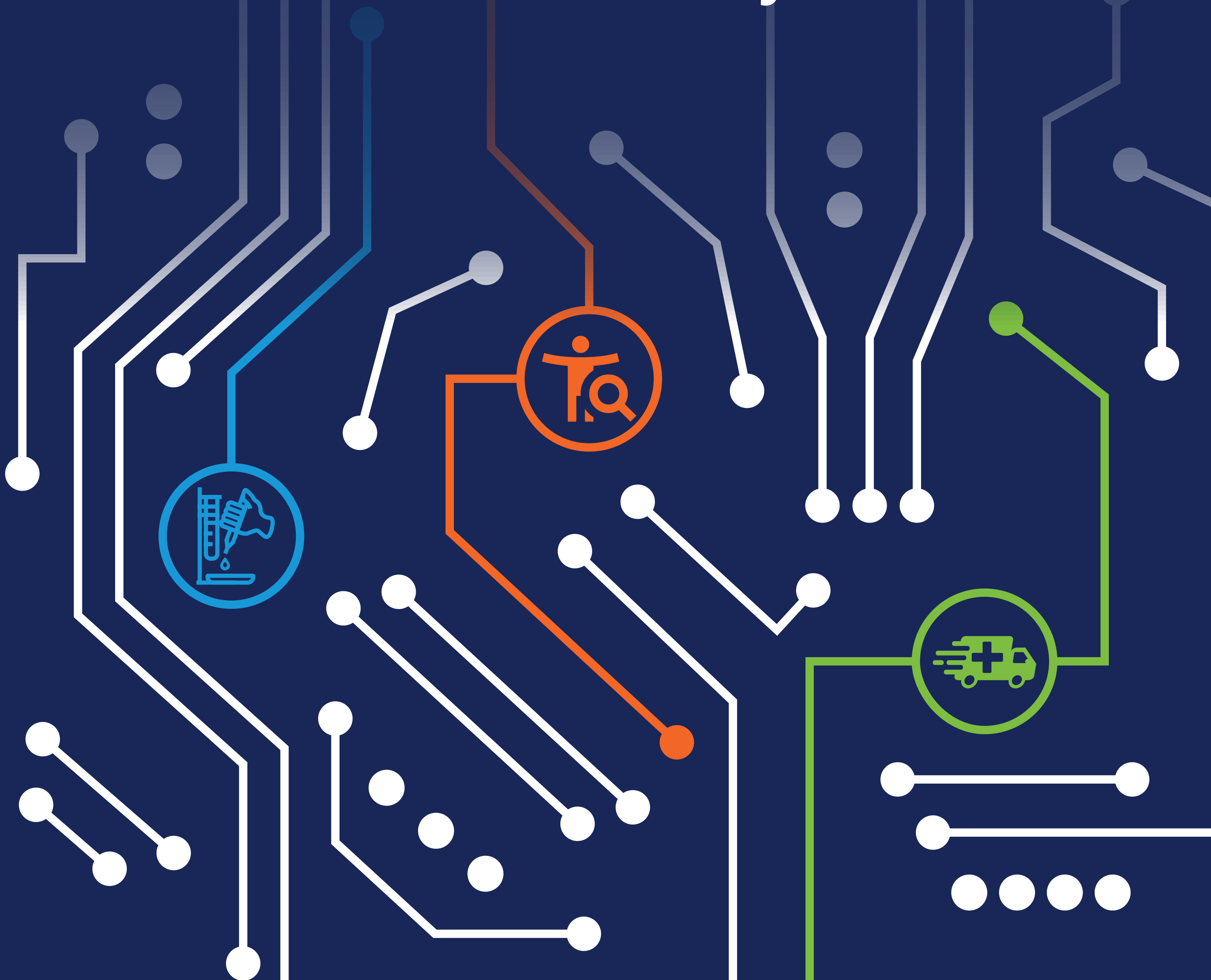
World Health Organization

Benefits and risks of using artificial intelligence for pharmaceutical development and delivery



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6 Challenges in governance

Introduction and use of AI in the pharmaceutical value chain will pose new challenges to governance of the pharmaceutical sector. Furthermore, although drug development is regulated both individually and collectively by governments, the introduction of AI will require revision of existing regulatory approaches and new standards to ensure quality, safety and efficacy. Some challenges in governance that should be addressed collectively by the international community and governments to keep up with this fast-changing sector are discussed below.

6.1 Governance of data

Data are critical to the discovery and development of medicines and vaccines with AI. The use and sharing of data raise considerations of privacy. In some situations, it will be illegal or unethical to share data that were collected only for purposes to which the user specifically consented. Datasets that were collected legally and ethically for use in drug development might not be available or permitted for use to improve the development of new medicines and vaccines *(29)*. This might be the case, for example, when generation of data was either supported financially or done by a company, when the data sets would be considered a commercial benefit that is proprietary and, in some jurisdictions, protected by intellectual property (IP) rights. At present, several types of IP rights, including trade secrets, copyright and database rights (in a few jurisdictions), may apply to data. Conferring IP and related rights to health data could discourage open sharing of the data, especially if companies that exercise IP rights do not make the data sets available to third parties or on commercially reasonable terms *(1)*.

