are required to demonstrate a deep understanding of legal requirements for nonprofit organizations and are encouraged to engage with appropriate experts, as needed, prior to submitting a response to this solicitation.

Prior to an award, an entity must be recognized and certified by the Internal Revenue Service as a tax-exempt organization with a defined mission that is able to meet the objectives of this partnership. Newly formed entities created specifically for purposes of responding to this solicitation will be considered ineligible for award.

(c) Potential Organizational Conflicts of Interest (OCI).

a. Respondents must disclose whether they are currently providing professional

consulting services[5] to any part of the USG. Respondents must also disclose if any individual member of their proposed team has provided professional consulting services to BARDA within the last two years. A determination will then be made whether a respondent has a conflict of interest and whether an appropriate mitigation plan is feasible. If this relationship is determined to create a conflict of interest that cannot be mitigated then the individual or entity will be ineligible to be a part of the proposal. Further, any individual who has provided professional consulting 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 sub-awardees or consultants) must affirm if their organizations and/or individual team members have provided any professional consulting services in support of any USG agency in the past three years. Adequate information about the services rendered must be provided to allow BARDA to make this determination. NOTE: Portfolio companies receiving investment from the Managing Entity are not considered sub-awardees.

b. If professional consulting services are currently, or have been, provided to any USG program(s) by a member of a proposed team, the proposal must include:
    i. The name of the USG program office receiving the support,
    ii. The contract number,
    iii. Identification of proposed team member (e.g., sub-awardee, consultant)

[5] In this context, "professional consulting services" refers to services where individuals support USG programs which award federal funding in the research and development (R&D) or health science. These services are often referred to as Subject Matter Experts (SME), Scientific, Engineering, Technical Assistance (SETA) Services, Advisory and Assistance Services (A&AS), or similar support type roles.

NOTE: In this context, "professional consulting services" does not include individuals working at companies performing R&D or other contracts, grants, or other transactions where the individuals do not support and/or advise government personnel as part of their agreement. Having previously received federal funding does not necessarily preclude an interested party from being considered under this solicitation.

providing the support, and

iv. A proposed OCI mitigation plan.

(d) Salary Rate Limitation. HHS is bound by applicable appropriations laws which direct that HHS funds cannot be used to pay extramural salaries at a rate in excess of Executive Level II ($197,300 as of fiscal year 2020). Accordingly, USG funds appropriated to HHS and received by the Managing Entity cannot be used to pay salaries in excess of the federal Executive Level II salary.

It is important to note that this does not limit the amount of salary a Managing Entity may compensate an individual, rather it limits the amount of salary that can be paid to an individual using HHS funds.

(e) Registration with System for Award Management

Prior to award, a successful entity must possess an active and valid registration in the federal System for Award Management (SAM).[6]

(f) Accounting System

The respondent must demonstrate the ability to maintain an accounting system that is capable of tracking the expenditures of USG funds and investments of those funds given the financial requirements of this partnership as outlined in Section IX. PROPOSAL PREPARATION, 8. Financial Projections and Operational Expenses.

V. INTENT TO EXECUTE SINGLE AGREEMENT

BARDA intends to make a single award (the Agreement) from this solicitation to a Managing Entity with an anticipated initial period of performance of 10 years, but could be extended. It is BARDA's intent that the Agreement would be entered through BARDA's "other transaction" authority. The initial award would result in a 10 year Agreement for a minimum of $10

[6] See www.sam.gov

million[7]. Funding options would be included to allow for additional BARDA funding above $10 million. BARDA anticipates including options to provide an additional $40 million over the first five years of the initial 10 year agreement. The funding amounts provided to the Managing Entity under the Agreement could be modified as necessary up to $500 million over the initial 10 year period of performance of the Agreement. Additional funding provided through options or revisions to the agreement would be subject to approval and availability of funds.

VI. ACCESS TO RECORDS & FOREIGN OWNED INTERESTS

1. Access to Records.

The USG, at its discretion, will have access to and the right to examine records of the Managing Entity per normal course (pre, during, and post-execution) of the Other Transaction. This only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. BARDA may periodically request updates on investments that include technology, financial, and IP progress, in order to track impact, performance, progress, and overcome roadblocks towards accomplishing mission. These requests would be in addition to reporting requirements outlined in Appendix A. These updates and reports will be considered confidential and shared on a need to know basis within BARDA.

