GENERAL CATALYST INSTITUTE

FDA Request for Information: Foundational Innovation and RAPID Engagement (FIRE) (FDA-26-132067)

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Executive Summary

The Food and Drug Administration (FDA) stands at a critical inflection point where the velocity of biotechnological and digital innovation fundamentally outpaces the constraints of traditional federal procurement frameworks. The General Catalyst Institute strongly advocates for the immediate adoption of a Venture Capital firm as prime contractor model as both a strategic imperative and a practical solution to accelerate the agency's access to transformative technologies that directly advance health innovation and safety for the American people. This procurement structure leverages the sophisticated due diligence, portfolio management, and ecosystem coordination capabilities inherent in venture capital firms to provide the FDA with a curated pipeline of vetted, investment-backed innovators while maintaining the highest standards of clinical efficacy and patient safety. This is not merely a theoretical framework; General Catalyst is already operationalizing this approach through HATCo Services. HATCo, a General Catalyst transformation company, currently acts as a prime contractor for health systems, contracting directly with GC portfolio companies to deliver managed, bundled, and integrated technology solutions that would otherwise be difficult for these systems to access individually.

By shifting the burden of technical coordination and vendor management from the agency to a centralized strategic partner, this model enables the FDA to focus its internal expertise on core regulatory science while dramatically reducing the bureaucratic barriers that currently prevent breakthrough companies from engaging with the federal government. The implementation of this approach is essential for building a resilient medical technology ecosystem, strengthening domestic supply chain security, and ensuring that American patients and providers benefit directly from the rapid advancements occurring within the private sector. The alternative, continuing with pass-through organizations and traditional

prime contractors that prioritize labor-based work over technology scaling, will result in the FDA falling further behind the innovation curve at a moment when emerging health threats and technological capabilities demand unprecedented agility and American leadership in medical breakthroughs.

Company Information

General Catalyst is a global investment and transformation company that partners with the world's most ambitious entrepreneurs to drive resilience and applied AI. We support founders with a long-term view who challenge the status quo, partnering with them from seed to growth stage and beyond. With offices in San Francisco, New York City, Boston, Berlin, Bangalore, and London, we have supported the growth of 800+ businesses, including Airbnb, Anduril, Applied Intuition, Commure, Glean, Guild, Gusto, Helsing, Hubspot, Kayak, Livongo, Mistral, Ramp, Samsara, Snap, Stripe, Sword, and Zepto.

General Catalyst's health assurance investment thesis and mission is to create a more affordable, accessible, proactive, and equitable system of care by leveraging innovative technology, new business and payment models, and human capital. By investing in innovative health assurance portfolio companies, partnering with 27 + health system and payer partners and operating a wholly-owned subsidiary to serve as a blueprint for innovation (Summa Health) through the Health Assurance Transformation Company (HATCo), and shaping public policy that advances our health assurance thesis through the General Catalyst Institute, we are reimagining how healthcare is delivered.

The General Catalyst Institute is focused on the intersection of transformative technology, capital formation, and the public interest. We work to ensure that the benefits of the digital and biological revolutions are broadly shared and responsibly governed through sustained collaboration between the private and public sectors. Our expertise lies in identifying scalable solutions to complex societal challenges, particularly in healthcare delivery and access, and fostering the development of frameworks that enable rapid innovation within secure and transparent regulatory environments. By bridging the gap between high-growth technology ecosystems and public policy, we support national priorities, including healthcare resilience and the modernization of care delivery to underserved populations.

Contact information for this submission includes **Charlotte Rock, reachable at crock@generalcatalyst.com and (917)-690-0668.**

Bottom Line Up Front

General Catalyst is deeply interested in serving as a prime contractor under the proposed FDA contract vehicle structure with our portfolio companies functioning as eligible subcontractors. We bring demonstrated capability through our recent and ongoing work with the Health Assurance Transformation Company (HATCo), a General Catalyst

transformation company that both operates an integrated health care system and partners with health systems to modernize and transform healthcare delivery. Our interest is backed by the proven success of HATCo Services, which already utilizes a prime contractor model to serve health systems. In this capacity, HATCo Services identifies, contracts, and bundles solutions from across the GC portfolio, providing health systems with a streamlined and managed 'prime' interface for diverse technological needs.

Our healthcare portfolio includes over 150 companies spanning medical devices, diagnostics, digital therapeutics, artificial intelligence-enabled clinical decision support, healthcare infrastructure, and regulatory technology. Specific portfolio examples include Aidoc with 18 FDA clearances providing AI-powered diagnostic imaging analysis; Paradigm Health, providing patients in underserved areas access to cutting-edge clinical trials; Hippocratic AI, demonstrating massive scalability in addressing workforce shortages; and Commure, providing healthcare infrastructure and real-world evidence (RWE) aggregation. These companies have undergone rigorous due diligence regarding technical feasibility, market viability, regulatory pathway clarity, and team capability.

