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China continues to strengthen regulation of Artificial Intelligence (AI) in the Life Sciences sectors: New compliance challenges for businesses

DigiCure: Legal insights at the intersection of Technology and Life Sciences and Health Care

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In recent years, artificial intelligence (AI) technologies have rapidly penetrated the life sciences industries and have been widely applied in areas such as new drug research and development, target discovery, clinical trial design and patient recruitment, medical imaging analysis, digital therapeutics, AI-based medical devices, real-world evidence analytics, and generative AI-assisted scientific research. At the same time, Chinese regulators are accelerating the establishment of a multi-layered regulatory framework covering data, algorithms, cybersecurity, biosafety, and health care regulation. On July 7, 2026, the National Health Development Plan for the 15th Five-Year Plan Period was officially released, expressly proposing to "promote AI-enabled upgrading across the entire pharmaceutical industry value chain."

For pharmaceutical companies, biotechnology companies, contract research organizations (CROs), health care institutions, and AI technology providers, future compliance priorities are no longer limited to traditional data privacy requirements. Rather, they are gradually expanding to multiple dimensions, including AI training data provenance, model governance, algorithm filing requirements, human genetic resources management, cross-border data transfers, and regulation of AI-based medical products.

Over the past year, the following Chinese regulry developments and policy documents have been particularly significant and warrant close attention:

- ***Measures for the Ethical Review and Services of Artificial Intelligence Science and Technology Activities (Trial)*** (issued by the Ministry of Industry and Information Technology, and nine other authorities, March 2026): The first dedicated regulation specifically governing AI ethics review. It requires ethical governance to be embedded throughout the entire lifecycle of AI scientific and technological activities. Responsible entities must establish an AI ethics committee or rely on a designated Chinese ethics review service center to conduct the required review procedures.

- ***Implementation Opinions on "AI + Drug Regulation***" (issued by the National Medical Products Administration (NMPA), March 2026): Clarifies the introduction of AI into regulatory oversight throughout the entire lifecycle of pharmaceutical products, while imposing mandatory requirements regarding the traceability, controllability, and human oversight of AI models.

- ***Implementation Opinions on Promoting and Regulating the Development of "AI + Health care" Applications*** (issued by the National Health Commission and four other authorities, October 2025): Promotes the use of intelligent diagnostic services for medical imaging and AI-powered patient services, while emphasizing classified and tiered regulation, data security, and privacy protection.

- ***Enhanced Enforcement of Existing Foundational Laws and Regulations***: The Personal Information Protection Law (PIPL), Data Security Law (DSL), Biosecurity Law, and Regulations on

the Administration of Human Genetic Resources continue to play a critical role in regulating AI training data sources, cross-border data transfers, and the processing of human genetic information. At the same time, China has established a series of regulatory regimes specifically governing algorithm recommendation technologies, deep synthesis services, and generative artificial intelligence. These regulations impose obligations relating to algorithm governance, security assessments, filing requirements, content management, transparency, labeling of AI-generated content, training data compliance, protection of intellectual property rights, and prevention of the generation or dissemination of unlawful information. Companies developing or deploying AI systems in the life sciences sector should assess whether their products, services, or platforms fall within the scope of these regimes and whether regulatory filings or other compliance obligations may be triggered. For pharmaceutical, biotechnology, digital health, and AI-enabled medical device companies, these rules are increasingly relevant where AI technologies are used for patient-facing services, medical information generation, clinical decision support, health care recommendation functions, digital therapeutics, or scientific research support tools.

New compliance challenges facing enterprises

1. Compliance of training data and biological data: Ensuring a "lawful source"

- Expansion of the scope of sensitive data: Data used for AI model training, including for example electronic medical records (EMRs), medical imaging data and human genetic resource information, generally possesses the dual attributes of sensitive personal information and important data/core biological data. Reliance solely on "de-identification" is insufficient to satisfy the compliance requirements under the PIPL and the Biosafety Law, particularly where cross-border data transfers are involved, which may trigger CAC-administered data export procedures and/or approval requirements from the National Health Commission (NHC) from human genetic resources perspective in China.

- Reconstruction of informed consent: Patient authorizations obtained in traditional health care settings generally do not cover the use of personal data for commercial AI algorithm training

and continuous optimization. Regulatory developments and emerging industry practice are increasingly requiring specific notice and separate consent for such purposes.

- Third-party data supply chain risks: Where data is obtained through cooperation with hospitals, CROs, or cloud service providers, downstream pharmaceutical companies and AI service providers may bear compliance risks if upstream parties have failed to obtain valid authorization or fulfill anonymization obligations.

2. Algorithm explainability and regulatory resistance to "black box" models

In high-risk scenarios such as assisted diagnosis, drug recommendation, and clinical trial participant screening, regulators, including the NMPA and the NHC, are placing increasing emphasis on algorithm explainability and traceability. "Black box" models that cannot provide the basis for their decision-making logic are likely to be disadvantaged in medical device registration reviews and ethics assessments.