2. Foreign Owned Interests

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

VII. RIGHTS RESERVED DURING THE SOLICITATION PROCESS

BARDA reserves specific rights, in addition to rights by law or regulation, including but not limited to:

- The right to request additional, necessary documentation upon initial review. Such

[7] Note this initial amount may be increased by up to $250 million in the first year depending on federal appropriations received and availability of funds.

additional information may include, but is not limited to, a further detailed proposal, budgets, and representations and certifications.

- The right not to select a Managing Entity.
- The right to remove a Managing Entity from consideration should (i) the parties fail to reach agreement on terms, conditions, and cost within a reasonable time; (ii) the partner fails to provide requested additional information in a timely manner; or (iii) BARDA believes it is in the best interests of the USG.

VIII. SUBMISSION OVERVIEW AND INSTRUCTIONS

All interested parties should notify BARDA of their intent to respond to this solicitation as soon as possible by emailing DRIVe.Contracting@hhs.gov. While not required in order to submit a proposal, it is strongly encouraged.

All proposals should be submitted to the BARDA Division of Research Innovation and Ventures (DRIVe) Head of Partnering, Matt McCord, via email to DRIVe.Contracting@hhs.gov. Proposals are due by 8 December, 2020 at 12:00PM ET.

All proposals will be kept confidential and be reviewed pursuant to the criteria established. Any interested parties that respond to this solicitation will be deemed a Respondent. Those Respondents not selected for award will be notified of the decision. Formal debriefings will not be offered.

Respondents must be registered in the System for Award Management (SAM) to be eligible for award. (NAICS: (523910)) Registration can be completed here: https://www.sam.gov/

IX. PROPOSAL PREPARATION

The Respondent should submit Summary of Eligibility Requirements and a proposal consisting of a narrative (including figures, schematics, diagrams, graphics, etc. which must be labeled) that describes the organization's capabilities, experience, and approach, for performing the tasks and responsibilities outlined in the sections below.

Summary of Eligibility Requirements

Respondent must provide a summary and representations to satisfy each of the mandatory eligibility criteria described in Section IV. ELIGIBILITY CRITERIA. This portion of the submission should be kept to a maximum of two pages. **The summary of eligibility should stand on its own without the need for evaluators to do any external research outside of what is provided in the summary. Proper citations and supporting evidence are required.** The information provided in the summary will be used to determine if the Respondent satisfies the eligibility criteria.

1. Overview

Describe how the Respondent will partner with BARDA to help advance BARDA mission to Save Lives and Protect Americans from 21st Century Health Security Threats as outlined in the following strategy and implementation documents: National Health Security Strategy (2019-2022),[8] National Biodefense Strategy (2018), and the PHEMCE Strategy and Implementation Plan (2017-2018).[9]

2. Prospectus of Relevant Experience

This section only pertains to current and past performance. The Respondent must include detailed examples of its relevant current and past performance. The Respondent should also include experience and past performance of key personnel and collaborators who will deliver the objectives of the partnership. **All examples should stand on its own without the need for evaluators to do any external research outside of what is provided in the proposal. Proper citations and supporting evidence are required in the following areas:**

a. Experience partnering with the USG to meet identified strategic needs.
b. Experience supporting technologies with the intent to generate a measurable scientific, or social impact. That have demonstrably brought and addressed an unmet need in the healthcare, life sciences, and/or health security landscape.
c. Experience managing operational functions of a nonprofit to meet and maintain

[8] https://www.phe.gov/Preparedness/planning/authority/nhss/Pages/default.aspx
[9] https://www.medicalcountermeasures.gov/media/37041/2019_ns.pdf

requirements of the exempt status as required by the Internal Revenue Code. These include execution, tracking, and reporting of the stated mission of a nonprofit.

d. Experience managing a venture capital fund focused on healthcare, life sciences, medical devices, diagnostics, hardware, and software and other technology companies, including investing, bringing products to market, and generating financial proceeds for its investors.
e. Experience in sourcing and evaluating of new technologies and intellectual property from various sectors including universities, accelerators, and other sources.
f. Experience in attracting additional investment into portfolio companies from external sources either in syndication or follow-on rounds.
g. List 15 most recent investments including date of closing, name of company invested in, location of company, total dollar amount of the investment by the Respondent in that round, total dollar amount of the round, syndication partners (indicate if Respondent was the lead investor), and financing round (i.e., Seed, Series A, B, etc.) More weight will be given to deals made in the last 36 months. The examples provided here could be deals done by individual key personnel or the organization.
h. 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) net expenses and carried interest. Where possible, benchmark against performance of venture capital funds, include citation for source of the data.

