April 3, 2025

Martin Makary, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm 1061 (HFA-305)
Rockville, MD 20852-1740

Submitted electronically via https://regulations.gov/

RE: Comments for Draft Guidance on Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations [Docket No. FDA-2024-D-4488]

Dear Commissioner Makary,

On behalf of the American Academy of Dermatology Association (Academy), thank you for the opportunity to provide comments on the Food and Drug Administration's (FDA) January 2025 draft guidance entitled, "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations (Draft Guidance)."

As the leading society in dermatological care, representing nearly 17,500 dermatologists nationwide, the Academy is committed to excellence in the medical and surgical treatment of skin disease, advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease. **We support FDA recommendations and regulatory strategies that encourage scientific innovation and enhance medical device development while maintaining device efficiency and affordability. Additionally, we urge the FDA to continue strong collaboration with the physician community, ensuring that those who will ultimately use AI-enabled medical devices have a meaningful role in their development, design, testing, and implementation.**

In response to the draft guidance, the Academy offers the following comments regarding AI-enabled medical device marketing submissions.

CORRESPONDENCE
PO Box 1968
Des Plaines, IL 60017-1968
EMAIL: mrc@aad.org
WEB: aad.org

ROSEMONT, IL OFFICE
9500 W Bryn Mawr Avenue, Suite 500
Rosemont, IL 60018-5216
MAIN: (847) 330-0230
FAX: (847) 240-1859

WASHINGTON, DC OFFICE
1201 Pennsylvania Avenue, NW, Suite 540
Washington, DC 20004-2401
MAIN: (202) 842-3555
FAX: (202) 842-4355

I. Ensuring Patient and Physician Involvement in User Interface Development

Continuous physician and patient advocate engagement is necessary to enhance AI model integration, producing more accurate, effective, and personalized interactions with AI-enabled medical devices for their end-users. In dermatology, accessible image-based AI tools are widely available due to the use of photography as an assessment tool. Image descriptions that are used for dermatological AI tools may require significantly more detail than other medical imaging applications due to the wide variety of acquisition devices and techniques[1]. Accessible interfaces should optimize accuracy and usability, making AI-enabled devices safer and more effective in clinical practice.

To accomplish this, the Academy urges the FDA to require provider and patient advocate collaboration during user interface development to ensure AI tools and systems are explainable, intuitive, and understandable for their prospective users.

II. Developing and Defining Acceptable and Unacceptable Risk Levels

Risk mitigation should be a goal for all medical device approvals, and manufacturers of AI-enabled devices should evaluate and address risks associated with the models' performance, accuracy, and ability to analyze their target demographic. It is equally important that sponsors involve dermatologists and other physicians during development, allowing clinicians to have access to risk assessment information from AI-enabled devices, which will in turn allow them to make informed decisions about the suitability of these tools for their practices and patients.

The Academy urges the FDA to require risk assessment information be made available to clinicians for AI-enabled devices. Additionally, the FDA should engage stakeholders to establish clear definitions of acceptable and unacceptable risk levels and ensure that physicians and other stakeholders have access to this information for AI-enabled devices.

III. Ensuring Data Quality

Although the proposed draft guidance would improve data quality processes and enhance safety and accuracy standards for AI models in medical devices, the Academy recommends publishing additional standards to ensure transparency and validation of model outputs. Data quality, accuracy, and bias mitigation efforts associated with the data used to train AI models must be made public since increased transparency provides greater insight into the generalizability and limitations of AI-enabled devices, helping to maintain model standards. The size of the training, validation, and test sets, as well as clear explanations of how they were partitioned should be included, and the model training, validation, and test sets should also be independent to avoid data leakage.

The Academy emphasizes the importance of model validation, ongoing device performance monitoring, and post-market surveillance of models for AI-enabled medical devices. Additionally, we encourage the FDA to require clear documentation of validation methodology to ensure transparency and accountability throughout the medical device's lifecycle.

---

[1]See Daneshjou R, et. al., Checklist for Evaluation of Image-Based Artificial Intelligence Reports in Dermatology: CLEAR Derm Consensus Guidelines From the International Skin Imaging Collaboration Artificial Intelligence Working Group. JAMA Dermatol. 2022 Jan 1;158(1):90-96.

IV. Device Performance Monitoring Requirements

If finalized, required performance drift monitoring and notification to end-users would encourage ongoing device performance monitoring and post-market surveillance of AI models, which would sustain data collection throughout the device's lifecycle ensuring continued quality, efficiency, and accuracy of the model's performance. Dermatology image-based AI algorithms are unique in that they must account for the distinct characteristics of dermatology data challenges, including lack of standardization across imaging modalities, and the potential for bias due to noisy labels or demographically unrepresentative datasets[2]. To ensure that AI models are used only in contexts where they are known to perform well and to maintain device performance, warning potential users of activities outside of the device's intended use, as well as requiring user notification when there is performance drift would improve monitoring for potential performance decline and could facilitate the calibration and improvement of the AI model.

We urge the FDA to ensure that physicians and patient users are promptly notified if performance drift is detected.

V. Public Submission Summary Guidance

While the new public summary guidance encourages public trust and transparency throughout the device lifecycle, it is essential that the FDA clearly outlines the need for continued communication with physicians and patients during marketing submission and beyond. Public submission summaries could help inform physicians and patients who anticipate relying on AI models and AI-enabled medical devices to make informed decisions. The FDA's guidance highlights the importance of seeking public input prior to advancing regulatory measures, and public submission summaries facilitate this dialogue by encouraging open discourse and feedback.

The Academy encourages the FDA to continue supporting public input and the development of public submission summaries during the pre-market phase. Furthermore, we support the recommendation that public input be thoroughly addressed before advancing regulatory measures. This approach promotes physician and patient feedback while fostering transparency and trust in the development of AI-enabled devices.

VI. Conclusion

The Academy supports the FDA's continued efforts to enhance the functionality of software and models in AI-powered medical devices, improving AI-assisted decision-making by physicians and patient outcomes. We urge the FDA to continue ongoing collaboration between the agency, patient advocates, and dermatologists, ensuring that both physicians and patients are actively involved in the development, design, testing, validation, and implementation of AI-enabled medical devices, and ensuring the effectiveness, safety, and broad applicability of these AI tools, ultimately improving their use in clinical practice.

We appreciate the opportunity to provide comments on the draft guidance regarding the use of Artificial Intelligence in medical devices and urge the FDA to consider these recommendations in the finalized

[2] Id.

guidance. If you have any questions about the recommendations in this letter, please contact Nija Chappel, JD, MPH, Manager, Regulatory Policy at nchappel@aad.org or (202) 609-6313.

Sincerely,

Susan C. Taylor, MD, FAAD
President, American Academy of Dermatology Association