U.S. FOOD & DRUG ADMINISTRATION

Artificial Intelligence & Medical Products:

How CBER, CDER, CDRH, and OCP are Working Together

March 2024
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Introduction

Artificial intelligence (AI)[1] has the potential to revolutionize health care by advancing medical product[2] development, improving patient care, and augmenting the capabilities of health care practitioners. Aligned with its mission of protecting, promoting, and advancing public health, and building on the Agency's longstanding commitment to support innovative work in the development and regulation of medical products, the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Office of Combination Products (OCP) are jointly publishing this paper to provide greater transparency regarding how FDA's medical product Centers are collaborating to safeguard public health while fostering responsible and ethical innovation.

The complex and dynamic processes involved in the development, deployment, use, and maintenance of AI technologies benefit from careful management throughout the medical product life cycle[3]. Specifically, end-to-end management of AI applications is an iterative process that starts from ideation and design and progresses through data acquisition; preparation; model development and evaluation; deployment; monitoring; and maintenance. This approach can help address ongoing model performance, risk management, and regulatory compliance of AI systems in real-world applications. Importantly, AI management requires a risk-based regulatory framework built on robust principles, standards, best practices, and state-of-the-art regulatory science tools that can be applied across AI applications and be tailored to the relevant medical product.

This paper describes four areas of focus for CBER, CDER, CDRH, and OCP regarding the development and use of AI across the medical product life cycle (see Figure 1).

1 For the purposes of this paper, AI is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. AI systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action. AI includes machine learning, which is a set of techniques that can be used to train AI algorithms to improve performance of a task based on data. See 15 U.S.C. 9401(3). https://www.govinfo.gov/content/pkg/USCODE-2020-title15/html/USCODE-2020-title15-chap119.htm

2 For the purposes of this paper, the term "medical product" refers to biological products, drugs, devices (including device software), and combination products. Specifically, "drug" as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g)(1)); "biological product" as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)); "device" as defined in section 201(h) of the FD&C Act; and "combination product" as described in 21 CFR 3.2(e).

3 The use of AI in the medical product life cycle for the development of drugs, biological products, devices, or combination products may differ. For example, for drugs and biological products, the end product is typically the drug or biological product itself, which will generally not include AI in that end product. For devices, the end product is the device, which may itself be AI-enabled. When describing the life cycle of a medical device, including AI-enabled devices, the term "Total Product Life Cycle," or TPLC, is often used. For more information, see Total Product Life Cycle for Medical Devices, September 6, 2023. https://www.fda.gov/about-fda/cdrh-transparency/total-product-life-cycle-medical-devices

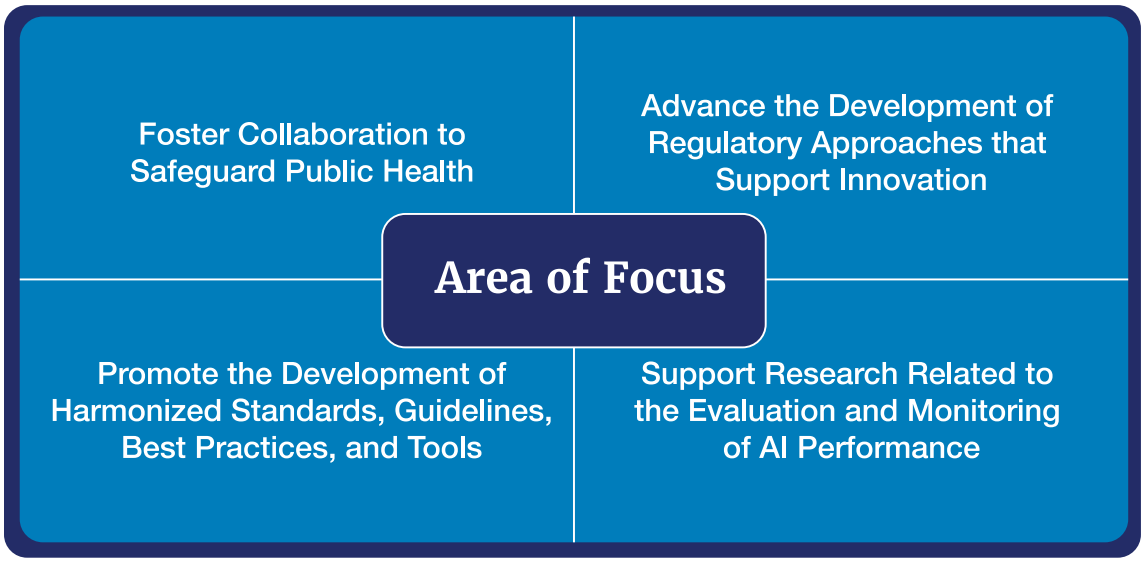

Figure 1. Four areas of focus regarding the development and use of AI across the medical product lifecycle.

Responsible Use of AI in Medical Product Development and in Medical Products

With a shared commitment toward fostering innovation and upholding quality, safety, and effectiveness, CBER, CDER, CDRH, and OCP plan to align their efforts to advance the responsible use of AI for medical products. This entails building regulatory approaches that, to the extent feasible, can be applied across various medical products and uses within the health care delivery system.

