HARNESSING AI FOR PHARMACEUTICAL INNOVATION

Artificial Intelligence (AI) is accelerating innovation across the pharmaceutical sector – from discovery to clinical development, manufacturing, distribution, and commercialization. Together these advances will help improve patient health outcomes, enhance access, and simplify the care delivery experience.

Pharmaceutical companies have been leveraging digital technology for decades and more recently AI, deploying these tools to help patients while ensuring continuous adherence within regulatory frameworks. Importantly, pharmaceutical companies are one of the most regulated sectors and governance frameworks have been designed to enable the incorporation of new technologies in a way that ensures safe innovation. The existing regulatory safeguards have helped to develop an environment that fosters trust and safety between industry, policymakers, institutions, and most importantly patients. Evolving these safeguards and future-proofing laws and regulations to unlock the promise of new and emerging technologies and their uses will be paramount moving forward.

There are still important questions for industry leaders and policymakers; for example, how can we effectively leverage AI to maximize benefits, mitigate potential risks, and account for its rapidly evolving nature? To explore these and other questions the 'Harnessing AI for Pharmaceutical Innovation' Summit was convened by Global Counsel on behalf of Pfizer, Inc. on July 16th in Washington, DC. The summit brought together an international group of key stakeholders, including industry leaders, policymakers, regulators, tech experts, researchers, and patient advocates to discuss these and other important questions.

The summit organizers look forward to continued conversations focused on enabling policy approaches that will ensure AI remains a tool for innovation for patients, guided by the insights and recommendations shared during the summit.

KEY TAKEAWAYS

The need for international regulatory alignment on AI

Global efforts are intensifying to align on AI regulations, aiming to balance innovation with safety through flexible and agile frameworks. The summit highlighted the pressing need for increased international regulatory alignment and cooperation in developing common standards and principles. Differing approaches can pose significant challenges; for example, disparities in healthcare regulations can undermine the cross-border sharing of medical data, hindering global health initiatives, and rapid pandemic responses. While speakers emphasized the need for shared frameworks and standards, they acknowledged the importance of allowing for some variations based on jurisdictional differences.

KEY TAKEAWAYS

Future-proofing regulation for evolving AI technologies.

As AI technology advances, the regulatory frameworks that govern its use must be equally dynamic and responsive. Many speakers pointed to regulatory sandboxes as an effective and collaborative tool for testing new AI applications in a controlled environment, allowing regulators to gather insights and update policies without compromising public safety or contravening existing policies. Relatedly, the need for ongoing dialogue and collaboration among stakeholders was identified as key for future-proofing AI regulation. These collaborative approaches help ensure that regulations are informed by the latest technological insights and industry practices, preventing them from becoming obsolete as AI evolves.

Strengthening the effectiveness of AI through improved data sharing and access.

The summit's speakers broadly agreed that access to high-quality, diverse datasets are the backbone of effective AI, and emphasized the need to break down data siloes. Public-private partnerships may play an important role in efforts to increase access to these types of datasets. Multiple speakers pointed to the need to improve data sharing mechanisms to better train AI models and reduce duplication in data collection and analysis. Sharing non-confidential clinical data through secure mechanisms, for example, could help accelerate drug discovery and improve predictive models for patient care.

Evidence-based assessments of risk is key

Across the panel discussions, the speakers recognized the need to move beyond an "amorphous" concept of risk and instead adopt a nuanced, risk-based approach tailored to different AI applications and risk levels. For example, a different approach is needed for AI used in patient care versus AI used to optimize company travel. As such, consensus emerged about the importance of leveraging AI Safety Institutes. These institutes provide technical expertise and resources to governments, aiding in the understanding and mitigation of AI-related risks. Moreover, they could assist policymakers in developing risk and evidence-based strategies for crafting precise and effective regulations. The growing international network of AI Safety Institutes will likely contribute to a shared understanding of definitions such as "risk" and "safety" which will help drive global regulatory alignment.

Human-centred approaches to AI

Several speakers highlighted the importance of educating patients about AI, empowering them to actively engage with their healthcare providers and make informed decisions about AI use in their care. Similarly, for healthcare providers, there is value in educating them on how AI can complement rather than diminish their capabilities. When providers are comfortable using AI, it also benefits patients, who gain from the enhanced care these tools provide. Ultimately, education "demystifies" AI technologies, making them more accessible, trustworthy, and transparent — ultimately leading to greater adoption and use of these tools.

Exponential solutions to solve exponential problems

Given the increased complexity in drug development and delivery, utilization of additional tools like AI may support improved outcomes for patients by potentially bring significant efficiencies to the pharmaceutical industry and transform patient care. For example, as discussed during the summit, AI is revolutionizing drug development and patient care by enabling the analysis and interpretation of vast amounts of data at unprecedented rates, allowing for the development of more personalized treatments. Clinical trials are undergoing significant change, with AI boosting diversity, leading to broader and more representative participation in trials. AI's benefits also extend to the pharmaceutical supply chain, where companies are leveraging AI to gain greater visibility across their networks.