IFPMA | Ethoscope

Artificial intelligence ("AI") ethics principles

JULY 2022

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**