The barriers we foresee are significant but surmountable. Managing conflicts of interest requires independent evaluation panels and transparent scoring criteria. Portfolio fluidity requires quarterly updates with clear eligibility thresholds. Intellectual property concerns require tiered data rights frameworks. Compliance burdens require simplified pathways proportionate to contract size and risk. The structural requirements necessary for success include clear eligibility criteria for portfolio companies, flexible task order mechanisms that accommodate diverse capabilities, prime contractor responsibility for compliance assistance and federal contracting education, provisions for regular portfolio reviews, and prioritization of domestic manufacturing and supply chain resilience.

We strongly recommend the FDA launch an initial pilot program with two to three venture capital firms across different investment focus areas to identify and resolve implementation challenges before full-scale deployment. This pilot should run for 18 to 24 months with defined task orders testing competition among portfolio companies, compliance pathway effectiveness, intellectual property management, and administrative efficiency. A phased approach with clear milestones for engagement, partnership agreements, federal funding notifications, sub-award agreements, site selection, workforce recruitment, technology platform integration, and phased deployment could provide a proven template to replicate this structure permanently.

Detailed Responses

(Interest and Feasibility)

1. Prime/Subcontractor Model: Would your firm be interested in functioning as a prime contractor such that any of your portfolio companies can be treated as subcontractors?

GCI Response: General Catalyst is highly interested in serving as a prime contractor under this proposed structure. We currently serve a crucial role in coordinating complex technology deployments on behalf of our portfolio companies through HATCo Services, managing simultaneous integrations across regional health systems. This contract vehicle aligns directly with our mission to bridge high-growth technology ecosystems and public policy to support national priorities in health innovation and regulatory modernization.

Supporting Evidence: We have already refined this exact structure through HATCo Services. HATCo manages the entire lifecycle of the prime-subcontractor relationship—contracting with portfolio companies, bundling their services into cohesive offerings, and managing the resulting delivery to large-scale health systems. This demonstrates our existing capability to serve as the single point of accountability for the FDA.

Expected Impact: Implementing this prime contractor model will enable the FDA to access breakthrough technologies from the startup ecosystem while maintaining appropriate federal oversight. By serving as a strategic integrator, we can provide the FDA with a curated pipeline of vetted, investment-backed technologies while individual portfolio companies focus on their core mission of developing and delivering innovative solutions. This model will accelerate the FDA's ability to leverage artificial intelligence, biotechnology, medical devices, digital therapeutics, and regulatory science tools.

2. Anticipated Hurdles: What barriers or challenges do you foresee with this approach?

GCI Response: The primary barriers fall into four categories. First, managing potential conflicts of interest between venture capital firm incentives and federal procurement requirements. Second, the dynamic nature of venture capital portfolios creates administrative complexity as companies are constantly being acquired, failing, pivoting business models, or graduating to larger-scale operations. Third, intellectual property and data rights considerations may deter portfolio company participation if the terms create unintended technology-transfer obligations. Fourth, compliance requirements designed for established government contractors may be prohibitively burdensome for early-stage startups that lack dedicated federal contracting staff, financial systems capable of government auditing standards, or cybersecurity infrastructure meeting federal requirements.

Supporting Evidence: Our experience advising portfolio companies on government engagement has demonstrated that early commitment to pursue prime contractor status provides significant first-mover advantages in workforce recruitment, securing the best talent before competitive programs launch. State partnerships benefit from preferred vendor status with Medicaid agencies. Technology capacity depends on platform partner availability before market saturation. Community trust requires rural relationship building before competitive alternatives emerge. These dynamics demonstrate that managing a portfolio of technology providers requires careful coordination of timelines, capabilities, and

stakeholder relationships. In addition, HATCo's health system transformation work illustrates that the model works when there is clear alignment on objectives, transparent processes for partner selection, and ongoing communication.

Expected Impact: Addressing these barriers through proper contract design will be essential to success. Conflicts of interest can be managed through independent evaluation panels, transparent scoring criteria published in advance, and requirements that prime contractors recuse themselves from technical evaluations. Portfolio fluidity can be accommodated through quarterly portfolio updates with clear eligibility criteria for adding or removing companies based on objective thresholds. Intellectual property concerns can be addressed through tiered data rights frameworks where the government receives appropriate access for specific tasks while companies retain broader commercial rights. Compliance burdens can be reduced through simplified pathways proportional to contract size and risk, such as streamlined cybersecurity requirements for contracts under certain dollar thresholds or phased compliance where companies meet basic standards initially and scale to full requirements as contract values increase.