3. Organizational Capabilities

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

a. Provide an overview of the entire organization including organizational structure, number of funds under management, total capital managed, a high

level overview of current sources of capital such as family offices, endowments, pension funds, etc. (we do not need to know the actual limited partners) and describe any plans (if any) to change or expand the organization.

b. Demonstrate the ability to maintain daily operations and high performance of organization should managers or key personnel leave the organization. Respondent should submit a continuity plan or provide existing operating practices to ensure continuity during the event of turnover.
c. Indicate if the organization, fund, and/or personnel have been involved in any litigation, either, directly or indirectly involving alleged financial malfeasance.
d. Provide a risk management strategy to identify, track and address any financial or programmatic risks and provide mitigation strategies.
e. Provide operational processes including governance, cash flow management, method of accounting, tax, audit, and valuation.
    i. Provide specific details on how Respondent plans to account for portion of capital deployed with funds awarded by BARDA.
    ii. Provide Respondent's method for accounting of proceeds derived from such funds.
f. Provide a detailed description how the Respondent will protect against conflicts of interest. It is up to the Respondent to establish policies and manage all internal conflicts of interests. Upon award the Agreement must contain comprehensive set of policies that are agreed upon by both parties that address potential conflicts of interest, ethics and disclosures (see Appendix D: Conflict of Interest Plan).
g. Provide a description of the Respondent's existing facilities and infrastructure and any future plans for scale up to address the requirements of this partnership.

4. Key Personnel

Provide the following for each key personnel and support staff (including key subcontractors, consultants, etc.) who will be responsible for the management and operations of the Respondent including providing subject matter expertise and consultation to the management team.

a. Name
b. Description of role and contribution

c. Curriculum Vitae (CV) or Resume (attached as an appendix)

Provide specific roles, duties and the proposed level of effort (as a percentage of full time employment, as necessary) proposed for listed personnel.

5. Investment Strategy and Approach

Provide a detailed investment thesis and strategy for this partnership 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 based on realistic returns given investment thesis and mix while providing sufficient supporting information and data. It is important to note that funding for the Managing Entity beyond the initial award would be subject to available appropriations. For purposes of evaluation of this section only, the proposed investment thesis should be based on the assumption that $50 million of funding is provided to the Managing Entity over a 5 year period (i.e. $10 million at the time of award, then $10 million each year the next four years. This assumption is not a guarantee of funding and is used here for evaluation purposes. Any resulting award beyond the initial amount would be subject to the availability of funding. It is expected that the Managing Entity will ensure that sufficient reserve is available to support follow-on investments. Additional weight will be given to the investment thesis that is adaptable and scalable to effectively execute additional tasks and deploy a larger amount of funding should BARDA provide additional funding to the Managing Entity.

It is expected that the Respondent will provide real world examples of investments, or intended investments that fit within the BARDA mission, with at least one example of an investment in the area of pandemic preparedness or pandemic response (e.g., COVID-19, influenza, emerging infectious diseases, etc.). Provide the rationale and criteria (e.g., stage of technology development, market or sub-market segmentation, size of investment, and unique features of investments, etc.) for investment in technologies that align with the proposed thesis. BARDA and the Managing Entity will agree upon a technology area's applicability to support the BARDA mission; however, it is expected that the Managing Entity will conduct all aspects of management as it relates to investments from deal sourcing to oversight of portfolio companies independently.

The Respondent should propose a model where the Managing Entity could become self-sustaining within the life of this partnership (e.g. 10 Years). Should self-sustainment occur within the life of this partnership, it is expected that the Managing Entity continues to advance the BARDA mission in accordance to an agreed upon manner to continually bring forth technologies and innovations to market that address an unmet national health security needs. Any proceeds recycled back to Managing Entity will be governed and/or limited by the charter and relevant legal requirements applicable generally to nonprofit entities, which may include reasonable operational expenses of the Managing Entity or further investment in medical countermeasures.

