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# A Cross-Border Regulatory and Public Policy Analysis of Machine Learning and Artificial Intelligence: The Future of AI in Life Sciences

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Artificial intelligence ("AI") and machine learning ("Machine Learning" or "ML") are growing rapidly and transforming the global economy. AI can optimise the efficiency, precision, and performance of many existing technologies. The development and application of these technologies is an industry in its own right, but AI is also transforming business models across many sectors, including the Life Sciences industry.[1]

AI/ML-enabled technological tools are capable of dissecting large quantities of data faster than ever before and, in some cases, in real time. From 2006-2016, there were 40,758 patents – roughly 12% of all patents mentioning the term "AI" – filed in connection with medical and life sciences applications.[2] The current value of artificial intelligence in life sciences is approximately $1.25 billion and is anticipated to grow to $5.4 billion by 2026, a compound annual growth rate of 29.13%.[3] However, the increasingly widespread use of AI challenges regulators to balance the benefits of innovation while protecting patient safety, public health and privacy rights.

This article provides a cross-border analysis of the evolving regulatory landscape in the United States, Europe, and China seeking to respond to technological advances that may revolutionise all facets of research and development ("R&D") and healthcare delivery.

## DEFINITION FOR MACHINE LEARNING IN GEOGRAPHIC REGIONS

In practice, AI broadly refers to the science and engineering of making intelligent machines, especially computer programmes. AI commonly utilises a combination of computer science, statistics, and engineering. Using these tools, AI technology creates algorithmic models capable of learning from prior data to make decisions and predictions regarding new data. Machine Learning, a significant subset of AI, uses computer algorithms to find patterns in

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and learn from data in order to perform tasks, such as predicting the behaviour of future datasets.

Proposed EU regulations group all ML under the umbrella term "AI," but then subdivide Machine Learning into: (i) supervised Machine Learning, where a labelled dataset is used to train algorithmic software to accurately classify data or predict outcomes; (ii) unsupervised Machine Learning, which uses unlabelled data to discover patterns that help solve for clustering or association problems; and (iii) reinforcement Machine Learning, which is a behavioural machine learning model, similar to supervised learning, but the algorithm is not trained using sample data.[4] Rather, reinforcement ML features an algorithm that self-improves and learns from new situations using trial and error.

By contrast, the U.S. Food and Drug Administration ("FDA")[5] has subdivided ML into two categories: (i) "locked" ML algorithms, where an algorithm does not change with use and will provide the same result each time the same input is applied to it, and (ii) "adaptive" ML algorithms, where an algorithm can change its behaviour continuously over time as it learns from real-world use without input from developers.[6] Adaptive algorithms fit less easily within the agency's traditional medical device regulatory paradigm, which contemplates control and careful consideration of each modification to a cleared or approved device before it is implemented, to determine if a new clearance or approval is required.

The Guiding Principles for the Technical Review of AI-Enabled Medical Device Registration ("AI-Enabled MD Guiding Principles"), promulgated by the Center for Medical Device Evaluation ("CMDE") of China's National Medical Products Administration ("NMPA"), also position ML as a subset and a core area of AI.[7] The CMDE notes that AI and ML are interchangeable terms in the context of medical device software reviews and approvals. Due to the inter-relationship of AI, ML, and the devices through which they operate, it is common practice in China to refer to AI/ML-enabled medical devices as the same regulated products.

## CURRENT ML ECONOMIC ENVIRONMENTS AND REGULATORY SYSTEMS

Globally, three geographical regions are particularly active in developing artificial intelligence for the life sciences industry: (i) the United States; (ii) China; and (iii) Europe. The United States remains dominant in global AI investment: Americans received approximately $25 billion of investment in the sector in 2019, accounting for 64% of the $40 billion global total.[8] On June 8, 2021, the U.S. Senate approved the U.S. Innovation and Competition Act, intended to inject $250 billion into scientific and technological innovation in the United States over five years, including $80 billion earmarked for AI, robotics, and biotechnology.[9] Nonetheless, China leads global output in academic AI research papers, rising from 4% of global output in 1997 to nearly 28% in 2017.[10] China has also filed 389,571 AI patents in the past decade, accounting for 74.7% of the global total.[11] The Chinese government has declared its ambition for China to become the world's primary AI innovator by 2030.[12] Finally, the European Union is expected to increase its spending on AI from $17.3 billion in 2021 to over $50 billion in 2025, a compound annual growth rate of 26.7%.[13]

Each of these jurisdictions has also started to consider regulatory approaches to ML:

