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# Issue brief

# Balancing openness and control: Cross-border health data and AI governance in China

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*This issue brief examines how China's approach to cross-border health data governance is shaping AI development, biotechnology innovation, and international research collaboration. It analyzes the legal and regulatory frameworks governing the transfer of health, genomic, and biometric data, explores the role of data sovereignty and national security in Beijing's policymaking, and assesses the implications for multinational corporations, policymakers, and the future of global health data governance.*

## Introduction

The approach of the People's Republic of China (PRC) to health data sits at the intersection of national security, economic development, and technological competition. The regulatory system examined in this report reflects a clear set of drivers: a push for data sovereignty, the strategic importance of health and biometric data, and the role of large-scale datasets in advancing artificial intelligence (AI). At the same time, the rapid digitization of China's healthcare system, which increasingly deploys AI across clinical, administrative, and pharmaceutical domains, generates strong demand for integrated, high-quality data.

This dynamic creates a core tension for both Beijing and the multinational companies operating within China's health sector. China seeks to expand the use of health data to support AI-driven innovation, biotechnology competitiveness, and pharmaceutical development, while maintaining strict controls over high-sensitivity genetic and genomic information. Recent draft reforms, notably the 2026 updates to the PRC's 2019 Regulations on the Management of Human Genetic Resources,[1] suggest Beijing will further its efforts to differentiate between lower-risk clinical and biomedical collaboration, which regulators strive to facilitate through narrower human genetic resource (HGR) regime definitions and ethics-based governance mechanisms,

1. Zhōnghuá Rénmín Gònghéguó Rénlèi Yíchuán Zīyuán Guǎnlǐ Tiáolì (中华人民共和国人类遗传资源管理条例) Zhōnghuá rénmín gònghéguó guówùyuàn líng dì 717 hào (中华人民共和国国务院令第717号) [Regulations of the People's Republic of China on the Management of Human Genetic Resources, State Council Decree of the People's Republic of China No. 717] (promulgated by the State Council, May 28, 2019, effective date July 1, 2019) Ministry of Science and Technology of the People's Republic of China, 306-10-2019-044, https://www.most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/flfg/201906/t20190612_147044.html (China).

and higher-risk genomic or strategically sensitive datasets that remain tightly controlled.[2] The result is a system that enables large-scale domestic data use and selective international collaboration, but constrains global data pooling and interoperability. This has led to a complex regulatory and compliance environment governing cross-border data transfers. Uncertainty is a defining feature of the PRC's data governance regime, especially for large firms operating at scale.

The report argues three core points:

- **First, China views health and biometric data as both strategic economic resources and national security assets.** This is especially true for genomic, multimodal, and population-scale datasets that Beijing sees as important to biotechnology competition, AI development, and state security. As a result, an overlapping regulatory architecture among multiple agencies—including the Cyberspace Administration of China (CAC), also known as Office of the Central Cyberspace Affairs Commission, the National Health Commission (NHC), institutional ethics committees, and sectoral and provincial authorities—primarily governs cross-border health-data transfers, with the NHC increasingly assuming functions previously associated with the Ministry of Science and Technology (MOST) under China's HGR regime. This creates compliance complications for multinational health firms.
- **Second, while China maintains strict formal controls, system signals reveal an opening up of more routine and pragmatic channels for data exchange**. Increases in more sector-specific guidance for collaboration pathways, as well as publicly disclosed approvals, pilot programs, and multinational oncology partnerships, demonstrate that cross-border cooperation has actively become more institutionally facilitated in selected sectors, especially oncology, pharmaceuticals, and multinational clinical trials.[3] However, these collaborations typically depend on strong Chinese institutional partners and may include some form of localized infrastructure, formal ethics review, and iterative engagement with regulators. In practice, access remains highly managed and case-specific.
- **Third, China's AI ambitions are increasing pressure for greater internal data integration while simultaneously reinforcing restrictions on external access**. AI systems tailored to the health sector depend on large-scale clinical, imaging, genomic, and behavioral datasets, creating tension between China's industrial AI goals and its emphasis on cyber sovereignty and data controls. Health AI systems often involve sensitive personal information, user inputs, usage logs, and model outputs derived from protected medical data. The AI rules then add extra obligations around lawful sourcing, consent, training-data quality, data security, annotation governance, content labeling, misuse prevention, and explainability. So, a provider trying to move health data or health-data-derived AI workflows across borders must satisfy *both* the ordinary transfer regime and the AI-specific requirements related to training data, consent, data security, labeling, and output control.[4]

This report examines how China's overlapping data-security, privacy, health-data, and AI-governance regimes shape cross-border health-data transfers and international biomedical collaboration. It aims to provide insights for policymakers on China's shifting cross-border data-transfer regime. Moreover, the report highlights how these rules affect multinational corporations (MNCs)—in particular, pharmaceutical firms—seeking to navigate China's evolving regulatory environment.

In the near term, China's future cross-border data policy will likely move toward a more refined, sector-specific system that selectively eases lower-risk transfers while preserving strict

2. "Guānyú rénlèi yíchuán zīyuánguǎnlǐ tiáolì shíshīxìzé (zhēngqiúyìjiàn gǎo) gōngkāi zhēngqiúyìjiàn de gōnggào" 关于人类遗传资源管理条例实施细则 (征求意见稿) 公开征求意见的公告 [Public Notice on Soliciting Opinions on the Draft Implementing Rules of the Regulations on the Management of Human Genetic Resources], National Health Commission of the People's Republic of China, May 8, 2026, https://www.nhc.gov.cn/wjw/yjzj/202605/9b38dffa8d8047ea94813f40aca8d282.shtml?mc_cid=028691596e&mc_eid=fb99565a58; Réntǐ Jīyīn Shùjù Yánjiū Lúnlǐ Zhǐyǐn (《人体基因数据研究伦理指引》) [Ethical Guidelines for Human Genome Data Research] (promulgated by the Sub-committee on Life Sciences Ethics, National Science and Technology Ethics Committee, May 2026) National Health Commission of the People's Republic of China, May 25, 2026, https://most.gov.cn/kjbgz/202605/P020260525349602273926.pdf (China).
3. National Health Commission of the People's Republic of China, "Public Notice on Soliciting Opinions on the Draft Implementing Rules – 2026," (entry at note 2); National Health Commission of the People's Republic of China, "Ethical Guidelines for Human Genome Data Research – 2026," (entry at note 2).
4. See: Caroline Schuerger, Vikram Venkatram, and Katherine Quinn, *China and Medical AI: Implications of Big Biodata for the Bioeconomy, Center for Security and Emerging Technology*, May 2024, https://cset.georgetown.edu/publication/china-and-medical-ai/.

oversight of strategically sensitive data, especially in areas tied to AI, biotechnology, and national security. The expectations are for regulators to expand free trade zones (FTZs) and other pilot negative-list mechanisms alongside industry-specific guidance while continuing to treat more sensitive data types (known in PRC regulatory terms as "important data") flexibly and conservatively.

Over the medium term, China will likely institutionalize a more differentiated regime organized by sector, risk level, and geography, while shifting more oversight toward audits, compliance obligations, and post-transfer supervision rather than focusing on front-end approvals. Recent draft HGR regime revisions also suggest a broader shift toward institutional ethics governance and scientific ethics committee review replacing some front-end security approvals for lower-risk biomedical collaboration.[5] AI development has become more central to how this system develops, with Chinese policymakers explicitly linking data circulation, data infrastructure standardization, and the construction of sector-specific datasets to national AI strategy.

In the long term, Beijing appears to pursue a model of what this report terms "managed openness" in which some forms of international data exchange remain permitted through structured and state-supervised channels, while highly sensitive data related to AI, health, genomics, and priority industrial sectors remains tightly governed under a sovereignty-centered framework.

For policymakers, China's evolving system illustrates how AI competition, geostrategic competition over biotechnology, and national security concerns work to reshape global data governance. Beijing is integrating the privacy, industrial policy, and security aspects of data into a unified governance framework centered on state visibility and control over strategically valuable datasets.

For foreign MNCs operating in China, the practical implications of China's health-data regime differ significantly depending on the type of data involved, the sector, the geographic location, and whether AI systems are part of the workflow. Successfully navigating this environment may require firms to:

- Differentiate among types of health data and understand which datasets regulators treat as strategically sensitive.
- Align operations with the distinct authorities governing outbound transfers, clinical records, and HGR.
- Assume localization for many categories of sensitive health and AI-training data.
- Invest in privacy-enhancing approaches such as federated learning, trusted research environments, synthetic data, and localized inference infrastructure.
- Build strong partnerships with local institutional actors, including Chinese partners, hospitals, contract research organizations, research institutes, and other actors.
- Maintain sustained and iterative engagement with regulators across both national and provincial levels.
- Prepare for growing regulatory divergence—especially in the context of growing US-China geopolitical tensions—through more localized, parallel, and flexible China-facing operational structures.

In short, this research identifies China's health data regime as "managed openness." It is relatively open where data use advances state-backed innovation, clinical research, pharmaceutical development, and AI industrial policy. It is closed where data mobility threatens state visibility, sovereign control, public health security, biosecurity, or geopolitical positioning. China's regulatory system incentivizes a "China-for-China" health AI architecture, even when firms continue to participate in multinational research and development (R&D) pipelines. The outcome is a regulatory system that facilitates selected forms of collaboration while preserving a veto point for the state.

This report first outlines the drivers of China's approach to data—namely, the dual security and economic rationales that undergird its regulatory approach. It assesses, in particular, the role of health data in China's core data governance laws (i.e., the Cybersecurity Law, Data Security Law, and Personal Information Protection Law) that classify the data into specific categories and prescribe requirements for export. The next section examines the role of health data in China's AI sector, with special attention to how the intersection of AI, data regulations, and health data protections impacts cross-border data transfers. Lastly, this report analyzes the near-, medium-, and long-term policy horizons and offers recommendations for MNCs to successfully navigate the shifting regulatory landscape governing the health data sector.

5. "China Loosens Genetic Data Rules, Shifts Oversight Toward Ethics Committees," Trivium, May 27, 2026, https://triviumchina.com/2026/05/27/china-loosens-genetic-data-rules-shifts-oversight-toward-ethics-committees/?mc_cid=028691596e&mc_eid=fb99565a58.

## Drivers of China's approach to personal data

Before the advent of China's current data protection regime, governance of foreign access to health data—including genetic datasets, hospital records, and clinical trial data—was comparatively less centralized and less systematic.[6] Prior to 2012, China's data rules were a patchwork of sectoral regulations responding to industry-specific challenges.[7] However, most now widely consider that China operates one of the world's more restrictive data control regimes for personal data, especially and including sensitive health data,[8] due, in large part, to how Beijing has come to view data resources as both a strategic economic resource and as national security assets.

### Data as a strategic economic resource

Alongside the rapid growth in the global digital economy, the PRC has come to define data as a "fifth factor of production" (alongside land, labor, capital, and technology) and a source of national competitive advantage.[9] This framing has significant implications for the evolution of China's cross-border data policy. The PRC's macroeconomic regulator, the National Development and Reform Commission (NDRC), has identified secure cross-border data flow as key to extracting the economic value from data and toward China's self-sufficiency.[10] Cross-border data flows support China's push to expand the country's digital economy and improve productivity in sectors such as manufacturing, logistics, and finance.[11] In particular, discussions of cross-border data flows have become increasingly salient in geopolitics as major powers compete for AI advantage. AI-fueled technologies require access to large, diverse datasets, and are thus heavily dependent on the free flow of data across borders.[12]

Beyond the macro-level economic benefits of secure but abundant cross-border data flows, China's 14th Five-Year Plan (2021 to 2025) frames the integration of AI with the life sciences as a key driver of industrial growth. Backed by top-level policy and financial support, this plan contains goals to advance sectors including biomedicine, bioengineered breeding, biomaterials,

6. See: Smriti Mallapaty, "China Expands Control over Genetic Data Used in Scientific Research," May 6, 2022, https://www.nature.com/articles/d41586-022-01230-z. See also: Planning Commission on Issuing the Measures for the Governance of Population Health Information (for Trial Implementation), "Notice of the National Health and Family," No. 24, issued and effective on May 5, 2014, http://www.lawinfochina.com/display.aspx?id=17535&lib=law.
7. Prior to the 2012, the NPC Standing Committee Decision on Strengthening Network Information Protection, China's data governance framework consisted largely of sector-specific rules, including earlier HGR controls, rather than a general personal information protection regime. The 2012 decision marked an early national turn toward personal information protection, though health-specific restrictions hardened later, including the 2014 Population Health Information Measures, which required stronger controls over population health information and restricted overseas storage. See also: Qian Yin, Data Privacy Rights in Health Data Sharing: A Government-Centric Paradigm in China, *International Data Privacy Law*, 15, No. 3 (August 2025): 242, https://doi.org/10.1093/idpl/ipaf007. For example, China's early healthcare data regulations emphasized in-hospital practices for patient record confidentiality Provisions on the Administration of Medical Records in Medical Institutions (issued by the Ministry of Health of the People's Republic of China, Order No. 20 of the Ministry of Health 2002).
8. Wenling Tan, "National Security as the Trump Card: Assessing China's Legal Regime on Cross-Border Data Transfer," *Information and Communications Technology Law* 33, No. 3 (2024): 368–83, https://www.tandfonline.com/doi/abs/10.1080/13600834.2024.2375125; Andrew Silver, "China's Data Protection Rules Prompt Pause from Major European Research Funders," Reuters, April 25, 2025, https://www.reuters.com/sustainability/society-equity/chinas-data-protection-rules-prompt-pause-major-european-research-funders-2025-04-25/; Qian, "Data Privacy Rights in Health Data Sharing," 238–55.
9. In April 2020, China's State Council officially designated data as the fifth factor of production, alongside land, labor, capital, and technology. See: "Zhonghua renmin gongheguo gongye he xinxi hua bu" 中华人民共和国工业和信息化部 [Ministry of Industry and Information Technology of the People's Republic of China], "Shisiwu da shuju chanye fazhan guihua" 十四五大数据产业发展规划 [14th Five-Year Plan for Big Data Industry Development]," 2021, https://img9.qianzhan.com/policy/202603/14/20260314-5f1240c-ccffe6564.pdf
10. "Chàngtōng shùjù yàosù 'shuāng xúnhuán' wánshàn quánqiú shùjù 'dìngjià liàn' 畅通数据要素"双循环" 完善全球数据"定价链" [Facilitate the «dual circulation» of data elements and improve the global data «pricing chain».], National Development and Reform Commission, December 12, 2021, https://www.ndrc.gov.cn/xxgk/jd/jd/202212/t20221220_1343699.html.
11. https://www.oecd.org/en/publications/economic-implications-of-data-regulation_aa285504-en/full-report/component-5.html
12. Desmond Israel, "A Commentary on Assessing the Effectiveness of Cross-Border Data Flow Regulations in the Age of Artificial Intelligence (AI)," *Journal of Research and Development* 11, No. 4 (2023): 245; https://www.longdom.org/open-access-pdfs/a-short-commentary-on-assessing-the-effectiveness-of-crossborder-data-flow-regulations-in-the-age-of-artificial-intellig.pdf.

and bioenergy and to scale the broader bioeconomy.[13] As such, China seeks cross-border health data to support multinational biomedical research and clinical trials, to improve AI model development and validation through access to more diverse datasets, and to enable cooperation in public health surveillance and scientific exchange.[14] These needs help explain why China seeks to facilitate selected forms of data mobility even while tightening controls over sensitive health and genomic data.

## Data as a national security asset

The PRC's view of health data and national security is explicit in official documents and legal frameworks. In 2016, China's top administrative body, the State Council of the People's Republic of China (PRC State Council), defined medical and health data as "important foundational strategic resources" for the nation and for advancing its data-driven health industry.[15] The PRC has linked genetic data in particular to national security—China's 2019 HGR Regulation states that the purpose of the regulation is to: "effectively protect and rationally utilize our country's human genetic resources, and safeguard public health, national security, and the public interest."[16] Similarly, China's 2020 Biosecurity Law links "security in biotechnology research, development, and applications" to "preserving national security."[17] Various regulatory NHC guidelines also list health and medical big data as "important foundational strategic national resources," the security of which "concerns natio-

13. "Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035 [中华人民共和国国民经济和社会发展第十四个五年规划和2035年远景目标纲要]," Center for Security and Emerging Technology, March 12, 2021, trans. May 13, 2021, https://cset.georgetown.edu/publication/china-14th-five-year-plan.

