Digital Health and Artificial Intelligence (AI): Rapid development of new technologies and regulatory frameworks will transform the sector

DIGITAL HEALTH AND AI TRENDS:

Wearables and mobile health will increasingly be used to collect real-world data (RWD) for potential use as real-world evidence (RWE) in regulatory decisions.

New AI and digital health regulatory frameworks are on the horizon in the U.S., China, and Europe.

Medical software to support physician decision-making and medical robotics will continue to evolve.

Digital diagnostics and digital therapeutic medical devices have emerged as an exciting opportunity to innovate in the provision of healthcare, but require careful planning as to coverage and payment.

Enhanced use of AI raises new questions about tort liability and risk mitigation.

Much of the rapid change that the life sciences industry is currently experiencing is technology driven. The growth of digital health is likely to be a defining feature of the decade for the industry. Fast technological advancements mean that AI technologies will reach mainstream adoption in the next five years. The International Data Corporation has estimated that worldwide spending on AI across all industries will increase from the US$50.1 billion spent in 2020, to more than US$110 billion by 2024.

The impact of digital health and AI will be much wider than new products — such as wearables and diagnostics — and new processes — such as decentralized clinical trials. We anticipate that, with the advent of cloud-based, off-the-shelf AI tools, AI technologies will become more widely accessible and affordable. New types of life sciences companies will arise within the industry, and will face a diverse and novel legal and regulatory landscape in relation to the use and commercialization of digital technologies.

Developments will be spurred, in part, because life sciences companies and regulators are increasingly using RWD — data generated by patients and doctors outside of clinical trials — as RWE to support a range of product development and regulatory decisions.

Wearables and mobile health (mHealth) technologies will enable the increased collection and evaluation of digital biomarkers, measurable indicators of a biological state or condition, that provide valuable data for the application of AI systems. Edge AI applications, which run AI algorithms locally, e.g., on Internet of Things (IoT) devices, will become increasingly relevant, as will federated learning, a machine learning setting in which models can be trained on distributed data. The application of AI systems will occur both from a privacy-enhancing perspective — where the evaluation of data takes place in a decentralized manner — and on IoT devices themselves.

Medical robotics using AI and virtual/augmented reality will continue to evolve. Software tools that support disease diagnoses or therapeutic interventions may be regulated as medical devices, and may create unique regulatory challenges and require new reimbursement/

payment considerations to optimize commercialization and uptake in the marketplace. Continuous data mining by wearables and mHealth devices is well-suited for the application of adaptive AI systems. The conflict between the availability of large amounts of data and privacy/data protection considerations will drive the uptake in the life sciences industry of privacy-enhancing technologies such as homomorphic encryption, multi-party computing, edge AI, and blockchain-based solutions.

Technological advances around wearables and mHealth will increasingly be used to collect RWD for use as RWE in regulatory decision-making. We expect to see an increasing acceptance of RWD and RWE in the drug approval processes, as well as an increase in the use of RWD and RWE in decentralized clinical trials.

In the U.S., the FDA has been undertaking its 21st Century Cures Act obligation to create a framework for the use of RWD in pre- and post-marketing decisions, issuing recent guidance on sourcing RWD from electronic health records and medical claims, addressing the use of RWD in regulatory filings for the approval of therapeutic human and animal drugs, and discussing study design elements and the use of RWD to satisfy post-approval study requirements. Companies have obtained or are seeking approval from the FDA for digital diagnosis and digital therapeutic devices that carry tremendous promise to change care delivery pathways and opportunities in the U.S. European regulators have also launched several initiatives aimed at establishing the position of RWE in regulatory decision-making.

Litigation related to AI and digital health is likely to emerge with more widespread use of these technologies. Life sciences companies operating in these spaces will be looking for ways to minimize risks, and regulatory agencies may well support the development of innovative technology by increasing predictability and transparency.

New regulations that contain requirements specific to AI and digital health are also on the horizon, including China's guidelines for AI-incorporating medical device software, the U.S. FDA's total product life cycle approach, and the proposed EU AI regulation

(which, once adopted, will result in novel legislation), which will provide the legal basis for adaptive AI systems/continuous learning systems.

DIGITAL HEALTH AND AI TIPS:

- Life sciences companies should monitor and map emerging standards and regulatory frameworks.

- Life sciences companies have to be involved in the development of standards.

- There is a need to acquire, and train, a workforce skilled in data science and machine learning.

- The industry needs to embrace responsible and trustworthy AI as the basis for large-scale uptake through the establishment of governance systems, including interdisciplinary governance committees and AI ethics boards.

- Investors and executive teams should understand FDA regulatory and coverage and payment pathways for digital diagnosis and digital therapeutic tools and medical devices, and understand the potential approval and clinical evidence development requirements and compliance obligations associated with such innovation.

- Companies should look for opportunities to minimize risk of tort liability potentially associated with AI and digital health use.

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