- In July 2022, the UK government set out a proposal for a new rulebook on the future regulation of AI. The proposal, which is based on six core principles that regulators must apply, is aimed at providing clarity to businesses and confidence to investors to promote innovation while boosting public trust in AI technology. In parallel, the Data Protection and Digital Information Bill has been introduced which will transform the UK's data laws to foster innovation in technologies such as AI;[14]

- In October 2021, the FDA,[15] UK Medicines and Healthcare products Regulatory Agency ("MHRA"), and Health Canada collaborated to propose ten guiding principles for Good Machine Learning Practice;[16]

- In January 2021, the US FDA published an AI/ML action plan, which followed on its 2019 publication of a proposed regulatory framework for AI/ML-based software as a medical device ("SaMD");

- On 19 February 2020, the European Commission published a white paper on proposed regulations on AI for the European Union;[17] and

- On 8 July 2017, the State Council of China announced its development plan for a new generation of artificial intelligence.[18] The plan seeks to establish an initial set of laws and regulations, ethics norms, and policies to govern artificial intelligence. China has been continuously promulgating and improving regulations concerning SaMD and AI-enabled Medical Devices. Such regulations include: (i) the Guiding Principles for the Technical Review of Medical Device Software Registration, published by NMPA in 2015 and revised by the CMDE in 2022;[19] (ii) the Guiding Principles for the Classification of Artificial Intelligence Medical Software, published by NMPA in 2021;[20] and (iii) the AI-Enabled MD Guiding Principles, promulgated by the CMDE in 2022.

Though these regions have made significant strides in policy development related to AI/ML, the international marketability and deployability of AI/ML-enabled medical devices demands a harmonised international approach. For this reason, two working groups convened under the United Kingdom's 2021 G7 presidency to consider AI governance and interoperability in digital health.[21] As of December 2021, the UK Department of Health and Social Care had published six documents created by these working groups, including white papers on (i) principles to assure the safety, effectiveness and ethicality of AI/ML-enabled medical devices, and (ii) principles to support the development and deployment of AI/ML-enabled devices across jurisdictions.

## WHAT CHALLENGES DOES ML POSE?

The largely autonomous nature of AI development based on complex algorithms presents a unique challenge to regulators, who typically regulate human behaviours in the conduct of either R&D or manufacture and control of tangible products. AI and ML-based systems do not fall within the conventional regulatory paradigm, and penetrating the underlying software often requires a high degree of expertise. There is limited scope for human oversight in ML and AI, which aim to build algorithms that can learn, and make predictions, from data. This means that the algorithm operates dynamically, adapting itself to changes in the data, relying not only on statistics, but also on mathematical optimisation. The objective is to make machines mimic the human brain's cognitive processes. ML aims to make accurate predictions by generalizing based on patterns originally detected and refined by experience.

Additionally, software developers can use ML to create an algorithm that is locked, so that its function does not change, or adaptive, where its behaviour can change over time as it learns from new data. Adaptive ML-based software's ability to continuously learn and adjust is one of its key benefits. However, this constant adaptation poses challenges under traditional regulatory frameworks for medical devices, including software medical devices, which assess safety and performance at discrete points of the product lifespan. Moreover, changes to the product characteristics of conventional medical devices are based on incremental research initiated by manufacturers. In contrast, AI and ML are self-learning machines that can train themselves using unlabelled data without human operators.

In short, ML raises novel regulatory compliance questions that may arise from (i) limited generalisability; (ii) continuous learning; and (iii) lack of transparency, each of which stems from ML's ability to operate and develop without, or with limited, human input.

## GENERALISABILITY (QUALITY OF SOURCE DATA IN INITIAL PRODUCT DEVELOPMENT)

AI/ML-enabled devices' ability to process and learn from large quantities of data is central to their commercial value. The functional characteristics of ML-based software are influenced by the data that are used to train an ML algorithm or model. AI could fail or became untrustworthy either because the output data were not representative of what it was taught to do or because the data were not fit for the task to which they were applied. Therefore, the key to making an ML-based system more trustworthy is ensuring data quality and confirming that algorithms are sufficiently robust and fit for their intended purpose. Accordingly, the safety and effectiveness or the desired performance of such AI/ML systems depends on verification of data quality and validation of its suitability for the algorithm model.