14. See: Cao Zhen, "Beijing Completes Its First Filing of Negative List for Cross-Border Data Flow," Foreign Affairs Office of Beijing Municipal Government, September 19, 2024, https://wb.beijing.gov.cn/en/express/202411/t20241119_3945122.html; Lei Li and Lianying Wan, "Pharma Companies in Beijing Free Trade Zone to Benefit from Relaxed Data Transfer Rules," Sidley, September 19, 2024, https://datamatters.sidley.com/2024/09/19/pharma-companies-in-beijing-free-trade-zone-to-benefit-from-relaxed-data-transfer-rules/; "China Relaxes Security Review Rules for Some Data Exports," Reuters, March 22, 2024, https://www.reuters.com/technology/cybersecurity/chinas-cyberspace-regulator-issues-rules-facilitate-cross-border-data-flow-2024-03-22/. See also: Ward Zhou and Du Zhihang, "Cancer Collaboration Becomes First Overseas Data Transfer Approved Under New Regime," Caixin Global, January 19, 2023, https://www.caixinglobal.com/2023-01-19/cancer-collaboration-becomes-first-overseas-data-transfer-approved-under-new-regime-101991040.html; "Beijing E-Town Completes the City's First Negative List Filing for Cross-Border Data Transfers," Beijing Economic-Technological Development Area, Yahoo Finance (paid release), September 19, 2024, https://finance.yahoo.com/news/beijing-e-town-completes-citys-094000205.html; "NMPA Issued the Announcement on the Guidelines for Real-World Evidence to Support Drug Development and Review (Interim)," National Medical Products Administration (China), January 7, 2020, https://english.nmpa.gov.cn/2020-01/07/c_456245.htm; Jiayue Xu et al., "The Use of Real-World Evidence for Regulatory Decisions in China," Clinical Pharmacology and Therapeutics 116, No. 1 (July 2024): 82–95, https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3257?af=R&; Zihuan Wang, "Artificial Intelligence in Chinese Healthcare: A Review of Applications and Future Prospects," Biomedical Engineering Letters 15 (October 2025): 1065–72, https://pmc.ncbi.nlm.nih.gov/articles/PMC12638562/.

15. "Guówùyuàn bàngōng tīng guānyú cùjìn hé guīfàn jiànkāng yīliáo dà shùjù yìngyòng fāzhǎn de zhǐdǎo yìjiàn" 国务院办公厅关于促进和规范 健康医疗大数据应用发展的指导意见 "guó bàn fā〔2016〕47 hào" 国办发〔2016〕47号 [Guiding Opinions of the General Office of the State Council on Promoting and Regulating the Application and Development of Health and Medical Big Data, Document No. 47], General Office of the State Council, 000014349/2016-00132, June 21, 2016, https://www.gov.cn/zhengce/content/2016-06/24/content_5085091.htm.

16. Author emphasis; Ministry of Science and Technology of the People's Republic of China, Regulations of the People's Republic of China on the Management of Human Genetic Resources (see introduction, note 1). Meanwhile, the 2023 implementing guidelines also repeat this language. See: Kēxué Jìshù bù líng dì 21 Hào Rénlèi Yíchuán Zīyuán Guǎnlǐ Tiáolì Shíshī Xìzé" (科学技术部令第21号 人类遗传资源管理条例实施细则) [Order No. 21 of the Ministry of Science and Technology: Detailed Rules for the Implementation of the Regulations on the Management of Human Genetic Resources] (promulgated by the Ministry of Science and Technology of the People's Republic of China, May 26, 2023, effective date July 1, 2023), Ministry of Science and Technology of the People's Republic of China, 306-10-2023-221, https://www.most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/bmgz/202306/t20230601_186416.html (China).

17. "Biosecurity Law of the P.R.C.," China Law Translate, October 18, 2020, https://www.chinalawtranslate.com/en/biosecurity-law/.

nal strategic security."[18] China's Ministry of State Security has also defined securing biometric data as a matter of national security and recently warned of foreign entities using scientific cooperation as a cover to exfiltrate sensitive data.[19]

This securitized view of data—especially sensitive personal health data—is due, in part, to issues that arose from the rapid expansion of China's digital economy during the mid- to late-2000s decade. During this period, Chinese technology companies accumulated vast amounts of user data, and the lack of regulation over the sector led to a series of high-profile incidents involving fraud and the illegal sale of personal information.[20] PRC leadership came to view the vast troves of user data possessed by technology companies as potential vectors for exfiltration and thus as serious risks to national security.[21] In 2012, China's top decision-making body, the National People's Congress Standing Committee, issued the "Decision on Strengthening Information Protection on Networks," one of the earliest instantiations linking national security with data protection in regulatory guidance.[22]

Alongside these domestic developments, accusations of widespread surveillance by US companies at the behest of the US government in 2013–2014 exacerbated longstanding fears about reliance on foreign technology infrastructure and the vulnerability of Chinese data to foreign intelligence collection.[23] China's President Xi Jinping argued in 2014 that "no matter how developed a country's internet technology is, it simply cannot violate the information sovereignty of other countries," explicitly linking US surveillance activities to China's emerging concept of cyber sovereignty.[24] Chinese policymakers also spoke of the US policy position of supporting the "free flow of data" as a mechanism to enable US firms' dominance of global supply chains for data extraction.[25] This catalyzed efforts to gain greater control over data collection, storage, and cross-border transfers.

18. "Guānyú yìnfā guójiā jiànkāng yīliáo dà shùjù biāozhǔn, ānquán hé fúwù guǎnlǐ bànfǎ (shìxíng) de tōngzhī" 关于印发国家健康医疗大数据标准、安全和服务管理办法(试行)的通知"Guó wèi guīhuà fā〔2018〕23 hào" 国卫规划发〔2018〕23号 [Notice on Issuing the National Health and Medical Big Data Standards, Security and Service Management Measures (Trial), National Health and Family Planning Document No. 23 of 2018], National Health Commission of the People's Republic of China, July 12, 2018, https://www.nhc.gov.cn/wjw/c100175/201809/a3223ef7768140a786b308c2064de14b.shtml; "Guójiā jiànkāng yīliáo dà shùjù biāozhǔn, ānquán hé fúwù guǎnlǐ bànfǎ (shìxíng)" jiědú gǎo《国家健康医疗大数据标准、安全和服务管理办法(试行)》解读稿 [Interpretation of the "National Health and Medical Big Data Standards, Security and Service Management Measures (Trial)"], National Health Health Commission of the People's Republic of China, September 13, 2018, https://www.nhc.gov.cn/guihuaxxs/c100132/201809/be1ac7ce1f7a492d9d9ce46652c44725.shtml.

19. "Shùjù huò chéng "shēngwù zhàdàn" yuánliào kuàguó hézuò jǐnfáng shēngwù shùjù xièlòu" 数据或成"生物炸弹"原料 跨国合作谨防生物数据泄露 [Data Could Become Raw Material for «Biological Bombs»; Guard Against Biological Data Leaks in Cross-Border Cooperation], Shanghai Observer, January 26, 2026, https://www.shobserver.com/staticsg/res/html/web/newsDetail.html?id=1058116&sid=11.

20. See, for example: "Wangshang 'heishi': nide simi xinxi jishi yuan jiu neng chadao 网上"黑市":你的私密信息只要几十元就能查到![Online "Black Market": Your Private Information Can Be Accessed for Just a Few Dozen Yuan!]," Xinhuanet, 2017, http://www.360doc.com/content/17/0219/20/34781380_630367467.shtml; Li Shaozhuan and Liu Jialu, "Shei maile nide yinsi? Cheqi yonghu mingan xinxi shiluo diaocha 谁买了你的隐私?车 企用户敏感信息失落调查[Who Sold Your Privacy? An Investigation of Sensitive Information Leaks of Vehicle company Users]," Xiaofeizhe baodao 7 [Consumer Report, No. 7], 2015, https://m.fx361.com/news/2015/1205/14102329.html; Paul Mozur, "Apple Customer Data in China was sold Illegally, Police Say," *New York Times*, June 9, 2017, https://www.nytimes.com/2017/06/09/business/china-applepersonal-data-sold.html.

21. See Hong Y., "Shuju chujing anquan pinggu: Baohu jichuxing zhanlüe ziyuan de zhongyao yihuan 数据出境安全评估:保护基础性战略资源的重要一环 [Data outbound security assessment: An important part of protecting basic strategic resources]," Zhongguo Xinxi Anquan (China Information Security) 6, 2017, as cited in Creemers, "China's Emerging Data Protection Framework." https://www.cac.gov.cn/2017-08/07/c_1121443948.htm

22. Digichina, "National People's Congress Standing Committee Decision Concerning Strengthening Network Information Protection," trans. Rogier Creemers, Stanford University, December 28, 2012, https://digichina.stanford.edu/work/national-peoples-congress-standing-committee-decision-concerning-strengthening-network-information-protection/.

23. Glenn Greenwald and Ewen MacAskill, "NSA Prism program taps in to user data of Apple, Google and others," *Guardian*, June 7, 2013, https://www.theguardian.com/world/2013/jun/06/us-tech-giants-nsa-data.

24. Wu Jiao and Zhao Shengnan, "Xi: Respect Cyber Sovereignty," *China Daily* USA, July 17, 2014, https://www.chinadaily.com.cn/kindle/2014-07/17/content_17819008.htm.

25. Wu 吴, "Shuju zhuquan shiye xia geren xinxi dua jing guize de jiangou 数据主权视野下个人信息跨境规则的 建构" [The Construction of Personal Information Cross-Border Transfers Rules under A Digital Sovereign Perspective].

Beijing formalized this security orientation in the 2015 National Security Law of the People's Republic of China, which links data governance directly to national and political security.[26] Xi's concept of a "comprehensive national security" is a national security policy framework that places internal security—in particular, regime survival—at its core. It is the standard against which China measures other national security considerations.[27] Under this concept, maintaining data "security" is integral to the system,[28] making control over information flows essential.[29] The law grants authorities broad and flexible powers to regulate economic activity, including cross-border data flows, based on perceived security risks. Central to this framework is the requirement that data be "secure and controllable," a concept tied to China's doctrine of cyber sovereignty, which asserts that the state has full authority over data generated within its borders. [30]

## Health data under China's data governance system

China regulates health data through overlapping frameworks under three core laws: The 2016 Cybersecurity Law (CSL) and the 2021 Data Security Law (DSL), which focus on data security, and the 2021 Personal Information Protection Law (PIPL), which centers on personal information protection. These laws provide comprehensive baseline protections, with more specific requirements tailored by sector.

On data security, the CSL, DSL, and related regulations require managing China's data within a hierarchical, increasingly restrictive three-tier classification system: general data, important data, and core data.[31] Broadly, the term "general data" refers to ordinary commercial or operational information with limited national security implications; the "important data" classification refers to data that, if tampered with, leaked, or misused, could harm national security, economic stability, public health, or major public interests; and the "core data" tier refers to data tied directly to national security, critical sectors, or major state interests whose compromise could seriously threaten political stability, economic security, or state functioning.[32]

Assessment procedures for the export of this data increase in scrutiny and restrictiveness based on where the data sit, in terms of the three classifications. Health data, especially genetic and genomic data, often fall under the category of important data due to their national-security and industrial significance and, in some cases, may also implicate core data concerns.[33] Notably, both laws are intentionally vague on what constitutes important data and the factors considered as to who is an important data processor, to give regulatory authorities the broadest leeway to conduct context-specific assessments, as well

26. Renmin Wang 人民网 [People's Daily Online], "Xijinping guanyu zongti guojia anquan guan lunshu zhaibian" 习近平关于总体国家安全观论述摘编" [Excerpts from Xi Jinping's Discourse on the Comprehensive National Security Concept]. http://theory.people.com.cn/GB/68294/419481/index.html
27. Wang, "Excerpts from Xi Jinping's Discourse."
28. Wang, "Excerpts from Xi Jinping's Discourse."
29. Lizhi Liu, *"The Rise of Data Politics,"* 52.
30. Hunter Dorwart, "Chinese Cybersecurity Law: An Overview," Practicing Law Institute: Cybersecurity, November 30, 2022, https://dx.doi.org/10.2139/ssrn.4526102; Yang Yuxuan 杨宇轩, "Shuju zhuquan shijiao xia shuju chujing zhidu wanshan yanjiu 数据主权视角下数据出境制度完善研究 [Research on Data Export System from the Perspective of Data Sovereignty]," Huaibei shifan daxue xuebao (zhexueshehui kexue ban 淮北师范大学学报(哲学社会科学版) [Journal of Huaibei Normal University (Philosophy and Social Sciences)], no. 3 (2025): 96.
31. See also: Data Security Technology–Rules for Data Classification and Grading, GB/T 43697-2024, Article 6.1 (issued by State Administration for Market Regulation and National Standardization Administration on 15 March 2024, effective 1 October 2024).
32. "Data Security Law of the PRC," China Law Translate, June 10, 2021, https://www.chinalawtranslate.com/en/datasecuritylaw.
33. Ministry of Science and Technology of the People's Republic of China, "Order No. 21 of the Ministry of Science and Technology: Detailed Rules for the Implementation – 2023," (entry at note 16).The most relevant to understanding cross-border implications for health data is the "important data" category, as this is where the majority of regulatory complexity comes in (as general data faces much fewer restrictions, and core data is rarely, if ever, permitted for export).

as determine restrictions and handling determinations of data by sector.[34]

On personal information protection, in addition to its status as important data under China's data security laws, health data often figure as "sensitive personal information" under China's personal information protection regime, namely, 2021's PIPL. This status renders health data subject to additional protections and specific regulations governing its sale, use, and transfer.

In the case of health data, an overlap emerges from an often dual categorization as both important data under the DSL (due to implications for national security) and sensitive personal information under the PIPL (due to implications for personal information protection) (Figure 1).

- **Important data:** Whether health datasets qualify often depends on scale, aggregation, strategic context, sector, and foreign involvement. Both the CSL and DSL frequently categorize health data as important data,[35] a category requiring increased protection due to its significance to national security.[36] Health datasets are more likely to qualify as important data when they are large-scale systems (i.e., they are population-level datasets, for example census data or genetic resource databases) that link to public health networks, which regulators believe could affect national security, economic operations, social stability, public health, or major public interests if tampered with, leaked, destroyed, illegally obtained, or transferred abroad.[37]

34. See, for example: Xiao Bei, "Zhòngyào shùjù dìngyì guānxì shùjù ānquán jiānguǎn gōngzuò kāizhǎn, biāozhǔn qiān hū wàn huàn shǐ chūlái" 重要数据定义关系数据安全监管工作开展，标准千呼万唤始出来。[Standards defining "important data" and governing data security oversight have finally been released after much anticipation.], Ānquán nèicān 安全内参 [Security Insider], September 23, 2021, https://www.secrss.com/articles/34569?mc_cid=13faacfcb3&mc_eid=f8a3931b69; "Guójiā hùliánwǎng xìnxī bàngōngshì guānyú "wǎngluò shùjù ānquán guǎnlǐ tiáolì (zhēngqiú yìjiàn gǎo)" gōngkāi zhēngqiú yìjiàn de tōngzhī" 国家互联网信息办公室关于《网络数据安全管理条例（征求意见稿）》公开征求意见的通知 [Notice from the Cyberspace Administration of China on Soliciting Public Comments on the Draft Regulations on Network Data Security Management], Cyberspace Administration of China, November 14, 2021, https://www.cac.gov.cn/2021-11/14/c_1638501991577898.htm; http://cac.gov.cn/2021-10/29/c_1637102874600858.htm; "Gōngyè hé xìnxī huà bù bàngōng tīng guānyú zǔzhī kāizhǎn gōngyè lǐngyù shùjù ānquán guǎnlǐ shìdiǎn gōngzuò de tōngzhī" 工业和信息化部办公厅关于组织开展工业领域数据安全管理试点工作的通知 "Gōng xìn tīng wǎng ān hán〔2021〕295 hào" 工信厅网安函〔2021〕295号 [Notice from the General Office of the Ministry of Industry and Information Technology on Organizing and Carrying Out Pilot Work on Data Security Management in the Industrial Sector, MIIT Network Security Office Letter (2021) No. 295], Ministry of Industry and Information Technology of the People's Republic of China, December 10, 2021, https://www.miit.gov.cn/zwgk/zcwj/wjfb/tz/art/2021/art_231a7d92a8ef4b90a314ce3d263f18c8.html; "Guójiā hùliánwǎng xìnxī bàngōngshì fābù "shùjù chūjìng ānquán pínggū shēnbào zhǐnán (dì yī bǎn)" 国家互联网信息办公室发布《数据出境安全评估申报指南（第一版）》[The Cyberspace Administration of China has released the «Guidelines for Data Cross-border Security Assessment and Declaration (First Edition)».], Cyberspace Administration of China, August 31, 2022, https://www.cac.gov.cn/2022-08/31/c_1663568169996202.htm; "Zìrán zīyuán lǐngyù shùjù ānquán guǎnlǐ bànfǎ yìnfā" 自然资源领域数据安全管理办法印发 [Measures for the Administration of Data Security in the Natural Resources Sector Issued] General Office of the State Council, March 29, 2024, https://www.gov.cn/lianbo/bumen/202403/content_6942234.htm.

