Our position on
Responsible Artificial Intelligence (AI)

What is the issue?

Artificial Intelligence (AI) is impacting innovation, growth, and productivity in nearly every industry. The World Economic Forum predicts up to a 40 percent increase in labour productivity from AI in developed countries by 2035.[i]

In biopharma, one of the greatest strategic opportunities for the application of AI is in R&D. Harnessing AI is playing a role in getting safe and effective treatments to patients faster by driving greater pace and efficiency in the discovery and development of new medicines and vaccines. Moreover, AI has applications across the entire biopharma value chain and business operations.

Although the opportunity to positively impact human health is enormous, AI also carries societal risks. To promote trustworthy and ethical use of AI, it is important that AI is adopted in ways that safeguard against:

- Undermining human rights, data privacy and security.
- Errors that could cause patient harm.
- Promoting discrimination and worsening inequalities.
- Potential for misinformation.

This policy sets out GSK's view on the role of AI in biopharma, our commitments to develop and use AI responsibly, and what actions policymakers can take to support safe and effective AI adoption.

What is GSK's view?

- **AI presents a transformative opportunity to improve medicine and vaccine development, innovation, and growth.** AI can accelerate our pipeline by helping us to find the right target, with the right medicine or vaccine, for the right patient - and to do that better, faster and with greater precision. For example, AI is already accelerating the discovery of new drug targets and improving patient selection into – and their experience in – our clinical trials. Generative AI[1] can already support researchers by suggesting new areas for exploration based on patterns, connections, and research gaps found in scientific data and literature.[ii] Beyond R&D, AI can optimise efficacy across all functions, from manufacturing and supply chain to corporate processes.

- **It is crucial that AI is developed and adopted responsibly.** Responsible AI development and deployment, guided by robust ethical frameworks, is not just a necessity but a moral imperative. By placing patient safety and accountability at the forefront of our work, we strive to create a future where AI serves as a powerful tool for positive impact by empowering our workforce and human decision-making and enabling us to transform healthcare while upholding the utmost integrity.

- **Government policies and regulatory approaches should foster global innovation, be sector-specific and proportionate to the associated risk.** Whilst recognising the need for policymakers to craft regulatory frameworks informed by their unique legal traditions and values, diverging approaches could significantly limit the pace of innovation globally. Policymakers should also focus on regulating how AI is used, rather than the AI technology itself. In biopharma, healthcare regulators are best placed to assess risk, based on AI use in medicine and vaccine development, and take a proportionate risk-based approach.

[1] Generative AI deploys machine learning models, trained on very large data sets, to create new content, such as written text, code, images, music, simulations, and videos. Gen AI can draw on patterns and structures within its source data to generate new and original content, that feels like it was created by a human.

Our commitments

GSK has established a new governance framework for the development and adoption of AI. This includes five AI principles, underpinned by our ethical standards[iii], to set clear expectations for all employees to ensure that we apply AI responsibly and for greater societal good.

To oversee the safe and ethical deployment of AI, GSK has formed a cross-functional AI Governance Council which is sponsored by members of the GSK Leadership Team, representing Digital & Technology and Legal & Compliance. Our AI Governance Council is responsible for enforcing our principles by reviewing projects, providing guidance, and monitoring compliance. The AI Governance Council also keeps abreast of the latest developments in AI so that we can evolve our approach and continue to act responsibly. GSK's approach to managing the risks from AI is integrated with our existing risk governance framework.[2]

Our AI principles

These principles are underpinned by a commitment to maintain human oversight in critical decision-making processes involving AI tools and systems and avoid fully autonomous AI solutions in areas with significant ethical and/or legal implications.

1. **Ethical innovation and positive impact**: We take a comprehensive approach to AI responsibility and have a specific principle to be thoughtful, throughout our use and development of AI, about how to prevent unintended negative consequences or harms that could arise from AI systems. This is essential to ensure our use and development of AI remains safe and responsible as the technology evolves, and that our innovation delivers long-term positive impact on patients' health and wellbeing. We prioritise human rights and welfare in our design and deployment of AI.

