Takeda's Position on Use of Artificial Intelligence (AI)

Summary

The Takeda position on Artificial Intelligence (AI) includes principles that provide a sustainable approach to the ethical use and deployment of AI systems across Takeda, its affiliates, and partners to ensure that we:

- Help our business innovate responsibly
- Prioritize medical and social benefit
- Promote freedom of choice
- Establish fair and balanced systems
- Build robust and reliable AI
- Ensure safe and secure platforms
- Strive for explainable AI
- Establish an auditable process
- Keep humans in the loop

Artificial Intelligence Defined

AI has varying definitions across media and scientific literature. At Takeda, we adapt and simplify the technical definition proposed by the European Commission's Expert Group on AI (see *Appendix I*): ***AI is a system or software that learns from data to find patterns, take actions, make decisions, or assist in decision making.***[1]

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[1] *High-level expert group on artificial intelligence*. Shaping Europe's digital future. (2022). Retrieved 25 May 2022, from https://digital-strategy.ec.europa.eu/en/policies/expert-group-ai.

Takeda is committed to responsible AI that generates sustainable value by learning from and acting on insights derived from analytics and artificial intelligence. We also actively contribute to the broader scientific, industry, and technology communities that are strengthening and evolving AI practices. This is exemplified by our participation in the International Pharmaceutical Federation of Manufacturers & Associations (IFPMA) working groups and the MIT-Takeda Program that aims to "fuel the development and application of artificial intelligence to benefit human health and drug development."[2]

Given the rapid evolution of AI compared to the speed at which legislation, regulations, and guidance governing these technologies are developed, Takeda's principles provide direction for ethical decision-making around AI.

Background

Takeda strives to become the most trusted, science-driven, digital biopharmaceutical company. We understand that our work impacts people in a fundamental way – with regard to their health and when they are at their most vulnerable. We're committed to following the highest ethical standards, including in the use of technology.[3] Because AI is an emerging field with the potential to impact all areas of medicine from drug development to product distribution to patient care, it is imperative to clearly articulate and interpret general principles for its ethical use. The principles described in this document were established via the Takeda Ethics Advisory Council (TEAC). The TEAC is comprised of a diverse group of professionals that include prominent external ethics experts and selected Takeda leaders. The primary responsibility of the TEAC is to perform analyses of ethics topics and provide advice, informing Takeda's development of robust and principled positions on these issues. Our principles for ethical AI were designed to encompass and extend the traditional principles of biomedical ethics including beneficence, nonmaleficence, autonomy, and justice.[4]

Takeda's Perspective

Takeda is committed to a responsible innovation approach that shapes our use of data and digital technologies. We strive to bring the best solutions to individuals, including solutions that incorporate

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[2] https://mittakedaprogram.mit.edu/

[3] Fjeld, J., Achten, N., Hilligoss, H., Nagy, A., & Srikumar, M. (2020). Principled Artificial Intelligence: Mapping Consensus in Ethical and Rights-Based Approaches to Principles for AI. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.3518482

[4] Beauchamp, T., & Childress, J. (2019). *Principles of biomedical ethics* (8th ed.). Oxford University Press.

cutting-edge AI systems that help discover new medicines, better understand fundamental biology, optimize treatments, or enhance the experience of patients, HCPs and others. Doing this well means investing in the practices and cultural change needed to make Takeda's AI-based algorithms and digital infrastructure secure, ethical, and trustworthy. It also means recognizing that, because AI is a tool with broad application potential, its ethical considerations are often an evolution of existing biomedical ethics discussions and require cross-functional collaboration.

We believe algorithms deployed by Takeda and its partners and vendors, should:

1) Comply with local and international laws and regulations (Legal AI). Software and algorithms are developed and deployed with appropriate legal oversight, and compliance is managed by experts in relevant laws and regulations.

2) Prioritize security and technical soundness (Robust AI). This should reflect best practices in the biopharmaceutical industry and within Takeda.

3) Align with the ethical criteria described in this document (Ethical AI).

To make ethical AI a reality at Takeda, this document describes a framework of principles that will maximize the benefits of AI to individuals, the environment, and the sustainability of our business. These principles apply from the earliest moments of innovation, through the development of internal protocols, to the ultimate adoption of AI technology. The management of AI and its ethical design is an ongoing process that will be in continuous development with relevant experts and stakeholders.

The following principles outline Takeda's strategic approach to ethical AI:

- **Help our business innovate responsibly**
  Takeda recognizes that the deployment of AI is imperative to the sustainability of our business. We value AI systems that improve efficiency, enhance benefits, and minimize, as much as feasible, environmental impact.

- **Prioritize medical and social benefit**
  Takeda seeks to balance risk with providing clinically meaningful outcomes. We aim to always examine whether AI is the appropriate tool, pay particular attention to vulnerable groups, and to the extent possible and meaningful, include patient, HCP, and others' input on AI systems design and use when AI may directly impact health.

- **Promote freedom of choice**
  We promote the building of AI systems that maximize our ability to deliver healthcare solutions without compromising an individual's freedom to make their own choices. To the extent possible and meaningful, we aim to include patient, HCP and others' perspectives during the development and implementation of AI systems.

- **Establish fair and balanced systems**

  Takeda believes the data used to train and test AI should be, to the extent feasible, epidemiologically representative of the intended populations, appropriately diverse[1], including, but not limited to, age, gender, race, ethnicity, and social determinants of health.

- **Build robust and reliable AI**

  Takeda seeks to build and test AI systems using best practices in machine learning and software engineering with independent test sets that are representative, to the extent feasible, of the intended population. When clinical use is involved, we encourage demonstrating performance in clinically relevant conditions using established methods such as rigorous testing, use of independent controls and test data, documentation, and - where possible - peer review, and open access sharing of our algorithms.

- **Ensure safe and secure platforms**

  Takeda believes that personal data should be secure and anonymized when possible. Internal data governance practices align with Takeda's policies on Privacy and IT Security as well as Takeda's Position on Data Sharing and Reuse of Health Data.

- **Strive for explainable AI**

  Takeda intends to provide patients, HCPs, and others with essential information about AI based systems. This includes a clear estimation of risk, communicated in a clear and contextually relevant manner to support human decision-making. The level, degree, and type of explanation may differ depending on need and technical feasibility.

- **Establish an auditable process**

  In healthcare settings, Takeda promotes the use of AI systems that are fully documented and version controlled using industry standard best practices from testing through live use such that decisions can be traced to the version, data, and parameters used.

- **Keep humans in the loop**

  Takeda believes that higher risk systems should operate with a human in the loop. Takeda seeks to develop and deploy AI systems that are continually subject to operational and ethical review and to promote personal accountability for the system's performance, including collecting feedback to improve the system.

Conclusion

Takeda recognizes that AI provides many opportunities both for the patients, HCPs and others we serve, as well as our company. We accept responsibility for its use and hold ourselves accountable to high standards when we deploy AI.

Given the rapid evolution of AI compared to the speed at which legislation, regulations, and guidance governing these technologies are developed, these principles provide Takeda's commitment and framework for ethical decision-making around AI. These principles will be regularly revisited by Takeda to ensure they meet the expectations of patients, HCPs and others, both today and in the future.

About Takeda Pharmaceutical Company Limited

Takeda is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetics and Hematology, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines.

September, 2022