4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0743]

Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of a discussion paper entitled "Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products." To fulfill its mission of protecting, promoting, and advancing public health, FDA's Center for Drug Evaluation and Research (CDER), in collaboration with the Center for Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH), including the Digital Health Center of Excellence (DHCoE), is issuing this document to facilitate a discussion with stakeholders on the use of artificial intelligence (AI) and machine learning (ML) in drug development to help inform the regulatory landscape in this area.

DATES: Either electronic or written comments on the framework must be submitted by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-0743 for "Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products." Received comments, those filed in a timely manner (see ADDRESSES),

will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Tala Fakhouri, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6330,

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SUPPLEMENTARY INFORMATION:

I. Background

FDA aims to ensure safety and effectiveness while facilitating innovations in the development of drugs. Recent rapid technological innovations in sophisticated data collection and generation tools, combined with robust information management and exchange systems, and advanced computing abilities may prove transformational in the way drugs are developed and used[1]. This evolving ecosystem presents unique opportunities and challenges, and FDA is committed to working across its medical product centers with partners domestically and internationally to ensure that the full potential of these innovations is realized for the benefit of the public.

Developers, manufacturers, regulators, academic groups, and other stakeholders are working to develop a shared understanding of where and how specific innovations, such as AI and ML, can best be utilized across the drug development process, including through the use of AI/ML-enabled tools, which may include devices. FDA is publishing this discussion paper as part of a multifaceted approach to enhance mutual learning and to establish a dialogue with FDA stakeholders on this topic. While AI and ML are not consistently defined across all disciplines

[1] See https://pubmed.ncbi.nlm.nih.gov/35319833/.

and stakeholders, AI can be generally described as a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions. ML is generally considered a subset of AI that allows ML models to be developed by ML training algorithms through analysis of data, without models being explicitly programmed. Additionally, there are a variety of ML methods and different types of algorithms that may be utilized in a given context. For the purposes of this discussion paper, AI and ML will be referenced together as AI/ML, and references to drug development and the drug development process include a wide scope of activities and phases, including manufacturing and surveillance, among others.

This discussion paper, which considers the application of AI/ML in the broad context of the drug development process, is not FDA guidance or policy, and is not meant to endorse a specific AI/ML use or approach in drug development. Rather, it is an initial communication with stakeholders, including academic groups, that is intended to promote mutual learning and discussion. Specifically, FDA is soliciting feedback on the opportunities and challenges with utilizing AI/ML in the development of drugs, as well as in the development of medical devices intended to be used with drugs. This feedback will provide an additional resource to help inform the regulatory landscape in this area. Additionally, it is beneficial for researchers and technology developers, particularly those new to drug development and human subjects research, to recognize some of the initial thinking and considerations involved with utilizing these technologies, including having familiarity with FDA's current activities, initiatives, practices, and potentially applicable regulations.

II. Electronic Access

Persons with access to the internet may obtain the discussion paper, "Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products: Discussion Paper" at https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-machine-learning-aiml-drug-development.

Dated: May 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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