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: Food and Drug Administration Information Technology Strategy; Request for Comments

To Whom It May Concern:

The Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO) are pleased to submit these comments to the Food and Drug Administration (FDA or the Agency) in response to the Agency's request for comments on the FDA Information Technology Strategy (IT Strategy).[1] PhRMA and BIO appreciate FDA's timely publication of the IT Strategy and its efforts to meet its commitment under the most recent Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act (BsUFA) agreements,[2] as well as requirements under the Food and Drug Omnibus Reform Act of 2022 (FDORA),[3] to develop a comprehensive framework that will shape the future of FDA's data and technology capabilities.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to

[1] FDA, Food and Drug Administration Information Technology Strategy; Request for Comments. Available at https://www.federalregister.gov/documents/2023/10/10/2023-22388/food-and-drug-administration-information-technology-strategy-request-for-comments-correction.
[2] PDUFA VII: Fiscal Years 2023-2027. Available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027. BsUFA III: Fiscal Years 2023-2027. Available at https://www.fda.gov/media/152279/download?attachment.
[3] FDORA was enacted in Title III of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328. Section 3627 of FDORA includes requirements related to improving FDA's IT systems, including the development of FDA's Strategic IT Plan.

treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

I. GENERAL COMMENTS

PhRMA and BIO commend FDA for progressing a coordinated, agency-wide strategic plan to modernize the Agency's approach towards data and technology. We are encouraged by the internal and external stakeholder outreach that the Agency conducted to help develop the IT Strategy and support FDA's plan to update the Strategy annually to reflect updates in industry and technology as well as stakeholder feedback. We also recognize and appreciate the paradigm shift of the Strategy towards an Agency-level of operation and integration of Agency and Center strategies.

While PhRMA and BIO recognize that the Agency's data and technological transformation will be an iterative process, in its current form, we believe that the IT Strategy reads more as a guiding principles document than a comprehensive strategic plan envisioned in the PDUFA VII and BsUFA III Goals Letters. Details on how the strategy will be executed are paramount for successful implementation of the IT Strategy. Specifically, it would be informative to include the following information for each goal: 1) Where is the Agency now? 2) Where does the Agency want to be and when? 3) What is the desired outcome? 4) How will the Agency measure success? and 5) What may be the potential impact to industry and other external stakeholders?

Furthermore, we believe some of the commitments in the PDUFA VII and BsUFA III Goals Letters may not be adequately addressed in the IT Strategy and would benefit from additional discussion in the document, including the commitment for FDA's Data and Technology Modernization Strategy to "draw[] a line of sight between [PDUFA/BsUFA] initiatives and the enterprise strategy."[4] Similarly, we believe the IT Strategy falls short of the requirements in FDORA to include "specific activities and strategies for achieving the goals and priorities identified […] and specific milestones, metrics, and performance measures for assessing progress against such strategic goals and priorities."[5]

PhRMA and BIO note that the IT Strategy makes mention of an FDA IT Operating Plan that "will define an IT roadmap with a combination of projects already in progress and new projects."[6] As the IT Operating Plan is not yet published, we strongly encourage FDA to utilize the IT Operating Plan to provide additional details, including specific milestone and metrics, regarding how the Agency plans to execute the IT Strategy and how it will define and measure success.

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[4] PDUFA VII: Fiscal Years 2023-2027. Available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027. BsUFA III: Fiscal Years 2023-2027. Available at https://www.fda.gov/media/152279/download?attachment.

[5] FDORA, Sec. 3627.

[6] FDA, FDA Information Technology Strategy for Fiscal Years 2024 to 2027. Available at https://www.fda.gov/media/172067/download?attachment.

In addition to the comments above, PhRMA and BIO provide the following specific comments and answers to the questions posed by FDA about the IT Strategy.

