REAL-WORLD EVIDENCE ALLIANCE

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

Re: Food and Drug Administration Information Technology Strategy; Request for Comments (Docket No. FDA-2023-N-3636)

To the Food and Drug Administration:

The RWE Alliance appreciates the opportunity to comment on the development of an "FDA Information Technology Strategy" (referred to here as the "IT Strategy").[1] We are a coalition of real-world data ("RWD") and analytics organizations with a common interest in harnessing the power of real-world evidence ("RWE") to inform regulatory decision making to improve patients' lives. Our members have deep knowledge and experience working with healthcare data across disease areas and patient populations, and we aim to bring these collective insights to bear in support of RWE policies.[2]

The RWE Alliance envisions a future in which data generated in everyday clinical practice and everyday life through electronic health records ("EHRs"), administrative claims and billing data, product and disease registries, personal devices, wearables, and health applications will be used to generate evidence that complements clinical trial data to inform regulatory decisions. To achieve this goal, the RWE Alliance advocates for policies that will (1) advance FDA's RWE Framework, (2) encourage the use of RWE to better understand treatment effects in underrepresented populations, (3) enhance opportunities for RWE organizations to consult with FDA, (4) increase communication on the generation and use of RWE, and (5) recognize the unique aspects of and opportunities for RWD/E.[3]

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[1] 88 Fed. Reg. 64435 (September 19, 2023).

[2] For information about our members, please see our website, https://rwealliance.org/who-we-are/.

[3] Additional information about what we believe is available on our website, https://rwealliance.org/what-we-believe/.

We appreciate FDA's (the "Agency's") issuance of the Request for Comments ("RFC"), which builds on the existing FDA Modernization Framework[4] to coordinate data and technology infrastructure improvements across centers. As a coalition dedicated to the use of data to support the Agency's mission, we strongly support efforts to scale data sharing across the Agency and modernize the data and technical infrastructure to accelerate medical product development and evidence generation.

The RWE Alliance submitted comments in response to FDA's Data and Technology Modernization Strategic Plan, and we appreciate that the Agency has addressed points from our letter in its IT Strategy. We applaud the Agency for naming distinct objectives to accelerate cloud adoption and to improve interoperable and secure data exchange across FDA. We encourage FDA to hasten adoption of cloud-based systems for data submission. Doing so would in turn encourage interoperability which is a critical requirement to leveraging the power of RWE in drug development. In addition, adoption of cloud-based systems would allow FDA to consider technologies such as centralized, platform-based analytics that can help enable the review and analyses of RWD from a variety of sources. Such an approach could enable reviewers to access source data in a workable manner.

Below, we provide additional comments for consideration on two of the questions posed by FDA in its RFC as the Agency continues to advance its efforts to modernize its data and technology infrastructure.

I. In Response to Question #1: What goals and objectives are most important to you? Why?

- We support FDA's goal to create a shared OneFDA Ecosystem and to modernize enterprise business objectives, as these objectives will help to enhance efficient, secure, and broad access to a variety of data and improve FDA's technical capabilities.

- We appreciate FDA's intention to strengthen data sciences, analytics, and artificial intelligence ("AI") and machine learning ("ML") capabilities and explore the use of other emerging technologies to unlock the potential of data assets within FDA. We welcome additional details and look forward to working with FDA to advance FDA's objectives.

II. In Response to Question #4: What challenges or risks do you foresee in executing the FDA IT Strategy?

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[4] FDA, Office of Digital Transformation Strategic Plan 2023-25 (Dec. 2022), https://www.fda.gov/media/163918/download.

- As the use of AI and ML in drug development rapidly increases,[5] there will be an exponential increase in the use of RWD/E for a wide range of areas relevant to FDA, which will require resources and expertise to manage. We appreciate FDA naming a distinct goal to address the impacts of emerging technologies on FDA's IT portfolio and regulatory operations. Ensuring the Agency has relevant and modern capabilities—including a more advanced data infrastructure—is mission critical.

- Investing in a suite of platform capabilities built with flexibility, interoperability, and exchangeability to support a range of data types, enhance data standards, and facilitate stakeholder communication will be critical for the volume of medical product applications and post-market surveillance, as well as the support of collaboration and harmonization. In particular, the Agency should anticipate new types and forms of data enabled by digital heath technologies, which are useful to monitor patients at home and to assess patient experience. In addition, there will be continued opportunities to share experience and guidance on the use of new data, standards for interoperability, and validation techniques critical to ensuring data provenance and quality in the use of new data and the evaluation of new clinical endpoints.

- FDA's data strategy should remain focused on the area of data quality and governance as many sources of data, including RWD, become increasingly important for FDA submissions and reviews across product categories. FDA's data strategy should ensure that the Agency has the infrastructure and processes to implement its expectations for submission, review, and verification of datasets that accommodate data from many sources, potentially with different usage, access, and sharing permissions.

III. Conclusion

The RWE Alliance appreciates the Agency's commitment to using technology and data to improve the lives of patients. Thank you for considering these comments, and please let us know if you have any questions. We welcome the opportunity to discuss further.

Best regards,

The RWE Alliance

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[5] *See* FDA, Using Artificial Intelligence & Machine Learning in the Development of Drug and Biological Products - Discussion Paper and Request for Feedback (2023), https://www.fda.gov/media/167973/download; RWE Alliance, Comments on Using Artificial Intelligence & Machine Learning in the Development of Drug and Biological Products - Discussion Paper and Request for Feedback, Docket No. FDA-2023-N-0743 (Aug. 9, 2023).