



August 28, 2024

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2024-N-2886 for Food and Drug Administration Customer Experience Strategy for Fiscal Years 2024 to 2027**

To Whom it May Concern:

Accumulus Synergy, Inc. (“Accumulus”) appreciates the opportunity to provide feedback to the Food and Drug Administration (FDA or the Agency) on FDA’s Customer Experience Strategy for Fiscal Years 2024 to 2027 (CX Strategy). Accumulus applauds the Agency’s commitment to improve the internal and external customer experience. Accumulus considers FDA’s CX Strategy to be a crucial component to enhancing the efficiency and effectiveness of regulatory processes, ultimately benefiting public health and fostering innovation.

Accumulus is a non-profit industry association working to address the global need for digital transformation. Accumulus’ mission is to dramatically accelerate access to therapies by reimagining the way stakeholders across the life sciences and regulatory ecosystems interact and exchange information. Accumulus is developing a transformative cloud-based information exchange platform to enable efficient collaboration between the life sciences industry and national regulatory authorities. The common-platform approach aims to drive improvements in the regulatory process by leveraging advanced technology, including data science and artificial intelligence (AI), as well as tools for secure information exchange to improve patient safety, help reduce the cost of innovation, and bring patients safe and effective medicines faster. Accumulus will work with partner companies, key stakeholders, and global health authorities to build and sustain a platform that meets regulatory, cybersecurity, and privacy requirements spanning clinical, safety, chemistry and manufacturing, and regulatory exchanges and submissions.

**FDA QUESTIONS ON INFORMATION TECHNOLOGY STRATEGY**

**1. Which goals and objectives are most important to you? Why?**

Deploy Inclusive Platforms

Deploying inclusive platforms is crucial to ensuring that FDA systems are accessible and meet the needs of all users, both internal and external, including those with varying levels of technological maturity. Modernizing these platforms and conducting extensive testing helps create a consistent user experience across different devices. This inclusivity and consistency enhance usability, improve efficiency, and ensures that everyone, regardless of their technological expertise or the device they use, can access and benefit from the Agency’s resources and services.

## Issue Customer Experience (CX)/User Experience (UX) Roadmap

Accumulus believes a CX/UX Roadmap is important because it clearly outlines the Agency's strategy to enhance interactions with its stakeholders. By publishing this information, the Agency demonstrates its commitment to providing the best possible experience for its users. Regular updates to the roadmap ensure that it remains relevant and aligns with ongoing and future CX/UX projects and initiatives. This transparency and continuous improvement foster trust and engagement, ultimately leading to more effective and satisfactory interactions between the Agency and its stakeholders.

## Rollout the Latest Technology and Tools to Facilitate Work

Improving collaboration tools and communication channels can strengthen working relationships with the FDA, sponsors, and other national regulatory authorities, fostering a shared understanding of the FDA's digital transformation initiatives. Modern tools can streamline processes, reduce wait times, and improve response times for stakeholder inquiries. Enhanced accessibility can provide more user-friendly and accessible platforms, making it easier for stakeholders to interact with the FDA across different devices and different levels of technological proficiency. Additionally, cutting-edge technology, such as AI and data analytics, can offer a better customer experience by better understanding needs, and up-to-date communication tools can improve the quality and clarity of interactions with the Agency and with external stakeholders. Finally, modern tools can include improved security to protect the exchange of data and information, fostering trust in the Agency's ability to protect sensitive information.

## Build Public Trust

Creating customer-centric solutions is crucial for enhancing stakeholder satisfaction and engagement with FDA IT services. Simplifying and optimizing processes makes them more efficient, reducing the time and effort required for internal and external users to adopt IT solutions. Considering regional-specific needs and requirements ensures that IT solutions are effective for all users and enhances satisfaction, engagement, and adoption. Prioritizing stakeholder engagement allows for FDA to better understand and address the needs and concerns of its stakeholders, fosters a sense of partnership, and leads to stronger adoption of FDA IT solutions. Additionally, timely and externally facing communication is essential to keep stakeholders informed and engaged, facilitating transparency and trust in FDA initiatives.

## **2. What gaps do you see in the CX Strategy's goals or objectives?**

### Definition of "External Stakeholder"

Accumulus acknowledges that the term "external stakeholder" can encompass the expansive number of individuals, groups, and organizations that the Agency serves and collaborates with. However, without a clear and comprehensive understanding of who constitutes an external stakeholder, the Agency risks overlooking critical perspectives and needs. This ambiguity can lead to misaligned priorities, insufficient stakeholder engagement, and ineffective communication strategies. The FDA may also struggle to tailor its programs and policies to address the diverse concerns and expectations of different groups, such as patients, global national regulatory authorities, and industry representatives. This gap can hinder the FDA's ability to foster robust partnerships, gain valuable insights, and ultimately achieve its mission of protecting and promoting public health.

## Data and Information Exchange

Accumulus appreciates the Agency's acknowledgement of the need for collaboration tools, however an excessive focus on entry points into the FDA can hinder the Agency's ability to effectively collaborate on a global scale. While improving entry points to facilitate access for stakeholders is essential, neglecting the broader aspect of global information and data exchange can limit the FDA's capacity to share and receive critical data with international regulatory agencies, industry partners, and other stakeholders. This may lead to duplicated efforts and missed opportunities for leveraging global insights. The FDA should consider a CX Strategy that prioritizes seamless and secure global information exchange, ensuring that valuable knowledge and innovations are shared globally, which will enhance the FDA's role in the global regulatory landscape, improve its responsiveness to international health challenges, and foster stronger, more cohesive partnerships worldwide.

### **3. What has been your customer experience when interacting with FDA?**

Accumulus is grateful for the Agency's commitment to public health and the frequent interactions and communication with highly knowledgeable and dedicated staff. However, one challenge has been navigating through various siloes within the Agency, where information can be compartmentalized and can lead to inconsistent or unclear information. A lack of cross-functional transparency in communication can exacerbate these challenges, making it difficult for stakeholders to align objectives and effectively plan their own internal strategies.

### **4. What is one thing FDA can do to improve your customer experience?**

Accumulus suggests that customer engagement should be treated as a strategic tool for enhancing the Agency's IT and customer experience initiatives. By actively involving industry stakeholders in the development and refinement of IT systems and processes, the FDA can ensure that these platforms are efficient and tailored to meet the needs of their users. Viewing the industry as partners rather than simply regulated entities fosters a collaborative environment where feedback is not only welcomed but actively sought. This approach can help the FDA identify and address pain points, streamline communication, and develop more effective and transparent systems. By leveraging the insights and expertise of their industry partners, the FDA can create a more integrated and responsive customer experience, ultimately leading to better regulatory outcomes and greater satisfaction for all stakeholders involved.

## **CONCLUSION**

Accumulus thanks the Agency for the opportunity to share our thoughts on the CX Strategy and we look forward to the implementation of such an important initiative. We welcome the chance to further collaborate with the FDA to provide our regulatory and technological expertise as we all work to accelerate access of therapies to patients worldwide.