35. The CSL, enacted in 2016, was China's first systematic effort to regulate cross-border data transfers for personal information. The law requires that "important data" gathered by Critical Information Infrastructure Operators, or CIIOs, must reside domestically; it also put forward the requirement for security assessments for data prior to export. See, for example, National People's Congress, Cybersecurity Law of the People's Republic of China, promulgated in November 2016, http://www.npc.gov.cn/npc/c30834/202108/a8c4e3672c74491a80b53a172bb753fe.shtml, Article 1; "Cybersecurity Law of the People's Republic of China (2026 revised version)," China Law Translate, November 17, 2025, https://www.chinalawtranslate.com/en/22075-2/. The DSL, passed in 2021, built on the legal scaffolding of the CSL and established a national classification system of data into hierarchical categories based on the "importance of the data in economic and social development, and the impact on national security, public interests, or individuals and organizations once it is tampered with, destroyed, leaked, or illegally obtained or used." While still vague, the DSL established an implicit hierarchy for data, which would later include three categories mentioned above: general data, important data, and core data, with the addition that "important data" was a category requiring increased protection due to its significance to national security. The DSL also outlined requirements for risk assessments and reporting obligations for processors of important data. Later, in 2024, China's standards body formalized the classification hierarchy laid out in the DSL, releasing a national technical standard (GB/T 43697-2024) for the three data categories, including classification by type and sector, grading by risk level, and outlining compliance obligations for each grade. See: China Law Translate, "Data Security Law of the PRC"; Arendse Huld, "China Releases Technical Standards Guiding the Classification of 'Important' Data," *China Briefing*, April 3, 2024, https://www.china-briefing.com/news/china-data-classification-standards-important-data/.

36. China Law Translate, "Data Security Law of the PRC."

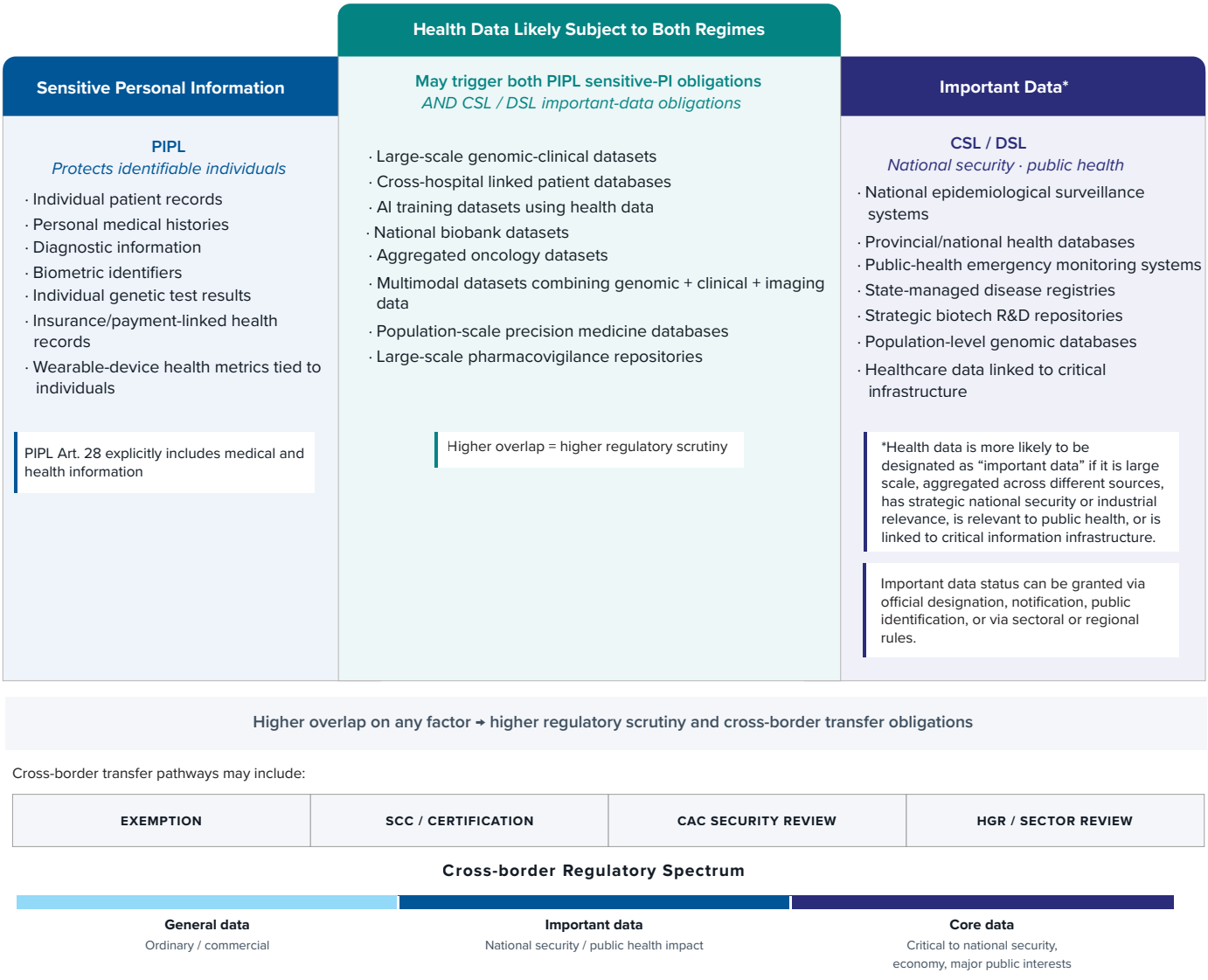
37. Huld, "China Releases Technical Standards Guiding the Classification."

- **Sensitive personal information:** China's PIPL explicitly defines medical and health information as sensitive personal information. Article 28 states that sensitive personal information includes data which, once leaked or illegally used, could easily infringe personal dignity or endanger personal or property safety, including "medical health information" and also includes specific mention of "biometric information" under its description of sensitive personal information.[38] Health datasets also qualify as sensitive personal data at the individual level when they reveals details, such as individual health records, genetic information, and ethnic characteristics.[39] Regulations passed by China's standards body and market regulator also support this interpretation, defining health data as sensitive personal information.[40] The PIPL, moreover, stipulates that personal information handlers may only handle *sensitive* personal information "under circumstances of strict protection measures" and when "there is a specific purpose and need to fulfill."[41]
- **Personal information:** When it rises to the level of concern for national security or public interest, personal information joins the important data category. In terms of health data, it becomes more likely to cross into important data territory when one or more of the following conditions apply:
  - Large-scale data (e.g., provincial or national level datasets, datasets including millions of patient records, and population-wide statistics).[42]
  - Strategically relevant data (e.g., AI training datasets using sensitive health information, biotechnology R&D, an epidemiological focus, and data tied to strategic industries).[43]
  - Aggregated data that integrate sources defined as important data (e.g., cross-hospital linked datasets, multimodal patient profiles, combined genomic data with clinical data/repositories; this also includes derivative data—including certain types of bulk data, integrated data that combines information across different populations, sectors, and use scenarios, and mined multidimensional data generated from a large amount of personal information[44]).[45]
  - Critical Information Infrastructure Operator (CIIO) linked data (e.g., data controlled by major public hospital systems, national health infrastructure platforms, or other healthcare CIIOs).[46]
  - Data with public health or national security implications (e.g., data related to infectious disease monitoring, pandemic response, and state-managed health registries).[47]

38. Digichina, "Translation: Personal Information Protection Law of the People's Republic of China – Effective Nov. 1, 2021," trans. Rogier Creemers and Graham Webster, Stanford University, September 7, 2021 [last revised], https://digichina.stanford.edu/work/translation-personal-information-protection-law-of-the-peoples-republic-of-china-effective-nov-1-2021/.
39. GB/T 43697; Huld, "China Releases Technical Standards." Standards guidance GB/T 35273-2020 (Personal Information Security Specification) and GB/T 43697-2024 (Data Classification and Grading Rules), which provide illustrative lists and guidance on identifying sensitive personal information, reinforce that health data and biometric data are treated as high-sensitivity categories.
40. Article 3.2, Information Security Technology–Security Requirements for Processing of Sensitive Personal Information (Draft for Comments) (issued by State Administration for Market Regulation and National Standardization Administration on 8 August 2023). The Information Security Technology - Guide for Healthcare Data Security (GB/T 39725 - 2020) and the Information Security Technology–Security Requirements for Processing of Sensitive Personal Information.
41. Digichina, "Translation: Personal Information Protection Law."
42. https://cgc.law.stanford.edu/wp-content/uploads/sites/2/2021/07/Peking_University_CGCL_Translation_Data-Security-Law-PRC_20210701_EN.pdf; https://www.dlapiper.com/en/insights/publications/2023/07/china-regulation-of-cross-border-transfer-of-healthcare-data.
43. https://cset.georgetown.edu/publication/chinas-emerging-data-governance-framework/; https://www.gov.cn/zhengce/content/2022-05/10/content_5689353.htm
44. Art 3.1 of Information Security Technology—Guidelines for Identification of Critical Data; Data Security Technology–Rules for Data Classification and Grading (n 21) Appendix I. Appendix I: Derivative Data Classification Reference.
45. https://www.kwm.com/cn/en/insights/latest-thinking/china-important-data-identification-guidelines.html; https://digichina.stanford.edu/work/chinas-emerging-data-governance-framework.
46. Digichina, "Translation: Cybersecurity Law of the People's Republic of China (Effective June 1, 2017)," Rogier Creemers and Graham Webster, trans., Stanford University, June 29, 2018, https://digichina.stanford.edu/work/translation-cybersecurity-law-of-the-peoples-republic-of-china-effective-june-1-2017; https://digichina.stanford.edu/work/translation-regulations-on-the-security-protection-of-critical-information-infrastructure-effective-sept-1-2021.
47. https://npcobserver.com/2021/06/chinas-data-security-law; https://www.csis.org/analysis/chinas-data-governance-model

In short, China views all identifiable health data as sensitive personal information and deems health datasets as important data, when they aggregate or represent sectors defined as strategic by the state (and at the regulator's discretion). This conditional dual categorization means complex compliance requirements before export.

**Figure 1:** Data overlap in China's health data governance system




Note on genetic data: HGR rules apply to HGR materials and human gene/genome data generated from HGR materials. Clinical, imaging, protein, and metabolic data are excluded unless they contain human gene/genome information.

## Exporting health data as sensitive personal information and important data

Following the passage of the CSL, DSL, and PIPL, China's CAC developed a unified framework governing outbound data transfers.[48] The first major instrument was the 2022 Measures for the Security Assessment of Outbound Data Transfers, followed by the 2023 Measures on Standard Contracts for the Outbound Transfer of Personal Information, the 2024 Provisions on Promoting and Regulating Cross-Border Data Flows, and the October 2025 Measures for Certification of Cross-Border Personal Information Transfer (which took effect on January 1, 2026). Together, these measures define the current framework governing outbound transfers of health data.

*Constraints on exporting health data*

For healthcare data, the key issue is that many medically relevant datasets, especially genetic and genomic data, trigger overlapping regulatory requirements. Under Article 38 of the PIPL, three pathways exist for transferring personal information abroad: Processors must either 1) pass a CAC-led security assessment, 2) obtain certification from an approved institution, or 3) sign a CAC standard contract with the foreign recipient.[49] Regardless of pathway, firms must first conduct a self-assessment to identify data protection risks,[50] and the law prohibits firms from splitting datasets to remain below regulatory thresholds.[51] The status of health data under PRC law has implications for cross-border data transfer. For certain types of health data, export is subject to parallel requirements to those under the CAC.

Nucleic-acid-sequence-based genetic and genomic data fall within China's most restrictive category of health data. The PRC's 2019 HGR Regulation links safeguarding the country's genetic resources, as essential to the country's "public health, national security, and the public interest."[52] Foreign entities generally cannot independently collect or store Chinese HGR within China, and the country prohibits commercial transactions involving such data. In addition, foreign entities and researchers must partner with Chinese institutions, with collaborations requiring approval from authorities, such as the NHC and, in some cases, the MOST. The draft revisions also appear to relax restrictions on some foreign-invested entities, potentially reducing compliance burdens for Chinese biotechnology firms with minority foreign investment or variable interest entity structures.[53] The PRC government has subjected violators of these genetic data export restrictions to fines and significant administrative penalties.[54]

This creates an overlapping approval environment for cross-border health-data transfers. In May 2023, China's MOST identified several categories of genetic data that automatically trigger outbound security review. Historically, mandatory security review has applied in specified scenarios involving sensitive genomic datasets, important families, specific

48. "Shùjù chūjìng ānquán pínggū bànfǎ" 数据出境安全评估办法 Guójiā hùliánwǎng xìnxī bàngōngshì lìng dì 11 hào 国家互联网信息办公室令 第11号 [Measures for Security Assessment of Cross-border Data Transfer, Order of the Cyberspace Administration of China No. 11], Cyberspace Administration of China, July 7, 2022, https://www.cac.gov.cn/2022-07/07/c_1658811536396503.htm.
49. Zhōnghuá Rénmín Gònghéguó Gèrén Xìnxī Bǎohù Fǎ (中华人民共和国个人信息保护法) [Personal Information Protection Law of the People's Republic of China] (adopted by 13th National People's Congress, August 20, 2021), Articles 38–39, Cyberspace Administration of China, https://www.cac.gov.cn/2021-08/20/c_1631050028355286.htm.
50. TC260: 关于发布《网络安全标准实践指南—网络数据安全风险评估实施指引》的通知. Note: Even when using standard contracts, firms must file documentation with the CAC, including the contract and a Personal Information Protection Impact Assessment report. In all scenarios, risk assessment is a required first step. The law also prohibits firms from avoiding security review by splitting data into smaller batches to stay below regulatory thresholds
51. TC260: 关于发布《网络安全标准实践指南—网络数据安全风险评估实施指引》的通知. The law also prohibits firms from avoiding security review by splitting data into smaller batches to stay below regulatory thresholds.
52. Author emphasis, see: Ministry of Science and Technology of the People's Republic of China, "Regulations of the People's Republic of China on the Management of Human Genetic Resources – 2019," (entry at note 1). The 2023 implementing guidelines also repeat this language, see: Ministry of Science and Technology of the People's Republic of China, "Order No. 21 of the Ministry of Science and Technology: Detailed Rules for the Implementation – 2023," (entry at note 16).
53. National Health Commission of the People's Republic of China, "Public Notice on Soliciting Opinions on the Draft Implementing Rules – 2026," (entry at note 2); National Health Commission of the People's Republic of China, "Ethical Guidelines for Human Genome Data Research – 2026," (entry at note 2).
54. See: "Kējìbù shǒudù gōngbù rénlèi yíchuán zīyuán xíngzhèng chǔfá huádàjīyīn děng 6 jiā jīgòu shèshì" 科技部首度公布人类遗传资源行政处罚 华大基因等6家机构涉事 [The Ministry of Science and Technology has for the first time announced administrative penalties for human genetic resources, involving six institutions including BGI Genomics.], Baidu News, October 25, 2018, https://baijiahao.baidu.com/s?id=1615284301298549371&wfr=spider&for=pc. Articles 41 and 42 of the 2019 HGR Regulation prohibit the sale of data and outline the penalties for violations. See: Ministry of Science and Technology of the People's Republic of China, "Regulations of the People's Republic of China on the Management of Human Genetic Resources – 2019," (entry at note 1).