6. Partnership and Portfolio Management

In addition to the overall investment strategy the Respondent should at minimum address the following regarding their plan to manage their partnership with BARDA and their portfolio:

a) Describe how the Respondent will manage a unique partnership with BARDA and the USG. The Respondent should outline all aspects of the partnership throughout the investment life cycle (pre-investment, post-investment, and exits). Describe Respondent's vision of how BARDA and the Respondent will work together as part of the JOC to agree on which technologies fall within the BARDA mission and how feedback and guidance from BARDA can effectively be addressed during the investment life cycle. Respondents should refer to Figure 2 in Section III. JOINT OVERSIGHT COMMITTEE.

b) Sourcing, evaluation and due diligence process, and investment timeline and decision tree

    i. Sourcing – Describe how deals will be sourced and any unique processes the Respondent will use to find the best technologies relevant to BARDA's mission and/or impact areas. NOTE: It is expected that deal sourcing and technology scouting will occur nationally and internationally. If the Respondent currently does not have this capability describe, how the Respondent will develop and maintain the capability.

ii. Evaluation and Due Diligence - Outline the due diligence process and specific criteria for investment (i.e., stage of technology development, market or sub-market segmentation, size of investment, and indication) that the Respondent will utilize to meet the overarching objectives of the partnership. These should include, but not be limited to the unique processes as well as specific evaluation indicators (negative or positive) that the Respondent utilizes in the investment evaluation process.

iii. Investment Timeline and Decision Tree - Respondents should outline and provide the envisioned investment timeline and decision tree including mapping out decision points 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 to further diligence as well as delineating steps at which BARDA involvement on consultation and applicability to the BARDA mission. Provide the envisioned frequency (e.g., ad hoc, monthly, quarterly) and volume (e.g., number of deals under review) of the deal flow process.

c) Respondent should outline the criteria in which follow-on investments will be deployed, how investment positions will be maintained and managed, and general principles to provide follow-on investment to portfolio companies.

d) Outline and identify parameters which would be used for gauging strategic and financial success and key performance indicators for the partnership.

e) Respondent should describe how it plans to attract and manage syndication partners. Provide examples of previously syndicated deals and any positive or negatives as it relates to syndication.

f) Respondent should describe how it will manage funding that may not be distributed at the same time each fiscal year nor guaranteed year to year, as BARDA funding provided to the Managing Entity will be subject to annual appropriations. Respondent should provide strategies that can best ensure success of the partnership under these uncertainties.

7. Non-investment and Acceleration Activities

a) Describe/provide how the Respondent will foster, promote, accelerate, deploy, and implement the development of portfolio companies through a portfolio management strategy including any non-monetary resources provided to portfolio companies in order to minimize risks and maximize impact.

b) Describe how the Respondent will help provide market intelligence and strategic input through market research and engagement with the entrepreneurial community to help advance the USG and BARDA's mission.

c) Describe how the Respondent will define, track, and report on BARDA mission related impact metrics.

8. Financial Projections and Operational Expenses

The Respondent should provide financial modeling and projections based upon the amount of BARDA funding provided. The financial projections and operational expenses outlined here should reflect what is proposed in the investment thesis above.

It is anticipated there will be four primary cost categories taken into account and tracked separately as part of an award:

- Venture Capital Activities:
    - Investment funding outlays year over year (Investment Pool)
    - Direct/Indirect operational expenses related to management and oversight of the investments
- Non-Venture Capital Activities:
    - BARDA Ventures Partnership Activities. Government reporting requirements and oversight costs associated with conducting business and operating within a partnership with BARDA (i.e. this section should only include those costs that would be in addition to traditional fund management expenses)
    - Additional Activities to Foster Countermeasure Development: – include all costs associated with activities not that are not included in investment funding outlays, direct/indirect operational expenses or BARDA Ventures partnership activities (such as the ad hoc additional services describes in Section II.

OBJECTIVES)

Respondents should respond to the following financial models which are meant to be representative of potential funding scenarios, but not guaranteed. These proposed models will be used for evaluation purposes.

a) Venture Capital Activities:
    i. 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 subject to what is allowable by law) as well as associated operating cost for the first 10 years of the fund's life based. Describe the key variables and assumptions based on the following potential funding scenarios::
        a. Scenario 1: $10 million annual funding from BARDA to Respondent for years 1-5 (total of $50 million).
        b. Scenario 2: $10 million funding from BARDA to Respondent in year 1 and $60 million annual funding from BARDA to Respondent for years 2-5 (total of $250 million).

