May 31, 2023

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

Re: Docket No. FDA-2023-N-1052 for "FDA Data and Technology Strategic Plan."

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 the development of the Data and Technology Strategic Plan (Strategic Plan). Accumulus commends FDA on seeking input from stakeholders as they develop the framework for the Strategic Plan and how the information technology budget should best be allocated to achieve modernized data collection, medical product development, and regulatory review. When implemented, the Strategic Plan offers the potential to transform every aspect of the healthcare ecosystem, allowing for expedited access to new treatments for patients and significant improvements to public health outcomes.

Accumulus is a non-profit trade association working on behalf of industry to address the global need for digital transformation. Accumulus' mission is to dramatically accelerate access to therapies by reimagining the way stakeholders in the healthcare ecosystem interact and exchange information. To help solve for this need, Accumulus is developing a transformative cloud-based data exchange platform to enable efficient collaboration between the biopharma 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 data exchange to improve patient safety, help reduce the cost of innovation, and ultimately 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 STRATEGIC PLAN

1. ***What are up to three outcomes the FDA Data and Technology Strategic Plan can help you achieve, e.g., speed to market?***

<u>Real-time Data Exchange</u>
The Strategic Plan should modernize data management through advancement of standardization and interoperability between industry and regulators across global regions. The plan should take steps to implement the real-time exchange of information, including data, as it becomes available throughout the drug development lifecycle. The Strategic Plan can work toward completing the transformation to a cloud-based system that can allow for the integration of data from multiple sources, ensure data security and integrity, and serve as a repository for the exchange of information between all stakeholders.

Real-time Engagement and Collaboration

The Strategic Plan could support and promote regulatory harmonization, which can effectively accelerate the availability of critical therapies to patients around the globe. By utilizing cloud-based technology, health authorities and life science organizations can also improve transparency and knowledge management to combat misinformation, empowering individuals to make informed healthcare choices.

Streamline Product Development and Regulatory Decision-Making

The Strategic Plan could enable the use of innovative technologies that have the capability to allow for tremendous progress in the regulatory space. New advances, such as artificial intelligence and machine learning (AI/ML), offer the potential to streamline medical product development and regulatory decision-making.

2. ***What are up to three challenges you are facing while trying to achieve these outcomes?***

Divergence Between Regulators

The Strategic Plan needs to be implemented in coordination with global regulators and consistent with regulatory policies and efforts across other regions. Without common regulatory requirements, data standards, and submission specifications, the strategic improvements threaten the success of these approaches. FDA should prioritize continual engagement and interactions with peer agencies to focus on these issues and ensure harmonization to advance efforts and operationalize the consensus future state into technical solutions.

Collaboration With Industry

The Strategic Plan needs to be developed in conjunction with industry and other stakeholders that will also be using these tools to ensure there is consistency and alignment. If the data standardization and analytics efforts or the information technology improvements are not compatible with existing or planned processes and technologies, they will be of limited utility and create undue burden and costs for regulated industry.

Delays in Implementation

Given the dynamic and rapidly evolving nature of data and technology advancement, there is a risk that not acting quickly enough on certain issues will impede successful implementation of the plan. FDA can utilize demonstration projects to advance change in a more timely manner. Also, leveraging the input and knowledge from stakeholders and other regulators can help to expedite the transformation in a more efficient and effective way.

3. ***What data and technical capabilities could FDA strengthen to help support its public health mission?***

Improving the information technology capabilities of the Agency is needed to allow for the exchange of structured data in alignment with changing regulatory needs. FDA can leverage new, non-traditional players bringing innovative technologies to the space to help facilitate the transition to cloud-based submissions and data exchange.

FDA should also work toward improving its ability to detect safety signals, monitor product efficacy, quality and performance, and identify areas of unmet medical need. This can be done through AI/ML

that can enable the analysis of large datasets, apply natural language processing techniques, and utilize predictive modeling to forecast potential safety issues. Additionally, FDA should consider tools that allow for ingestion of structured and unstructured data to allow for faster movement of information between health authorities and life science organizations. FDA should continue to foster innovation in these areas and provide additional clarity for sponsors when utilizing these approaches.

4. ***What opportunities or risks do you foresee for the FDA Data and Technology Strategic Plan?***

Opportunity: Standardization and Harmonization

If the Strategic Plan enables standardized data approaches between sponsors and FDA and between FDA and international regulators, it could significantly improve the quality, timeliness, and acceptability of submissions. The harmonized approach can lead to expedited access to new therapies and options for patients not only in the U.S., but around the world.

Risk: Sufficient Resourcing

Creation and implementation of the Strategic Plan will require a significant investment in funding, staffing, and other dedicated resources. The user fee agreements passed in 2022 provide new funding and staffing for these priorities, but the commitments only last for five years. The only way for the Agency to maintain these efforts is to ensure the funding from industry and government continues to be available and is predictable to allow for expansion. Mutually, the Strategic Plan needs to continue to evolve, and stakeholders need to ensure the goals are advancing in concert with the resources.

5. ***What changes or trends in your industry could impact the FDA Data and Technology Strategic Plan?***

Life sciences organizations continue to advance tools to enhance collaboration among regulatory stakeholders in a secure environment that will help manage data and information within and across organizations. FDA and the Strategic Plan should account for these changes and ensure their processes and infrastructure are compatible with current and future systems, which would include acceptance of validated regulatory data in a common format, utilization of templates for common data and structured filings across global regulators, and flexibility to import and export data through key integrations.

6. ***How might FDA best communicate and engage stakeholders in developing and implementing the strategy?***

Continually seeking input from stakeholders at each step of the process will be key to ensuring there is robust knowledge sharing and informative input throughout implementation. As a trade association working at the intersection of industry stakeholders and health authorities, Accumulus is continuing to reimagine how current ways of working can be enhanced through advocating and influencing in the digital transformation space. Accumulus is in a unique position to act as a convener of the wide variety of regulators and the regulated industry impacted by the data and technology transformation, enabling diverse viewpoints and broader expertise to help inform the Agency's efforts.

FDA should continue to participate in public meetings, their own and those put on by stakeholders, as well as send staff to forums and conferences, when appropriate, to learn how the industry is advancing, and encourage collaboration and engagement with outside experts. It will be important for staff to remain current on the latest developments to keep pace with the advancements of technology.

FDA should also be open and transparent about the implementation efforts and activities, sharing the successes and opportunities via public meetings and industry days as well as the challenges and barriers so that stakeholders can assist in addressing the needs where possible.

CONCLUSION

Accumulus would like to be a partner with FDA as the Strategic Plan is developed and ultimately implemented. Our expertise and experience in these issues can contribute to the successful adoption of innovative approaches to the information technology efforts at the Agency. Accumulus asks that the Agency continues to reach out to stakeholders and seek input as the plan progresses.