



## Request for Information (RFI)

**Request # FDA-26-132067**

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**FOR: Foundational Innovation and RAPID Engagement (FIRE)**

**DEPT/AGENCY INFORMATION:** Department of Health and Human Services, Food and Drug Administration

**Requiring Offices:** Office Of Digital Transformation (ODT)

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### **GENERAL INFORMATION**

The Food and Drug Administration (FDA) is issuing this under the authority of the Federal Acquisition Regulation (FAR) Part 15.201 and FDA acquisition policies. All responses will be handled in accordance with applicable federal regulations and FDA procedures for “**FDA Foundational Innovation and RAPID Engagement (FIRE)**”.

This is a Request for Information ONLY, not a Request for Quote (RFQ) and does not commit the Government to award a contract now or in the future. The U.S. Food and Drug Administration (FDA) is seeking information from **Venture Capital (VC) firms** regarding their interest in and requirements for a novel contract vehicle that would enable portfolio companies to compete directly for FDA contracts and task orders.

Submission of any information in response to this market survey is purely voluntary and the Government assumes no financial responsibility for any costs incurred. Respondents are advised that information submitted may be subject to disclosure under the Freedom of Information Act (FOIA). Clearly mark any proprietary or confidential information in accordance with applicable regulations.

The FDA will use the results of the market research to determine if Venture Capital (VC) are capable of satisfying the agency's requirements exist based on its response to the questions contained in this notice. The FDA does not intend to make a selection decision or award a contract on the basis of responses.

Acknowledgement of receipt of responses will not be made, nor will respondents be notified of the outcome of the FDA's review of the information received. Additionally, the FDA does not intend to hold discussions concerning this Request for Information with any interested parties. The FDA may conduct follow-up discussions with selected respondents to clarify or expand upon submitted information. Such discussions do not indicate selection for any future procurement opportunity.

### **INSTRUCTIONS**

A complete response should include answers to all the questions below. Please note that a respondent's failure to provide a complete response to a question will be interpreted to mean that it does not understand the question and does not demonstrate the capability to provide services required. Responses should demonstrate capability, not merely affirm the respondent's capability (i.e. the response must go beyond the statement that, "XYZ company can provide technical support").



Respondents will not receive individualized feedback on any suggestions. No basis for claims against the United States government shall arise as a result of a response to this request for information or from the United States government's use of such information. Proprietary, classified, confidential, or sensitive information should not be included in your response. The Federal Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s). The Government is not obligated and will not pay for any information received from potential sources as a result of this RFI.

**Response Due Date/Time: January 18, 2026 at 2:00 PM ET**

**Email to:** Phillip.Frame@fda.hhs.gov

Please include the **Request for Information # FDA-26-132067 FDA Foundational Innovation and RAPID Engagement (FIRE)** in the subject line. No phone calls will be accepted for this notice.

### **Purpose**

The U.S. Food and Drug Administration (FDA) is seeking information from Venture Capital (VC) firms regarding their interest in and requirements for a novel contract vehicle that would enable portfolio companies to compete directly for FDA contracts and task orders.

### **Background**

The FDA recognizes that many breakthrough technologies and innovative solutions relevant to our public health mission are being developed by companies within VC portfolios. These companies often possess cutting-edge capabilities in areas such as artificial intelligence, biotechnology, medical devices, and regulatory technology that could significantly benefit FDA operations and the broader public health ecosystem.

Historically, the FDA's engagement with startup and emerging technology companies has been constrained or limited due to:

Utilization of pass-through organizations or prime contractors, which can create barriers to direct engagement and limit scalability. Furthermore, disincentives often exist such that prime contractors focus on increasing labor-based work instead of scaling technologies.

Navigation of a complex federal bureaucracy that may be prohibitive for innovative firms focused on product development. It takes small and innovative companies a lot of dedicated time, energy, and funding to provide products and services to the government.

### **Information Requested**

Organizations are invited to submit a response tailored to the information requested, taking into consideration the "Purpose" and "Background" described above. Respondents shall include, but are not limited to, addressing their experience and capabilities in the following areas:

### **Company information:**

Interested and capable vendors (parties) shall submit electronically in PDF Capability Statement with a



maximum of 20 pages, excluding appendices in response to this notice with the following information:

Provide a brief description of your firm's investment focus and portfolio composition, specific responses to the information requested, and any additional recommendations or considerations not addressed.

Information in this profile to the maximum extent practicable shall include:

- Company Name
- Mailing Address
- Name, telephone number, and e-mail address of a point of contact having the authority and knowledge to clarify responses with Government representatives.
- SAM Status. Companies must be registered in the SAM ([www.sam.gov](http://www.sam.gov)) at the time of contract award to be considered as potential sources. SAM registration is not required to respond to this RFI.
- Unique Entity Identifier (UEI)
- Socio Economic Status
- Your proposed NAICS for this effort
- Your GSA Schedule

**Please respond to the questions below broadly; specificity is not necessary at this time.**

The FDA is exploring the development of a contract vehicle that would:

- Establish direct contractual relationships with qualified VC firms
- Enable any company within an approved firm's portfolio to compete for and receive task orders under the vehicle. To adhere to federal contracting requirements, portfolio companies will be treated as subcontractors.
- Streamline the procurement process for innovative technologies and services
- Provide a scalable mechanism for engaging with the startup ecosystem
- Maintain appropriate oversight and compliance with federal acquisition regulations

### Interest and Feasibility

- Would your firm be interested in functioning as a Prime contractors such that any of your portfolio companies can be treated as subcontractors?
- What barriers or challenges do you foresee with this approach?

### Structural Requirements

- Current government contracting regulations would require that the VC firm would be the Prime and any portfolio companies who can provide technology or services would be subcontractors. Is this a structure your firm can support? If not, please provide feedback a type of structure that would work.
- How should intellectual property rights be structured and protected?

### Venture Capital Firm Qualifications

- How should the FDA evaluate a firm's track record in portfolio company oversight and governance?
- What financial stability and bonding requirements should apply to participating VC firms?
- Should there be requirements related to the firm's investment thesis, sector focus, assets under management, years in operation, or geographic presence?
- What ongoing certification or recertification processes should be established for participating firms?
- How should the FDA assess a firm's capability to ensure portfolio company compliance with federal contracting requirements?



- What organizational structure or dedicated resources should firms maintain to support this contract vehicle?

#### Financial and Administrative Considerations

- What payment and invoicing structures would be most efficient?
- How should performance bonds, guarantees, or other financial assurances be handled?
- What reporting requirements would be appropriate for both the VC firms and portfolio companies?

#### Regulatory and Compliance Framework

- What compliance requirements should apply to participating VC firms?
- How should conflicts of interest be identified and managed?
- What due diligence processes would be necessary for both firms and portfolio companies?

#### Implementation Timeline and Process

- What would be a reasonable timeline for implementing such a vehicle?
- What pilot or phased approach would be most effective?
- What industry engagement would be necessary during development?

**No Further Entries this Page.**