"Generalisation" means how well a trained model can classify or forecast unseen data. Therefore, in order to generate a generalised ML model, the training dataset should be of high quality, valid, and

diverse. Training and validation datasets should have sufficiently large sample sizes that are clinically representative. A diverse training dataset not only helps train the classifier from a specific subset of data, but also improves generalisation. For these reasons, data warehouses for the training data integrate data from multiple sources. Such data require some human involvement to analyse or process, and they could be prone to errors. Appropriate process control over data acquisition, cleaning, transformations, linking, and integration are critical.

Geographical generalisability is often considered a proxy for validity for a methodological approach or tool. However, in order to create ML systems that are clinically useful, the emphasis should shift from demanding geographical generalisability to understanding how, when, and why an ML system works. Such an understanding will help healthcare professionals to use the system correctly; and in a healthcare setting, patients and practices change. Many factors could help determine the potential threats to an ML system's generalisability, including changes in practice pattern over time; differences across health systems; patient demographic variation; socio-economic variation; and hardware and software variation for data capture.

## CONTINUOUS ASSURANCE (ONGOING HUMAN OVERSIGHT VS. MACHINE SELF-DEVELOPMENT)

Traditional models of medical device regulatory oversight focus largely on evaluating safety and functional characteristics against pre-defined criteria at a given point of the product lifecycle. Such evaluation should ensure that the marketed devices can be used safely and effectively to protect public health and patient safety. Manufacturers initiate design and manufacturing process changes throughout the product span. Regulators expect that such changes are supported by data generated by incremental R&D efforts for independent regulatory assessment, to ensure that the benefits continue to outweigh the anticipated risks.

In contrast, adaptive AI/ML-enabled devices, having a design based on a self-learning mechanism, can continually change and operate with limited human intervention. For supervised Machine Learning, oversight concerns are somewhat diminished by data-labelling and by the accompanying human input, though inaccurate or inconsistent data-labelling can itself lower product efficacy whilst introducing human biases into the system.[22] For these reasons, many regulatory authorities have recognised that the traditional paradigm of medical device regulation may not be adequate to control AI/ML technologies, which have the potential to adapt and optimise device performance in real time to continuously improve healthcare for patients. The highly iterative, autonomous, and adaptive nature of these tools requires a new, total product lifecycle regulatory approach ("TPLA") that facilitates a rapid cycle of product improvement and allows these devices to continually improve, while providing effective safeguards against deterioration of the performance characteristics. Some advocate for the TPLA to include a continuous assurance protocol whereby the product undergoes continual (or frequent periodic) monitoring and review.

Even with a continuous assurance protocol in place, the fundamental regulatory question is how and when self-developing devices would require a new premarket review or conformity assessment. The G7 working groups have indicated that a new conformity assessment may be necessary where "self-learning" results in a significant change to the product. The threshold of a "significant change" is not yet adequately defined.

The coalition of international regulatory and enforcement authorities is also considering developing new good practice principles in response to technological advances and innovative AI-based applications and services.

In March 2022, the CMDE released the AI-Enabled MD Guiding Principles, which emphasise the importance of the whole-life-cycle quality control of AI enabled devices. The whole-life-cycle quality control requires continuous research on algorithm generalisation capabilities after an AI enabled device is marketed, so as to identify previously unforeseen risks and to ensure that clinical needs are continuously being met. Where an AI-enabled medical device's algorithm undergoes a significant update that might affect a device's safety or effectiveness, an application for change registration should be submitted to the regulatory authorities for review and approval before the updated algorithm is adopted.

Both the FDA and EU proposals anticipate the initial regulatory review involving review of the device's self-development mechanism. FDA's 2019

Proposed Regulatory Framework for Modifications to AI/ML-Based SaMD provides for FDA review, during the initial premarket review for an AI/ML-based device of a "Predetermined Change Control Plan," that details information about both the types of anticipated modifications to the software and the methodology underlying algorithm changes, to ensure that the device remains safe and effective after the modification. FDA's proposed framework further clarifies, however, that subsequent regulatory reviews may still be required, depending on the type of modification being made to an AI/ML-based SaMD product.

Similarly, in the European Union, the conformity assessment approves the means by which the product self-learns, thereby negating the need for further conformity assessments. However, these regulatory approaches necessitate a limitation on the extent to which unsupervised machine learning can occur. As addressed in the EU White Paper, for such a system of approval to succeed, all systems would have to contain in-built operational constraints that the software itself cannot override, effectively limiting the extent to which any truly unsupervised machine learning could be implemented. To go beyond these regulatory constraints, human input and a further conformity certification would be required.

