



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 Information Technology Strategy**

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 Information Technology Strategy (IT Strategy). Accumulus applauds the Agency’s commitment to continually advancing FDA’s technology maturity and highlights its previous comments on FDA’s Data and Technology Strategic Plan and IT Strategy.<sup>1 2</sup> Accumulus considers FDA’s IT Strategy to be a key component of the Agency’s data and technology transformation initiative. Once implemented, Accumulus believes the IT Strategy will enhance communication pathways and collaboration between FDA and sponsors, ultimately expediting access to new medical products.

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?**

Accelerate Cloud Adoption

Accumulus believes that using cloud-based technology can improve communication between national regulatory authorities and sponsors, enhance information exchange, streamline regulatory processes, and speed up product development. Additionally, this technology will aid in implementing enterprise solutions across all FDA Offices and Centers, promoting greater transparency, collaboration, coordination, and communication. It will also enable national regulatory authorities and life sciences

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<sup>1</sup> See Accumulus’ Comments Letter on “FDA Data and Technology Strategic Plan,” May 31, 2023. Available at <https://www.regulations.gov/comment/FDA-2023-N-1052-0045>.

<sup>2</sup> See Accumulus’ Comments Letter on “FDA Information Technology Strategy,” October 30, 2023. Available at <https://www.regulations.gov/comment/FDA-2023-N-3636-0005>.

organizations to enhance transparency and knowledge management, empowering individuals to make informed healthcare decisions.

### Enhance Secure Information Exchange and Collaboration

As the amount and frequency of information exchanged among sponsors, the FDA, and other stakeholders rises, Accumulus recognizes the critical need to strengthen and enhance secure information exchange. Ensuring secure information exchange will promote interoperability, leading to a more streamlined and dynamic review process. Accumulus acknowledges that collaboration and communication among the FDA, sponsors, and other national regulatory authorities is critical to the drug development and review process, and while communication and collaboration exists today, it can be made better and improved. The current methods of sharing information between regulators and industry regarding drug products – via email and attachments, fax, and hard paper, are outdated and inefficient – increasing drug development time. Additionally, despite existing laws, regulations, and traditional practices posing barriers to improved collaboration, adopting cloud technologies can overcome many logistical and practical hurdles, facilitating greater cooperation while ensuring security and trust.

### Improve Customer Experience

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 are up to three outcomes the IT Strategy has helped or will help you achieve? Please provide examples.**

As previously mentioned, Accumulus believes that the FDA IT Strategy will lead to more dynamic and efficient review processes. Enhancing communication channels can improve working relationships between the FDA, sponsors, and other national regulatory authorities. Increased transparency in IT solutions, development, and execution can help establish a common understanding of the FDA's digital transformation efforts. Strengthening the FDA's cybersecurity defenses by partnering with trusted IT providers can boost industry and stakeholder confidence when exchanging confidential commercial information. Leveraging AI-driven innovations can enable the Agency to interpret and analyze complex data sets more quickly. Lastly, the FDA's dedication to improving secure information exchange, in line with international and industry standards, can streamline regulatory review processes and integrate data from multiple sources securely.

## **3. What gaps do you see in the IT Strategy?**

### Global Regulatory and Data Harmonization and Standardization

Accumulus suggests that the FDA IT strategy could support and encourage regulatory harmonization. Given the global nature of most drug development initiatives, such as Project Orbis, the CoGenT pilot, and the International Coalition of Medicines Regulatory Authorities (ICMRA) Regulatory Collaboration Pilots, there is a need to harmonize specifications, requirements, and standards. Accumulus recommends that the IT Strategy should, when possible, promote the alignment and harmonization of global regulatory

initiatives by leveraging the efforts of international collaborators, such as the International Council for Harmonisation (ICH). Additionally, Accumulus suggests that the IT strategy considers global data harmonization and standardization. Increased use of cloud technologies and secure data exchange relies upon adoption of structured data and harmonized data standards.

