



Artificial intelligence (“AI”) ethics principles

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Preamble

Artificial Intelligence (AI) has the potential to bring about positive transformations in science and society, including in healthcare. As a powerful enabler of progress and innovation, AI can increase individual well-being and contribute to the common good. However, while offering tremendous opportunities, relatively new AI technology could also raise concerns relating to potential misuse and inadequate accountability, as well as systemic risks inherent to algorithmic bias and discrimination.

The member companies of IFPMA are committed to the responsible development and use of AI to discover, develop, manufacture, and deliver medicines and healthcare solutions. This is grounded in IFPMA’s commitment to improve healthcare for patients and society. In developing and deploying AI algorithms or applications (“AI systems”), IFPMA’s member companies should act with integrity to maintain the trust of patients, healthcare professionals, payors, public authorities, and other stakeholders.

These principles are intended to help IFPMA’s member companies use AI systems responsibly and sustainably in alignment with the [IFPMA Ethos](#) of care, fairness, respect, and honesty. The principles strive to promote values-based decision-making and the creation of pragmatic, appropriate, and risk-based AI frameworks and controls.

These IFPMA AI Ethics Principles aim to provide a set of guardrails that member companies should consider, adapt, and operationalize within their organizations.

The IFPMA AI Ethics Principles complement and align with the broader [IFPMA Data Ethics Principles](#), with specific emphasis on the considerations relevant to design and use of AI. Moreover, the IFPMA AI Ethics Principles are meant to work in the context of other existing AI principles, laws, or regulations of both general application and in healthcare specifically. The principles below embed an “ethics by design” approach and apply both to AI developed in-house or sourced from third parties.

Definition and scope

An AI system means software that is developed by using techniques and approaches including, but not limited to, machine learning, analytics, and statistical approaches. Since this

is a very broad definition, for the purposes of implementing the principles below, the definition applied here excludes rudimentary analytics or statistical approaches and simple rules-based systems. The IFPMA AI Ethics Principles also recognize that the definition of AI is continually evolving. IFPMA will monitor developments and recommends member companies to remain vigilant and readjust their definitions to ensure they reflect a balanced and pragmatic approach that is aligned with industry practices.

AI systems could generate outputs such as content, predictions, recommendations, or decisions influencing the environment they interact with. In other words, an AI system is the simulation of human intelligence processes by computer systems.

The AI Ethics Principles are relevant and apply to all forms and use of AI by IFPMA's member companies including, but not limited to, in research and business operations.

The AI Ethics Principles should be applied with a risk-based approach, with a particular focus on AI enabled business activities or applications that may potentially pose higher risk for patients, as defined by member company policies, relevant laws, and regulations. Depending on the areas and/or activities where AI is used (e.g., early research with potential lower risk to patients, versus late clinical development with clinical applications directly affecting patients), some principles might require less or greater emphasis.

Principles

1. Empowering humans

AI systems should be designed and utilized with the idea that the use of AI needs to respect the rights and dignity of all people. When developing AI systems, member companies should consider both the societal benefit and any impact to individuals. Where applicable, the responsible individual or organization should strive to utilize AI as a means by which those impacted by AI can retain control of their own healthcare according to their evolving needs.

2. Accountability

IFPMA member companies should take accountability for the use of AI systems, including those developed by third parties, throughout the lifecycle of AI deployed by or on behalf of their member organization. This includes establishing within the member organization proper governance, appropriate deployment of risk and impact-based controls, and incorporation of strategies for any unintended negative consequences of AI systems, including continual monitoring and feedback loops as AI evolves over time.

3. Human Control

AI systems should be deployed with an appropriate level of human control and oversight, based on the assessed risk to individuals. Where there is a potential for direct and significant impact on individuals because of deploying AI, AI should not be given complete autonomy in decision making.

4. Fairness and minimization of bias

Developers and owners should strive to minimize bias and maximize fairness in AI systems. Any development of an AI system should include a process to review selection of datasets used in training and assumptions used in the design to evaluate if those assumptions minimize any bias of the developer or a bias that is present in the data, design, or architecture the developer has relied upon. IFPMA member companies should continuously monitor and adapt AI systems to correct for bias throughout the AI lifecycle. IFPMA member companies should also seek diversity among the designers and developers of AI within their organization.

5. Privacy, security, and safety by design

Privacy and security should be considered as part of the design of any AI system. Member companies should implement adequate measures to mitigate risks to the privacy, security, and safety of individuals, including, where relevant, compliance with applicable data protection regulations and technical limitations on the re-use and use of data, and state-of-the-art security and privacy-preserving measures, such as pseudonymization, anonymization, or encryption.

6. Transparency, explainability, and ethical use

When deploying AI, member companies should publicly describe, to the extent possible and where appropriate, when and how AI is used; how personal data, if any, is used; the goals, underlying data and any limitations of such data, and assumptions that power a given AI system; and the limitations of that system.

When using non-explainable AI in a context that has the potential for direct and significant impact on individuals, companies should ensure extra focus on transparency, human control, and elimination of bias.

What happens next?

These principles are a starting point for each IFPMA member company to consider how their internal processes, controls, operations, and policies could be adapted to incorporate AI Ethics and ethical decision-making around AI systems. However, exercising AI Ethics is an ongoing journey and will require sustained effort and commitment from IFPMA member companies, their vendors and collaborators, individuals, and the biopharmaceutical industry generally. Therefore, AI Ethics programs need to be routinely revisited to consider evolving technologies, specific applications, e.g., big data and AI, the regulatory environment, stakeholder expectations, and current understanding of the risks and benefits of data use to individuals.