regions, or large-scale sequencing activities.[55] However, the May 2026 draft revisions suggest regulators are moving away from some of the dedicated HGR Regulation security-review mechanisms and toward ethics-committee-centered oversight for lower-risk research activities.[56] The shift does not eliminate CAC export controls, important-data obligations, or broader national-security authorities. However, it does imply a partial shift from centralized pre-approval toward embedded ethics and compliance governance. At the same time, cross-border transfers involving personal or strategically sensitive data may still fall within the scope of Article 38 of the 2021 PIPL, requiring a separate security assessment by the CAC when meeting personal data thresholds. The two systems operate separately, meaning approval under one framework does not guarantee approval under the other.[57]

China also imposes strict controls on health data generated in medical settings. Regulations require that the storage of patient data, including genetic information from clinical testing, reside on domestic servers.[58] Access to medical records has tight time restrictions and strict return requirements, with research purposes dependent upon institutional approval.[59]

Current rules prohibit foreign entities from collecting or storing Chinese HGR data within China and ban commercial transactions involving such data. Foreign researchers cannot directly access genetic data unless they partner with Chinese institutions,[60] and such collaborations require NHC authorization.[61] Permission for cross-border sharing is only in limited circumstances: (1) when Chinese holders provide HGR data access to foreign parties, and file the transfer with the NHC, including a backup copy and risk assessment, or (2) when HGR data sharing occurs within approved international research collaborations.[62]

In addition to the above requirements, the fragmentation and uncertainty throughout the various consent requirements in China's cross-border regulatory regime often constrain research collaborations. Multiple government-issued biomedical ethics and human subject research regulations outline general procedures for informed consent, ethics review, and clinical research oversight, but they do not fully address key issues related to cross-border health data sharing. These unresolved issues include how researchers should explain foreign jurisdictional risks, overseas recipient obligations, onward data

55. See: Ministry of Science and Technology of the People's Republic of China, "Order No. 21 of the Ministry of Science and Technology: Detailed Rules for the Implementation – 2023," Article 37 (entry at note 16).
56. https://triviumchina.com/2026/05/27/china-loosens-genetic-data-rules-shifts-oversight-toward-ethics-committees/?mc_cid=028691596e&mc_eid=fb99565a58
57. Trivium, "China Loosens Genetic Data Rules."
58. Measures for the Administration of Population Health Information; See Articles 2 and 10 of the PHI Measures (2014).
59. See Article 16 of the Regulations for Medical Institutions on Medical Records Management, 2013.
60. China's HGR regime defines eligible domestic partners as "research institutions, schools of higher learning, medical establishments, and enterprises from our nation." Referring to these as "Chinese Units," the 2023 Implementation Rules for the Regulations on the Management of Human Genetic Resources further clarify that domestically invested and domestically controlled institutions established in Hong Kong or Macau also qualify as Chinese Units. Entities considered "foreign units" include not only foreign organizations and individuals themselves, but also institutions established in China that foreign organizations or individuals "actually" control. The rules define foreign control broadly, including situations where foreign parties directly or indirectly hold more than 50 percent ownership, possess sufficient voting rights to influence decisions, or exercise effective control through contractual or other arrangements. See: "P.R.C. Regulation on the Management of Human Genetic Resources," China Law Translate, June 10, 2019, https://www.chinalawtranslate.com/en/p-r-c-regulation-on-the-management-of-human-genetic-resources; "Implementation Rules for the Regulations on the Management of Human Genetic Resources," China Law Translate, May 26, 2023, https://www.chinalawtranslate.com/en/Implementation-Rules-for-the-Regulations-on-the-Management-of-Human-Genetic-Resources.
61. See: Ministry of Science and Technology of the People's Republic of China, "Regulations of the People's Republic of China on the Management of Human Genetic Resources – 2019," (entry at note 1), Articles 22, 27, and 28; Guówùyuàn Guānyú Xiūgǎi Hé Fèizhǐ Bùfèn Xíngzhèng Fǎguī De Juédìng (Guó lìng dì 777 hào) (国务院关于修改和废止部分行政法规的决定 (国令第777号)) [Decision of the State Council on Amending and Repealing Certain Administrative Regulations (National Order No. 777)] (promulgated by the State Council, March 10, 2024, effective date May 1, 2024), Section IV, General Office of the State Council, 000014349/2024-00026, https://www.gov.cn/zhengce/content/202403/content_6939590.htm (China). See also: Guówùyuàn Guānyú Xiūgǎi Hé Fèizhǐ Bùfèn Xíngzhèng Fǎguī De Juédìng (Zhōnghuá rénmín gònghéguó guówùyuàn lìng dì 797 hào) (国务院关于修改和废止部分行政法规的决定 (中华人民共和国国务院令 第797号)) [Decision of the State Council on Amending and Repealing Certain Administrative Regulations (State Council Decree No. 797 of the State Council)] (promulgated by the State Council, December 16, 2024, effective date January 20, 2025), Ministry of Ecology and Environment of the People's Republic of China, https://www.mee.gov.cn/zcwj/gwywj/202412/t20241216_1098631.shtml (China).
62. See: Ministry of Science and Technology of the People's Republic of China, "Regulations of the People's Republic of China on the Management of Human Genetic Resources – 2019," (entry at note 1), Articles 27–28.

transfers, breach notification responsibilities, or available remedies once data leaves China.[63]

For example, China's 2023 Measures for Ethical Review of Life Sciences and Medical Research Involving Humans does require informed consent forms to cover research participant rights, confidentiality, compensation, contacts for problems, result returns, and, for human biological samples collected, the type, quantity, purpose, preservation, use, sharing, secondary use, privacy protection, external provision, and destruction of those samples.[64]

In May 2026, China's National Science and Technology Ethics Committee (NSTEC) issued new guidance on ethics governance for human genetic data research. The guidance reinforces Beijing's shift toward institutional ethics governance as a core mechanism for supervising biomedical and genetic-data research. Under this emerging model, scientific ethics committees increasingly function as frontline governance institutions responsible for evaluating research necessity, consent procedures, data handling, privacy protections, external sharing arrangements, and risk management obligations.[65] This development suggests China is attempting to streamline lower-risk international biomedical collaboration while retaining state oversight through institutionally embedded governance structures rather than relying exclusively on centralized security review.

At the same time, China's PIPL outlines a separate consent requirement, stipulating that sensitive personal information, including medical health and biometric information, requires separate consent, and cross-border use requires notice of the overseas recipient's identity, contact information, processing purpose, processing method, categories of personal information, and procedures for individuals to exercise rights against the overseas recipient. PIPL also gives individuals the right to withdraw consent and requires renewed consent when the processing purpose, method, or categories of personal information change.[66]

HGR rules add another layer: The 2019 HGR Regulation, as revised, requires prior informed consent for the collection, preservation, use, and external provision of Chinese human genetic data, and requires providers to receive information about the purpose and use of collection, health impacts, privacy protections, and their rights to voluntary participation and unconditional withdrawal. The 2023 HGR Implementing Rules further require written informed consent, ethics review by a registered ethics committee, and Chinese institutional involvement for Chinese HGR data collected, preserved, used, or provided abroad.[67]

While consent is a necessary and important part of a cross-border data regime, these parallel regimes remain unintegrated under a unified cross-border data framework and thus require separate—and often duplicative—consent processes. For example, consents for clinical studies, sensitive personal information processing, cross-border transfers, and HGR collections or external provisions, while related they are not interchangeable.

The concept of broad consent appears in some ethics-facing contexts, particularly regarding future use, sharing, and secondary use of biological samples,[68] but its legal status remains uncertain. The 2023 ethics measures require consent materials involving human biological samples to clarify their use for product development, sharing, secondary use, external provision, and destruction. This creates room for future-use consent, but it does not provide detailed standards for how broad consent should operate, how specific the future uses must be, how withdrawal should function after de-identification

63. Cross-Border Health Data Transfer for Scientific Research Purposes, p.174
64. "Guānyú yìnfā shèjí rén de shēngmìng kēxué hé yīxué yánjiū lúnlǐ shěnchá bànfǎ de tōngzhī" 关于印发涉及人的生命科学和医学研究伦理审查办法的通知 "Guó wèi kējiào fā〔2023〕4 hào" 国卫科教发〔2023〕4号 [Notice on Issuing the Measures for Ethical Review of Life Science and Medical Research Involving Human Subjects, Document No. 4 (2023)] National Health Commission of the People's Republic of China, February 18, 2023, https://www.nhc.gov.cn/wjw/c100375/202302/902b4a1dc3af4aba862a6387e6e376dc.shtml.
65. National Health Commission of the People's Republic of China, "Public Notice on Soliciting Opinions on the Draft Implementing Rules – 2026," (entry at note 2); National Health Commission of the People's Republic of China, "Ethical Guidelines for Human Genome Data Research – 2026," (entry at note 2).
66. Digichina, "Translation: Personal Information Protection Law."
67. See: Ministry of Science and Technology of the People's Republic of China, "Regulations of the People's Republic of China on the Management of Human Genetic Resources – 2019," (entry at note 1); Ministry of Science and Technology of the People's Republic of China, "Order No. 21 of the Ministry of Science and Technology: Detailed Rules for the Implementation – 2023," (entry at note 16).
68. National Health Commission of the People's Republic of China, "Notice on Issuing the Measures for Ethical Review of Life Science –2023," (entry at note 64).

or overseas transfer, or what protections apply to vulnerable groups.[69]

PIPL further complicates broad consent because it requires separate consent for sensitive personal information and for cross-border provision of personal information. Article 14 requires that consent be informed, voluntary, and explicit, with renewed consent when the processing purpose, method, or categories of personal information change.[70] Article 39 requires separate consent for cross-border transfer after notifying the individual of the overseas recipient and processing details.[71] These requirements sit uneasily with broad or open-ended consent for unspecified future research uses, especially where future recipients, research purposes, or data-transfer pathways are unknown at the time of enrollment.[72]

Recent judicial interpretation points in the same direction. In a 2024 cross-border personal information transfer case, a Chinese court found that consent bundled into a long privacy policy did not satisfy PIPL's separate consent requirement.[73] The court treated separate consent as specific authorization for a particular handling activity and distinguished enhanced notice from general notice. Although the case was not a health-data case, it suggests that broad, bundled, or vague consent mechanisms face legal risk when used for cross-border transfer.[74]

*Recent moves reduce burdens on exporting health data*

The PRC has recently moved to reduce some of China's regulatory burdens on lower-risk data transfers. Regulators have introduced adjustments to clarify review procedures and facilitate transfers.[75] The CAC, in 2024, passed cross-border data flow measures that have provided more detailed rules, standardized templates for the application process, and defined timelines for reviews and approvals—including a five-day completeness check, a seven working-day decision window, and a fifteen working-day reconsideration period.[76] The measures have also expanded exemptions and raised requirement thresholds for reviews and extended the validity of security assessments from two to three years with easier renewal processes.[77] The 2025 certification measures issued by the CAC and the State Administration for Market Regulation further clarify certification requirements for cross-border transfers of personal information, including health and biometric data.[78] These reforms aim to provide more predictable regulatory mechanisms for firms and researchers looking to conduct studies or clinical trials.[79]

69. National Health Commission of the People's Republic of China, "Notice on Issuing the Measures for Ethical Review of Life Science –2023," (entry at note 64).
70. Digichina, "Translation: Personal Information Protection Law."
71. Digichina, "Translation: Personal Information Protection Law."
72. Digichina, "Translation: Personal Information Protection Law."
73. Digichina, "Translation: Personal Information Protection Law."
74. Todd Liao and Sylvia Hu, "Chinese Court Concluded Landmark Case on Cross-Border Transfer of Personal Information," Morgan Lewis, November 12, 2024, https://www.morganlewis.com/pubs/2024/11/chinese-court-concluded-landmark-case-on-cross-border-transfer-of-personal-information.
75. Is cross-border transfer of China's human genetic data an impossible mission?
76. Cùjìn Hé Guīfàn Shùjù Kuà Jìng Liúdòng Guīdìng (促进和规范数据跨境流动规定) Guójiā hùliánwǎng xìnxī bàngōngshì lìng dì 16 hào (国家互联网信息办公室令 第16号) [Regulations on Promoting and Regulating Cross-Border Data Flow, Order from the State Internet Information Office No. 16] (promulgated and effective March 22, 2024), Cyberspace Administration of China, https://www.cac.gov.cn/2024-03/22/c_1712776611775634.htm.
77. Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76).
78. Qian Zhou, "China Releases Certification Measures for Cross-Border Data Transfers – The Last Piece of the Regulatory Puzzle," *China Briefing*, October 24, 2025, https://www.china-briefing.com/news/china-cross-border-data-transfer-certification/. See also Shunsuke Tabeta, "China Releases Draft Rules on Cross-Border Personal Data Transfer," Nikkei Asia, January 7, 2025, https://asia.nikkei.com/business/technology/china-releases-draft-rules-on-cross-border-personal-data-transfer; "Guójiā hùliánwǎng xìnxī bàngōngshì guānyú "gèrén xìnxī chūjìng gèrén xìnxī bǎohù rènzhèng bànfǎ (zhēngqiú yìjiàn gǎo)" gōngkāi zhēngqiú yìjiàn de tōngzhī" 国家互联网信息办公室关于《个人信息出境个人信息保护认证办法（征求意见稿）》公开征求意见的通知 [Notice from the Cyberspace Administration of China on Soliciting Public Comments on the Draft Measures for the Protection and Authentication of Personal Information When Transferring Personal Information Across Borders], Cyberspace Administration of China, January 3, 2025, https://www.cac.gov.cn/2025-01/03/c_1737600915141373.htm.
79. Partick Beyrer, *U.S.-China Cancer Trial Collaboration: Political and Regulatory Challenges and the Path Forward, Asia Society Policy Institute,* February 4, 2025, https://asiasociety.org/policy-institute/us-china-cancer-trial-collaboration-political-and-regulatory-challenges-and-path-forward.

In particular, under the CAC's 2024 adjustments,[80] non-CIIO entities exporting sensitive personal information of fewer than 10,000 individuals cumulatively since January 1 of the current year generally use China's standard contract for cross-border data flows (known as an SCC) or a certification route, while exports above that threshold require a CAC security assessment.[81]

In the case of genetic data, in 2022, Beijing introduced reforms to the HGR regime, creating a separate pathway for some non-sensitive research activities. Subsequent 2023 revisions further narrowed the definition of regulated HGR information by excluding most ordinary clinical data and clarifying the scope of "foreign parties" subject to the rules.[82] The May 2026 HGR draft revisions continue this trajectory by explicitly excluding ordinary clinical, imaging, protein, and metabolic data unless those datasets contain human gene or genome information. The draft revisions also appear to relax restrictions on some foreign-invested entities, potentially reducing compliance burdens for Chinese biotechnology firms with minority foreign investment or variable interest entity structures. At the same time, the draft preserves heightened oversight for certain large-scale genomic sequencing activities involving more than 500 individuals and continues to subject higher-sensitivity genomic and genetic datasets to stricter review.[83]

Under the revised framework, some collection activities involving fewer than 3,000 cases no longer require the same level of formal HGR approval, while some international clinical trials became eligible for exemptions.[84] The 2023 HGR regime measures also clarified the scope of permit applications for international scientific research cooperation, and the May 2026 draft revisions suggest regulators are shifting portions of oversight responsibility toward institutional ethics review mechanisms.[85] These reforms appear designed to reduce friction for multinational pharmaceutical collaboration and improve the international competitiveness of Chinese biotechnology firms. One study found that international collaboration projects accounted for 84.51 percent of human genomic permits in 2024, with US firms remaining key partners despite increasing US-China geopolitical tensions.[86] The 2026 draft revisions reinforce this differentiated approach by further separating lower-risk clinical and biomedical collaboration from higher-sensitivity genomic and national-security-relevant datasets. At the same time, genomic, exome, important-family, specified-region, or important-data cases remain tightly controlled, reflecting China's approach of "managed openness." Rather than broadly prohibiting international biomedical collaboration, China seems to be moving toward a conditional-governance model that selectively permits cross-border access through institutionally supervised and sector-specific channels, with the state maintaining broad visibility.

Post-2023 HGR regime adjustments have reduced one source of friction for routine cross-border clinical-trial data flows, but they have not removed China's broader data-export controls. MOST's 2023 HGR Implementing Rules clarify that the regulatory category of "human genetic resources information" covers human gene and genome data generated from HGR materials, but does not include clinical, imaging, protein, or metabolic

80. Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76); "Zhuānjiā jiědú lcùjìn hé guīfàn shùjù kuà jìng liúdòng de zhòngyào guiding" 专家解读｜促进和规范数据跨境流动的重要规定 [Expert Interpretation | Important Regulations for Promoting and Regulating Cross-Border Data Flow], Cyberspace Administration of China, March 22, 2024, https://www.cac.gov.cn/2024-03/22/c_1712776625820516.htm; "Provisions on Promoting and Regulating the Cross-Border Flow of Data," China Law Translate, March 22, 2024, https://www.chinalawtranslate.com/en/Provisions-on-Promoting-and-Regulating-the-Cross--Border-Flow-of-Data/.

81. Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76). See also: "International Data Privacy Compliance, Overview – China's Standard Contract for Cross-Border Transfer of Personal Information (SCC)," Bloomberg Law, accessed June 5, 2026, https://www.bloomberglaw.com/external/document/X8VUT1EO000000/international-data-privacy-compliance-overview-china-s-standard-.

82. Jiang Moting, Cui Xiaotian and Han Wei, "Cover Story: China Set to Ease Controls on Genetic Resources to Plug Biotech Innovation," *Caxin Global*, May 20, 2024, Gap https://www.caixinglobal.com/2024-05-20/cover-story-china-set-to-ease-controls-on-genetic-resources-to-plug-biotech-innovation-gap-102198001.html.

83. National Health Commission of the People's Republic of China, "Public Notice on Soliciting Opinions on the Draft Implementing Rules – 2026," (entry at note 2); National Health Commission of the People's Republic of China, "Ethical Guidelines for Human Genome Data Research – 2026," (entry at note 2).

84. China Law Translate, "Implementation Rules for the Regulations."

85. National Health Commission of the People's Republic of China, "Public Notice on Soliciting Opinions on the Draft Implementing Rules – 2026," (entry at note 2); National Health Commission of the People's Republic of China, "Ethical Guidelines for Human Genome Data Research – 2026," (entry at note 2).

86. Lingquiao Song, Zhenyu Liu, and Fanlin Meng, "Statistic Tells: The regulatory Pendulum of Permit Trajectories in China's Genetic Governance (2021–2024)," *Frontiers in Genetics* 16, No. 1611003 (July 2025), doi:10.3389/fgene.2025.1611003.

data where those datasets do not contain human gene or genome information.[87] The practical effect is to make it easier for China-based clinical-trial data to support global clinical development pathways where regulators accept multiregional clinical-trial data.[88] It has also expanded the ability to include Chinese patient cohorts in global oncology datasets,[89] as well as real-world evidence studies without lengthy approval processes.[90] The 2026 draft revisions reinforce this trajectory by further separating lower-risk clinical and biomedical collaboration from tightly controlled nucleic-acid-sequence-based genetic and genomic information.[91]

The HGR adjustment also does not override separate obligations under the PIPL, DSL, CSL, or CAC data-export rules. CAC's March 2024 Provisions state that China's outbound data framework operates through the CSL, DSL, and PIPL, and CAC explains that outbound data security management applies to important data and personal information rather than all data.[92] Because clinical-trial and pharmaceutical data often include medical health information, these often remain sensitive personal information under PIPL even when it no longer triggers the HGR threshold.[93] Therefore, the same dataset might avoid HGR review while still requiring CAC analysis, SCC filing, certification, or a CAC security assessment depending on the transfer scenario, data type, exporter status, and volume.[94]

Under the March 2024 CAC rules, CAC security assessment remains mandatory for CIIO exports of personal information or important data, non-CIIO exports of important data, non-CIIO exports of personal information above 1 million individuals cumulatively since January 1 of the current year, and non-CIIO exports of sensitive personal information above 10,000 individuals cumulatively since January 1 of the current year.[95] The March 2024 CAC rules therefore remain central for pharma-

87. Ministry of Science and Technology of the People's Republic of China, "Order No. 21 of the Ministry of Science and Technology: Detailed Rules for the Implementation – 2023," (entry at note 16); "Rénlèi yíchuán zīyuán guǎnlǐ tiáolì shíshī xìzé" zhèngcè jiědú《人类遗传资源管理条例实施细则》政策解读 [Policy Interpretation of the Detailed Rules for the Implementation of the Regulations on the Management of Human Genetic Resources], Ministry of Science and Technology of the People's Republic of China, June 1, 2023, https://www.most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/zcjd/202306/t20230601_186417.html.

88. See: "E17 General Principles for Planning and Design of Multiregional Clinical Trials: Guidance for Industry," U.S. Department of Health and Human Services, July 2018, https://www.fda.gov/media/99974/download. The guideline asks that multiregional clinical trial designs work so that data "can be accepted by regulatory authorities across regions … to support marketing approval." China's adoption of the National Medical Products Association's International Council for Harmonization (ICH) guidelines means the structure of clinical trial data generated in China is for the US's Food and Drug Administration (FDA) and EU's European Medicines Agency (EMA) acceptance and inclusion in global submissions. See also: "China Clinical Trials: Cost, Speed, and Regulatory Advantages for Global Pharma," Vision Lifesciences, February 28, 2026, https://visionlifesciences.com/insights/china-clinical-trials-advantages-global-pharma.

89. Under ICH E17, Chinese trial sites are routinely included in global "pivotal datasets" used for regulatory approval, See:Vision Lifesciences, "China Clinical Trials." One 2024 report shows rapid growth in China-based clinical trials and regulatory reforms facilitating integration into global development and approval pipelines. See: Chia-Feng Lu et al., "China on the Move: Breaking Barriers and Accelerating Growth: Clinical Trials, Drug Approvals, and Cross-Border Data Transfers in Biotech," Greenberg Traurig, July 24, 2024, https://www.gtlaw.com/en/insights/2024/7/china-on-the-move-breaking-barriers-and-accelerating-growth-clinical-trials.

90. Aaron Gu, Pengfei You, and Duzhiyun Zheng, "Key Takeaways on the New HGR FAQs Issued by the MOST of China," Han Kun Law Offices at Lexocology, September 9 2023, https://www.lexology.com/library/detail.aspx?g=dd7a83cc-8a80-4808-abb6-414f934d1d65&.

91. National Health Commission of the People's Republic of China, "Public Notice on Soliciting Opinions on the Draft Implementing Rules – 2026," (entry at note 2); National Health Commission of the People's Republic of China, "Ethical Guidelines for Human Genome Data Research – 2026," (entry at note 2).

92. Cyberspace Administration of China, "Personal Information Protection Law – 2021," (entry at note 49); Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76); "Cùjìn hé guīfàn shùjù kuà jìng liúdòng guīdìng" dá jìzhě wèn"《促进和规范数据跨境流动规定》答记者问 [Q&A on the «Regulations on Promoting and Regulating Cross-Border Data Flows], Cyberspace Administration of China, March 22, 2024, https://www.cac.gov.cn/2024-03/22/c_1712776611649184.htm.

93. Cyberspace Administration of China, "Personal Information Protection Law – 2021," (entry at note 49).

94. Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76); https://www.cac.gov.cn/2024-03/22/c_1712776625820516.htm

95. https://www.cac.gov.cn/cms/pub/interact/downloadfile.jsp?fText=%E6%95%B0%E6%8D%AE%E5%87%BA%E5%A2%83%E5%AE%89%E5%85%A8%E8%AF%84%E4%BC%B0%E7%94%B3%E6%8A%A5%E6%8C%87%E5%8D%97%EF%BC%88%E7%AC%AC%E4%B8%89%E7%89%88%EF%BC%89&filepath=NUtqEIwGiCjGm2BhI20cvHqn7o%2FMvQuLITXk87eUWCGu8MErDOpRDCR%2F~xsXjBW6O9RLR6Az65N~jUdQI0tAHjZS2%2FBjnic3oqu3HpPj8kk%3D; Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76).

ceutical data exports, especially where transfers involve important data, large volumes of personal information, sensitive personal information above the threshold, or a CIIO entity.[96]

## Standard contracts as a middle ground compliance pathway

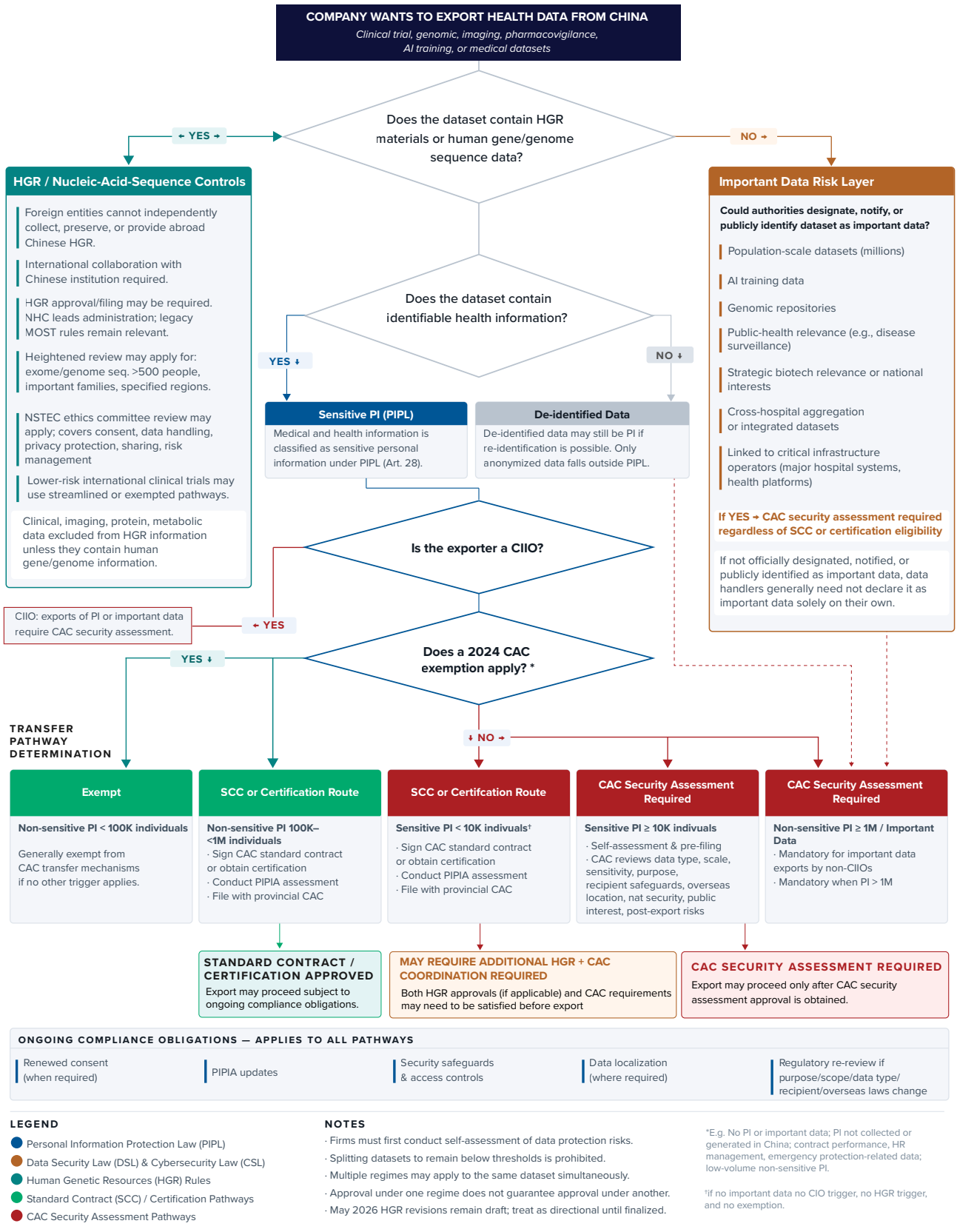
For smaller sensitive personal information exports, SCCs are a contractual compliance route, offering a lighter, more attractive regulatory pathway for multinational pharmaceutical and clinical-trial operations with more procedural predictability than CAC security assessments, which can be resource-intensive, slower, and less predictable, particularly where regulators might scrutinize national security implications, important data classification, foreign government access risks, large-scale aggregation, AI training use cases, and genomic or population-level datasets. The SCC process is more procedurally standardized.[97] Companies execute the CAC standard contract, conduct a personal information protection impact assessment (PIPIA), and file materials with the provincial CAC, rather than undergoing a more intensive security assessment process.

MNCs also use SCCs as a lower-friction compliance pathway for datasets that fall below CAC security-assessment thresholds yet still contain sensitive personal information. This is especially relevant for clinical-trial data because even though HGR revisions exclude many non-genomic clinical datasets from HGR information, the PIPL still treats medical and health information as sensitive personal information.[98] For example, most clinical-trial data qualify as sensitive personal information under PIPL because this law explicitly categorizes health information as such (Figure 2). And pharmaceutical companies may approach or exceed the sensitive personal information thresholds relatively quickly through repeated exports tied to multicenter trials, adverse event reporting, imaging repositories, companion diagnostics, and long-term patient follow-up, which can cumulatively involve thousands of Chinese participants across repeated exports (while smaller single-study transfers may remain below it).[99] Companies therefore often structure transfers to remain within SCC eligibility ranges where possible, as they leave room for regulators to revisit filings where transfer purposes, scope, data sensitivity, overseas storage location, recipient processing methods, or foreign legal conditions change.[100]

In addition, even where firms rely on certification or SCCs, CAC review remains mandatory for data considered important data.[101] Firms remain cautious because the important-data classification remains a major uncertainty in sensitive sectors.[102] Chinese regulators have deliberately preserved discretion around what counts as important data, especially in strategic sectors that directly intersect with healthcare (e.g., biotechnology, genomics, AI medical training data, etc.). In health, biotechnology, genomics, AI medical training data, and pharmaceutical contexts, that uncertainty gives companies reason to adopt the use of SCCs as a more conservative compliance strategy even when a transfer appears to fall below the formal CAC security-assessment thresholds.

96. Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76).
97. Gèrén Xìnxī Chūjìng Biāozhǔn Hétóng Bànfǎ" Yǐjīng Gèrén Xìnxī Chūjìng Biāozhǔn Hétóng Bànfǎ (个人信息出境标准合同办法) Guójiā hùliánwǎng xìnxī bàngōngshì lìng dì 13 hào (国家互联网信息办公室令 第13号) [Standard Contractual Measures for Cross-Border Transfer of Personal Information, Order of the Cyberspace Administration of China No. 13] (promulgated on February 22, 2023, effective June 1, 2023), Cyberspace Administration of China, https://www.cac.gov.cn/2023-02/24/c_1678884830036813.htm; https://www.cac.gov.cn/2025-10/31/c_1763633376984070.htm.
98. Ministry of Science and Technology of the People's Republic of China, "Policy Interpretation of the Detailed Rules – 2023," (entry at note 88); Cyberspace Administration of China, "Personal Information Protection Law," (entry at note 49).
99. Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76).; https://www.cac.gov.cn/2022-07/07/c_1658811536396503.htm
100. Cyberspace Administration of China, "Standard Contractual Measures for Cross-Border Transfer – 2023," (entry at note 98); https://www.cac.gov.cn/2025-10/31/c_1763633376984070.htm
101. The March 2024 CAC rules require security assessment for important-data exports by non-CIIOs, and the CAC Q&A states that outbound data security management focuses on important data and personal information, with "important data" referring to national-level interests versus just enterprise or personal interests. See: Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76); Cyberspace Administration of China, "Q&A on the «Regulations on Promoting and Regulating Cross-Border – 2024," (entry at note 93); Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76), Article 7.
102. "China Relaxes Security Review Rules for Some Data Exports," Reuters, March 22, 2024, https://www.reuters.com/technology/cybersecurity/chinas-cyberspace-regulator-issues-rules-facilitate-cross-border-data-flow-2024-03-22.

**Figure 2:** China's health data export regulatory pathway



*Collaboration under the new regulatory regime*

Cancer research is one area where examples of increased cross-border research collaboration under the new regime are evident.[103] For example, Chinese clinical trial data have in some cases fed directly into global drug development pipelines. The US-based biotechnology firm Amgen partnered with the China-based BeiGene on multinational oncology trials, using data from clinical trials conducted in China to support its global development of oncology medicines.[104] Swedish-British pharmaceutical company AstraZeneca's Shanghai-based entity routinely integrates Chinese clinical trial data into global development pipelines. The company runs multi-country cancer trials, including large global Phase III oncology studies, such as the FLAURA2 trial for lung cancer, which enrolled patients across regions and incorporated a Chinese patient cohort alongside the global population.[105] Evidence from these trials shows that outcomes for Chinese patients are part of the overall global dataset analyzed and used to support regulatory approvals in multiple jurisdictions, including China, the United States, and Europe.[106] Lastly, Roche conducts extensive oncology trials in China, including in immunotherapy and precision medicine;[107] the company explicitly highlights the use of both clinical trial data and real-world evidence to support regulatory and reimbursement decisions across jurisdictions, indicating that data generated in China contributes to broader global evidence packages for cancer therapies.[108] As the examples above illustrate, Chinese patient data is already embedded in global oncology research workflows, and recent regulatory changes expand the scope of potential collaboration.