(Structural Requirements)

3. Regulatory Alignment: Current government contracting regulations would require that the VC firm be the Prime and any portfolio companies providing technology or services be subcontractors. Is this a structure your firm can support? If not, please provide feedback on a type of structure that would work.

GCI Response: We fully support this structure and believe it is the most viable path forward for integrating startup innovation into federal workflows. Our experience demonstrates that a centralized coordinator is necessary to align diverse technology providers with complex federal requirements. The prime contractor serves as the strategic integrator that translates FDA requirements into accessible opportunities for innovators, providing the scaffolding necessary for early-stage companies to successfully deliver while the agency focuses on core regulatory science.

Supporting Evidence: We convene proven solutions that expand access without requiring new capital-intensive facilities and, with this model, can leverage advocacy through the General Catalyst Institute to ensure applications align with federal priorities. This centralized model ensures that all participants remain in compliance with federal acquisition regulations while focusing on technical delivery. The value for stakeholders is clear. Hospitals and providers get expanded access to capital, technology, and workforce solutions. Communities get better access to care locally. The federal government gets demonstration sites that generate data and proof points for scalable sustainable models.

Expected Impact: This structure will result in a more agile regulatory environment that can respond effectively to emerging health threats and technological breakthroughs. It provides the FDA with a single point of contact for complex technology deployments, reducing the

burden on agency contracting officers. By adopting this framework, the FDA can focus its internal resources on its core mission of safety and efficacy while utilizing the private sector to manage the coordination of diverse technology providers while maintaining the highest standards of efficacy and safety.

4. IP Management: How should intellectual property rights be structured and protected?

GCI Response: Intellectual property and data rights should be managed through a tiered framework where the government receives appropriate access for specific tasks while companies retain their broader commercial rights. It is essential to distinguish between proprietary intellectual property that companies bring to the work (including extensions thereof and improvements thereto) and custom intellectual property separately developed during performance. Clear protections for proprietary algorithms, datasets, and manufacturing processes are necessary to ensure that participation in federal contracts does not jeopardize a company's commercial viability or future investment potential.

Supporting Evidence: By establishing clear boundaries and data rights in our large-scale healthcare partnerships, we have successfully facilitated collaborations between innovative firms and public sector stakeholders without compromising underlying technology.

Expected Impact: Clear intellectual property management will increase the participation of top-tier technology firms in FDA initiatives. When companies feel their core innovations are secure, they are more likely to bring their best solutions to the federal government. The tiered framework provides the government with the access it needs for mission-critical tasks while preserving the commercial incentives that drive continued innovation and investment in breakthrough technologies. This balance is essential for creating a sustainable procurement vehicle that attracts the most innovative companies rather than deterring them through overly broad intellectual property transfer requirements.

(Venture Capital Firm Qualifications)

5. Governance Oversight: How should the FDA evaluate a firm's track record in portfolio company oversight and governance?

GCI Response: The FDA should evaluate a firm based on its demonstrated ability to manage complex multi-stakeholder initiatives and its history of supporting companies through rigorous regulatory pathways. Our health systems transformation work demonstrates our governance capabilities, as we coordinate technology deployments across multiple jurisdictions and capabilities. This involves ensuring that all partners meet strict performance metrics and alignment on goals.

Supporting Evidence: The FDA can look to the governance framework of HATCo Services, which proactively manages its subcontractors (portfolio companies) to ensure they meet the high integration and performance standards required by its health system customers. HATCo Service's role as a prime contractor includes rigorous oversight of these bundled

services to ensure seamless, managed delivery. When deploying advanced technologies within complex health systems, we implement a rigorous oversight framework that bridges the gap between startup agility and institutional requirements. HATCo Services will maintain institutional-grade feedback loops across multiple jurisdictions, ensuring that subcontractors within our ecosystem remain aligned with data standards, ethical guidelines, and performance milestones, providing the FDA with a transparent and reliable oversight mechanism that mitigates risk at the source.

Expected Impact: Robust governance oversight ensures that only the most capable and compliant companies are brought into the federal ecosystem. This reduces the risk of project failure and ensures that federal funds are being used effectively. By selecting firms with a proven track record of oversight, the FDA can leverage private sector expertise to maintain high-quality standards of performance across its technology providers. Strong governance will provide the agency with confidence that the prime contractor has the internal processes and expertise necessary to manage subcontractor performance, ensure compliance with federal requirements, and maintain continuity of service delivery even as portfolio composition evolves over time.