#### Technical Requirement Transparency

Lack of transparency in the technical requirements for IT services and solutions creates a significant gap that can affect the success of an organization's technology initiatives. When the specific technical needs are not clearly communicated, it leads to misalignment between stakeholders and external partners. This can result in misunderstandings, inefficient resource allocation, and delays as stakeholders work towards different or unclear objectives. The absence of clear technical requirements also impedes the ability to accurately measure progress and performance, making it difficult to identify and address issues promptly, hindering innovation and reducing the Agency's ability to adapt to changing technological landscapes.

#### **4. What challenges or risks do you foresee in executing the IT Strategy beyond those captured in the IT Operating Plan?**

##### Delays in Implementation

As noted in the PDUFA VII Cloud Assessment Summary,<sup>3</sup> the FDA continues to face technical, financial, process, and policy challenging that is impacting its interactions with industry and its ability to utilize cloud solutions. Further, as described in the FDA IT Operating Plan,<sup>4</sup> Accumulus agrees that siloes will lead to lack of prioritization, focus, wasted resources, and missed opportunities. Delays in implementation can have several detrimental effects, such as overspending as prolonged timelines can often increase costs due to extended use of legacy resources. Stagnation can also occur, stalling progress and innovation and preventing timely introduction of new technologies that could benefit public health. Moreover, these delays can erode public trust in the FDA's ability to act as an effective leader in public health by giving the impression that the FDA is slow to act or inefficient in its processes. Timely implementation is crucial for maintaining both the efficiency and the credibility of the FDA as a leading global regulatory authority.

##### Resources

Accumulus notes that the implementation of the IT Strategy will require significant funding and staffing with the right skill set. Accumulus applauds the Agency for recognizing the need to further expand and enhance their technology workforce. However, as described in the PDUFA VII Cloud Assessment Summary for example, the "current staffing capacity and knowledge base is not sufficient to support an optimal path to cloud."<sup>5</sup> Accumulus encourages the Agency to be transparent about their technology recruitment efforts.

#### **5. How have you leveraged the IT Strategy and/or Operating Plan since they were published in 2023?**

Since the IT Strategy and Operating Plan was published in 2023, Accumulus has been in the process of reviewing and aligning our current initiatives with the outlined objectives and goals. We continue to

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<sup>3</sup> Eagle Hill, "PDUFA VII Cloud Assessment Summary," December 2023. Available at <https://www.fda.gov/media/175118/download?attachment>.

<sup>4</sup> FDA, "IT Operating Plan," February 2024. Available at <https://www.fda.gov/media/177127/download?attachment>.

<sup>5</sup> Eagle Hill, "PDUFA VII Cloud Assessment Summary," December 2023. Available at <https://www.fda.gov/media/175118/download?attachment>.

actively integrate its principles into our planning processes to ensure our efforts are in sync with the Agency's strategic direction. We look forward to continued engagement with the FDA as the Agency continues to advance the transformation of FDA's IT capabilities.

**6. How might FDA continue to communicate and engage interested parties in developing and implementing the strategy?**

Accumulus values the ongoing opportunities to offer feedback to the Agency, and the FDA can continue to communicate and engage with stakeholders through several key initiatives. Transparent and consistent communication can be achieved by providing regular updates and reports on the strategy's progress via newsletter, press releases, and the FDA's official website, which helps build trust. Public meetings and virtual town halls enable direct engagement and discussion with stakeholders, while the creation of advisory panels and working groups brings in diverse perspectives from those who typically lack opportunities for interactive feedback. Additionally, implementing pilot and demonstration projects will showcase practical applications and allow the Agency to share outcomes, facilitating the effective and inclusive development and implementation of the IT strategy.

**CONCLUSION**

Accumulus is ready to collaborate with the FDA to support the ongoing development and implementation of the IT Strategy. We believe that our expertise and experience in these areas could be valuable in helping to advance innovative IT solutions at the Agency. We are grateful for the opportunity to share our thoughts on the IT Strategy and look forward to the chance for further collaboration.