DRIVe VENTURES

Investing in National Security Preparedness

Request for Information (RFI)

January 16, 2019

Saving Lives. Protecting Americans.

ASPR

Title: DRIVe Ventures Market Research: Request for Information

HHS-18-BARDA-MR-00021

DRIVe

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Washington, DC 20201

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BARDA DRIVe VENTURES REQUEST FOR INFORMATION

Special Notice No.: HHS-18-BARDA-MR-00021

I. PURPOSE

The Division of Research, Innovation and Ventures (DRIVe), under the Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) intends to use responses to this notice for planning potential future acquisitions related to the DRIVe Ventures program. DRIVe Ventures is one of two components of BARDA's Medical Countermeasure Innovation Partnership (MCIP)[1]. BARDA will not execute any awards based on this notice, but rather obtain availabilities, capabilities and other pertinent marketplace data to strengthen BARDA's understanding of organization's current and future capabilities to address the requirement.

The purpose of this notice is to allow DRIVe Ventures, a component of the MCIP, to survey the market for venture capital organizations that are capable of managing a sustainable portfolio of medical countermeasure products and technologies to address influenza, emerging infectious diseases and chemical, biological, radiological and nuclear (CBRN) threats. DRIVe Ventures will foster and accelerate the development and innovation of medical countermeasures and technologies to enhance National Health Security preparedness and response in ASPR's mission to "Save Lives and Protect Americans from 21st Century Health Security Threats." Venture capital organizations, including but not limited to venture capital firms, corporate venture capital, impact venture capital funds, with experience identifying promising innovative products and technologies, linking innovators and investors, leveraging partnerships and resources to address strategic needs of the federal government are desired.

The DRIVe Ventures will have the ability to leverage venture capital practices and methods, similar to a corporate venture capital model, to identify, invest-in and promote the development of innovative dual utility[2] medical countermeasures to enhance National Health Security. Following an anticipated period of seed funding from the USG, DRIVe Ventures will transition to a self-sustaining, "evergreen fund" via reinvesting revenues generated from portfolio investments, ultimately creating a sustainable fund to foster Health Security Innovation.

[1] Established in "21st Century Cures Act" PUBLIC LAW 114–255—DEC. 13, 2016

[2] **Dual Utility products and technologies:** Products or technologies with both commercial and biodefense applications. This will enhance our Nation's ability to respond effectively to the broad array of threats with the products being viable in the traditional commercial market in order to ensure sustainability and reduce long term government procurement costs.

II. BACKGROUND

BARDA within the Office of the ASPR at the U.S. Department of HHS intends to use responses to this notice for planning purposes towards the possible acquisition of services from non-profit[3] entity venture capital organizations, with the ability to run DRIVe Ventures, leveraging a corporate venture capital model. In addition, BARDA is interested in receiving feedback from venture capital organizations that are not categorized as non-profit organizations that may have the ability to spin off or launch a non-profit venture capital fund under a separate non-profit entity.

BARDA 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 biological, chemical, radiological, nuclear 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 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. The 2016, "21st Century Cures Act" authorized ASPR/BARDA to establish the MCIP and further enabled the MCIP to utilize "strategic venture capital practices and methods."

III. PROJECT REQUIREMENTS & OBJECTIVES

This notice seeks information from non-profit entities with regard to their current qualifications, experience and capability and/or their ability to establish these capabilities to build and manage a sustainable portfolio of innovative technologies and products, with particular attention to ALL of the following:

To be eligible to enter into a future agreement, an entity must:

a) "Be an independent, non-profit entity" not within the Department of Health and Human Services,"

b) "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 Federal Government"

[3] 501C organization as outlined in 26 U.S. Code § 501.

c) "Have experience in promoting novel technology innovations"

d) "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)."

e) "Demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products,"

f) "Demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures."

g) In addition, "the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs."42 U.S.C. 247d-7e(c)(4)(E)(ii).

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 (see law https://www.gpo.gov/fdsys/granule/USCODE-2011-title42/USCODE-2011-title42-chap6A-subchapII-partB-sec247d-7e)

IV. NARRATIVE TECHNICAL REPRESENTATION

Respondents shall make the capability statements to ASPR/BARDA in the order listed below in a narrative format. (Note: sections not relevant to the respondent and may be marked 'NA/Reserved,' to maintain the section numbering). The capability statement should address each of the following areas listed below:

1. Overview:

The narrative (including figures, schematics, diagrams, photographs, etc.) that describes the abilities of the organization. Compensation for potential ventures candidates and managers should be consistent with market standards including management and exit fees.

2. The following outline should be used in the response document:

1) The qualifications and experiences of the organizations staff to build and manage a diverse investment portfolio that results in a positive 2.5-3x net return. Experience evaluating innovative healthcare technologies and medical products from a scientific and market perspective to facilitate venture capital investment decisions

2) Experience evaluating financial and business practices of prospective companies in biotech/pharma industry to facilitate investment decisions

3) Experience and examples of promotion and generation of additional investment funds into companies within established portfolios from outside sources (e.g. additional venture capital funds).

4) Experience taking investment positions into product developers with Infectious Disease products either as a "Lead Investor" setting the price and terms of the investment and as a "Co-Investor"

5) Experience providing business management services, guidance to companies currently under investment and experience representing the venture round on the board

6) Examples of technology portfolios under management and the growth and maturation of the technologies over 5 year period.

7) Examples of ongoing or prior partnerships/contracts with the government; ongoing or prior experience managing investment portfolios with U.S. Government or non-governmental organizations (NGO's); references; and other related information.