    Operational/management expenses should be proposed as a rate/percentage of funds under management but include general break down supporting those fees (e.g., salaries, benefits, rent, equipment, travel, professional service fees, etc.) for years 1-10. The management should include all costs typically associated with managing venture capital investment activities, including but not limited to sourcing (e.g., attending conferences, networking, etc.), conducting due diligence, managing the portfolio, and providing routine reports such as those outlined under Appendix A of this solicitation. Indicate how these expenses may change based on annual funding assumptions and how estimates are determined.
    ii. Propose a model by which a portion of proceeds will cover part or all of operational expenses based on the assumption that Managing Entity is structured to recycle proceeds.
    iii. Provide a plan on segregating specific USG funds that may be provided to the Managing Entity for specific mission priorities so that these funds could be tracked separately on an accounting and reporting basis should they be

provided.

b) Non-Venture Capital Activities. Independent from the proposed cost models described above under the "Venture Capital Activities" section, please propose costs separately for each section below, based the following assumptions:

   i. BARDA Ventures Partnership Activities.

      a. Participation in Joint Oversight Committee (JOC):

         1. Organize and attend monthly progress meetings. These will be conducted using a video or teleconference platform.
         2. Organize and attend quarterly strategy meetings each year. These will be conducted in person and occur twice at BARDA offices in Washington, DC and twice at Managing Entity office.

      b. Annual impact report – A summary of investment and portfolio activities with an emphasis on accomplishments related to the BARDA missions.

      c. Regular interaction with BARDA Ventures team – Ad hoc interactions to coordinate outside of JOC meetings on aspects regarding portfolio companies, investment activities, market research, and due diligence.

   ii. Additional Activities to Foster Countermeasure Development.

      a. It is anticipated that some activities may arise over the course of the partnership that BARDA would require of the Managing Entity to foster countermeasure development which could not be reasonably estimated with any certainty at the time of award. These could include, but are not limited to:

         1. Host/sponsor an industry meeting/conference focused on MCM innovation and development.
         2. Host BARDA/USG focused partnering/sourcing forum.
         3. Promote BARDA mission at various local and regional innovation hubs throughout the country, and hold office hours to meet with local innovators.
         4. Conduct detailed market analysis of specific sectors, as

requested, in areas related to BARDA mission.

5. Host and manage potential competitions in relation to MCM innovation and development.

b. These activities will be requested by BARDA as specifics of the requirement arise and would be negotiated on a case-by-case basis. For purposes of establishing parameters of future work, please provide labor rates for the following roles which would be incorporated into the Agreement:

    1. Marketing and Event Coordinator – coordinate promotion of BARDA mission and activities of the BARDA Ventures partnership
    2. Investment/Market Analyst – support sourcing and market research activities
    3. Program Manager/Alliance Manager – manage program activities specific to BARDA mission.

9. Fundraising and Expense Sharing Plan

The Respondent should outline the strategy and timeline to independently attract private investors (e.g., Limited Partners) into a fund established for the purpose of this partnership**.** The goal is to raise additional capital that at least matches the funding provided by BARDA.

The Managing Entity should attract private investors and donors that share the vision and goals of BARDA. Capital contributions made by others into a fund established for the purpose of this partnership will solely support the BARDA mission as outlined in this solicitation and subsequent agreements between the Managing Entity and BARDA**.**

This strategy would allow the Managing Entity to share expenses with private investors in a fund(s), related to operations, risks, and share the benefits of investment proceeds. Should any exit or proceed opportunities occur, the Managing Entity would allow private investors to recycle the funds or take their proceeds. The strategy should also convey structures and terms that satisfy the private investors' investment goals and at the same time, meet the goals

of BARDA's mission. The Managing Entity must ensure funds invested by the Managing Entity and private funds are adequately tracked for proper capital accounting to maintain clear pro rata assignment of any investment made by the Managing Entity. Additional methods of capital deployment that meet the objectives of this partnership can also be proposed.

The Managing Entity should provide documented evidence of existing and newly established private investors and corporate partnerships, engagement specific to this opportunity. If available, letters of support or commitment should be provided.