6. Financial Requirements: What financial stability and bonding requirements should apply to participating VC firms?

GCI Response: Financial requirements should be commensurate with the scale of the contract vehicle but should also recognize the unique capital structure of venture capital firms. Flexible financial frameworks should prioritize project milestones and delivery over static bonding. This approach ensures financial accountability while allowing for the rapid deployment of capital and resources to meet urgent needs.

Supporting Evidence: Our financial capability to manage complex initiatives at scale is proven through our ongoing coordination of large-scale healthcare partnerships involving multi-system technology deployments. While still in the early stages, HATCo Services will successfully streamline the financial administration for health systems by bundling multiple portfolio company services into a single prime contract. This model significantly reduces invoicing complexity for the customer while ensuring that individual portfolio subcontractors are paid through a centralized, managed process. This orchestration expertise ensures that the prime contractor, HATCo Services, acts as a financial backstop, providing the system with the necessary fiscal protections while enabling innovative, high-growth companies to participate in federal missions without the prohibitive upfront costs of traditional performance bonding.

Expected Impact: Appropriate financial requirements will ensure the stability of the contract vehicle without stifling innovation. By adopting modern financial standards that recognize the unique structure of venture capital firms, the FDA can attract a wider range of sophisticated investment firms to serve as prime contractors. This leads to a more competitive and resilient procurement ecosystem that can support long-term agency goals.

The financial framework should provide the government with appropriate protections while recognizing that venture capital firms operate under different capital structures than traditional government contractors and that overly rigid bonding requirements could exclude the most capable firms from participating.

7. Firm Criteria: Should there be requirements related to the firm's investment thesis, sector focus, assets under management, years in operation, or geographic presence?

GCI Response: Yes, the FDA should prioritize firms with a clear investment thesis in healthcare, life sciences, and technology, as well as a proven sector focus that aligns with the agency's mission. Our investment thesis is centered on health assurance and national resilience, which has led us to support companies that are directly relevant to the FDA's regulatory and health innovation mandates. Our healthcare portfolio includes over 150 companies spanning medical devices, diagnostics, digital therapeutics, artificial intelligence enabled clinical decision support, healthcare infrastructure, and regulatory technology.

Supporting Evidence: Our commitment to these criteria is evidenced by our healthcare portfolio, which includes over 150 companies spanning medical devices, diagnostics, digital therapeutics, AI-enabled clinical decision support, and healthcare infrastructure. We prioritize investments in "Health Assurance"—a thesis dedicated to making healthcare more proactive, accessible, and affordable—which aligns directly with the FDA's public health mandates. Our experience managing complex initiatives across multiple jurisdictions demonstrates both our geographic reach and our operational capacity to coordinate large-scale federal initiatives. By orchestrating partnerships that include AI-powered diagnostics (Aidoc), care coordination (Hippocratic AI), and healthcare infrastructure (Commure), we have proven that a sector-focused firm can provide the FDA with a curated, high-fidelity pipeline of innovation that a generalist firm cannot replicate.

Expected Impact: Establishing clear firm criteria will ensure that the FDA partners with organizations that have a deep understanding of the regulatory and technical landscape. This alignment reduces the learning curve for the prime contractor and leads to more effective communication between the agency and its technology providers. The result is a more targeted and impactful procurement process that connects the agency with firms that have the sector expertise, portfolio depth, and operational capacity necessary to successfully manage this novel contract vehicle. Firm criteria should be designed to identify partners with genuine capability and commitment to the FDA's mission rather than creating arbitrary barriers that exclude qualified firms.

8. Ongoing Compliance: What ongoing certification or recertification processes should be established for participating firms?

GCI Response: Ongoing compliance should involve regular portfolio reviews and annual recertifications to ensure that the prime contractor and its subcontractors continue to meet federal standards. General Catalyst has the ability to maintain regular reporting cadences to ensure that all stakeholders are informed of progress and that any issues are addressed

proactively. This model of ongoing oversight ensures that the project remains on track and that all participants are held to the highest standards of performance.

Supporting Evidence: Our capability to manage ongoing compliance at scale is demonstrated through our management of complex technology deployments where we maintain rigorous monitoring of project milestones and adherence to evolving regulations. In executing contracts, HATCo Services will utilize standardized templates and digital reporting tools to ensure that data from diverse subcontractors remains accurate, timely, and aligned with institutional priorities. This phased approach—spanning from initial launch to long-term sustainability—enables HATCo Services to synchronize complex, multi-jurisdictional initiatives while maintaining continuous alignment. This experience in maintaining regular reporting cadences ensures that potential issues are addressed proactively, allowing for iterative improvements and providing a proven template for the sustained oversight required in a federal innovation sandbox.

