Provisional Translation (as of November 2026)[*]

Basic Principles for the Use of AI in Regulatory Activities (Early Consideration)

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Center for Regulatory Science
Pharmaceuticals and Medical Devices Agency

I. Purpose of this Document

Artificial Intelligence (AI) has the potential to ultimately improve the quality of healthcare through greater efficiency and optimization in the methods and processes for the development and evaluation of medical products.

In recent years, the use of AI throughout the life cycle of medical products has increased significantly, and its applications have diversified beyond development to include post-marketing data evaluation and the provision of information. However, such use should help safeguard the interests of patients and the public.

This document, prepared by the Pharmaceuticals and Medical Devices Agency (PMDA), sets out the principles that regulatory stakeholders are encouraged to take into account in common in order to promote the responsible use and development of AI in activities involving regulatory judgment and decision-making. In doing so, this document takes into consideration the concepts set forth in the Social Principles of Human-Centric AI[†] and the Guidelines for the Use of Medical Digital Data in AI Research and Development[‡], among others.

II. Scope of this Document

Activities Covered

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[*] This English version of the Japanese Early Consideration is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

[†] Cabinet Office, Government of Japan, Social Principles of Human-Centric AI (tentative translation), March 29, 2019.
https://www8.cao.go.jp/cstp/english/humancentricai.pdf

[‡] Study Group for the Development of Guidelines on the Use of Digital Data for AI Research and Development, Guidelines on the Use of Medical Digital Data for AI Research and Development [in Japanese], March 31, 2024.
https://www.mhlw.go.jp/content/001310044.pdf

This document primarily applies to settings in which AI technologies, including generative AI, are used in activities involving regulatory judgment and decision-making throughout the entire life cycle of pharmaceuticals, quasi-drugs, cosmetics, medical devices, and regenerative medical products, from the development stages, including nonclinical and clinical studies, through manufacturing and post-marketing activities.

The development of AI used for such activities, including operational processes such as ongoing updates, may also fall within the scope of this document.

The use or development of AI in basic research or in general medical practice is not intended to be the primary focus of this document.

Intended Audience

This document is primarily intended for regulatory stakeholders engaged in the activities described above, including PMDA, applicants, marketing authorization holders, manufacturers, sponsors, and contract research organizations (CROs).

Developers and providers of AI models or systems incorporating AI models (hereinafter referred to as "AI systems") used in such activities are also part of the intended audience.

III. Position of this Document

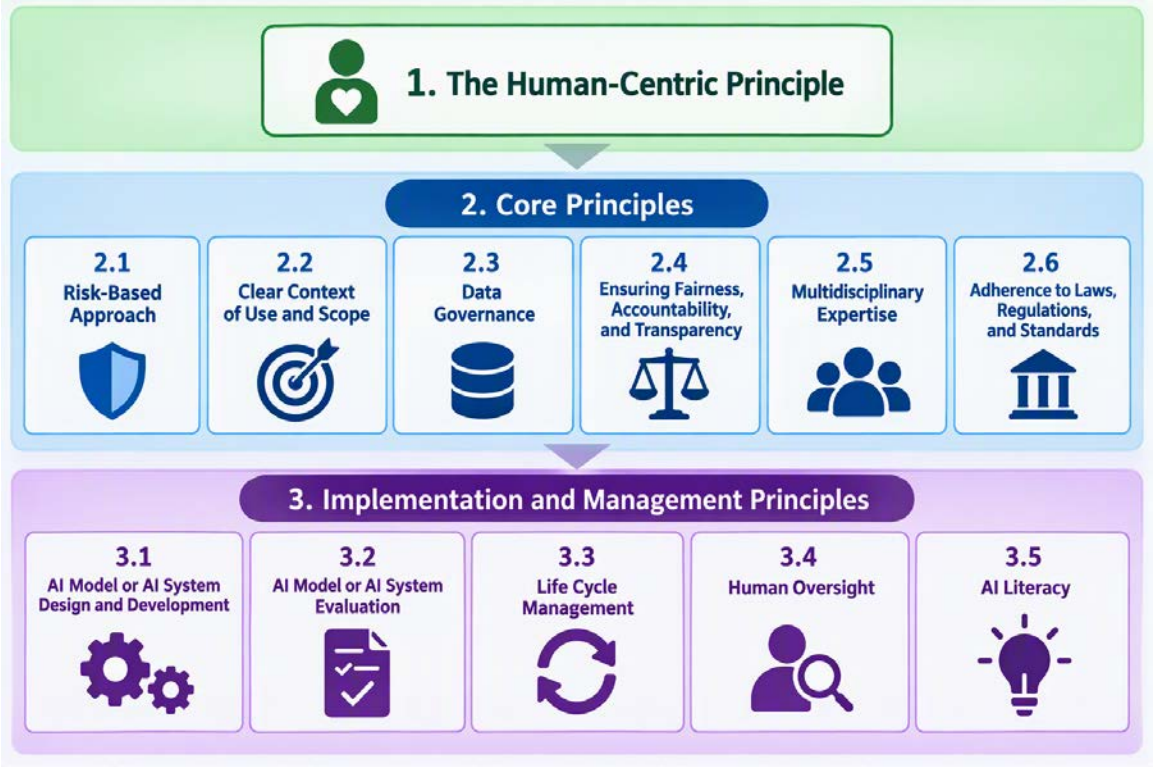
This document is not intended to establish new regulatory requirements.