In addition, publicly available approval notices and disclosed cases do show that foreign universities and multinational pharmaceutical firms have in the past obtained permission to use Chinese health or HGR data through approved collaborations, clinical trials, CAC export assessments, and pilot-zone filing mechanisms, especially following the 2022 and 2023 easing. Examples include:

- Beijing Friendship Hospital and the University of Amsterdam: This collaboration is an early example of a successful approval case. It involved clinical-trial data exports between Beijing Friendship Hospital, a public institution, and medical research centers at the University of Amsterdam. However, the project is not necessarily representative as it included sponsorship from the National Health Commission as a "poster project" for medical and health data transfers.[109]
- Bayer Healthcare's China (Beijing) Pilot Free Trade Zone negative-list filing: Bayer Healthcare became Beijing's first enterprise approved to transfer data abroad under the Chinese capital's FTZ negative-list mechanism. Beijing authorities stated the filing review took five working days and simplified the procedures needed for compliant data export. They framed it as supporting Bayer's business operations and the introduction of innovative drugs and therapeutics in China.[110]
- MOST approvals of HGR projects: MOST has approved scientific research projects for Roche (urothelial cancer trial, follicular lymphoma trial, gastric and gastroesophageal junction cancer umbrella study), Pfizer and Array BioPharma (colorectal cancer trial), Novartis (BRAFV600E-mutant non-small cell lung cancer trial), AstraZeneca, (acalabrutinib hematologic malignancy trial and tezepelumab severe asthma trial), AstraZeneca

103. Beyrer, *U.S.-China Cancer Trial Collaboration: Political and Regulatory Challenges*; Zhou and Zhihang, "Cancer Collaboration Becomes First Overseas Data Transfer Approved."
104. "Amgen Commences Strategic Collaboration with BeiGene to Expand Oncology Presence in China," release, Amgen, January 2, 2020, https://www.amgen.com/newsroom/press-releases/2020/01/amgen-commences-strategic-collaboration-with-beigene-to-expand-oncology-presence-in-china.
105. AstraZeneca Plans to invest $15 Billion in China through 2030 to Pioneer the Next-Generation of Innovative Medicines," release, AstraZeneca, January 29, 2026, https://www.astrazeneca.com/media-centre/press-releases/2026/astrazeneca-invests-15bn-in-china-through-2030.html; "Tagrisso with the Addition of Chemotherapy Approved in China as 1st-Line Treatment for Patients with EGFR-Mutated Advanced Lung Cancer," release, AstraZeneca, June 26, 2024, https://www.astrazeneca.com/media-centre/press-releases/2024/tagrisso-with-the-addition-of-chemotherapy-approved-in-china-as-1st-line-treatment-for-patients-with-egfr-mutated-advanced-lung-cancer.html.
106. AstraZeneca, ""Tagrisso with the Addition of Chemotherapy Approved in China."
107. "Clinical Trials Support the Search for New Solutions," Roche, accessed June 7, 2026, https://www.roche.com/innovation/clinical-trials.
108. https://www.roche.com/innovation/personalised-healthcare/real-world-data
109. Rebecca Arcesati and Jeroen Groenewegen-Lau, "China's Data Management: Putting the Party-State in Charge," Hinrich Foundation, MERICS, December 2023, https://merics.org/sites/default/files/2023-12/Chinas%20data%20management%20-%20MERICS%20-%20Hinrich%20Foundation%20-%20December%202023.pdf
110. Cao, "Beijing Completes Its First Filing of Negative List."

and Alexion (AL amyloidosis trials), and Sanofi (fitusiran hemophilia trial and chronic rhinosinusitis trial).[111] All of these cases required Chinese participating institutions as partners (e.g., hospitals (cancer-specific and general), medical institutes, clinical testing/medical research firms, laboratory partners, pharmaceutical and drug development firms, etc.).[112]

In practice, foreign access to Chinese health data is highly mediated and approved on a case-by-case basis. Existing rules lack clarity on application procedures and do not specify whether foreign and domestic researchers receive equal treatment.[113] Foreign access to Chinese genetic resources remains highly managed, with hospital approvals, ethics review, sectoral HGR controls, CAC data-security requirements, and pilot-zone mechanisms shaping whether access occurs onsite, through domestic servers, or through approved outbound transfer channels. Recent approvals offer more insights into the particular use cases that make up successful applications, but companies exporting important data or large volumes of personal information still face detailed, complicated, and overlapping compliance procedures and tend to have to rely heavily on domestic partners to navigate PRC regulatory processes.[114]

## Implications for cross-border data transfer activities and cooperation on health research

For multinational firms operating in China's health sector, cross-border data transfer is possible in certain circumstances, yet remains heavily conditioned on the regulatory classification of the transferred data, local partnerships, and government discretion. A key operational issue is whether regulators classify a health dataset as important data. Once regulators classify it as important data, an outbound transfer becomes substantially more difficult and generally requires CAC-led security review regardless of which transfer mechanism a company intends to use.

On data, firms should assume that:

- Identifiable health datasets trigger PIPL obligations.
- Large-scale or strategically significant datasets likely trigger DSL "important data" requirements (including mandatory security assessments).
- Genetic and genomic data face the highest barriers and frequently trigger parallel CAC and HGR approvals.

The CAC is the main driver of the general cross-border data-transfer architecture, but it is not the only meaningful regulator for health data. For health and biomedical data, sector regulators shape what data counts as sensitive, what research activities require approval or filing, and what foreign entities may access. In May 2024, China shifted management of the HGR regime—historically administered by MOST—to the NHC.[115] One could characterize the current system as CAC-led at the horizontal data governance layer, but sectorally co-governed in practice.

Companies face overlapping regulatory requirements from multiple authorities simultaneously:

- CAC for data export.
- NHC and hospital systems for medical-data access.
- HGR authorities for genomic information.
- Ethics committees for research approval.

Taking genetic data as the most restrictive case, PRC rules significantly hinder international cooperation on genomic research. For example, HGR rules enforced by health authorities might block commercial use of genetic data, yet not raise issues under cybersecurity reviews. In practice, genetic data are subject to separate security assessments, one by the MOST under the HGR regime and one by the CAC under the 2021 PIPL. These parallel processes create significant compliance burdens for data processors. Existing regulations do not clarify

111. "Zhōngguó rénlèi yíchuán zīyuán xíngzhèng xǔkě shìxiàng 2023 nián dì 13 pī shěnpī jiéguǒ" 中国人类遗传资源行政许可事项2023年 第13批审批结果 [Results of the 13th Batch of Administrative Licensing Items for Human Genetic Resources in China in 2023], Ministry of Science and Technology of the People's Republic of China, July 18, 2023, https://fuwu.most.gov.cn/html/tztg/xzxkzx/20230718/123124746.html.

112. Ministry of Science and Technology of the People's Republic of China, "Results of the 13th Batch of Administrative Licensing Items – 2023," (entry at note 112).

113. Cross-Border Health Data Transfer for Scientific Research Purposes...171

114. Cross-Border Health Data Transfer for Scientific Research Purposes...171; Arendse Huld, "Beijing Releases Negative List to Facilitate Data Export in Free Trade Zone," China Briefing, September 6, 2024, https://www.china-briefing.com/news/beijing-data-negative-list-to-facilitate-data-export-in-free-trade-zone/.

115. Lu Zhou and Jessie Xie, "China Update: Human Genetic Resources Administration Rules support HGR Implementing Rules," Hogan Lovells, May 20, 2024, https://www.hoganlovells.com/en/publications/china-update-human-genetic-resources-administration-rules-support-hgr-implementing-rules.

whether or how to align these processes, and the absence of any coordination mechanisms for these parallel processes adds uncertainty and may slow international biomedical collaboration.[116] Operationally, this implies that:

- Local partnerships are essential. Approval processes are highly discretionary and require ongoing coordination with hospitals, ethics committees, provincial authorities, CAC offices, and sector-specific regulators. Foreign firms rarely interact directly with regulators without Chinese institutional counterparts. In addition, approval processes remain discretionary and opaque, with timelines and documentation requirements varying significantly across jurisdictions and sectors. Compliance is also increasingly sector- and locality-dependent, particularly as pilot FTZs and provincial authorities have begun to further shape implementation of cross-border data transfer regimes. heightening the importance of a well-positioned local partner(s).
- Consent practices that tackle each stage of the transfer process. For companies and researchers, consent practices should separately address participation in the study, processing of sensitive personal information, collection or use of biological samples, secondary research use, sharing with third parties, cross-border transfer, identity and role of overseas recipients, withdrawal rights, remedies, data localization limits, and whether HGR review or CAC security assessment applies. Compliance risks can arise with practices like reliance on a consent form that is too general to satisfy PIPL, too narrow to support secondary research, or insufficient for HGR-related transfer.
- Many successful collaborations rely on managed-access models. Examples include on-site access use (versus data sharing), domestic servers for data storage, federated analysis of sensitive data, and approved partnership structures. Meanwhile, research, cloud, storage, and AI-development workflow designs will likely need to be more intentional about China's localization and approval requirements from the outset, versus treating them as a downstream legal issue.

### The AI factor

China's health data regime only becomes more complex when applied to AI. AI systems depend on large, diverse, and often integrated datasets; for health data, this can include clinical records, imaging data, and, in certain cases, genomic information.

As a result, the same legal categories discussed above (i.e., sensitive personal information, important data, and HGR) directly affect allowable training, validation, and deployment of AI models in the China context. Cross-border data transfer restrictions therefore not only shape whether data can move, but also the organization of AI development across jurisdictions, including whether training occurs within China, through localized datasets, or via alternative approaches, such as federated analysis.[117]

Similar to China's approach to cross-border transfer of health data, the PRC is selectively open where cross-border data use advances state-backed goals, such as AI development, pharmaceutical innovation, clinical trial participation, and industrial upgrading. It remains highly restrictive where data movement implicates sovereignty, biosecurity, strategic industries, public opinion control, or foreign visibility into sensitive datasets. The PRC system of "managed openness" is one of controlled pathways for approved collaboration combined with broad state discretion to intervene, delay, or deny transfers where state security is concerned. AI intensifies this tension. China simultaneously needs larger, more diverse, and internationally integrated datasets for AI competitiveness, while it also treats many of those same datasets as strategic national resources.

The next section examines how AI both intensifies existing constraints and creates new points of friction within China's health data governance system.

## State of health data in the AI sector

### AI in China's healthcare sector

China directly embeds AI into state-led health policy. Beginning with the "Healthy China 2030" plan and the "Next Generation Artificial Intelligence Development Plan," the government has

116. Zhangyu Wang, Benjamin Gregg, and Li Du, "Regulatory Barriers to US-China Collaboration for Generative AI Development in Genomic Research," CelPress, June 12, 2024, https://www.cell.com/action/showPdf?pii=S2666-979X%2824%2900130-7; Cross-Border Health Data Transfer for Scientific Research Purposes, p.171

117. See: Shēngchéng Shì Réngōng Zhìnéng Fúwù Guǎnlǐ Zhànxíng Bànfǎ (生成式人工智能服务管理暂行办法) ling dì 15 hào (令第15号) [Interim Measures for the Administration of Generative Artificial Intelligence Services, Order No. 15] (promulgated July 10, 2023, effective August 15, 2023), Cyberspace Administration of China, https://www.cac.gov.cn/2023-07/13/c_1690898327029107.htm.

identified healthcare as a priority sector for AI deployment.[118] These plans depict AI as playing a key role in optimizing resource allocation in the healthcare sector, expanding access to medical services and treatment (through telemedicine, for example), and improving diagnostic accuracy, among other benefits.[119]

More recently, China's 2025 "AI Plus Initiative" set targets for widespread adoption of AI across society, including aiming for 70 percent adoption by 2027 and 90 percent by 2030, with the goal of a fully "intelligent society" by 2035.[120] The NHC followed with its AI Plus plan, outlining dozens of AI use cases across clinical care, hospital management, and public health, including AI-assisted medical record generation, clinical decision support, pharmacy management, and epidemic prediction.[121]

These initiatives identify health data as a core enabling resource. The NHC's AI Plus plan calls for building high-quality healthcare datasets, improving data labeling and interoperability, expanding data access across institutions, and establishing trusted data spaces for high-quality medical and health data. It emphasizes cross-departmental data sharing and the compliant, efficient use of medical data to support AI development.[122]

Extensive digitalization across the healthcare system supports this data environment.[123] Internet hospitals illustrate this model, delivering their services across clinical pathways, from consultation and diagnosis to prescription and reimbursement, through digital platforms.[124] Supporting infrastructure extends to backend governance as well. For example, China's National Healthcare Security Administration has implemented a nationwide drug traceability system that assigns a unique code to each unit of medicine, allowing regulators to track prescriptions, dispensing, and reimbursement across the supply chain.[125] Piloted in April 2024, the system had reached nearly 95 percent coverage of designated hospitals and pharmacies by early 2025, enabling large-scale monitoring of drug use and insurance claims.[126]

## Implications for cross-border data transfer activitie-sand cooperation on health research

For health data specifically, AI can make cross-border compliance harder in practice even if the legal transfer mechanism stays the same. Health AI systems often involve sensitive personal information, user inputs, usage logs, and model outputs derived from protected medical data. China's AI rules add additional obligations related to lawful sourcing, consent, training data quality, data security, annotation governance, content labeling, misuse prevention, and explainability. So, a provider trying to move health data or health-data-derived AI workflows across borders must satisfy *both* the ordinary transfer regime and the AI-specific requirements related to training data, consent, data security, labeling, and output control.

Medical AI often depends on precisely the types of data that trigger the most stringent regulation. The NHC's own AI guidance highlights use cases involving electronic medical records, clinical trial data, adverse event reporting, and

118. "Full Translation: China's 'New Generation Artificial Intelligence Development Plan' (2017)," Elsa Kania et al., trans., New America, August 1, 2017, https://www.newamerica.org/insights/full-translation-chinas-new-generation-artificial-intelligence-development-plan-2017/.
119. Wang, "Artificial Intelligence in Chinese Healthcare: A Review of Applications."
120. New America, "Full Translation: China's 'New Generation Artificial Intelligence."
121. "Guójiā wèishēng jiànkāng wěiyuánhuì bàngōng tīng guānyú yìnfā wèishēng jiànkāng hángyè réngōng zhìnéng yìngyòng chǎngjǐng cānkǎo zhǐyǐn de tōngzhī" 国家卫生健康委员会办公厅关于印发卫生健康行业人工智能应用场景参考指引的通知 "Guó wèi bàn guīhuà hán 〔2024〕420 国卫办规划函〔2024〕420号"[Notice from the General Office of the National Health Commission on Issuing Reference Guidelines for Artificial Intelligence Application Scenarios in the Health Sector, NHC General Office Planning Letter [2024] No. 420], National Health Commission of the People's Republic of China, November, 14, 2024, https://www.nhc.gov.cn/guihuaxxs/c100133/202411/3dee425b8dc34f739d63483c4e5c334c.shtml.
122. National Health Commission of the People's Republic of China, "Notice from the General Office of the National Health Commission on Issuing Reference Guidelines for Artificial Intelligence – 2024," (entry at note 123).
123. Ruby Wang, "China's 'Internet Hospitals': How the World's Largest Health System Went Digital," *China Health Pulse*, October 20, 2025, https://www.chinahealthpulse.com/p/chinas-internet-hospitals-how-the.
124. Wang, "China's 'Internet Hospitals.'"
125. "China to Tighten Medical Insurance Fund Supervision Using Traceability Codes," Xinhua, January 2, 2025, https://en.people.cn/n3/2025/0102/c90000-20261440.html.
126. https://www.chinadaily.com.cn/a/202501/18/WS678ba2dca310a2ab06ea7da4.html

real-world data.[127] As systems become more multimodal and individualized, they are more likely to intersect simultaneously with PIPL and DSL classifications, HGR rules, and ethical review requirements, triggering complex compliance obligations.