Respondents are asked to provide only the most pertinent information, data, and materials necessary to adequately convey the capability in line with this notice. The submission should not exceed 10 pages. A page is defined as a double-spaced, on 8 ½" x 11" plain white paper with 1" margins on both sides, and a font size of not less than 11. No additional pages in the form of attachments or use of appendices will be accepted. Title page, table of contents do not count against the page limits.

3. EXPERIENCE AND CAPABILITIES

Respondents to this notice are to also complete the applicable "**Experience and Capabilities Table"** below. The response is separate from the **"Narrative Technical Representation"** described above. The Experience and Capabilities Table can be tailored into any preferred format/presentation, but must not exceed 10 pages (in addition to the 10 pages allotted for the Narrative Technical Representations section detailed above.). No additional pages in the form of attachments or use of appendices will be accepted. However the title page, table of contents do not count against the page limits. A page is defined as a double-spaced, on 8 ½" x 11" plain white paper with 1" margins on both sides, and a font size of not less than 11.

NOTE: If you believe any of the questions in the below table were addressed in the Narrative Technical Representation section, please feel free to reutilize the same language (i.e. copy and paste) into the appropriate places within the table. The table is being presented in a uniform format so that we may categorize responses effectively.

EXPERIENCE AND CAPABILITIES TABLE

	Information Sought	Response	Details (as necessary)
"Be an independent, non-profit entity not within the Department of Health and Human Services,"			
1.	Is your entity currently within the Department of Health and Human Services?	Yes/No	
2.	Are you currently an entity exempt from federal income taxation under Section 501(c) (3) (or a similar provision) as recognized by the Internal Revenue Code?	Yes/No	
	2(a). If no, do you have the ability to spin off or launch a non-profit venture capital fund?	(Text)	
	2(b). If yes, when was your entity established as a Section 501(c) (3) (or similar classification) as recognized by the Internal Revenue Code?	(Text)	
"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 Federal Government,"			
3.	Capability and experience with creating linkage between innovators and investors to address the strategic needs of the Federal Government.	(Text)	
4.	Capability and experience with creating linkage between innovators and investors to support product or technology development in context with the objectives of the DRIVe Ventures.	(Text)	

"Have experience in promoting novel technology innovations,"			
5.	Capability and experience with promoting novel products and technology innovation utilizing strategic venture capital practices and methods.	(Text)	
6.	Please identify if any of these novel technology innovations led to product or technologies that successfully transition from research and development to the clinic, commercial market, were out- licensed, acquired and/or transitioned to Federal partners for support.	(Text)	
7.	Capability and experience with promoting novel technology innovations and leveraging capital from multiple sources.	(Text)	
8.	Capability and experience with to leverage the new "Opportunity Zones" to attract additional capital to support Health Security Innovation.	(Text)	
9.	Please provide perspectives on types of leadership experience and capabilities required to manage a non-profit self-sustaining venture capital entity to foster Health Security Innovation.	(Text)	
"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).),"			
10.	Capability and experience with providing solutions to gaps identified by your customer/partner.	(Text)	

11.	Please provide examples of where your entity has helped identify technologies or products, then invested in a company, provided financial oversight of that investment that ultimately resulted in a new product to support a customer/partner.	(Text)	
"Demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products,"			
12.	Please list therapeutic area(s) where your organization has helped or managed pharmaceutical product development or technology development. Describe your organization's contributions to advancing the specified product's stage of development.	(Text)	
"Demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures."			
13.	Does your entity have GMP/GLP/GCP/ISO experience?	Yes/No	
14.	Does your entity have experience supporting a BLA, NDA and/or FDA clearance submission?	Yes/No	
15.	With which Pharma/ Biotech companies, startups, academic spinouts, etc. have you invested in?	(Text)	
Demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs."			
16.	Capability and experience with partnering with the Federal Government to address their strategic need.	(Text)	

V. DISCLAIMER AND OTHER INFORMATION

BARDA encourages respondents to submit currently available marketing or extant information, or to notify BARDA of the publicly available location; thereof to the maximum extent consistent with this notice's requirements and limitations. Respondents shall mark confidential, privileged, proprietary, trade-secret, copyrighted information, data, and materials with appropriate restrictive legends. BARDA will not publicly disclose proprietary information obtained as a result of this survey. Unless otherwise marked, the Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. BARDA will presume that any unmarked information, data, and materials were furnished with an "unlimited rights" license; assumes no liability for the disclosure, use, or reproduction of the information, data, and materials.

Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted.

VI. INQUIRIES

Questions regarding this announcement should be submitted via e-mail to both Troy Francis, Contracting Officer: troy.francis@hhs.gov , and Matt McCord, Director of Partnering (Acting): matthew.mccord@hhs.gov. Phone conversations are also permissible to clarify questions. Answers to relevant questions will be posted o fbo.gov. Accordingly, questions should not contain proprietary or classified information.

BARDA DRIVe does not guarantee that questions received after 5:00 P.M. ET on March 1, 2019 will be answered.

VII. INFORMATION SUBMISSION INSTRUCTIONS

Responses must consist of two separate components (detailed above):

1. Narrative Technical Representations; and
2. Experiences & Capabilities Table.

These components may be combined into a single document or sent in the same email as two separate documents. Respondents must provide documents in either Microsoft Office ®, Corel® WordPerfect®, or Adobe® Acrobat® format.

Responses must be submitted via email transmitted to the following addressee for receipt by **5:00 P.M. ET on March 4, 2019**. Responses must be submitted via emailed to both troy.francis@hhs.gov and matthew.mccord@hhs.gov with the Subject Line: **DRIVe Ventures: Response to RFI**. It is recommended that submissions are sent at least two hours in advance of the deadline to allow for any server delays.