It is understood that the ability to raise any additional non-federal funding may be contingent upon the execution of a partnership with BARDA and the timing around the raising of such funds will be agreed upon during the time of negotiation. BARDA encourages Respondents to propose creative structures to most effectively meet the objectives of the partnership while maximizing private co-investment.

10. 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 five year period of healthcare technology portfolios under management (e.g. successful clinical trials, lab tests, U.S. Food and Drug Administration approvals, revenue, successful product commercialization, and/or licensure activities).

X. QUESTIONS

Please submit all questions to DRIVe.Contracting@hhs.gov. Answers to questions submitted will be made publically available to all interested parties during the open period to the maximum extent practicable. Relevant questions submitted and accompanying answers will be

provided publicly as deemed appropriate by BARDA to ensure information is provided equitably to all interested parties. Responses posted publically will be anonymized and contain no identifying information.

XI. EVALUATION CRITERIA

The summary of eligibility requirements will be reviewed against the mandatory eligibility criteria established by legislation and defined in Section IV. ELIGIBILITY CRITERIA, of this solicitation. If it is determined that the Respondent does not satisfy the eligibility requirements, the proposal will not be evaluated further. If it is determined the Respondent does satisfy the eligibility requirement, the proposal will be evaluated against the following evaluation criteria listed in descending order of importance:

1. **Relevant Experience**

   BARDA will place a high value on relevant experience if it addresses all of the outlined points in Section IX. 2. Prospectus of Relevant Experience, of this document and provides supporting examples, references, and backup documentation. A high value will be placed on proposals that include an investment/management team with the appropriate expertise to effectively invest in and manage companies successfully in the healthcare sector with additional demonstrated experience in partnering with the USG to meet identified strategic needs. Entities with experience partnering with the USG will be rated higher on this aspect of the evaluation criteria than individuals that do not have experience working with the USG. NOTE: This does not preclude entities or individuals without experience partnering with the USG. Additionally, the Managing Entity proposed would reflect a clear, successful track record demonstrating venture investments and accelerating product development to the marketplace in medical and health sciences. Realistic case studies, supported by references, must be provided to support the feasibility of the proposed approach.

2. **Soundness of Proposed Approach**

   The proposed approach will be evaluated as to whether the plan is viable, realistic, and

nimble enough to satisfy BARDA's mission[10]. A strong approach would include a model that would support the ability to operate within this unique partnership with BARDA and other non-federal co-investors, including providing realistic and real world examples of investments or intended investments that fit within BARDA's mission while seeking maximum impact. Provides a model that clearly addresses the ability to reinvest proceeds and proposes a structure that can adequately address and define all major risks including the ability to manage uncertain capital outlays. The ability to source from a national and international outreach, manage, develop, and commercialize investments, and provide non-investment and acceleration activities and services will be evaluated. A sound proposal will clearly define all necessary activities, identify and address all major risks, and propose planned mitigation efforts for identified risks.

3. **Potential to Impact Health Security Landscape (Including Proposed Cost-Share)**

The Managing Entity is expected to assist BARDA in rapidly advancing technologies that can make the biggest impact on improving the United States' capability to be prepared against any chemical, biomedical, radiological, nuclear, pandemic and epidemic threats to public health. The ability to make investments in technologies that meet this mission while also becoming commercially viable, without reliance on federal funding alone, is the desired goal of this partnership. The Respondent should clearly demonstrate and convey an understanding of the best approach to managing and presenting a strategy that can execute all programmatic objectives outlined in Section II. OBJECTIVES including rapid acceleration services and wrap-around support services to the entrepreneur and development community. BARDA will place great importance on Respondents that can demonstrate their ability by providing a cogent vision of how this partnership and subsequent activities and investments can meet the objectives of the partnership to revolutionize the landscape against current and future threats, including pandemics and emerging infectious diseases (e.g., COVID-19). The level of proposed expense-sharing through co-investment partners will also be evaluated. Expense sharing plans will be rated favorably if they demonstrate a

[10] https://www.phe.gov/about/barda/stratplan/Pages/barda-vision-mission-and-values.aspx#:~:text=BARDA's%20mission%20is%20to%20develop,natural%20or%20intentional%20in%20origin.

feasible plan to source external capital (e.g., supported by letters of commitment) or if the prospective Managing Entity proposes to commit in-house capital.

