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AI IN HEALTHCARE AND LIFE SCIENCES – THE LEGAL LANDSCAPE IN 2025

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From personalised medicine, improvements in medical robotics, new methods of drug discovery and design to medical research, AI is enabling advancements and efficiencies across healthcare and life sciences. Navigating relevant, evolving legal frameworks is essential. What will new AI legislation and other digital regulation mean for AI-enabled healthcare, research, devices, applications and systems? What can organisations do to protect their intellectual property and manage IP, data and cyber risks? In this briefing, we discuss key legal considerations for organisations leveraging AI in healthcare and life sciences and for investors in the sector.

The impact of new European AI regulation on the healthcare and life sciences industry

The EU AI Act entered into force in August 2024. It is the first harmonised and cross-border legal framework for the regulation of AI worldwide and already affects many organisations. “In healthcare, most AI systems used in medical devices or clinical decisions are classified as high-risk. This is automatic if the AI requires third-party assessment. It is stricter than the EU Medical Device Regulation (MDR), where the risk is based on clinical use. With the EU AI Act, the classification depends on the technology and how it is developed and deployed,” says Patrice Navarro, a Clifford Chance IP and Tech/Digital Partner based in Paris.

Other regulations include a revised Product Liability Directive, which, although not focused on healthcare or life sciences creates a stronger liability framework for harm caused by AI systems. For example, if an AI tool gives an incorrect recommendation and this leads to harm to a patient, the new rules make it easier for the injured party to bring a claim. “At the same time, privacy law continues to apply. Health data is sensitive and protected under the GDPR. Authorities such as France’s Commission Nationale de l’Informatique et des Libertés (CNIL), are paying more attention to how AI uses this type of data. We see stricter expectations on transparency, explainability and limits on reuse,” says Navarro.

There is also the European Health Data Space regulation which aims to improve access to health data for innovation and for AI training. But it also brings new technical rules and access conditions, so organisations need to prepare both from a legal and practical point of view.

“Broadly, there is concern about the growing number of overlapping legal instruments. We hear this regularly from clients. The framework is complex and, in some cases, may discourage innovation,” Navarro says. One sign that this concern is being taken seriously is the recent announcement by the European Commission that it plans to withdraw the AI Liability Directive, which was originally intended to complement the AI Act by harmonising fault-based claims across the EU. The withdrawal suggests that the Commission recognises the risk of creating too much legal complexity at once, and is trying to keep the system workable, especially for businesses already subject to strict product safety and data protection rules. “In our work with clients, our message is clear. There is no need to create an entirely new AI compliance structure. In most cases, companies can adapt their existing policies and governance frameworks. For example, quality systems, risk assessments and data protection processes can often be extended to cover the AI rules. This approach is more efficient and helps avoid confusion or duplication,” Navarro says.

AI regulation in the US

AI regulation in the United States, and its impact on healthcare and life sciences, continues to be an evolving landscape. "US regulation of AI in this sector – as for other jurisdictions – faces a tension between competing, high-stakes priorities: overregulating could risk stunting innovation, on the one hand, and underregulating could risk patient safety, patient privacy and security, transparency, non-discrimination and other 'must haves,' on the other hand," says Christine Kim, a Counsel in Clifford Chance's corporate group based in New York.

There is no comprehensive AI legislation at the federal level, whether for healthcare, life sciences or otherwise. The US Food and Drug Administration, which regulates AI as a medical device (AIaMD) and software as a medical device (SaMD), for example, has provided some guidance. But so far, the real action has been at the state and local levels; in the first quarter of 2025, hundreds of new AI-related bills were introduced by state and local legislatures. Some take a blanket approach to AI, and the general regulation affects the healthcare and life sciences sector. Notable examples include the Colorado Artificial Intelligence Act – the first comprehensive AI law in the US – which is expected to come into effect in 2026, and the Texas Responsible AI Governance Act, which is being considered this year. They cover "high-risk artificial intelligence systems" that make or are a "substantial factor" in making "consequential decisions" (including, among others, decisions about the provision or cost of healthcare services). Another example of this type of risk-based approach is the Utah Artificial Intelligence Policy Act, which became effective in 2024 and applies to "regulated occupations" (including, among others, physicians). By contrast, some take a direct approach to regulating AI in healthcare and life sciences. Selective examples include California's AI-related bills applying to health facilities, clinics, physician's offices, offices of a group practice and healthcare service plans, Utah's bill targeting suppliers of mental health chatbots, and Virginia's bill focusing on hospitals, nursing homes and certified nursing facilities on the use of digital or virtual "intelligent personal assistants."