However, international alignment is necessary to evaluate AI/ML-enabled medical devices to protect patient safety across the world and to drive responsible, trustworthy innovation. Without international harmonisation, there will be considerable regional and national variations among regulatory standards and approaches for such self-learning systems. Such variations would exist, notwithstanding the efforts that certain regulatory authorities, including MHRA, FDA, and Health Canada, have sought to address this lack of conformity by jointly developing some basic guiding principles for GMLP to help promote safe, effective, and high-quality medical devices that use AI/ML.

## TRANSPARENCY (TRANSPARENCY VS. COMPLEXITY OF OUTPUT)

Many international bodies, including the Organisation for Economic Cooperation and Development, consider one of the core value-based principles for the successful development of AI/ML systems to be transparency and responsible disclosure. Transparency ensures that consumers understand when they are engaging with AI/ML systems and can make an informed assessment. The transparency principle requires manufacturers to provide meaningful information that is contextually appropriate and consistent with the state of art.

The principle aims to achieve four overarching objectives: (i) to foster a general understanding of AI systems; (ii) to make stakeholders aware of their interactions with AI systems, including in the workplace; (iii) to enable those affected by an AI system to understand the system's outcomes; and (iv) to enable those adversely affected by an AI system to challenge its outcome based on plain information about the factors and logic on which the prediction, recommendation, or decision is based.[23]

Both the GMLP Guiding Principles published by the FDA, MHRA, and Health Canada and the G7 Working Group publications of 30 December 2021 emphasise the importance of transparency regarding AI/ML technologies. The G7 Working Group publications recommend that manufacturers of the AI/ML-enabled medical devices should be sufficiently transparent and provide information to users about the rationale and intended purpose of the device. Such information assists the users in developing an informed view on the suitability, performance, limitations, user interface, and clinical workflow integration of the AI/ML model. In particular, users should also be given access to clear, contextually relevant information. Such information should include any updates or modifications following real-world performance monitoring that may impact the device's intended use or differing performance for certain population subgroups.

In the United States, the FDA's AI/ML action plan acknowledges that AI/ML-based devices have unique considerations that necessitate a proactive patient-centred approach to their development and utilisation that takes into account issues including usability, equity, trust, and accountability. One way that FDA plans to address these issues is by promoting transparency to users about the devices' functioning. In response to stakeholder feedback pointing to the unique challenges of labelling for AI/ML-based devices, including the complexity of describing the training and validation, inputs, and logic of an AI/ML algorithm, FDA plans to work with stakeholders to clarify the types of information that FDA would recommend a manufacturer

to include in the labelling of AI/ML-based medical devices to support transparency to users.

In China, the CMDE published a draft guideline on humanised design of medical devices for public comments in May 2020.[24] This draft guideline requires developers to consider user characteristics, application scenarios, and human-machine interaction when designing a medical device, so as to ensure the usability of such device. If the draft guideline comes into effect in its current form, such usability requirement will also apply to AI/ML-enabled medical devices. In that case, an AI/ML-enabled medical device, especially its user interface, must be designed to provide users with sufficient information to reduce the risk for misuse. Furthermore, significant product updates or modifications should be highlighted to regulators. Where an AI/ML-enabled device is marketed internationally, additional information regarding data provenance, permissions for processing, and any processing of sensitive or personal data will also be relevant. As a result, manufacturers should build transparency into every stage of product operation, rather than simply into the product's output and target population.

## PRODUCT LIABILITY AND AI/ML-ENABLED DEVICES

Product liability generally seeks to remedy injuries or property damage arising from product defects or misrepresentation on the market. Under a strict liability standard, manufacturers can be held liable for unsafe defects, without establishing whether the defect arose from an identifiable fault or the manufacturer's negligence. Strict liability confers upon a consumer the right to expect general product safety. When such an expectation is not met, the injured party is entitled to bring a claim against the manufacturer, provided that the injured party establishes the causal relationship between the injury and the product defect.

AI/ML-enabled devices raise novel and complex questions about how the potential product liability exposure is assessed, given that AI/ML systems do not simply implement human-designed algorithms; rather, they create their own self-learning algorithms based on real-world experience by revising algorithms originally designed by humans. Many of these complex legal questions centre on (i) attributing responsibility for the harm caused, and (ii) whether AI/ML systems could be viewed as a product and not a service.