II. SPECIFIC COMMENTS

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

Overall, we believe the six goals of the IT Strategy are directionally aligned with the FDA commitments outlined in the PDUFA VII and BsUFA III Goals Letters as well as requirements in FDORA towards FDA IT modernization. Each of the goals marks an important pillar toward helping enable a secure, modernized, technology-enabled, data-driven approach to submissions, data exchange, and regulatory review.

For example, we believe that Goal 1, Create a Shared OneFDA Ecosystem, shows an envisioned paradigm shift of the IT Strategy towards an Agency-level of operation and alignment across Centers. We are also appreciative of the objectives within this goal to enhance communication and collaboration and promote transparency with internal and external stakeholders. PhRMA and BIO encourage the Agency to seek enhanced engagement with external stakeholders to provide input into the Agency's IT modernization planning.

Modernizing foundational IT infrastructure and subsequently, the IT services portfolio, as detailed in Goals 2 & 3, Strengthen IT Infrastructure and Modernize Enterprise Services and Capabilities, is critical to FDA's IT modernization activities. PhRMA and BIO believe these goals may have the greatest direct impact to industry/sponsors as modernizing IT infrastructure and increased investment in cloud technologies can change how sponsors submit information to the Agency and how FDA assesses received information. As detailed in PhRMA's and BIO's previous comments on FDA's request for information on the IT Strategy, we support FDA's objective to accelerate cloud adoption.[7] Leveraging cloud-based technologies could encourage interoperability by removing current limitations on exchanging data and information, real-time data assessments, and the use of advanced analytics, thus transforming the current submission and regulatory review paradigm. Furthermore, cloud-based technologies can help move away from static, PDF-based submissions toward a more dynamic method of data exchange. In addition, PhRMA and BIO recommend that enterprise services and capabilities should be applied across the Agency and into Center-specific systems and services.

PhRMA and BIO also note that the Agency is looking to enhance and strengthen data sciences, analytics, and artificial intelligence/machine learning (AI/ML) capabilities and explore the use of other emerging technologies to unlock the potential of data assets within FDA to facilitate and expedite decision-making and foster innovation as detailed in Goals 4 & 5, Share Data for

[7] *See* comments filed by PhRMA and BIO. Docket No. FDA-2023-N-1052: Food and Drug Administration Data and Technology Strategic Plan; Request for Information and Comments. Available at https://www.regulations.gov/comment/FDA-2023-N-1052-0059 and https://www.regulations.gov/comment/FDA-2023-N-1052-0054.

Mission Outcomes and Adopt AI and Mission-Driven Innovations. Leveraging these approaches, where scientifically feasible and appropriate, can enable FDA to make decisions faster and more accurately. PhRMA and BIO recommend that FDA seek input from and involve, as appropriate, external stakeholders, such as industry and other global regulators, as the Agency plans implementation of Goal 5.

PhRMA and BIO also believe that successful implementation of Goal 6, Cultivate Talent and Leadership, will be crucial to a successful implementation of the IT Strategy overall. PhRMA and BIO commend the Agency for looking to help train staff on new skills and build a robust talent pipeline to keep pace with the increasing complexity of data and rapidly evolving technology. As detailed in the objectives for this goal, this will require specific programs to attract, retain, and develop talent.

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

The IT Strategy provides direction for current and future state data-derived regulatory initiatives. Pending additional details on how the IT Strategy's goals and objectives will be executed, their specific impact to various stakeholders, including industry, and additional information on how the IT Strategy aligns with other global regulatory initiatives, PhRMA and BIO believe the IT Strategy will impact the biopharmaceutical and biotechnology industries in the following ways:

- **Leveraging cloud-based technologies.** PhRMA and BIO believe increased use of cloud-based technologies across the Agency can help support the FDA's public health mission. As discussed above, we recommend that cloud-based technologies be utilized to their full extent, which could help address some of the current challenges in transmitting and reviewing regulatory submissions and move toward dynamic and ongoing data exchange.