Rather, it presents principles intended to promote the responsible use and development of AI and to maximize the benefits of AI while appropriately managing risks that may arise from its use in regulatory activities.

This document presents key considerations that warrant particular attention in the use and development of AI within the three-tier structure illustrated below. Addressing only the matters described in this document should not be considered sufficient to fulfill all necessary obligations and responsibilities.

Organizational governance, appropriate operational frameworks, and other generally applicable requirements should be addressed appropriately regardless of whether they are explicitly described in this document.

As AI technologies continue to evolve, good practices and the concepts supporting them should also evolve. Accordingly, this document will be reviewed and updated, as necessary, in light of technological developments, practical experience, and international harmonization.


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1. The Human-Centric Principle

AI is intended to support, rather than replace, human judgment and decision-making.

The interests of patients and the public should be the highest priority, and the ultimate responsibility associated with the use of AI rests with humans.

2. Core Principles

2.1 Risk-Based Approach

When using or developing AI, appropriate measures should be implemented in accordance with the level of risk estimated from the probability and severity of undesirable events arising from the use of AI.

2.2 Clear Context of Use and Scope

When using or developing AI, its context of use, including its purpose and scope of application, should be clearly defined, taking into account the expected role of AI, the settings in which it is used, the accuracy of its outputs, and the judgments or decisions that may be influenced by those outputs.

2.3 Data Governance

When using or developing AI, appropriate governance and management processes should be established to continuously maintain a sound data foundation, including data reliability and privacy protection.

When using AI, the appropriateness of data to be input or processed should be confirmed in light of the intended use.

With respect to data used for AI development, data characteristics, data sources, processing steps, change histories, and the basis for decision-making should be appropriately documented and managed, and traceability should be maintained.

2.4 Ensuring Fairness, Accountability, and Transparency

When using or developing AI, consideration should be given to avoiding undue bias in AI outputs or in judgments or decisions based on such outputs.

To promote the appropriate use of AI, clear, understandable, and contextually appropriate information regarding the intended use, actual use, and the limitations of AI should be disclosed appropriately.

Necessary information should also be appropriately disclosed by AI developers and providers to AI users, and by AI users to relevant stakeholders, including patients, members of the public, and healthcare professionals.

2.5 Multidisciplinary Expertise

Across all stages of AI use and development, multidisciplinary expertise should be secured so that evaluations do not rely solely on any particular discipline and can incorporate technical, medical,

pharmaceutical, legal and regulatory, ethical, and societal perspectives in a comprehensive manner. The perspectives of patients and members of the public should also be taken into account, as appropriate.

2.6 Adherence to Laws, Regulations, and Standards

When using or developing AI, relevant laws and regulations should be complied with, and relevant ethical, technical, scientific, security, and regulatory standards or norms should be observed.

3. Implementation and Management Principles

3.1 AI Model or AI System Design and Development

When developing AI, AI models or AI systems should be designed and developed in accordance with the intended use and scope.

The AI model or AI system should be developed using data appropriate for the intended use and should be reliable and robust, while ensuring the level of explainability appropriate to the intended use and associated risks.

3.2 AI Model or AI System Evaluation

Prior to the use of AI, performance assessment and validation appropriate to the intended use, scope, and estimated risks should be conducted.

Such assessments should consider not only AI performance but also its operation in the actual use environment.

3.3 Life Cycle Management

Continuous monitoring and evaluation should be conducted after AI has been placed into use.

Rather than concluding after a single evaluation, periodic reviews should be undertaken to support the maintenance and improvement of AI models and AI systems.

3.4 Human Oversight

When using AI, AI outputs should not be relied upon excessively in order to maximize the benefits of AI.

Appropriate human oversight should be exercised based on the characteristics and limitations of AI.

Human review and judgment should be performed as appropriate to the intended use, scope, and estimated risks, and appropriate operational arrangements should be established to enable intervention.

3.5 AI Literacy

When using AI, it is important to continuously improve knowledge and understanding of the characteristics and limitations of AI in order to maintain effective human oversight.

It is also important to continue learning about emerging technologies and newly identified risks.