Expected Impact: Regular recertification processes will maintain the integrity of the contract vehicle over time. It ensures that the FDA is always working with the most capable and compliant partners and that the portfolio remains aligned with evolving agency needs. This proactive approach to compliance reduces the risk of long-term project drift and ensures sustained value for the government. Ongoing compliance mechanisms provide the agency with visibility into portfolio health and performance while creating accountability for both the prime contractor and subcontractors to maintain high-quality standards throughout the contract period.

9. Regulatory Assurance: How should the FDA assess a firm's capability to ensure portfolio company compliance with federal contracting requirements?

GCI Response: The FDA should assess a firm's capability by reviewing its internal compliance infrastructure and its history of supporting companies through complex regulatory environments. The Prime Contractor’s role is to serve as the single point of accountability, ensuring that federal requirements are integrated into the subcontracting agreements from the outset. Rather than managing the granular administrative tasks of each subcontractor, the Prime Contractor provides the centralized oversight and legal framework necessary to ensure all portfolio companies operate within federal compliance. This model allows the FDA to interact with a single, sophisticated entity while ensuring that all downstream participants are contractually obligated and technically equipped to meet federal expectations.

Supporting Evidence: Our portfolio companies have navigated rigorous FDA clearance processes. We provide our partners with the strategic guidance and referrals to the technical resources necessary to meet these requirements, serving as a bridge between innovative technology and regulatory expectations. This experience demonstrates our capability to act as a regulatory assurance partner for the FDA and to provide the compliance support necessary for portfolio companies to successfully engage with federal

contracting requirements. We conduct thorough vetting of all technology partners to ensure they have the technical capability, financial stability, and regulatory compliance necessary to successfully deliver on project objectives.

Expected Impact: Strong regulatory assurance will reduce the administrative burden on the FDA by shifting the primary responsibility for subcontractor compliance to the prime contractor. This allows the agency to focus on its core mission while having confidence that its technology providers are meeting all necessary standards. By serving as the compliance integrator, the prime contractor ensures that portfolio companies receive the education and support necessary to meet federal requirements while the agency maintains appropriate oversight through the prime contractor relationship rather than managing compliance for dozens of individual subcontractors.

10. Organization Structure: What organizational structure or dedicated resources should firms maintain to support this contract vehicle?

GCI Response: We believe participating firms should maintain a dedicated office that serves as a specialized "central nervous system" between the FDA and the technology portfolio. To support this vehicle, we are prepared to finalize an organizational structure that integrates our existing policy and research expertise with new, execution-oriented services. This structure ensures that administrative complexity—such as FAR compliance, cybersecurity vetting (CMMC), and audit readiness—is handled at the Prime level, allowing subcontractors to remain focused on delivering technical breakthroughs.

Supporting Evidence: We have already established a robust organizational foundation through a dedicated policy and research institute led by global leaders in technology and public policy. This existing infrastructure provides the strategic "bridge" between emerging technology and the public interest, having already successfully coordinated multi-stakeholder health initiatives across multiple jurisdictions. To meet the specific requirements of the FDA FIRE vehicle, we are prepared to consider scaling this foundation. This will involve centralizing government procurement expertise, dedicated legal counsel for federal sub-award management, and technical project managers who understand the intersection of clinical data and federal security standards. By evolving our current platform orchestration model into a dedicated federal compliance arm, we ensure the FDA has a professional, single point of contact capable of de-risking startup innovation while maintaining institutional-grade accountability.

Expected Impact: A dedicated organizational structure ensures that the prime contractor has the capacity to manage the complexities of federal contracting. It provides the FDA with a reliable and professional partner that can respond quickly to agency needs and manage subcontractors effectively. This leads to better project outcomes and a more professional relationship between the public and private sectors. The organizational commitment demonstrates that the firm is treating this contract vehicle as a strategic priority rather than

an ancillary activity and has invested in the infrastructure necessary to ensure successful performance.

(Financial and Administrative Considerations)

11. Payment Efficiency: What payment and invoicing structures would be most efficient?

GCI Response: Payment structures should be streamlined through the prime contractor to ensure that subcontractors, particularly early-stage startups, receive timely payments. This approach maintains the momentum of the project and ensures that innovators can continue to focus on delivery rather than administrative delays. We recommend a milestone-based payment structure for research and development tasks and a subscription or usage-based model for commercial scale software and services.