- **Adoption of advanced analytics, AI/ML, and other emerging technologies.** PhRMA and BIO encourage FDA to leverage advanced analytics, AI/ML capabilities, and other emerging technologies, as appropriate, to improve detection of safety signals, analysis of data, and identification of areas of unmet medical need. As the Agency employs these new technologies, PhRMA and BIO strongly recommend that FDA do so in a transparent manner and seek stakeholder input to ensure alignment between the Agency and industry on how the technologies are used.

- **Expedited drug development and enhanced lifecycle management.** PhRMA and BIO believe that through structured and standardized data and advanced data analytics and technology, the IT Strategy may help streamline the drug development process, reduce the time to product registration globally, and improve the lifecycle management of submissions. To achieve this goal, international harmonization is also paramount.

- **Promote dynamic data exchange and greater interoperability.** Through structured data, leveraging new technologies, and modernized cybersecurity, PhRMA and BIO believe that the IT Strategy can help enable greater interoperability, thus supporting a rapid and efficient exchange of information for a more dynamic review process.

- **Enhanced stakeholder engagement and collaboration.** PhRMA and BIO are encouraged to see stakeholder engagement included in several of the IT Strategy goals and look forward to enhanced communication from the Agency as it progresses the implementation of the IT Strategy. Furthermore, we believe that stakeholder engagement will be critical to achieving the objectives set forth in the IT Strategy. For example, FDA, industry, and other stakeholders can work together to advance new approaches and technologies to modernize processes for submissions and regulatory review. Through stakeholder engagement and collaboration, common objectives can be identified, which may help prioritize certain goals and objectives as FDA implements the IT Strategy.

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

Overall, there are a few additional themes, not currently covered in the IT Strategy, that PhRMA and BIO think could be included to enhance the IT Strategy. For example, we believe that international collaboration to ensure global harmonization, as appropriate, would be key to FDA's modernization efforts. Where possible, the Agency should make efforts to avoid introducing or exacerbating further divergence in submission content and format, which can place undue burden and resource constraints both on global regulators/reviewers and sponsors. There is an opportunity to align the data and technology priorities in the IT Strategy with other global regulatory initiatives (e.g., the International Council for Harmonisation upcoming topic on Structured Product Quality Submissions, the International Coalition of Medicines Regulatory Authorities Pharmaceutical Quality Knowledge Management System pilots) to enhance global harmonization efforts. Similarly, it is imperative to ensure harmonization across FDA Centers with respect to data and processes. Ensuring "collaboration with FDA's Centers and Office partners"[8] may not be sufficient to accomplish the Agency's modernization goals. There is also an opportunity in the IT Strategy to support Computer Systems Validation (CSV) modernization when onboarding new software solutions. PhRMA and BIO also recommend that FDA provide cohesive mapping of how all of the Agency's data and technology modernization initiatives converge and support each other.

Additionally, as discussed above, PhRMA and BIO believe that additional details and metrics regarding how the Agency will implement the IT Strategy would greatly enhance the Strategy. These details could be included in the IT Operating Plan, a revised IT Strategy, or other relevant document. Some examples of additional details that PhRMA and BIO believe could be added to each goal are listed below:

[8] FDA, FDA Information Technology Strategy for Fiscal Years 2024 to 2027. Available at https://www.fda.gov/media/172067/download?attachment.

- Additional details that could enhance Goal 1 - Create a Shared OneFDA Ecosystem:
    - Examples of success stories where the Agency has moved from a Center-focus to a OneFDA approach.
    - Plans regarding FDA's process to enable a culture shift and examples where the Agency has had recent success in this area.

- Additional details that could enhance Goal 2 - Strengthen IT Infrastructure:
    - PhRMA and BIO note that harmonization with other global regulators is critical to the success of this goal.
    - Defining the term "foundational IT infrastructure." PhRMA and BIO suggest that all IT services and solutions need to be aligned, including Center-specific ones.
    - Example use cases of planned marketplace and cloud offerings.
    - Roadmap and timeline for onboarding new technologies, including cloud-based solutions.
    - Clarification on how the IT infrastructure will support ongoing regulatory modernization initiatives, including projects leveraging Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR), such as Product Quality/Chemistry, Manufacturing, and Controls (PQ/CMC). Adoption of FHIR data standards can be a potential step towards enabling global harmonization.