AI regulation in APAC

There are a range of strategic approaches to AI regulation across APAC. For example, there are targeted rules and regulations in China for certain types of AI use, including the use of generative AI for content generation to provide services to the public in China. Many other countries are currently relying on existing laws overlayed with guidance from key regulators. For example, in Singapore, the Ministry of Health, the Health Sciences Authority (HAS) and the country's health tech agency, Integrated Health Information Systems (IHiS), have jointly published guidelines on AI in healthcare. As with other jurisdictions, a key part of the existing legal frameworks for AI are the privacy laws, and some of these are being updated with AI in mind – for example, in Australia the first tranche of privacy law reforms includes provisions around automated processing," says Julia Peng, an IP and tech local Partner at Shanghai He Ping Law Firm.

Another important consideration in AI development, training and use, is cross-border data flows. Regulatory regimes are applying existing rules in this context, but it is possible that there may be additional hurdles due to the sensitivity of health data.

How the IP and AI position is developing in the UK and Europe

In the UK, the AI legal landscape is changing as the UK government is taking a 'pro-innovation' approach under the AI Opportunities Action Plan. The plan indicates a preference for leveraging existing laws, overlaid by regulatory guidance and oversight, but there is still potential for the introduction of targeted AI legislation focused on the most powerful AI models. Some are framing this as a 'middle ground' approach between that taken by the US and the EU. This action plan also makes several recommendations related to "unlocking data assets" in the UK public and private sectors – including: (1) making available high-impact public data sets to AI researchers and developers; (2) building public sector data collection infrastructure and financing the creation of new high-value datasets that meet public sector, academia and startup needs; (3) offering access to proprietary data sets alongside compute allocation in enticing researchers and start-ups to establish in the UK; and (4) incentivising researchers and industries to curate and unlock private data sets.

"Recently we saw an example of the UK BioBank providing anonymised medical data of 500,000 people to researchers in China for medical research purposes. There was quite a lot of media commentary and some public backlash about the sharing of that data. It raised questions of national security so there is a lot to monitor in the UK as we wait to see how the UK government evolves its approach," says Stephen Reese, an IP Partner based in London and co-lead of Clifford Chance's global healthcare & life sciences sector group.

A key issue regarding access to data sets for AI development is the navigation of intellectual property rights. There has already been a significant amount of copyright infringement litigation relating to AI training and several cases have commenced in the US and the UK. "The implication of those cases is that the data is protected by copyright laws and most of those laws will give the copyright owner the exclusive right to make copies of those works. So, the first question is whether actually in the course of training, you are making a copy or undertaking an activity that is prohibited by copyright. The next question is where there is a defence or some kind of exception to the rule. We have seen some jurisdictions introduce statutory exceptions for text and data mining," says Reese.

The UK's Action Plan recommends that the government "reform the UK text and data mining regime so that it is at least as competitive as the EU," stating that uncertainty around intellectual property is hindering innovation and undermining the UK's broader AI ambitions and the growth of the creative industries. In December 2024, the government opened a consultation on AI and copyright which outlined various options for reform, including a potential change to the existing data mining exception in UK copyright law to facilitate the training of AI models using copyrighted material. There has been some backlash to this, particularly from the creative and media industry, songwriters, authors and artists, who (rightly) see their innovation and creativity at risk.

There has also been a great deal of debate around a series of high-profile legal cases brought in relation as to whether AI technology can be an inventor for the purposes of being able to patent the inventions that come out from AI systems. "Importantly, the thrust of those cases is really about whether the technology could be an inventor and therefore give rise to a patentable subject matter, as opposed to questioning whether the invention that has come out of the AI tool is itself capable of being patented for meeting the relevant requirements. Generally, the upshot is that the various patent legislation around the world requires human input or a human author in order for something to be patentable," says Reese. However, he adds: "This hasn't answered the other pressing question which is, can an invention coming out of an AI tool itself be subject to patent protection? We have seen from a number of courts a direction for the legislators to look at this and provide greater clarity and guidance in relation to patentability. This creates some challenges within the healthcare sector and the healthcare market, particularly for those who are looking to use AI in relation to the development of, for example, drug delivery."

Medical devices regulation

Another key issue around the use of AI in healthcare and life sciences is medical devices regulation, given that most of the AI solutions in healthcare are used in medical devices, such as systems for recognising pathology in imaging, voice recognition for mental health assessments, predicting hospital readmissions or AI agents in medical robotics.

"Different jurisdictions have different rules for determining what meets the definition of a medical device. We are seeing increasingly sophisticated AI-based assistants, wearables, etc. helping with health diagnoses, management of conditions or other applications, making it important to understand where this line is for medical devices in different countries," says Gunnar Sachs, who is a partner based in Düsseldorf and co-lead of Clifford Chance's global healthtech team. One key challenge, for example, is product certification. "How can it work for AI systems which develop themselves and improve over time, and is the existing regulatory certification model actually suitable in this context? Or is a re-certification approach needed on a periodic basis, or other post-market monitoring for continuously developing devices? There are many questions which still need to be answered," says Sachs.