Supporting Evidence: This approach is modeled on the HATCo Services framework, which is designed specifically to simplify access to innovation for large-scale health systems. Under this model, HATCo Services is structured to act as the primary contracting and financial intermediary, 'flowing through' payments to a curated bundle of portfolio subcontractors. By centralizing financial controls and administrative oversight, this model is built to provide the "parent" organization with full transparency while utilizing the Prime's institutional capacity to manage the cash-flow needs of smaller technology partners. This orchestration expertise ensures that all participants receive timely compensation, allowing them to remain focused on technical execution and regulatory alignment rather than administrative cash-flow management.

Expected Impact: Efficient payment structures will increase the attractiveness of the contract vehicle for the most innovative startups. When companies know they will be paid promptly for their work, they are more likely to prioritize government contracts. This leads to a more robust and competitive pool of technology providers for the FDA. Streamlined payment through the prime contractor reduces the administrative burden on both the agency and subcontractors while maintaining appropriate financial controls and audit trails. This approach recognizes that cash flow is often a critical constraint for early-stage companies and that payment delays can force startups to deprioritize government work despite strong mission alignment.

12. Financial Assurances: How should performance bonds, guarantees, or other financial assurances be handled?

GCI Response: Financial assurances should be handled through a combination of prime contractor accountability and performance-based contract terms. This ensures financial accountability while allowing for the rapid deployment of resources to meet project objectives.

Supporting Evidence: In our ongoing work with health systems, we have successfully managed complex portfolios of technology providers by acting as the strategic financial backstop.

Expected Impact: Modernizing financial assurances will allow the FDA to work with a broader range of innovative companies. By shifting the focus from static bonds to performance-based outcomes, the agency can ensure high quality delivery while reducing the financial friction that often prevents startups from engaging in federal work. The prime contractor serves as the financial backstop, providing the government with appropriate protections while enabling portfolio companies to participate without the prohibitive upfront costs of traditional bonding. This approach balances risk management with accessibility and ensures that the contract vehicle achieves its goal of engaging with the startup ecosystem.

13. Reporting Standards: What reporting requirements would be appropriate for both the VC firms and portfolio companies?

GCI Response: Reporting requirements should be standardized and digital to reduce administrative burden while providing the FDA with full transparency. This could include utilizing standardized templates and digital tools to ensure that all data is accurate and timely. This centralized reporting model allows us to provide a comprehensive view of project progress while minimizing the time spent on manual data entry for our technology partners. The prime contractor should provide quarterly reports on overall contract performance, financial status, and portfolio health.

Supporting Evidence: Our approach to standardized reporting is proven through our communication architecture with institutional partners and health systems. We maintain regular reporting cadences that translate complex, high-velocity technology updates into structured milestones aligned with policy objectives. In our healthcare transformation work, we utilize digital dashboards to provide stakeholders with a comprehensive view of project progress, financial flows, and compliance status across multiple jurisdictions.

Expected Impact: Standardized reporting will improve the FDA's ability to monitor contract performance and make data driven decisions. It provides a clear audit trail for federal funds and ensures that all participants are held accountable for their results. Digital reporting through a centralized portal reduces administrative burden for all parties while providing the agency with real time visibility into contract performance. This approach enables proactive management of issues and ensures that the contract vehicle delivers the expected value to the government.

(Regulatory and Compliance Framework)

14. Firm Compliance: What compliance requirements should apply to participating VC firms?

GCI Response: Participating firms should be required to meet high-quality standards for cybersecurity, financial auditing, and ethical conduct. In recent years, more and more VC firms have registered with the U.S. Securities and Exchange Commission under the Investment Advisers Act of 1940, which we did in 2019. The compliance requirements for an SEC-registered investment adviser (RIA) are far more stringent than for an unregistered firm, so we strongly recommend that only RIAs participate. As an RIA, we maintain a rigorous internal compliance program that ensures all our activities are conducted with the highest level of integrity and transparency. This commitment to compliance is a core part of our organizational identity and is essential for our work with government agencies.

Supporting Evidence: We maintain the internal controls and audit processes necessary to ensure accountability and transparency in all our public sector engagements. We conduct thorough vetting of all technology partners to ensure they have the technical capability, financial stability, and regulatory compliance necessary to successfully deliver on project objectives. This due diligence process protects government stakeholders and ensures that only qualified partners are included in applications.

Expected Impact: High compliance standards for prime contractors will ensure the security and integrity of the contract vehicle. It protects the FDA from potential risks and ensures that all technology providers are operating within a secure and ethical framework. This leads to greater public trust in the agency's procurement processes. Strong compliance requirements demonstrate that the contract vehicle maintains the same high-quality standards as traditional government contracting while providing the flexibility necessary to engage with the startup ecosystem. This balance is essential for ensuring that innovation does not come at the expense of security, accountability, or ethical conduct.