These Centers and Offices are taking or intend to take the following actions, which are organized around the four areas of focus, regarding the uses of AI across the medical product life cycle:

1. Foster Collaboration to Safeguard Public Health

FDA's medical product Centers work closely with developers, patient groups, academia, global regulators, and other interested parties to cultivate a patient-centered regulatory approach that emphasizes collaboration.

To continue fostering these collaborative partnerships, the Agency intends to:

- **a.** Solicit input from a range of interested parties to consider critical aspects of AI use in medical products, such as transparency, explainability, governance, bias[4], cybersecurity, and quality assurance.
- **b.** Promote the development of educational initiatives to support regulatory bodies, health care professionals, patients, researchers, and industry as they navigate the safe and responsible use of AI in medical product development and in medical products.

4 The AI/ML Software as a Medical Device Action Plan (https://www.fda.gov/medical-devices/software-medical-device-samd/artificialintelligence-and-machine-learning-software-medical-device) includes a commitment to support regulatory science efforts related to the identification and elimination of bias. While a patient-centered approach to transparency can help mitigate the negative effects of bias, supporting advancements to prevent and eliminate bias remains an important priority of the Agency.

c. Continue to work closely with partners to promote standards, guidelines, and best practices to encourage innovation and high quality approaches to AI across the medical product landscape.

2. Advance the Development of Regulatory Approaches That Support Innovation

FDA's medical product Centers intend to develop policies that provide regulatory predictability and clarity for the use of AI as part of their longstanding commitment to protect public health and advance innovation. This includes:

a. Continuing to monitor and evaluate trends and emerging issues to detect potential knowledge gaps and opportunities, including in regulatory submissions, allowing for timely adaptations that provide clarity for the use of AI in the medical product life cycle.

b. Supporting regulatory science efforts to develop methodology for evaluating AI algorithms, identifying and mitigating bias, and ensuring the robustness and resilience of AI algorithms to withstand changing clinical inputs and conditions.

c. Leveraging and continuing to build upon existing initiatives[5] for the evaluation and regulation of AI use in medical products and in medical product development, including in manufacturing.

d. Issuing guidance regarding the use of AI in medical product development and in medical products, including, but not limited to:

- **i.** Final guidance on marketing submission recommendations for predetermined change control plans for AI-enabled device software functions[6]
- **ii.** Draft guidance on life cycle management considerations and premarket submission recommendations for AI-enabled device software functions[7]
- **iii.** Draft guidance on considerations for the use of AI to support regulatory decision-making for drugs and biological products[8]

5 See Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products https://www.fda.gov/media/167973/download, Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cders-framework-regulatory-advanced-manufacturing-evaluation-frame-initiative, and Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan https://www.fda.gov/media/145022/ download

6 See Guidance for Industry and FDA Staff: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions (December 2024) https://www.fda.gov/media/166704/download

7 See Draft Guidance for Industry and FDA Staff: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations (January 2025). When final, this guidance will represent FDA's current thinking on this topic. https://www.fda.gov/media/184856/download

8 See Draft Guidance for Industry and Other Interested Parties: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products (January 2025). When final, this guidance will represent FDA's current thinking on this topic. https://www.fda.gov/media/184830/download

3. Promote the Development of Standards, Guidelines, Best Practices, and Tools for the Medical Product Life Cycle

FDA's medical product Centers are committed to upholding safety and effectiveness standards across AI-enabled medical products. Building on Good Machine Learning Practice Guiding Principles[9], the Agency plans to:

- **a.** Continue to refine and develop considerations for evaluating the safe, responsible, and ethical use of AI in the medical product life cycle (e.g., provides adequate transparency and addresses safety and cybersecurity concerns).
- **b.** Identify and promote best practices for long-term safety and real-world performance monitoring of AI-enabled medical products.
- **c.** Explore best practices for documenting and ensuring that data used to train and test AI models are fit for use.
- **d.** Develop a framework and strategy for quality assurance of AI-enabled tools or systems used in the medical product life cycle, emphasizing continued monitoring and mitigation of risks.

4. Support Research Related to the Evaluation and Monitoring of AI Performance

To gain valuable insights into AI's impact on medical product safety and effectiveness, and subject to available resources, the Centers plan to support demonstration projects that:

- **a.** Identify projects that highlight different points where bias can be introduced in the AI development life cycle and how it can be addressed, including through risk management.
- **b.** Support projects that consider data representativeness to ensure that AI approaches are generalizable.

Support the ongoing monitoring of AI tools in medical product development within demonstration projects to ensure adherence to standards and maintain performance and reliability throughout their life cycle.

9 See Good Machine Learning Practice for Medical Device Development: Guiding Principles https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

Overarching Considerations and Next Steps

FDA's medical product Centers developed this paper to reaffirm our commitment to promoting the responsible and ethical development, deployment, use, and maintenance of medical products that incorporate or are developed with AI. This commitment aligns with our mission to ensure patient access to medical products that are safe and effective for their intended uses and underscores our dedication to facilitating innovation. This paper also highlights our goals to promote the development and use of standards that support our mission and to help ensure convergence, to the extent feasible, across the Agency.

CBER, CDER, CDRH and OCP plan to tailor their regulatory approaches for the use of AI in medical products to protect patients and health care workers and ensure the cybersecurity of medical products in a manner that promotes innovation. We acknowledge that AI is a rapidly progressing field, and we anticipate that these actions may evolve as we pursue these activities.

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