

FDA Publishes Machine Learning Transparency Guiding Principles for Medical Devices



CONTRIBUTORS



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ALERTS

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Further to the guiding principles on the use of artificial intelligence (AI) and machine learning (ML) technologies jointly published by the U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (i.e., the guiding principles on good ML practice for medical device development (Good ML Principles) issued in 2021 and the guiding principles on predetermined change control plans for ML-enabled medical devices in 2023),¹ the agencies recently released another set of guiding principles to specifically promote transparency for ML-enabled medical devices (MLMDs).² The Transparency Principles provide considerations for companies, such as MLMD manufacturers and developers, to adopt and implement good transparency practices throughout their devices' product lifecycles—considerations that can enable the safe and effective use of MLMDs in an era marked by the proliferation of ML technologies. The Transparency Principles reflect the FDA's ongoing, international efforts to help “optimize human-centered transparency by supporting predictability and harmonization across jurisdictions,” which, in turn, can impact the adoption of these devices and facilitate innovation in AI/ML technologies in the healthcare industry.³

The Transparency Principles emphasize the effective communication of relevant information about a MLMD to users, such as the intended use(s), device development, device performance, and method for reaching the output or result, or basis for a decision or action (i.e., the “logic”).⁴ They consider:

- **Who** – the relevant audiences for transparency;
- **Why** – the motivation for transparency;
- **What** – the relevant information;
- **Where** – the placement of information;
- **When** – the timing of communication; and
- **How** – the methods to support transparency.⁵

The Transparency Principles expand upon the Good ML Principles, which provide a broad foundation for developing safe, effective, and high-quality medical devices that use AI/ML technologies.⁶ The Transparency Principles especially offer further clarity for two Good ML Principles: i) focus on the performance of the human-AI team (Good ML Principle 7); and ii) provide users clear, essential information (Good ML Principle 9).⁷

The Good ML Principles and Transparency Principles are summarized in Table 1 and Table 2, respectively.

Table 1. Good ML Principles⁸

Principle No.	Principle
Principle 1	Multi-disciplinary expertise is leveraged throughout the total product lifecycle
Principle 2	Good software engineering and security practices are implemented
Principle 3	Clinical study participants and data sets are representative of the intended patient population
Principle 4	Training data sets are independent of test sets
Principle 5	Selected reference datasets are based upon best available methods
Principle 6	Model design is tailored to the available data and reflects the intended use of the device
Principle 7	Focus is placed on the performance of the human-AI team
Principle 8	Testing demonstrates device performance during clinically relevant conditions
Principle 9	Users are provided clear, essential information
Principle 10	Deployed models are monitored for performance and re-training risks are managed

Table 2. Transparency Principles⁹

Guiding Principle	Description
Who	Transparency is relevant to all parties involved in a patient's healthcare, including those intended to: ▪ use the device (e.g., healthcare providers, patients, and caregivers); ▪ receive healthcare with the device (e.g., patients); and ▪ make decisions about the device to support patient outcomes (e.g., support staff, administrators, payors, and governing bodies)
Why	Transparency supports: ▪ safe and effective use of MLMDs; ▪ patient-centered care; ▪ identification and evaluation of risks and benefits of a device; ▪ informed decision-making and risk management; ▪ device maintenance and detection of errors or decline in performance; ▪ health equity through identification of bias; ▪ increased fluency and confidence in MLMD use; and ▪ increased adoption of, and access to, MLMD technology
What	The type of relevant information depends on the benefits and risks of each MLMD, as well as the needs of the intended users. Relevant information may include: ▪ device characterization; ▪ the intended use(s); ▪ how the device fits into the healthcare workflow, including the intended impact on the judgment of a healthcare professional; ▪ device performance; ▪ device benefits and risks; ▪ product development and risk management activities across the product lifecycle; ▪ device logic, when available;

	▪ clinically relevant device limitations (e.g., biases, confidence intervals, and data characterization gaps); and ▪ how safety and effectiveness are maintained across the product lifecycle
Where	Information about the device should be accessible through the user interface (e.g., training, physical controls, display elements, packaging, labeling, and alarms), including the software user interface (e.g., on-screen instructions, and warnings). Maximizing the utility of the software interface can: ▪ make information more responsive; ▪ allow information to be personalized, adaptive, and reciprocal; and ▪ address user needs through a variety of modalities
When	The timing of communication depends on the stage of the product lifecycle, such as: ▪ detailed device information when considering whether to acquire or implement a device, and whether and how to use it; ▪ timely notifications of device updates or new information; and ▪ targeted information (e.g., on-screen instructions or warnings) at a specific stage in the workflow or upon specific triggers
How	The communication of information requires a holistic understanding of the users, use environments, and workflows. This may be addressed by applying human-centered design principles, which address the whole user experience and involve relevant parties throughout design and development.

The FDA is inviting public comments to the Transparency Principles through the [public docket \(FDA-2019-N-1185\)](#).

Contact Us

For questions regarding regulatory strategy and recent developments in FDA regulation, including the FDA's guiding principles and industry guidance for AI/ML-enabled medical devices, please contact [Eva Yin](#), [Jonathan Trinh](#), or any member of Wilson Sonsini's [FDA regulatory, healthcare, and consumer products practice](#).

[1] See U.S. Food and Drug Admin et al., *Good Machine Learning Practice for Medical Device Development: Guiding Principles* (Oct. 2021), <https://www.fda.gov/media/153486/download> (hereinafter "Good ML Principles"); U.S. Food and Drug Admin et al., *Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles* (Oct. 2023), <https://www.fda.gov/media/173206/download?attachment>.

[2] See U.S. Food and Drug Admin et al., *Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles* (June 2024), <https://www.fda.gov/media/179269/download?attachment> (hereinafter "Transparency Principles"); U.S. Food and Drug Admin., *Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles* (updated June 13, 2024), <https://www.fda.gov/medical-devices/software-medical-device-samd/transparency-machine-learning-enabled-medical-devices-guiding-principles>.

[3] U.S. Food and Drug Admin., Press Release, *CDRH Issues Guiding Principles for Transparency of Machine Learning-Enabled Medical Devices* (June 13, 2024), <https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-issues-guiding-principles-transparency-machine-learning-enabled-medical-devices>.

[4] Transparency Principles, at 1.

[5] *Id.* at 2.

[6] *Id.* at 1; see Good ML Principles, at 1; U.S. Food and Drug Admin., *Good Machine Learning Practice for Medical Device Development: Guiding Principles* (updated Oct. 27, 2021), <https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles>.

[7] Transparency Principles, at 1.

[8] Good ML Principles, at 2.

[9] Transparency Principles, at 2–4 and tbl. 1.