National and regional courts handle product liability claims across jurisdictions, many of whose legal systems have not yet adapted their rules in response to the digital age, AI, and circular economy. Therefore, there is considerable uncertainty regarding (i) the manufacturers' risk exposure in the course of the business; (ii) how damage could be prevented; and (iii) how to compensate the injured parties. The liability rules should seek to strike a fine balance between these competing interests while promoting innovation in this increasingly digitalised and knowledge-based economy. Additionally, AI/ML-enabled devices defy traditional classifications: there remains uncertainty whether such devices should be considered products, or whether their analytical output instead renders them services. National and regional courts may take considerable time to develop a body of case law, and legislatures may similarly require time to enact new rules specific to the intersection of AI/ML and product liability.

No specific product liability regulations have been enacted in China associated with AI/ML-enabled medical devices. Therefore, the general requirements prescribed in the PRC Civil Code[25] and PRC Product Quality Law[26] should apply. In general, manufacturers and distributors of an AI/ML-enabled medical device may be subject to tort liability in China. Such manufacturers and distributors may bear joint and several liability when defective products cause consumers' personal injury or property damage. However, distributors of a defective product have a statutory right of recourse against the manufacturer if the responsibility rests with the manufacturer. The manufacturer should not be held liable if it can prove one of the following: (i) the manufacturer did not put the product at issue into circulation; (ii) the defect did not exist when the product was put into circulation; or (iii) the defect could not be discovered by means of the scientific and technical knowledge at the time of circulation of the product. Considering the self-developing nature of AI/ML-enabled medical devices, manufacturers may find it difficult to prove that they should not be blamed for their products' defects.

The European Commission published an inception impact assessment roadmap on the adaptation of

civil liability rules for the digital age in 2021.[27] The roadmap emphasises that liability rules for AI should focus on: (i) providing legal certainty to companies about the risk profile of their business; (ii) preventing damage; and (iii) compensating injured parties. Shortcomings in current EU legislation, as it applies to AI/ML-enabled medical devices, stem from the inter-connectivity, intangibility, and complexity of the associated digital technologies. Furthermore, because such intangible items are available directly from extraterritorial sources, obtaining compensation via traditional avenues (those that focus on pursuing importers as producers) becomes particularly difficult. It is plain that current liability regimes need an update for the digital age, but regulatory authorities have not yet reached a clear consensus for categorising AI/ML-based devices.

AI/ML-enabled device developers in the European Union could face strict liability due to the adaptive nature of the software itself.[28] Traditionally, software developers have been protected from claims of failure to warn customers of potential harm their software could cause when used in a reasonably foreseeable manner (the informed intermediary theory). Under this theory, instructing the healthcare provider using the software of such potential harm would protect the programmer by accounting for all potential risks in foreseeable use. However, with truly adaptive code, it is harder to provide instructions that account for all potential risks or defects with future self-developed versions of the code. A defect in ML software may consequently expose developers to strict liability, but how far courts will extend strict product liability in relation to AI/ML products remains an open question.

In the United States, a unified approach to product liability for digital health technologies has not emerged, in large part because product liability law is still evolving to catch up to these novel technologies. Theories of product liability are governed by state law, meaning that each state in the United States has its own statutory and common law rules and standards for liability. While at a very high level, the theories of recovery are similar – i.e. liability can be imposed for defective design, manufacture, testing, and failure to issue adequate warnings – the application of these theories varies and can result in significantly different outcomes. Courts have differed, for example, on whether software is even considered a product at all, or rather a service, which would then nullify any product liability claims.[29] In cases where AI/ML applications incorporated in medical devices are subject to product liability claims as "products," those claims would be governed by traditional product liability theories noted above. However, as incorporation of AI systems in medical devices becomes more widespread, courts will likely adapt accordingly, and judges may develop a framework for applying traditional product liability theories of recovery to such systems. This may include upstream liability for developers of AI software as "component manufacturers," as is common in other industries.

Some aspects of traditional product liability law will present novel issues in the AI/ML context. For example, under the learned intermediary doctrine, which is settled law in a majority of states, a device manufacturer's duty to warn of risks is limited to communicating those risks to treating physicians (typically in the form of product labelling). The learned intermediary doctrine is comparable to the European Union's informed intermediary theory. Treating physicians serve as "learned intermediaries" and assume the duty to discuss the product's risks with the patient. Because the patients themselves are not relying on the product label warnings, but they are instead relying on the advice of the physician/intermediary, the doctrine has served an important role in limiting liability for failure to warn claims in the medical and pharmaceutical product context. However, as many digital health technologies empower consumers to make their own healthcare decisions without a physician, this important limitation on liability may be inapplicable in certain contexts. The impact on product liability of such consumer-driven decisions remains to be seen.