This creates particular challenges for cross-border collaboration. Local pilot mechanisms have sought to facilitate some specific cross-border collaboration on health data. For example, in March 2024, Beijing launched an AI data training base alongside a regulatory sandbox, offering firms access to computing resources, data, and compliance support to facilitate development while maintaining regulatory oversight.[128]

Public reporting indicates that the initiative focused on "large models + big data + massive computing power" and included the release of more than 100 high-quality datasets exceeding 150 petabytes (PB) in aggregate volume through partnerships involving the Beijing International Big Data Exchange, the Chinese Academy of Sciences, and other institutions.[129] Beijing policy documents further state that the intent of the training base was to support large-model training through access to compute, development tools, open-source resources, and data infrastructure.[130] While official reporting does not provide a detailed public catalog of health datasets specifically, broader Beijing AI policy documents and healthcare AI pilots indicate likely priority categories including clinical records, medical imaging data, pathology and radiology datasets, pharmaceutical and clinical trial data, public health datasets, and multimodal hospital data used for AI-assisted diagnostics and biomedical model training.[131]

However, the regulatory environment remains vague and confusing for most companies operating in this space. For example, clinical and imaging data may fall outside the HGR regime but remain regulated as sensitive personal information, while genomic datasets fall within HGR rules and are subject to additional approval and foreign-access restrictions. The most difficult compliance cases will involve multimodal datasets that combine clinical, genomic, and behavioral data, which tend to be patient-linked and biomarker-rich.[132] Companies that develop health AI have to comply with the same general personal info protection mandates that other tech companies do, in addition to complying with health data rules and rules on health data sets.

### *Legal and regulatory overlap of AI, health data, and China's data governance regime*

China's AI health strategy is, in large part, indexing on the availability of large domestic datasets.[133] The goal is a system where data can aggregate across hospitals, regions, and populations, to enable system-level insights that can support AI-driven decision-making, forecasting, and automation. At the same time, this data remains subject to strict localization requirements and government control.

Multiple overlapping regulatory frameworks govern health data. The 2018 Regulations on the Management of Health Big Data require that health data reside on secure domestic servers, while 2022 cybersecurity regulations for healthcare institutions mandate that data lifecycle activities, including collection, storage, processing, transmission, sharing, backup, and deletion, be conducted within China. In practice, this means hospitals, research institutions, and companies handling health data should maintain a localized infrastructure and tightly control how data moves across systems and organizational boundaries. The 2021 PIPL also classifies health data as

127. "Wèishēng jiànkāng hángyè réngōng zhìnéng yìngyòng chǎngjǐng cānkǎo zhǐyǐn" [Reference Guidelines on Artificial Intelligence Application Scenarios in the Health Sector], National Health Commission of the People's Republic of China, 2024, https://www.nhc.gov.cn/guihuaxxs/c100133/202411/3dee425b8dc34f739d63483c4e5c334c/files/1733227133524_47343.pdf.
128. "Beijing Releases Its 3.0 Plan for Comprehensive Supporting Reforms for Facilitating Cross-Border/Boundary Data Flows," People's Government of Beijing Municipality, April 7, 2026, https://english.beijing.gov.cn/latest/news/202604/t20260407_4575637.html.
129. "Beijing 'Two Zones' Attracted 3,098 Reserved Projects in the First Four Months of 2024," Foreign Affairs Office of Beijing Municipal Government, news release, May 26, 2024, https://wb.beijing.gov.cn/en/policy_release/further_opening_of_the_service_sector/202409/t20240918_3894143.html.
130. Ben Murphy, ed., "Translation: Beijing Municipal Action Plan to Promote "AI+" (2024-2025)," Center for Security and Emerging Technology, September 13, 2024, https://cset.georgetown.edu/wp-content/uploads/t0599_Beijing_AI_plan_2024_EN.pdf.
131. Wang, "Artificial Intelligence in Chinese Healthcare: A Review of Applications."
132. Ministry of Science and Technology of the People's Republic of China, "Order No. 21 of the Ministry of Science and Technology: Detailed Rules for the Implementation – 2023," (entry at note 16).
133. "Duì shísān jiè quánguó réndà sì cì huìyì dì 10294 hào jiànyì de dáfù" 对十三届全国人大四次会议第10294号建议的答复, [Reply to Proposal No. 10294 of the Fourth Session of the 13th National People's Congress], National Health Commission of the People's Republic of China, November 9, 2021, https://www.nhc.gov.cn/wjw/jiany/202202/025a29eaec5d4cae9285886795bc43c7.shtml.

sensitive personal information, triggering strict requirements for collection, use, and transfer.[134]

AI regulation reinforces and extends these data governance rules. Since the Generative AI Interim Measures took effect in August 2023, China has moved to institutionalize a formal filing and registration system for foundation models. The process involves layered compliance steps, including technical documentation, security assessment, and disclosure requirements, with provincial authorities conducting preliminary reviews before final oversight by the Cyberspace Administration of China. The 2023 Interim Measures for Generative AI also require the lawful sourcing of training data, alongside personal data use with consent or another legal basis, and that AI systems comply with existing laws, such as the CSL, DSL, and PIPL.[135] Several large models, including models used in healthcare and medical applications, have passed China's filing process and appeared on official or publicly released CAC filing registries.[136]

AI data regulations layer onto existing data governance structures, in addition to AI-specific mandates. This creates multiple points of intersection between AI and health data regulation. The DSL might classify certain training datasets as important data, if they include genetic or genomic resources the state views as critical to national security, triggering export restrictions and security assessment requirements.[137] Meanwhile, personal health data falls under PIPL, requiring consent, purpose limitation, and compliance with cross-border transfer mechanisms.[138] Genetic and genomic data fall under the HGR regime, which introduces separate approval requirements and restrictions on foreign access.[139] In addition, hospitals and health systems may qualify as critical information infrastructure, requiring domestic storage and security assessments for data export.[140]

AI-specific rules add further obligations. China's 2023 Interim Measures for the Management of Generative Artificial Intelligence Services require that providers of generative AI services (i.e., all companies or entities that develop or offer generative AI systems to the public in China) bear the responsibilities of a network information content producer and, when this involves personal information, the responsibilities of a personal information processor under the 2021 PIPL. Providers must safeguard user input information and usage records. They cannot collect unnecessary personal information, unlawfully retain input information or usage logs that can identify users, and nor unlawfully provide those inputs or logs to others. The measures also require AI providers who discover unlawful content to promptly stop generation and transmission, remove the content, take corrective steps (e.g., model optimization training), and report the discovery to the relevant authorities, among other obligations.[141] In practice, this means AI developers and platform operators are responsible not only for the legality and security of training data and generated outputs, but also for ensuring compliance with China's rules governing personal information collection, processing, storage, and transfer.

The Cybersecurity Technical Requirements for the Security of Generative AI Services establish detailed expectations for

134. See: https://www.nhc.gov.cn/wjw/c100175/201809/a3223ef7768140a786b308c2064de14b.shtml; "Guānyú yìnfā yīliáo wèishēng jīgòu wǎngluò ānquán guǎnlǐ bànfǎ de tōngzhī" 关于印发医疗卫生机构网络安全管理办法的通知 [Notice on Issuing the Administrative Measures for Cybersecurity in Medical and Health Institutions], National Health Commission of the People's Republic of China, 2022, https://wjw.bynr.gov.cn/uploadfile/2022/1102/1667383212396150.pdf; Cyberspace Administration of China, "Personal Information Protection Law – 2021," (entry at note 49).

135. Cyberspace Administration of China, "Interim Measures for the Administration of Generative Artificial Intelligence – 2023," (entry at note 118).

136. See: Kendra Schaefer, "Seeking the Next Deepseek: What China's Generative Ai Registration Data Can Tell Us about China's Ai Competitiveness," Trivium, April 29, 2025, https://triviumchina.com/research/seeking-the-next-deepseek-what-chinas-generative-ai-registration-data-can-tell-us-about-chinas-ai-competitiveness/; https://practiceguides.chambers.com/practice-guides/artificial-intelligence-2025/china/trends-and-developments; https://english.news.cn/20251225/af0c01628d2b43ab99169d9b93a66024/c.html; https://www.wired.com/story/china-ai-boom-algorithm-registry/

137. Source: https://www.npc.gov.cn/npc/c2/c30834/202106/t20210610_311888.html

138. https://www.npc.gov.cn/npc/c2/c30834/202108/t20210820_313088.html

139. Jiajia Yu, "Evolving Paradigms in China's Human Genetic Resource Regulation: From Biopiracy Prevention to Bridging National Interests and Global Collaboration," *Journal of Bioethical Inquiry* (April 2026), https://doi.org/10.1007/s11673-025-10524-6.

140. See: "China Releases New Regulations on the Protection of Critical Information Infrastructure," Perkins Coie, October 25, 2021, https://perkinscoie.com/insights/update/china-releases-new-regulations-protection-critical-information-infrastructure; "Regulations on Critical Information Infrastructure Security Protections," China Law Translate, August 17, 2021, https://www.chinalawtranslate.com/en/Regulations-on-Critical-Information-Infrastructure-Security-Protections/; Qian, "Data Privacy Rights in Health Data Sharing," 238–55.

141. "Interim Measures for the Management of Generative Artificial Intelligence Services," China law Translate, July 13, 2023, https://www.chinalawtranslate.com/en/generative-ai-interim/.

security of training data, model integrity, and implementation of risk controls.[142] Models that generate health-related outputs (e.g., diagnostics) must train on reliable, high-quality medical datasets and adhere strictly to ethical and clinical norms. Moreover, providers must maintain strict data-labeling practices, ensure high-quality annotation by data labelers, and deploy technical safeguards, such as content filtering and classification tools, to reduce potential safety risks and improve the quality of outputs.[143] Additional regulations, including the Internet Information Service Algorithm Recommendation Provisions, reinforce these requirements. They establish an ongoing governance obligation for AI suppliers throughout the entire data pipeline and impose obligations for algorithm review, data governance, transparency, and security monitoring, and require providers to assess both training data and outputs.[144]

Likewise, technical standards issued by China's national standards bodies and regulators regarding pre-training and fine-tuning data in generative AI set clear standards for how data handlers must treat their training datasets. Service providers must verify that data is legally obtained and ensure they have gathered all personal or sensitive health information in accordance with existing laws. The standard requires sample-based content reviews during the pre-processing phase to ensure the model meets safety standards. When datasets contain patient-level health records, handlers must engage in strict de-identification processes to meet legal obligations under the PIPL.[145]

China has also introduced new transparency and traceability obligations through the March 2025 Measures for the Identification of AI-Generated Content and the accompanying mandatory national standard, the Cybersecurity Technical Specification for Identifying AI-Generated Synthetic Content. Together, these rules require AI-generated content to carry both visible labels and embedded technical identifiers so users and downstream platforms can recognize its synthetic origin.[146] Applied in digital health settings, these requirements mean outputs, such as health guidance or diagnostic content, must clearly identify as AI-generated to reduce risks of confusion or misinformation. The rules also require metadata to include information on content provenance, provider identity, and traceable identifiers, extending accountability across the full chain of content distribution.[147]

AI is deepening the core contradiction at the center of China's health data governance system. On the one hand, China's ambitions in medical AI, biotechnology, pharmaceutical innovation, and precision medicine require access to massive, diverse, and internationally connected datasets capable of supporting advanced model training, validation, and deployment. This creates pressure for greater cross-border data integration, expanded clinical collaboration, and more flexible mechanisms for data sharing. On the other hand, China views many of the same datasets that make AI systems more effective, especially genomic, biometric, and large-scale health datasets, as strategic resources tied to national security, economic competitiveness, and sovereign control over critical technologies. This tension is visible in several areas already discussed in the report:

- Easing rules for multinational oncology trials while tightening genomic and population-scale data controls.
- Creating free-trade-zone pilots and negative lists while expanding the important data category.
- Encouraging AI-enabled healthcare while requiring localization, security reviews, and algorithm filings.
- Supporting cross-border pharmaceutical R&D while retaining discretionary approval authority.

In sum, AI regulation increasingly intersects directly with health-data governance (Figure 3). Firms developing health AI systems in China have obligations related not only to data security, personal data protection, and genetic resource management under China's current regime, but also to the lawful sourcing of training data, consent management, annotation quality, model explainability, content labeling, output traceability, and cybersecurity review.

142. China law Translate, ""Interim Measures for the Management of Generative Artificial Intelligence."
143. Interim Measures Arts. 7–8; TC260 Basic Security Requirements (2024); NHC AI application guidance (2024)
144. Digichina, "Translation: Internet Information Service Algorithmic Recommendation Management Provisions – Effective March 1, 2022," trans. Helen Toner, Rogier Creemers, and Graham Webster, Stanford University, January 10, 2022, https://digichina.stanford.edu/work/translation-internet-information-service-algorithmic-recommendation-management-provisions-effective-march-1-2022/.
145. "Translation: National Standard of the People's Republic of China: Cybersecurity Technology—Safety Specifications for Generative Artificial Intelligence Pre-Training and Fine-Tuning Data (Draft for Feedback)," Center for Security and Emerging Technology, November 7, 2025, https://cset.georgetown.edu/publication/china-gen-ai-training-data-safety-standard-draft/.
146. Digichina, "Translation: Internet Information Service Deep Synthesis Management Provisions (Draft for Comment) – Jan. 2022," trans. Rogier Creemers and Graham Webster, Stanford University, February 4, 2022, https://digichina.stanford.edu/work/translation-internet-information-service-deep-synthesis-management-provisions-draft-for-comment-jan-2022/.
147. Digichina, "Translation: Internet Information Service Deep Synthesis Management Provisions."

**Figure 3:** Regulatory/legal overlap of AI regulation and health-data governance

| Legal regime | When health/health AI data triggers it | Main legal function | How it overlaps |
|---|---|---|---|
| **Personal Information Protection Law (PIPL)** | Triggered when health or health-AI workflows process identifiable personal information, especially medical health information, biometric information, genetic information, user inputs, usage logs, or model outputs linked to an identifiable person. | Establishes baseline personal-information duties, including lawful processing basis, purpose limitation, necessity, PIPIA, individual-rights protections, strict protection measures for sensitive PI, and separate consent where required, including for overseas provision. | Often overlaps with CAC transfer rules because health data is sensitive PI. Also overlaps with HGR rules when involving genetic data, with ethics rules when research subjects or biosamples are involved, and with AI rules when protected health data is in public-facing AI services. |
| **Data Security Law (DSL) and Important Data Framework** | Triggered when health, genomic, public-health, population-scale, multimodal, or AI-training datasets are designated, notified, or publicly identified as important data, or otherwise treated by authorities as implicating national security, public health, economic security, or major public interests. | Creates the general data-security hierarchy, including general data, important data, and core data. Important data requires heightened protection, risk assessment, and export security assessment where outbound transfer is involved. | Can stack with PIPL when important data also contains personal information. Can stack with CIIO rules, CAC outbound transfer assessment, sectoral health-data rules, and HGR rules for genomic datasets. |
| **2024 CAC Cross-Border Data Transfer Provisions** | Triggered by outbound transfers of PI, sensitive PI, important data, and CIIO-held PI or important data. Non-sensitive PI under 100,000 individuals is generally exempt if no other trigger applies; non-sensitive PI from 100,000 to under 1 million, or sensitive PI under 10,000, uses SCC or certification; important data, CIIO exports, PI of 1 million or more, or sensitive PI of 10,000 or more requires CAC assessment. | Provides the central outbound transfer framework through exemptions, SCCs, certification, and CAC security assessment. Also extends assessment validity and creates more predictable routing for lower-risk transfers. | Does not replace HGR, PIPL, DSL, CSL, health-sector, or ethics obligations. A dataset may avoid HGR review but still require CAC analysis, SCC filing, certification, or CAC assessment. |