2. **Data ethics, privacy, and security**: AI models are trained using large datasets which may contain personally or commercially sensitive data. When using these models, we respect individuals' right to privacy and comply with legal and regulatory considerations, such as rules relating to the use of patient data. We apply appropriate measures to protect data and ensure the security of our AI systems.

3. **Robustness and reliability**: Systems which have not been appropriately tested may bring serious risk to GSK and its stakeholders by producing poor results or failing to perform critical tasks. Systems using AI are risk-assessed, rigorously tested, and managed to demonstrate robustness and reliability.

4. **Fairness and representation**: The data used to train AI models can include existing biases and may not be representative of desired population, and the design of the models themselves can cause discriminatory effects by treating individuals differentially or performing unequally for users from different demographic groups. We use data that is as representative as possible and embed fairness considerations when developing, monitoring, and managing AI systems, to minimise bias and aim to treat individuals fairly.

5. **Transparency and accountability**: All development, procurement and use of AI must demonstrate adherence to our AI Principles, overseen by our AI Governance Council, and our AI processes, data, and algorithms are clearly documented, traceable and open to audit. We will

[2] Details of GSK's risk governance framework can be found here: Committees | GSK

clarify with external users when they are interacting with an AI system. We will be transparent about the capabilities and limits of our AI systems, particularly where they affect healthcare decisions.

We are committed to continually raising ethical standards and we engage and discuss our approach with external experts and stakeholders. We fund fellowships at the Stanford Center for Biomedical Ethics to provide external challenge and advance research in AI. These fellows produce leading work with no editorial control from GSK. This ethics research is open-source and open to collaboration from our colleagues across the industry, because we believe that raising the ethical baseline across the industry is a benefit to all.[iv]

What actions should policymakers take?

- **Develop pro-innovation models for AI regulation, using sector specific regulators and risk-based approaches.** How AI is used is context specific. We believe a model where high-level cross-sector principles are established, but responsibility for how AI is regulated is devolved to sector specific regulators, is the best way forward. For biopharma, health regulators will be in the best position to minimise complexity across existing regulatory frameworks and understand and interpret risk based on how AI is being used and the outcome it is looking to achieve. For example, potential over-regulation in early research activities, like target discovery, may slow the discovery of new therapies without a corresponding benefit to public safety.

- **Collaborate internationally to develop and implement underpinning standards to support global interoperability across health regulators**. For example, by creating Good Machine Learning Practice (GMLP) standards for AI in health, building on the work to date from the G7 and UK, US, and Canadian health regulators.[v] Internationally agreed GMLP, applied consistently, would give the biopharma industry common technical standards to work to when developing AI technologies, give the public assurance that these have been developed in an appropriate way, and promote cross-border research.

- **Invest in the development of AI capacity and expertise among health regulators** to ensure they can keep pace with innovation. We welcome the development of 'regulatory sandboxes' as a policy development technique, which enable regulators and industry to come together in controlled environments to test and learn how regulation interacts with innovation, creating insight for future regulatory frameworks.

- **Work collaboratively and invest in an AI ecosystem that is diverse and representative of global populations**. AI is dependent on the quality and diversity of data on which it is built. To ensure the use of AI minimises, rather than exacerbates health inequalities, it is vital to invest in high quality, diverse and representative datasets and build a diverse pipeline of AI talent.

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[i] https://www.weforum.org/agenda/2020/12/ai-productivity-automation-artificial-intelligence-countries/.
[ii] AI Generates Hypotheses Human Scientists Have Not Thought Of - Scientific American
[iii] Ethical standards | GSK
[iv] The GSK.ai/Stanford Ethics Fellowship
[v] Good Machine Learning Practice for Medical Device Development: Guiding Principles - GOV.UK (www.gov.uk)