October 30, 2023

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

Re: Docket No. FDA-2023-N-3636 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.[1] Accumulus also recognizes that the issuance of this documents fulfills the Agency's commitment under the most recent Prescription Drug User Fee Act (PDUFA) agreement and under the Consolidated Appropriations Act, 2023.[2] 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 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 global health authorities. The common-platform approach aims to improve efficiencies in the regulatory process by leveraging advanced technology, including data science and 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.

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[1] 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.

[2] PDUFA VII: Fiscal Years 2023-2027. Available at https://www.fda.gov/industry/prescrip□on-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027. H.R.2617 Consolidated Appropriations Act, 2023, Sec. 3627. Available at https://www.congress.gov/bill/117th-congress/house-bill/2617/text.

FDA QUESTIONS ON INFORMATION TECHNOLOGY STRATEGY

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

Accelerate Cloud Adoption

Accumulus believes that the adoption and use of cloud-based technology can enhance communication between health authorities and sponsors, improve information exchange, streamline regulatory processes, and ultimately accelerate product development. In addition, cloud-based technology will assist with implementing enterprise solutions that can be used by all FDA Offices and Centers for greater and more efficient transparency, collaboration, coordination, and communication. It will also enable health authorities and life sciences organizations to improve transparency and knowledge management, providing individuals the opportunity to make informed healthcare decisions.

Enhance Communication and Collaboration

Accumulus notes that collaboration and communication between FDA, sponsors, and other health authorities remains a challenge. While certain laws, regulations, and legacy practices are a barrier to greater collaboration, the adoption of cloud technologies can address many of the logistical and practical challenges to greater cooperation.

Enhance Secure Information Exchange

As the volume and frequency of information exchanged among sponsors, FDA, and other stakeholders increases, Accumulus agrees that fortifying and enchaining secure information exchange is essential. Secure information exchange will enable interoperability, ultimately resulting in a more streamlined and dynamic review paradigm.

2. **Describe up to five ways the FDA IT Strategy will impact your industry.**

As noted above, Accumulus believes that the FDA IT strategy will ultimately result in more dynamic, efficient, and collaborative review processes. Specifically, enhancing communication channels can lead to an enhanced working relationship between FDA and sponsors, and amongst FDA and other health authorities. Meanwhile, greater transparency on IT solutions, development, and execution can help establish a common understanding of FDA's digital transformation efforts. Upgrading FDA's cybersecurity defenses, by working with trusted IT partners, can further enhance both industry and stakeholder's trust in the Agency when transmitting confidential commercial information. Exploring and adopting innovations driven by artificial intelligence (AI) can help the Agency interpret and analyze complex data sets more quickly. Lastly, FDA's commitment to improving secure information exchange in conjunction with international and industry standards can streamline regulatory review processes and support interoperability and efficiency to regulatory review processes, allowing for the

integration of data from multiple sources in a secure location as well as serve as a repository for the exchange of information between all stakeholders.

3. **What gaps do you see in the FDA IT Strategy's goals or objectives?**

Accumulus suggests that the IT Strategy could support and promote regulatory harmonization. There is a need for global harmonization of specifications, requirements, and standards for how processes are validated. Considering the global scope of most drug development programs, Accumulus suggests that the IT Strategy should, when feasible, promote the alignment and harmonization of global regulatory initiatives by leveraging the work of international collaborators, such as the International Council for Harmonisation (ICH).

Moreover, Accumulus suggests FDA's IT strategy considers data harmonization and standardization as well. Increased use of cloud technologies and secure data exchanges is reliant upon the adoption of structured data and harmonized data standards. Accumulus highlights current initiatives around structured data including FDA's Pharmaceutical Quality - Chemistry, Manufacturing & Controls (PQ/CMC)[3] and the European Medicine Agency's (EMA) Substances, Products, Organisations and Referentials (SPOR) Data Management Services.[4]

4. **What challenges or risks do you foresee in executing the FDA IT Strategy?**

Resourcing

Accumulus notes that the implementation of the IT Strategy will require significant funding and staffing. Accumulus applauds the Agency for recognizing the need to further expand and enhance their technology workforce. Recruitment and retention of technology talent will likely be a challenge and require significant financial resources. The current user fee agreement provides funding for hiring for these priorities. However, as these commitments last only five years, Accumulus encourages the Agency to be transparent about their technology recruitment efforts.

Delays in Implementation

As noted in previous comment letters,[5] there is an ever-present risk that failing to act quickly enough on certain issues can delay the successful implementation of the IT Strategy. To allay this risk, Accumulus suggests FDA use demonstration projects to advance change more quickly. Similarly, leveraging input from stakeholders and other regulators can also help the Agency execute the IT strategy as efficiently as possible.

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[3] FDA, "Pharmaceutical Quality - Chemistry, Manufacturing & Controls (PQ/CMC)," September 2023. Available at https://www.fda.gov/industry/fda-data-standards-advisory-board/pharmaceutical-quality-chemistry-manufacturing-controls-pqcmc.

[4] EMA, "SPOR Data Management Services." Available at https://spor.ema.europa.eu/sporwi/.

[5] 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.

CONCLUSION

Accumulus would like to partner with FDA to support the further development and implementation of the IT Strategy. We believe that our expertise and experience in these issues can contribute to the successful adoption of innovative approaches to information technology efforts at the Agency. Accumulus thanks the Agency for providing the opportunity to comment on the IT Strategy and looks forward to further collaboration.