Cyber risks

As AI is being used more and more in connected devices, cloud systems and critical services, there is an increasing risk of exposure to cyber attacks. In Europe, updated laws, such as the NIS 2 Directive, bring more healthcare organisations into scope and introduce stronger requirements for cyber resilience. The EU Cyber Resilience Act, which entered into force in December 2024, will apply to products with digital components, including AI features. This means more controls will be required at the design and development stage. "The challenge is not only technical," says Navarro. "If an AI system is affected by a cyber attack, it may not be easy to detect. The system may still produce outputs that appear normal. This makes it important to have good monitoring and clear responsibilities in place. AI can also be part of the defence. Some companies are using AI to detect threats faster. But the legal obligations still apply. AI used for security must also follow data protection and safety rules. Cyber risk is no longer separate from product risk or data risk. It is now part of overall compliance and needs to be managed across all areas."

Key regulatory issues for AI in healthcare

In the EU, there is an increased scrutiny and regulation of software as a medical device, whether using AI or software as a diagnostic tool or to operate a device such as a robotic surgical instrument. The long-delayed Medical Devices Regulation of 2017 has been slowly coming into effect (starting August 2025 through to 2027) and has a greater focus and regulation on software as a device. Medical AI devices are likely to be classified as high risk. "In addition to the assessment under the EU AI Act discussed earlier, they also need to be approved under the MDR 2017 – although hopefully notified bodies will be approved under both legislations and so can run approvals concurrently," says Stephen Reese.

One of the big challenges for AI, particularly for predictive or diagnostic tools in healthcare (less so in drug discovery), is being able to clearly describe and explain how the AI tool works. Being able to explain that understanding is part of the requirement of any conformity assessment as part of the regulatory approval for software. "However, with more sophisticated AI tools, the ability to provide a definitive explanation is more tricky and so that is something the regulators need to get to grips with," he says.

In China, the definition of "for medical purposes" can be quite broad when it comes to AI or software devices. For software powered medical devices, China adopts a three-class system in terms of assessing risks related to medical devices, which is similar to the three-class classification used in the US. Medical devices are usually required to be registered in higher risk classes and more substantial proof of safety and efficacy is needed. When assessing the risk level of medical software, the healthcare authority will assess not only the purpose of the medical software, but also the maturity and robustness of the underlying algorithm and data. "China's regulatory regime is evolving gradually with the development of AI-powered software and medical devices, and practitioners are advised to follow these developments closely," says Julia Peng.

Transactions and investments in healthcare and life sciences

The medical and healthcare space was the third-largest focus area for global private investment in AI in 2024 at approximately US$11 billion, according to the AI Index 2025 Annual Report by Stanford University. "Deal makers and other stakeholders considering M&A transactions, strategic investments and arrangements to license, collaborate, or co-develop need to consider how to allocate the unique risks at the intersection of AI and healthcare and life sciences that are expected to drive deal certainty or value," says Christine Kim. "Consider a deal involving a company's R&D division using computational approaches to identify potential drug candidates versus a deal involving a hospital system using ambient AI to take clinical notes. The underlying tech and data are different, and the attendant risks are different. There is no 'one size fits all' approach to deals in this space."

Key takeaways

- Acknowledge the risk and consider what steps you can take to try and mitigate and allocate it, particularly where the legislative and jurisprudence is moving rapidly in a number of the key markets. "My particular obsession at the moment is really about knowing the data and its providence and being able to partition it in so far as you can. I think that's good housekeeping for the years ahead in terms of where legislation and the courts will come out," says Stephen Reese.
- In some jurisdictions, existing regulatory data and IP legal regimes still remain, but watch for the guidance and cases because they are developing and it is important to keep abreast of how they apply.
- The legal framework is becoming more complex. But most organisations already have good structures in place. "You can work with what you have. There is no need to start again. The key is to bring the AI requirements into your existing systems. This makes compliance more practical and avoids unnecessary complexity," says Patrice Navarro.

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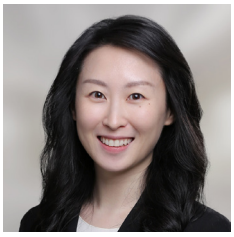

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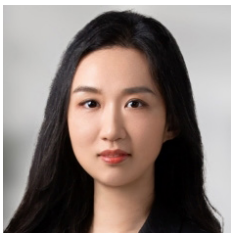

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