Currently, pharmaceutical companies are collaborating to develop systems for combining data to strengthen their work on drug discovery *(88)*. While such data-sharing platforms may be rich and can benefit the pharmaceutical industry *(8)*, they may not be available to other entities, including not-for-profit developers and smaller pharmaceutical firms that usually target unmet needs that will generate public health benefits *(29)*.

One means for wider distribution of the benefits of AI is to ensure open data or to make datasets that are legally collected and used for or generated by R&D open and freely available, at least for non-commercial use. This concept was supported by over 80 governments that adopted the "Open Data Charter", which commits signatory countries to develop policies for making data accessible and freely available, while protecting the individual rights of people and communities *(29)*. A concern related to open data approaches is that the data sets lack adequate "depth, dimensionality and scale" for application of AI to drug R&D *(8)*. Some governments have taken steps to improve the availability of open data for biomedical research by supporting cohorts of volunteers who have consented to use of their data in research. One of the largest is the UK Biobank in the United Kingdom, with 500 000 participants, which allows distribution of de-identified data to approved researchers who are investigating common and life-threatening diseases *(89)*. Its Ethics and Governance Council applies a framework to govern ethical use of the data that are collected and shared *(90)*.

Population-wide data, such as from an entire health-care system, would be preferable for research, rather than smaller, potentially biased cohorts. Citizens' concern about the privacy of sensitive health data, even after anonymization, has led to development of models in which data are not distributed, and can be accessed only by researchers in secure environments. The United Kingdom, through Health Data Research UK, has been advocating for adoption of "trusted research environments" (TREs), which are single locations from which researchers can access datasets, encourage collaboration and assure those who contribute data that such data are accessed securely and their privacy is protected *(91)*. The TRE approach has been adopted as policy by the English National Health Service, which is establishing a number of regional "secure data environments" to support research. The approach creates specific challenges for AI and for other intensive data analysis, as any software required by researchers should be moved into a TRE, which must have access to sufficient computer resources to run it.

At a multinational level, the European Union is developing a European Health Data Space *(92)*, a

> health-specific data sharing framework establishing clear rules, common standards and practices, infrastructures and a governance framework of electronic health data by patients and for research, innovation, policy making, patient safety, statistics or regulatory purposes.

Currently, it is envisaged that individual data will remain within national boundaries in TRE-like infrastructure. This will require use of "data federation" technology to analyse data from several countries, which will pose challenges for training AI models while preserving privacy. Introduction of broader standards that can be applied worldwide could improve data-sharing and governance but would require strong cooperation among databanks, academic institutions, funders and governments *(8)*.

6.2 Ownership and intellectual property

There is debate about assigning ownership for inventions that rely on AI, including whether an entity or an individual that uses AI can claim "inventorship". This raises the issue of whether new medicines developed with use of AI can be patented *(93)*.

The impact of IP on the development of and access to medicines is a long-standing, critical issue. While IP rights provide pharmaceutical companies with a limited right to recuperate investments in R&D through the exclusive right to register and market a new medicine or vaccine, such monopoly rights can lead to unaffordable prices and other practices, such as distortion of markets and inadequate supplies, which limit access *(94)*. Furthermore, IP rights do not encourage companies to invest in R&D for commercially unattractive areas, such as neglected tropical diseases, paediatric health, drug-resistant infections and pandemic threats *(95)*. Use of AI in drug development introduces new considerations for policy-makers, such as finding and using alternative models to pay for development of and access to AI to be used in the public interest.

First, mining of data can help to identify promising new compounds and vaccines. If the data are collected from individuals for other purposes, however, it is questionable whether they can be used for commercial purposes if the medicines developed from such data are not available to those who provided the data and more broadly if the compounds and vaccines are not available in the public interest, such as by setting affordable prices *(96)*.

Another concern is the increased patenting of algorithms used in drug development and the use of trade secrets to prevent use of algorithms except by their IP owner, which could lead to IP “lock-up” *(8)*. IP restrictions on algorithms will exclude most entities from using them to improve drug development, especially academic researchers, not-for-profit organizations and entities in low- and middle-income countries *(8)*, all of whom are more likely to focus on unmet needs ignored by the pharmaceutical industry *(97)*. Exclusive control of algorithms also impedes advancement of science and limits the potential broader social benefits of AI. Exercise of IP rights encourages secrecy, as companies will not disclose source code or other information about their proprietary algorithms. While companies may have a commercial rationale for lack of transparency, this can undermine public trust and prevent regulators from ascertaining whether medicines developed with AI meet regulatory standards. Patenting also often involves protection of AI algorithms that were originally developed with public funding or by publicly funded research *(97)*.

Companies that develop AI algorithms may not themselves develop medicines and vaccines but may issue licenses to the highest bidder, thereby limiting use of the technologies to the world’s largest pharmaceutical and technology firms or for use in certain geographical locations. Such licensing practices are ending, however, as companies that develop AI-based platforms and technologies are developing new medicines rather than out-licensing their software *(8)*. Pharmaceutical companies are also spending significant sums of money to acquire compounds developed by smaller companies that use AI for drug development *(98)*, thereby increasing the incentive for those companies to protect their proprietary algorithms and to focus on diseases that generate profits from the pharmaceutical industry.