4. **Operational Expenses and Projected Financial Models**
   Proposed financial models and investment outlays will be evaluated on the best value to the USG, forecasted financial proceeds based on realistic estimation, and reasonableness of assumptions. Proposed operational expenses will be evaluated on whether they represent realistic expenses necessary to execute Managing Entity objectives and overall value to BARDA.

XII. EVALUATION DEFINITIONS

Submissions will be evaluated using the following ratings:

1. **Excellent: An "Outstanding" submission is characterized as follows:**
   The submission indicates an exceptionally thorough and comprehensive understanding of the program objectives and the methods, resources, schedules, and other aspects essential to performance of the program. The risk of unsuccessful contract performance is extremely low.

2. **Good: A "Good" submission is characterized as follows:**
   The proposal indicates a thorough understanding of the program objectives and the methods, resources, schedules, and other aspects essential to the performance of the program. Risk of unsuccessful performance is very low.

3. **Acceptable: An "Acceptable" submission is characterized as follows:**
   The proposal indicates an adequate understanding of the objectives and the methods, resources, schedules, and other aspects essential to the performance of the program. The risk of unsuccessful performance is low.

4. **Unacceptable: An "Unacceptable" submission is characterized as follows:**

The proposal indicates a lack of understanding of the program objectives and the methods, resources, schedules, and other aspects essential to the performance of the program. The risk of unsuccessful performance is high.

XIII. AWARD DECISION

BARDA expects to make one award to a Respondent who proposes the greatest overall value to the USG in accomplishing its program objectives. BARDA reserves the right to engage with Respondents at any point in the process as deemed necessary by the OTAO for the evaluation process.

Following its evaluation of proposals, the Respondent whose submission appears to offer the best value to the USG will be invited to enter into negotiations with intent to reach and execute an Agreement. Through this process, if it is determined that the Respondent does not offer best value to the USG or mutual agreement on the terms cannot be reached, another Respondent may be invited to enter negotiations.

XIV. APPENDICES

Appendix A: Reporting Requirement
Appendix B: Curriculum Vitae and Resumes of Key Personnel
Appendix C: Letters of Commitment
Appendix D: Conflict of Interest Plan
Appendix E: Definitions

Appendix A: Reporting Requirement

BARDA expects to receive the following industry standard reports from the Managing Entity:

Report	Contents	Due Date
Portfolio Companies Performance Report	Financial reports, Milestones, Personnel, IP, Fundraising, and 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, and 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, and 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 and deployed capital to date.	Within 15 days after the end of each month.
Independent Audited Financial Statements	Full financial report	Within 120 days of the year-end.

Specific formats, contents, and timelines for these reports will be finalized during negotiations.

Appendix B: Curriculum Vitae and Resumes of Key Personnel

Please attach a 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 program and achieving program objectives. Please be sure 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

Respondent should provide any letters of support or commitment from any partners and 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 the Respondent's cost share, then this contribution is part of the proposal, the partners cost share must be included in the Letter of Commitment.

Appendix D: Conflict of Interest Plan

Respondent should propose a plan to address, identify, avoid, and mitigate any actual or perceived organizational Conflict of Interests (COI) associated with being a partner with BARDA as the Managing Entity. The Respondent 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 may require third party COI review and reports throughout the period of performance.

Appendix E: Definitions

Medical Countermeasure:

> Per 42 U.S. Code § 247d–6a a "Qualified countermeasure" is defined as a drug (as that term is defined by section 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)

Qualified Pandemic or Epidemic Product:

As per 42 U.S. Code 247d-6d, a "qualified pandemic or epidemic product" is a drug (as that term is defined in section 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 is:

(A) (i) manufactured, used, designed, developed, modified, licensed, or procured (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or (II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii) intended to enhance the use or effect of a drug biological product, or device described in clause (i) or (ii); and

(B) (i) approved or cleared under chapter V of title 21 or licensed under section 262 of this title,

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 355(i) or 360j(g) of title 21 or

(iii) authorized for emergency use in accordance with sections 360bbb-3, 360bbb–3a, or 360bbb–3b of title 21.

Security Countermeasure:

Per 42 USC § 247d-6b(c), the term "security countermeasure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that—

(i)

(I) the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or 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 against such an agent;

(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(III)

(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3].