3. Technology ethics review has become a corporate obligation

a. Ethics review is no longer solely a matter for research institutions. AI health care technology developers are also increasingly expected to establish AI ethics committees or rely on entrusted ethics review service institutions in China to carry out ethics review procedures.

b. Pursuant to the Measures for the Ethics Review and Services of Artificial Intelligence Science and Technology Activities (Trial), organizations conducting AI scientific research and technology development activities within China are required to conduct ethics reviews, risk assessments, and establish ongoing monitoring and early-warning mechanisms.

c. At present, certain AI-related activities, after completion of an internal ethics review, are further subject to expert ethics review. These activities include: (a) the development of human-machine integration systems with significant impacts on human behavior, psychological and emotional states, or health and wellbeing; (b) the development of algorithmic models, applications, or systems with capabilities to influence public opinion, conduct social mobilization, or guide social

consciousness; and

d. the development of highly autonomous automated decision-making systems intended for scenarios involving safety risks, personal injury risks, health risks, or similar concerns. This catalogue of activities is subject to dynamic adjustment.

4. Intensified cross-border compliance and geopolitical considerations

In the context of multinational clinical trials, offshore AI model deployment, and cloud-based training data flows, enterprises may be required to comply simultaneously with China's regulatory requirements on human genetic resources exports, data export security assessments, and parallel compliance obligations under the EU General Data Protection Regulation (GDPR) and relevant U.S. biotechnology-related restrictions. Managing and mitigating conflicts among these overlapping regulatory regimes has become an increasingly important regulatory compliance challenge for multinational life sciences and technology companies.

Corporate regulatory compliance checklist

To reduce regulatory uncertainty and strengthen regulatory compliance resilience, life sciences and biotechnology companies are advised to take the following actions:

a) Conduct end-to-end AI data compliance audits

- Inventory the sources, authorization documentation, degree of de-identification/anonymization, and cross-border data flows of training data, fine-tuning data, and feedback data; and

- Conduct focused reviews of the legal basis for processing human genetic resources, data relating to minors, and data concerning other special categories of individuals.

b) Establish or enhance AI and technology ethics governance frameworks

- Assess whether the company meets the thresholds requiring the establishment of an AI or technology ethics committee, or to obtain an ethics review through an independent third-party ethics review body.

- Where ethical review requirements are triggered, ensure compliance with applicable review procedures and submission requirements, including preparation of the AI science and technology plan, ethics risk assessment report, risk mitigation and control plan, and required commitment letter.

Ethics reviews typically focus on, among other things, whether: (i) the AI-related activities have sufficient scientific and social value; (ii) the selection of training data and the design of algorithms, models, and systems are reasonable, and adequate measures are implemented to prevent bias, discrimination, and algorithmic manipulation; (iii) users are provided with appropriate mechanisms to control, guide, and intervene in the operation of models and systems; (iv) continuous monitoring measures and contingency response plans have been established; (v) the purposes, operating logic, interaction methods, and potential risks of algorithms, models, and systems are appropriately disclosed; (vi) sufficient logging and recordkeeping mechanisms are maintained to ensure end-to-end traceability of data, algorithms, models, and systems; and (vii) adequate safeguards are implemented to ensure the effective protection of personal information and other privacy-related data throughout data processing activities.

c) Restructure contractual and risk allocation provisions

- In procurement, co-development, and service agreements, clearly allocate the parties' respective duties of care, defect remediation obligations, and compliance representations and warranties.

d) Monitor filing requirements and pre-market regulatory procedures

- Where generative AI services, algorithm recommendation services, or deep synthesis services are involved, evaluate in advance whether obligations relating to algorithm filing and foundation model filing apply; and

- For AI-based medical device products, concurrently assess and prepare for applicable regulatory documentation and regulatory compliance requirements under the NMPA AI-based medical device registration pathway.

Conclusion

China's regulation of artificial intelligence in the life sciences and biotechnology sectors has entered a new stage characterized by full-lifecycle oversight, granular regulation, and a strong ethics-driven approach.

For companies operating in these sectors, regulatory compliance is no longer merely a downstream cost of doing business. Rather, it has become a core strategic variable that directly influences product development, market authorization, commercialization, and global expansion strategies.

Our HLC China regulatory team can help life science companies navigate China's rapidly developing AI regulatory landscape, including AI governance, data and privacy compliance, human genetic resources regulation, cross-border data transfers, ethics review requirements, algorithm and generative AI filing obligations, AI-enabled medical product regulation, compliance audits, and the design of contractual and operational frameworks that mitigate legal, regulatory, and commercial risks.

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This article is the 32nd in our thought leadership series, "*DigiCure: Legal insights at the intersection of Technology and Life Sciences and Health Care*," which aims to help you stay informed about the broad array of legal and regulatory issues affecting companies operating at the intersection of the technology and life sciences & health care sectors. From using AI in clinical studies, to evolving

patient data concerns, to the entire digital health product lifecycle, our team will discuss novel issues arising in all parts of the world, including unique deal-making, litigation, and compliance concerns. Ensure you are subscribed to Our Thinking to receive these new insights!

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