Finally, U.S. federal law expressly preempts all state law claims, including product liability claims, directed at Class III medical devices (the highest-risk devices), unless those claims parallel federal requirements.[30] As such, to the extent that AI/ML applications are approved by FDA as Class III medical devices, manufacturers of those devices will have more rigorous protection against state laws than federal ones, though in practice, manufacturers seeking to assert preemption often face challenges.

## ARTIFICIAL INTELLIGENCE AND NATIONAL SECURITY LEGISLATION

Despite driving greater efficiency and performance of R&D for the benefit of patients and society, AI is also inherently dual-use and potentially easy to repurpose. Military and law enforcement organisations have shown increasing interest in advancing the use of AI in their domains. Bad actors could deploy AI applications for malicious uses: technologies used for the commercial market could also be repurposed in manners which could give rise to national security concerns. The opportunity to use AI positively across the global economy can only be harnessed if sensitive and critical applications of AI can be protected.

As AI technologies often have a general purpose and are used across sectors, national and regional laws have been enacted to capture entities that do not necessarily identify as "AI companies." A qualifying entity may focus solely on AI, or the entity may incorporate or develop AI as part of a wider approach to its business; the specific work the entity undertakes is the most important consideration.

In the European Union – separate from the proposed legal framework aimed at providing AI developers and users with clear obligations regarding specific use of AI – Regulation (EC) No. 428/2009 sets up a community regime for the control of exports, transfer, brokering, and transit of dual-use items (the EU dual-use Regulation). Dual-use items are goods, software, and technology that can be used for both civilian and military applications. The export controls take into account the European Union and its Member States' international obligations, including: UN Security Council Resolution 1540; the Nuclear Non-Proliferation Treaty; the Chemical Weapons Convention; and the Biological Weapons Convention. EU export controls reflect commitments in key multilateral export control regimes, such as the Australia Group, the Wassenaar Arrangement, the Nuclear Suppliers Group, and the Missile Technology Control Regime.

The National Security and Investment Act ("NSIA"), passed by UK Parliament in May 2021, gave the UK Government new powers to scrutinise and intervene in investments and business transactions, both foreign and domestic, where necessary to protect national security. The National Security and Investment ("NSI") regime is the UK Government's new approach to achieving the NSIA's goals. The NSI regime gives the Government the powers to screen investments and carry out national security assessments of certain transactions, before or after they take place. The regime came into force in the United Kingdom on 4 January 2022 and applies to transactions taking place on or after 12 November 2020. The NSI regime establishes a mandatory requirement for investors or other acquiring entities, proposing investments in a defined sensitive sector of the economy, to notify the Department for Business, Energy and Industrial Strategy ("BEIS") ahead of the transaction's consummation. This regime will be managed and carried out by the new Investment Security Unit within BEIS, with the scrutiny powers being conferred on the Secretary of State for BEIS. Mandatory notification is required ahead of transactions where an investor gains control in an entity. A notification requirement is triggered by the acquisition of more than 25%, more than 50%, or 75% or more of shares or voting rights in a qualifying entity, or by the acquisition of voting rights enabling or preventing the passage of a resolution governing a qualifying entity's affairs. This applies to acquisitions in one of the seventeen sensitive sectors of the economy as identified by the Government, which include Synthetic Biology and Artificial Intelligence.

In the United States, on 1 March 2021, the National Security Commission on AI submitted its final report to Congress.[31] The report determined that the US government was not sufficiently investing in AI innovation to defend and compete in the coming era of AI-accelerated competition and conflict, nor was it prepared to defend against AI-enabled threats or to rapidly adopt AI applications for national security purposes. The Commission made strategic recommendations concerning AI technology development in the context of national security, including the need to combat digital disinformation and to take certain domestic actions to protect privacy, civil rights, and civil liberties in relation to application of AI. A lack of public trust could potentially undermine development of AI as an enabling technological platform.

## CONCLUSION

The world of AI/ML-enabled medical devices has been expanding rapidly, a pace that has only accelerated because of the increased interest and investment. The United States, European Union,

and China continue to lead the charge towards innovation and development. While the law has trailed invention in this area, regulators in these key jurisdictions have been trending towards a more harmonised global approach. Updated regulatory frameworks have begun to address challenges posed by AI/ML-enabled devices, including (i) limited generalisability; (ii) continuous learning; and (iii) lack of transparency. Regulators have also grappled with fitting such devices into a traditional products liability framework. Current trends suggest that AI/ML-enabled devices represent an increasingly important component of the life sciences sector, but whether regulation can evolve at the pace of innovation remains to be seen.

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