15. Conflict Management: How should conflicts of interest be identified and managed?

GCI Response: Conflicts of interest should be managed through clear firewalls between the firm's investment activities and its role as a prime contractor. By establishing objective criteria for partner selection and maintaining open communication with all stakeholders, it ensures that recommendations are based on technical merit and mission fit rather than other considerations. A VC firm should provide transparency into our partner selection process and work collaboratively with government stakeholders to ensure that all decisions are aligned with public interest objectives.

Supporting Evidence: Our commitment to managing potential conflicts is rooted in our experience in multiple business areas, including coordinating large-scale healthcare partnerships. In our work orchestrating technology deployments across multiple jurisdictions, we maintain internal conflict disclosure and reporting processes, as well as clear boundaries between strategic advisory roles and the technology providers we convene. We utilize technical vetting to ensure that the solutions we propose are fit for the mission.

Expected Impact: Effective conflict management will ensure the fairness and competitiveness of the contract vehicle. It prevents the perception of favoritism and ensures that the FDA is always getting the best value for its investment. This leads to a more credible and sustainable procurement model. Clear conflict management processes provide confidence to both the government and potential subcontractors that the contract vehicle operates with integrity and that task order awards are based on merit rather than the prime contractor's investment interests. This transparency is essential for maintaining the legitimacy of the procurement vehicle and ensuring broad participation from the startup ecosystem.

16. Due Diligence: What due diligence processes would be necessary for both firms and portfolio companies?

GCI Response: Due diligence should include a thorough review of a firm's financial stability, governance structure, and track record. For portfolio companies, due diligence should focus on technical feasibility, market viability, regulatory status, and cybersecurity posture. Our portfolio companies undergo rigorous due diligence as part of our investment process. We evaluate companies based on their technical innovation, clinical evidence, and ability to scale within the healthcare ecosystem. This deep due diligence serves as a pre-qualification mechanism that reduces risk for our partners and ensures that we are only bringing the most capable solutions forward.

Supporting Evidence: Our due diligence model is proven through our history of vetting thousands of healthcare companies to identify those with the highest potential for impact. In our healthcare transformation work, we conduct thorough vetting of all technology partners to ensure they possess the cybersecurity infrastructure, financial stability, and regulatory compliance necessary to deliver on project objectives. This deep institutional knowledge allows us to act as a high-fidelity filter, orchestrating best-in-class partners rather than building unproven solutions from scratch and providing the FDA with an execution-ready pipeline of vetted innovation.

Expected Impact: Robust due diligence ensures that the FDA is working with high-quality, reliable technology providers that have already survived rigorous private-sector scrutiny. This leads to more successful project outcomes and a more resilient procurement ecosystem where federal funds are allocated only to the most capable firms. By shifting the burden of deep technical vetting to the Prime, the FDA can focus its resources on final regulatory science and mission-critical oversight.

(Implementation Timeline and Process)

17. Rollout Schedule: What would be a reasonable timeline for implementing such a vehicle?

GCI Response: A reasonable timeline would involve a phased rollout over 18 to 24 months. The first six months should focus on contract design, firm selection, and the establishment of governance structures. The following twelve months should involve an initial pilot

program with a limited number of task orders to test the model and identify implementation challenges. The final six months should be used to refine the process based on lessons learned before full-scale deployment.

Supporting Evidence: Our commitment to structured, phased implementation is demonstrated through our history of orchestrating large-scale technology deployments that require rapid coordination across multiple jurisdictions. We have managed initiatives with compressed timelines—moving from initial engagement and partnership agreements to full technology platform integration and phased deployment within defined fiscal windows. By setting clear milestones for workforce recruitment, site selection, and sub-award agreements, we have proven that complex, multi-stakeholder health programs can be launched effectively without compromising quality or compliance. This experience in platform orchestration ensures that we can provide the FDA with a proven template for rapid mobilization, allowing for the transition from a pilot concept to a nationwide innovation sandbox within the proposed 24-month window.

Expected Impact: A phased rollout will allow the FDA to identify and resolve implementation challenges in a controlled environment. It ensures that the contract vehicle is fully vetted before it is scaled, reducing the risk of systemic issues. The result is a more stable and effective procurement pathway for the agency. The phased approach provides opportunities for course correction based on real world experience and ensures that the final contract structure reflects lessons learned from the pilot phase. This reduces the risk of large-scale implementation of an untested model and provides confidence to all stakeholders that the vehicle has been thoroughly validated before full deployment.