- Additional details that could enhance Goal 3 - Modernize Enterprise Services:
    - PhRMA and BIO suggest that a "business-first approach"[9] would require the delineation of the business objectives in the IT Strategy, at least at a high level.
    - Specific initiatives that will enable the objectives of this goal.
    - Examples of how FDA intends to improve external-facing systems or to gather external stakeholder feedback on potential areas for improvement.

- Additional details that could enhance Goal 4 - Share Data for Mission Outcomes:
    - A timeframe for completing the specific actions for the objectives in this goal.
    - FDA's approach regarding how it will work to develop shared data management across the Agency.
    - FDA's plan to develop FDA staff skills or hire additional talent to realize the objectives in this goal.

- Additional details that could enhance Goal 5 - Adopt AI and Mission-Driven Innovations:
    - Connection between the AI-related priorities in this goal and the recent FDA discussion papers on AI in drug manufacturing and using AI/ML in drug development.[10]

[9] *Id*.
[10] FDA, Artificial Intelligence and Drug Manufacturing. Available at https://www.fda.gov/media/165743/download. FDA, Using Artificial Intelligence and Machine Learning in the Development of Drug & Biological Products. Available at https://www.fda.gov/media/167973/download.

- Connection between AI-based tools and emerging analytics capabilities such as Knowledge-Aided Assessment and Structured Application (KASA).
- FDA's plans to share exploration, thinking, insights, and advances with external stakeholders.

- Additional details that could enhance Goal 6 - Cultivate Talent and Leadership:
  - PhRMA and BIO recommend that this goal include an emphasis on seeing data as part of the core business of FDA, beyond technology expertise. PhRMA and BIO recommend that the IT Strategy encourage data citizenship and stewardship as a core capability for all staff.
  - FDA's vision for attracting, developing, and retaining personnel to attain the objectives in this goal.

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

The IT Strategy risks creating divergence with other global regulatory initiatives if the need for appropriate global harmonization is not addressed. As FDA implements the IT Strategy, we recommend that the Agency take measures to help ensure implementation is aligned and harmonized with other global regulatory initiatives, as appropriate and to the extent possible. Additionally, if there is not consistency in interpretation and implementation of the IT Strategy across the Agency, it can result in an increased manual and labor-intensive burden for sponsors and FDA staff. PhRMA and BIO encourage sufficient training of FDA staff and leadership involvement to ensure alignment and consistency across the Agency.

There is also the risk of not keeping pace with data and technology advancements if the Agency is not flexible and efficient in its implementation of the IT Strategy. Progressing too slowly or failing to update or modify implementation of the IT Strategy to reflect new developments could impede the acceptance, utility, and benefit of the IT Strategy. To that end, PhRMA and BIO support FDA's efforts outlined in the PDUFA VII and BsUFA III Goals Letters to share and update the IT Strategy annually.[11]

III. CONCLUSION

PhRMA and BIO appreciate the Agency's commitment to data and technology modernization and their efforts to meet the commitments outlined in the PDUFA VII and BsUFA III Goals Letters as well as the statutory directives from Congress.[12] PhRMA and BIO look forward to the publication of the IT Operating Plan and working with the Agency as it implements its modernization strategy to ensure these efforts advance greater efficiency, capability, and

[11] PDUFA VII: Fiscal Years 2023-2027. Available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027. BsUFA III: Fiscal Years 2023-2027. Available at https://www.fda.gov/media/152279/download?attachment.

[12] PDUFA VII: Fiscal Years 2023-2027. Available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027. BsUFA III: Fiscal Years 2023-2027. Available at https://www.fda.gov/media/152279/download?attachment. FDORA, Section 3627.

harmonization in drug development and ultimately enhance earlier patient access to life-saving medicines.

Respectfully submitted,

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