6.3 Governance of the private sector

The ownership of data sets and IP protection of algorithms contribute to potential concentration of decision-making and power in a small group of companies that use AI in drug development. There is concern about the emergence of “walled gardens” in the private sector with respect to use of AI *(98)*. Companies already exert significant control over data, including through industry-owned pre-competitive platforms. Furthermore, there is a growing number of partnerships between large technology companies and large pharmaceutical companies, which could consolidate power in the hands of a few. Such companies are likely to have not only significant financial resources but also data, computing power, technology and most AI programmers. The size of a company’s platform, including for drug development, may create a monopoly. As AI, such as generative AI to design new medicines, becomes increasingly sophisticated and requires more resources, few companies will be able to use it. Monopoly power can concentrate decision-making in the hands of a few individuals and companies, which can result in higher prices for goods and services, less consumer protection and less innovation, and the choices, priorities and outputs of AI will be limited by the decisions made by a few companies *(99)*. These could include decisions to deprioritize or abandon products and services that may be of significant public health importance and instead prioritize services that can generate revenue. In 2023, one major technology company “axed” the team that had developed the protein-folding model ESMFold (see above), and there is concern about whether the company will “absorb the costs to keep the database running, as well as another service that allows scientists to run the ESM algorithm on new protein sequences” *(29)*.

Competition and anti-trust laws, depending on the degree of concentration and exclusion, may be necessary to sustain or promote equitable access to critical AI technologies, a healthy innovation eco-system and affordable prices for end products, while avoiding ethical risks such as discrimination and bias.

Companies often refer to use of their own ethics codes to guide use of AI, and pharmaceutical companies are increasingly developing their own ethical standards for use of AI *(100)*. While consideration of ethics by a company is welcome, it can raise concern that the companies are engaging in “ethics-washing” and that the measures are intended to forestall regulation instead of adapting to oversight *(88)*. Such codes are not an alternative to or a substitute for legal rules and obligations set by governments. One means for governments to ensure that companies select and use AI appropriately is impact assessments, which can address ethics, human rights, safety and data protection throughout the life cycle of an AI system.

In addition to regulatory standards written and enforced by governments, open science machine learning can be promoted to improve access to AI technologies in drug development. Examples include the Therapeutic Data Commons *(1)*, the Open-Source Molecular Foundation and the Human Immunome Project *(101)*.

6.4 Regulatory oversight and approval of AI-developed medicines and vaccines

As AI increasingly automates or replaces some functions usually carried out by humans in the development and delivery of medicines, regulatory authorities could act to preserve "human-led governance" *(8)* of AI-based pharmaceutical R&D, particularly to uphold core ethical principles, human rights obligations and legal and safety requirements. New approaches will be needed to ensure that independent oversight and review of pharmaceuticals developed with AI technology do not impede use of such technologies but also do not ignore risks. This should be done individually and collectively, such as the on-going efforts of the International Coalition of Medicine Regulatory Agencies to reflect on the challenges of AI and to identify a common response *(47)*.

Regulators will have to address many challenges to assess both AI technologies that companies wish to use in development and delivery of medicines and the medicines and vaccines in which AI technologies have been used. First, as for all AI technologies, regulators will have to overcome the lack of explainability of how algorithms arrive at decisions that may guide pharmaceutical discovery and development, especially in highly complex models *(76)*. Secondly, there may be concern about the quality of the data used to train AI, including bias *(47)*. Thirdly, regulators will need to coordinate with other relevant government agencies, such as data protection agencies, to ensure that data were collected lawfully, according to national or international principles and standards for data protection. Fourthly, they must overcome the reticence of companies to be fully transparent about the source code or data sets used in AI technologies, which undermines the ability of regulators to assess the uses of AI *(102)*. Fifthly, different regulatory standards may emerge around the world, which could pose a challenge to both regulators who assess AI technologies and developers who use AI *(76)*.

Irrespective of such risks and challenges for regulatory authorities, it is the responsibility of developers who choose to use AI technologies to ensure that the tools and methods are "fit-for-purpose" and adhere to all ethical, technical, scientific and regulatory standards designated and enforced by regulatory agencies *(76)*.

7 Next steps

The promise of AI requires the international community and governments to ensure that use of the technology in pharmaceutical and vaccine development and delivery does not exacerbate inequity but contributes to addressing the needs of neglected populations (such as children and infants) and countries, and to find new vaccines and medicines for unmet needs. To do so, governments must establish an effective approach to governance, including defining standards, rules, regulations and legal frameworks that prioritize public health and the public interest. WHO will continue to examine and monitor how AI is affecting the development and delivery of medicines and vaccines and identify ways in which WHO, Member States, pharmaceutical companies, civil society and global health-oriented product development partnerships and researchers can harness AI to improve pharmaceutical development and access to address unmet health needs. WHO may also develop new ethics guidance and address issues of governance for management of data, regulatory considerations and legislation to address the many benefits and challenges associated with use of AI in the development and delivery of medicines and vaccines.

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