18. Strategic Phasing: What pilot or phased approach would be most effective?

GCI Response: The most effective approach would be to launch an initial pilot program with two to three venture capital firms across different investment focus areas, such as medical devices, digital health, and artificial intelligence. This pilot should include a defined set of task orders that test various aspects of the model, including competition among portfolio companies, compliance pathways, intellectual property management, and overall administrative efficiency compared to traditional procurement vehicles.

Supporting Evidence: Our commitment to strategic phasing is proven by our track record of orchestrating complex healthcare transformations that move from focused demonstrations to large-scale deployments. By utilizing a modular scaling strategy, we have successfully managed initiatives that begin with foundational infrastructure—such as care navigation and interoperability platforms—before expanding to broader populations and integrating into long-term value-based arrangements. This experience would ensure that federal resources are allocated to proven capabilities while maintaining the flexibility to course-correct based on real-time feedback from both providers and regulators, providing a reliable template for the FDA to bridge the gap between startup innovation and institutional stability.

Expected Impact: Strategic phasing will ensure that the contract vehicle is optimized for the FDA's specific needs. It allows the agency to test different configurations and identify the most effective ways to engage with the startup ecosystem. This leads to a more robust and impactful procurement model. The pilot provides real-world data on what works and what needs adjustment, enabling the agency to refine the contract structure based on evidence rather than assumptions. This approach reduces risk and increases the likelihood of long-term success for the contract vehicle.

19. Industry Collaboration: What industry engagement would be necessary during development?

GCI Response: The FDA should engage in continuous dialogue with the venture capital community, startup founders, and traditional government contractors during the development of this vehicle. We regularly participate in public-private dialogues and provide feedback to federal agencies on how to improve procurement and regulatory processes. This collaborative approach ensures that the final policies are informed by real-world experience and are more likely to achieve their intended goals.

Supporting Evidence: We maintain ongoing relationships with both government agencies and private sector innovators, positioning us to facilitate the dialogue necessary for successful contract vehicle development. Our phased approach could include listening sessions to conduct joint discussions with provider associations, health systems, and innovation partners to align local needs and integration opportunities.

Expected Impact: Industry collaboration will ensure that the contract vehicle is well-received by the market and attracts the best technology providers. By incorporating feedback from a wide range of stakeholders, the FDA can create a procurement pathway that is both innovative and practical. This leads to a more successful and sustainable program for the agency. Continuous engagement ensures that the contract vehicle evolves based on stakeholder input and remains aligned with both government needs and private sector capabilities. This collaborative approach increases buy-in from all parties and improves the likelihood of successful implementation and long-term adoption.

Enabling Nationwide Impact

The adoption of a venture capital firm as a prime contractor model represents a strategic imperative for strengthening national resilience. Our demonstrated capability in orchestrating healthcare transformation provides concrete evidence of nationwide impact potential. By coordinating a diverse technology stack—spanning AI-powered diagnostics, care coordination platforms, and interoperability infrastructure—we expand access to primary care and chronic disease management without requiring capital-intensive facilities.

The model deployed through HATCo Services—where a prime contractor proactively curates and bundles portfolio innovation—is ready to be scaled for federal use. This

approach ensures that the most impactful products and services reach those who need them most, managed through a single, accountable, and strategic partner. Health systems gain an execution-ready partner; providers gain access to technology; and the federal government gains demonstration sites that generate data and proof points for scalable models.

Conclusion

General Catalyst is supportive and prepared to serve as a cornerstone partner in an FDA pilot program for the FIRE model. We bring a healthcare portfolio of over 150 companies, proven experience in managing complex multi-stakeholder health initiatives, and deep relationships with both government agencies and private sector innovators. We stand ready to provide additional detail and serve as a pilot partner to accelerate health innovation for the American people.

Respectfully submitted,

Teresa Carlson

President
General Catalyst Institute
tcarlson@generalcatalyst.com

FDA Requested Information

Company Information & Point of Contact

Company Name: General Catalyst Group Management, LLC

Mailing Address: 20 University Road, Fourth Floor, Cambridge, MA 02138

Point of Contact:

- **Name:** Charlotte Rock
- **Title:** Vice President of Public Policy, Healthcare
- **Telephone:** (917)-690-0668
- **Email:** crock@generalcatalyst.com
    - *Note: This individual has the authority and knowledge to clarify responses with Government representatives.*

Registrations & Identifiers

SAM Status: Not Registered

Unique Entity Identifier (UEI): N/A

Socio-Economic Status: N/A

Proposed NAICS Code: 523910-03

GSA Schedule: N/A