Artificial Intelligence (AI) Policy Principles

REAL-WORLD EVIDENCE ALLIANCE

The use of real-world data (RWD) in the development and deployment of AI technologies in the healthcare and life sciences sectors has the potential to yield enormous benefits. AI tools are rapidly expanding the types of RWD that can be collected and the methods for that collection, as well as the ability to evaluate data and data quality. The use of high-quality, reliable, and representative RWD to train, improve, and evaluate AI systems used in medical product development and commercialization meaningfully advances medical innovation for patients. Moreover, AI developed using RWD can improve health equity and accelerate the discovery, research, development, and delivery of even more advanced and personalized treatments and cures.

RWD are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include electronic health records, medical claims and billing records, product and disease registries, wearables, and health applications.

As a coalition of RWD and analytics organizations with deep knowledge and experience working with healthcare data across disease areas and patient populations, the RWE Alliance believes that that any policy framework affecting healthcare AI should adhere to these principles:

PATIENTS FIRST

Policy frameworks should be developed with patients at the forefront and recognize the meaningful benefits to patients of incorporating RWD in the development and deployment of AI.

The use of RWD to train and evaluate AI has tremendous potential to benefit patients, including by helping to discover and develop new treatments and cures. With this in mind, efforts to regulate AI applications in healthcare and medical product development should be grounded in the overall objective of enhancing patient care and well-being and encourage the use of RWD in the development and deployment of AI to benefit patients.

HIGH-QUALITY AND RELIABLE DATA

Healthcare AI should be developed and deployed using high-quality and reliable data, including from real-world sources.

Unlocking the potential of healthcare AI depends on the quality of the data used to build and evaluate the technologies. Policy frameworks should encourage and facilitate the use of high-quality and reliable RWD, including by leveraging existing and emerging data fitness and quality standards.

REPRESENTATIVE DATA

Healthcare AI should be trained using representative data, including from real-world sources.

It is common consensus that using a representative training dataset is important for reducing biased and inaccurate AI outputs and decisions. RWD can play an important role in increasing the representativeness of data used to train healthcare AI, which promotes health equity through outputs that better reflect patient populations in real-world settings. Policymakers and stakeholders should pursue policies to ensure that training datasets for healthcare AI are fit-for-purpose and representative of the population in which the AI system will be deployed, taking into account the unique benefits of RWD for building, reviewing, using, and updating training datasets.

TRANSPARENCY

Policy frameworks should include transparency standards to promote trust in the use of the technologies.

Policy frameworks should establish transparency standards that enable regulators and stakeholders to assess the validity, reliability, and potential biases of AI technologies. For example, policy frameworks should establish guidelines to ensure transparency in how data, including RWD, are used and processed for the AI system, as well as guidance on how to properly validate and monitor AI models for accuracy and fairness as appropriate. In addition, guidance on effective internal governance and documentation practices, evaluation criteria, and monitoring practices can help to create a transparent and accountable environment for AI applications, thereby promoting trust in AI. At the same time, policy frameworks should ensure that appropriate protections are in place for proprietary information. Ensuring proprietary information is treated as confidential commercial or trade secret information under information disclosure laws will foster continued innovation of AI tools in healthcare settings.

PATIENT PRIVACY

Policy frameworks should encourage the use of RWD and AI not just for medical product development but also to enhance patient privacy.

AI tools can be used to enhance patient health data privacy while advancing public health outcomes. For example, AI can assist in the de-identification of real-world datasets, allowing for data analyses that can meaningfully advance clinical research while protecting individual identities. In addition, AI can create new, "synthetic" data by replicating the patterns and characteristics of an underlying real-world dataset. This synthetic data can be used in lieu of personal data to increase data volume and enable use and analyses of data that otherwise might not be available for training or research.

CONTEXT MATTERS

AI regulation should take into account the intended purpose of the AI system and the context in which it is used.

AI systems can support each stage of the medical product development and commercialization processes. Because each use case carries different risks and benefits, AI regulation should take into account the risk presented by a particular AI use case, balance the use case's risks and benefits to patients, and avoid stifling beneficial uses of technology. Regulation should also appreciate that actors in the AI ecosystem play different roles and should tailor requirements to those activities.

REGULATORY ACCEPTANCE

Policy frameworks should encourage and facilitate the responsible adoption of AI tools in medical product development that are developed and trained using RWD.

To facilitate technological innovation and responsible adoption of technology, policy frameworks should shape processes to identify when regulatory review of AI tools developed using RWD is appropriate, to expedite and streamline regulatory review when needed, and to ensure predictable regulatory acceptance. Policymakers also should create qualification programs for AI tools that require validation under existing regulatory frameworks. Increasing the volume of validated and qualified AI tools can streamline medical product development and, in turn, accelerate access to better treatments and cures for patients.

EXPERT CONSULTATION

Policymakers should consult industry experts to better inform the regulation of AI healthcare technologies when developing new policy frameworks.

Dialogue between policymakers, regulators, international health authorities, academics, and industry, including real-world data and analytics organizations, will help policymakers and regulators keep pace with the rapid development and global reach of technological innovation, consider the intersection of RWD and use of AI, and inform policy frameworks for the use of AI in our health system.