| | | | |
|---|---|---|---|
| **Cybersecurity Law (CSL) and CIIO Rules** | Triggered when health data is held by entities designated or treated as CIIOs, which may include some major health infrastructure operators, national health platforms, or public-health systems. | Requires localization and enhanced security controls for CIIO-held personal information and important data, plus CAC security assessment before export. | Stacks with PIPL, DSL, and CAC transfer rules. CIIO status can move otherwise ordinary health-data transfers into a higher scrutiny pathway. |
| **Human Genetic Resources (HGR) Regime and May 2026 Draft Direction** | Triggered by HGR materials, human gene or genome data generated from HGR materials, or nucleic-acid-sequence-based genetic or genomic data. Excludes clinical, imaging, protein, and metabolic data unless these contain human gene or genome information. May 2026 draft revisions further narrow the focus toward nucleic-acid-sequence data and remain draft pending finalization. | Requires Chinese institutional involvement, written informed consent, ethics review, approval or filing where applicable, and restrictions on foreign collection, preservation, external provision, and commercial transactions. NHC now leads HGR administration; legacy MOST rules remain relevant. May 2026 draft revisions remain draft and directional pending finalization. | Can operate in parallel with PIPL, CAC transfer rules, DSL important-data obligations, and biomedical ethics rules. HGR approval or filing does not replace CAC or PIPL obligations. May 2026 guidance also shifts more oversight toward institutional ethics review for human genetic data research. |
| **Health Big Data and Healthcare Cybersecurity Rules** | Triggered by population health information, hospital-held patient records, healthcare-generated data, and some data held by medical institutions or health-sector network operators. | Imposes domestic storage, lifecycle controls, institutional access restrictions, and cybersecurity duties for some population health information and healthcare-generated data. | Often overlaps with PIPL sensitive-PI obligations, CAC transfer mechanisms, CIIO rules where relevant, and clinical-research ethics obligations. |
| **Biomedical Ethics and Human-Subject Research Rules, including NSTEC Guidance** | Triggered by clinical research, biosamples, human-subject data, secondary research use, and human genetic data research. | Requires ethics review, informed consent, and review of research necessity, data handling, privacy protection, external sharing, and risk management. May 2026 NSTEC guidance makes scientific ethics committees more central in human genetic data research governance. | Overlaps with PIPL consent and notice duties, HGR informed-consent and ethics review requirements, and CAC transfer obligations when providing data abroad. |

| | | | |
|---|---|---|---|
| **Generative AI Interim Measures** | Triggered when health-related generative AI services are provided to the public in mainland China. Internal R&D or non-public deployment is not the main target unless other rules apply. | Imposes obligations for lawful sourcing, training-data governance, content safety, privacy protection, security assessment where applicable, and prevention of unlawful or harmful outputs. | Overlaps with PIPL when training data, prompts, usage logs, or outputs contain personal health information. Also overlaps with CAC transfer rules if health-AI workflows involve outbound transfer. |
| **AI Algorithm, Recommendation,, and Technical Governance Rules** | Triggered depending on the system and deployment context, including recommendation algorithms, annotation, model training, fine-tuning, and model-safety processes used in health-AI systems. | Sets technical and governance expectations for algorithmic systems, training-data quality, annotation management, model safety, transparency, and user protections where applicable. | Overlaps with PIPL, DSL, CAC, and sectoral health-data rules when AI systems rely on sensitive health data, large-scale datasets, or data transfers. |
| **AI Labeling and Synthetic-Content Rules** | Triggered when creating or distributing AI-generated or synthetic content through public online information services, including health-related content where applicable. | Requires explicit and implicit labeling of AI-generated synthetic content and supports traceability and accountability for public online services. | Overlaps with generative AI rules, platform governance, health-content compliance, and PIPL where generated outputs contain or reveal personal health information. |

Notes: May 2026 HGR revisions remain draft and directional pending finalization.

PI = personal information

## Future policy directions

### Near-term: Refinement, selective easing, and controlled facilitation

Now that China's cross-border data regime for personal information is largely complete, policy is likely to focus on refining implementation. China's 2025 Government Work Report calls for improving the basic data system, expanding data utilization, promoting and regulating cross-border flows, and signals a commitment to continuously refine the existing system.[148] Pilot mechanisms, including FTZ negative lists, are already in use, with the CAC calling out particular progress in the pharmaceutical sector.[149] These pilots refer primarily to recent FTZ initiatives in Beijing, Shanghai, Tianjin, and Hainan, where regulators have experimented with more flexible cross-border transfer rules for selected industries and data categories.[150] The CAC has stated that regulators intend to replicate and scale these pilot experiences, particularly FTZ negative-list approaches and streamlined approval mechanisms, to additional regions and sectors as implementation matures.[151] Negative list pilots reduce uncertainty by explicitly identifying categories that do not require CAC security assessment or related procedures, providing more procedural certainty to firms operating in the sector.

**At the same time, "important data" will remain tightly controlled.**[152] China recently expanded the DSL's important data category to include industrial, economic, and technical data deemed strategically sensitive. The definition remains intentionally vague, allowing regulators the flexibility to expand its scope.[153] As geopolitical competition around biotechnology increases, there is potential to deem a growing number of data categories strategically significant. Reflecting this dynamic, many firms still face uncertainty in determining what qualifies as important data, even after formal easing. Uncertainty is a defining feature of the revised regime, especially for large firms operating at scale.

**A second near-term priority is more sector-specific guidance.** China aims to establish a more refined regulatory framework centered on business scenarios and industry-specific rules to complement the existing more general legal guidance.[154] Supporting this interpretation, the National Development and Reform Commission has signaled plans to develop industry-specific rules for cross-border data flows, and also signaled plans for 2026 to finalize negative lists for additio-

148. https://english.www.gov.cn/news/202503/05/content_WS65e6b6bfc6d0868f4e8e9d2e.html; "Zhōngguó yíng shāng huánjìng fāzhǎn bàogào (2025)" 中国营商环境发展报告 (2025) [Report on the Development of China's Business Environment (2025)] National Development and Reform Commission, April 2025, https://www.ndrc.gov.cn/xwdt/tzgg/202504/P020250430371376827216.pdf; Li Qiang, "Draft: Report on the Work of the Government," National People's Congress, March 2025, https://npcobserver.com/wp-content/uploads/2025/03/2025-Government-Work-Report_NON-FINAL_EN.pdf.

149. https://www.chinalawtranslate.com/en/data-export-regulations-implementation/; https://www.merics.org/en/report/chinas-data-export-rules-and-negative-lists; China Law Translate, ""Provisions on Promoting and Regulating the Cross-Border Flow."

150. In the pharmaceutical sector, Beijing's FTZ has already approved several pilot cases involving cross-border clinical research and multinational pharmaceutical operations, including Bayer Healthcare's data export filing and the Beijing Friendship Hospital-University of Amsterdam cancer collaboration. Similarly, a 2024 pilot program launched in Shanghai's Pudong New Area allows foreign-invested enterprises to engage in the development and application of human stem cell, gene diagnosis, and gene therapy technologies. Merck Diagnostics became one of the first major multinational pharmaceutical companies to participate in the pilot. Under the policy change, Merck localized its advanced biotechnology testing capabilities in China and is providing services related to cell and gene therapies that were previously restricted under foreign investment rules. See: "Yīliáo lǐngyù kāizhǎn kuòdà kāifàng shìdiǎn zài pǔdōng luòdì" 医疗领域开展扩大开放试点在浦东落地 [Pilot program for expanded opening-up in the medical sector launched in Pudong.], *Pudong Times*, November 15, 2024, https://www.pudong.gov.cn/0060011/20241115/795784.html.

151. See: Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76); "Guójiā hùliánwǎng xìnxī bàngōngshì gōngbù "cùjìn hé guīfàn shùjù kuà jìng liúdòng guīdìng" 国家互联网信息办公室公布《促进和规范数据跨境流动规定》[The Cyberspace Administration of China has Released the «Regulations on Promoting and Regulating Cross-Border Data Flow.»], Cyberspace Administration of China, March 22, 2024, https://www.cac.gov.cn/2024-03/22/c_1712776612187994.htm; "Shùjù chūjìng ānquán guǎnlǐ zhèngcè wèndá (2025 nián 4 yuè)" 数据出境安全管理政策问答（2025年4月）[Q&A on Data Cross-Border Security Management Policies (April 2025)], Cyberspace Administration of China, April 9, 2025, https://www.cac.gov.cn/2025-04/09/c_1745906286623776.htm.

152. Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76).

153. Cyberspace Administration of China, "Q&A on Data Cross-Border Security Management Policies – 2025," (entry at note 153); see also: https://policy.mofcom.gov.cn/claw/policyInfo.shtml?id=8728&

154. Cyberspace Administration of China, "Cyberspace Administration of China has Released the 'Regulations on Promoting and Regulating Cross-border Data Flow,'" (entry at note 153).

nal FTZs.[155] For example, the PRC in April 2025 issued guidelines on cross-border flows of financial data,[156] and in February 2026 released guidance on cross-border automobile data transfers.[157]

**A third near-term trend is selective facilitation paired with continued supervision.** The 2024 CAC provisions introduced exemptions for lower-risk transfers, such as contract performance, human resource management, emergency scenarios, and limited volumes of non-sensitive data.[158] At the same time, the CAC has stated regulators continue building and using the negative-list mechanism as an approval boundary, versus moving to unrestricted flows, signaling that in the near term, lower-risk cases will see continued easing of restrictions, while the expectations are that state control and oversight over higher-risk categories will offer little movement.[159]

## Medium-Term: Differentiation, institutionalization, and post-transfer oversight

I**n the medium term, China is moving from a broadly restrictive model toward one that categorizes data flows by risk, sector, and location**. For example, sector-specific export rules have begun to emerge for autonomous and connected vehicles. Draft automotive data-transfer guidance issued in 2025 treats certain data used for autonomous-driving and advanced driver-assistance development as important data requiring approval for overseas transfer, while permitting lower-risk transfers through clearer compliance pathways.[160] At the same time, location-based pilots advance through FTZs. Shanghai's FTZ and Lingang Special Area introduced a negative-list model in 2025 under which data not listed as restricted may flow abroad without extra filings or declarations; Shanghai expanded this model citywide in April 2026.[161] Hainan has also issued a free trade port data-export negative list, adding a second major pilot location.[162]

**Meanwhile, the state will also likely move to enhance its regulatory oversight capabilities.** CAC's 2024 cross-border data-flow provisions relaxed some front-end approval requirements, including exemptions for transfers that do not involve personal information or important data, while preserving obligations for data handlers to protect exported data, take remedial action after incidents, and report problems to regulators.[163] Recent automotive data guidance points in the same direction by requiring designated compliance personnel, internal approval procedures, and multi-year transfer logs, suggesting that in the medium-term, lower-risk transfers will move more easily

155. Negative lists outline the sectors in which foreign investors face restrictions or outright prohibitions on market entry in China. If a sector is not on the list, it is supposedly completely open to foreign investment. For more, see: Arendse Huld, "How China's Foreign Investment Negative List Works – A Guide for Investors," *China Briefing*, April 13, 2026, https://www.china-briefing.com/news/chinas-foreign-investment-negative-list-guide/.

156. China Releases Guidelines to Facilitate Cross-Border Flows of Financial Data," Reuters, April 17, 2025, https://www.reuters.com/world/china/china-releases-guidelines-facilitate-cross-border-flows-financial-data-2025-04-17/.

157. Xinhua, "China Releases Security Guide on Cross-Border Automobile Data Transfers," State Council Information Office of the People's Republic of China, February 4, 2026, http://english.scio.gov.cn/pressroom/2026-02/04/content_118316071.html.

158. Cyberspace Administration of China, "Regulations on Promoting and Regulating Cross-Border Data – 2024," (entry at note 76).

159. Cyberspace Administration of China, "Q&A on Data Cross-Border Security Management Policies – 2025," (entry at note 153).

160. China Issues Draft Guidance on Car-Generated Data, Reuters, June 13, 2025, https://www.reuters.com/markets/emerging/china-issues-draft-guidance-transfer-car-generated-data-2025-06-13/; "China Auto Data Market," International Trade Administration, December 2, 2025, https://www.trade.gov/market-intelligence/china-auto-data-market.

161. Shanghai Observer, "Shanghai Expands Application of Negative List for Outbound Data Transfers to Entire City," Shanghai International Services, April 28, 2026, https://english.shanghai.gov.cn/en-PolicyInsights/20260428/82703407db56425da229e2e2673a3393.html; "Shanghai Unveils 13 Measures to Accelerate Development of Lin-Gang Special Area," *Shanghai Weekly Bulletin* 82, No. 2 (February 2025), https://english.shanghai.gov.cn/en-ShanghaiWeeklyBulletin/20250219/0720e1f855e94aa9816f7a4d87b3ae9d.html.

162. Alex Roberts, "China: Will Free Trade Zones' Negative- and Whitelists Ease Data Exports?" Linklaters, February 3, 2026, https://www.linklaters.com/insights/blogs/digilinks/2025/february/china-will-free-trade-zones-negative--and-whitelists-ease-data-exports; "Hainan Free Trade Port Releases Negative List for Data Export," LinkedIn, February 27, 2025, https://www.linkedin.com/pulse/hainan-free-trade-port-releases-negative-list-data-export-%E5%8D%9A%E7%9D%BF-%E4%B8%AD%E5%AF%8C-dqtlc

163. Reuters, "China Relaxes Security Review Rules for Some Data Exports"; China Law Translate, ""Provisions on Promoting and Regulating the Cross-Border Flow."

up front, while audits, inspections, and post-transfer compliance become more important.[164]

**AI is likely to deepen sectoralization in concrete ways, especially through the state-led development of sector-specific, AI training-ready datasets.** In a 2025 article published by the National Development and Reform Commission, Liu Liehong, one of China's top officials on data policy and digital governance, describes data as "the fuel that powers the development of artificial intelligence technology" and argues that data systems must enable circulation and use while also being secure.[165]

This policy direction is already visible in recent sectoral initiatives. For example, China's "Data Element ×" Three-Year Action Plan (2024–2026), issued by multiple central agencies, identifies at least 12 priority sectors, including healthcare, scientific research, and manufacturing, and calls for improving data supply quality, enabling circulation, and supporting advanced applications such as AI and large models.[166] In the health sector specifically, the plan and related policy efforts promote the standardization and sharing of electronic medical records and other clinical datasets to support AI-driven applications, with dataset standardization explicitly framed as necessary for machine learning and large model training.[167] More broadly, recent policy development has focused on building "AI-ready" sectoral datasets that can directly train models across industries, linking data governance reforms to AI industrial strategy.[168]

These initiatives align with a wider shift in China's digital policy, in which the state seeks to unlock the "multiplier effect" of data across sectors while maintaining centralized oversight through unified standards, security controls, and data classification frameworks.[169] **In practice, this means China is constructing structured, sector-specific pipelines to aggregate, standardize, and use data, including in some cases internationally sourced data, for AI training under state-defined governance systems.**

**Beijing may also continue to deepen international cooperation on data governance through multilateral forums, such as the United Nations and World Trade Organization, while advancing the Digital Silk Road and promoting governance approaches aligned with PRC preferences.**[170] China's National Data Administration recently announced the launch of a new office, the Department of International Data Governance Cooperation, as a means to assist the PRC in coordinating global cross-border data flows.[171] One analysis flagged developments like these could be a positive signal for data sharing in scientific research, stating that something like "a government-managed sandbox in which data sharing is encouraged

164. Carolyn Bigg and Amada Ge, "China: New Guidance on Data Transfer and Identification of Important Data in the Automotive Sector," DLA Piper, February 4, 2026, https://privacymatters.dlapiper.com/2026/02/china-new-guidance-on-data-transfer-and-identification-of-important-data-in-the-automotive-sector/.

165. "Shǔmíng wénzhāng | liúlièhóng: Jiākuài tuījìn shùjù kējì chuàngxīn fù néng shùzì zhōngguó jiànshè" 署名文章 | 刘烈宏：加快推进数据科技创新 赋能数字中国建设 [Signed Article | Liu Liehong: Accelerating Data Technology Innovation to Empower the Construction of Digital China], National Development and Reform Commission, December 29, 2025, https://www.ndrc.gov.cn/fzggw/wld/llh/zyhd/202512/t20251229_1402708.html; "Jīhuó shùjù yàosù shìchǎng huà pèizhì gǎigé dòngnéng, zhù láo "réngōng zhìnéng +" xíngdòng fāzhǎn jīshí" 激活数据要素市场化配置改革动能，筑牢"人工智能+"行动发展基石 [Activate the market-oriented allocation of data elements and consolidate the foundation for the development of the «Artificial Intelligence+» action.], National Development and Reform Commission, August 28, 2025, https://www.ndrc.gov.cn/xxgk/jd/jd/202508/t20250828_1400104.html.

166. https://english.www.gov.cn/news/202401/05/content_WS65973ab3c6d0868f4e8e2c44.html; "China Aims to Achieve an Annual Growth Rate of over 20% in the Data Industry by 2026," *Global Times*, January 5, 2024, https://www.globaltimes.cn/page/202401/1304844.shtml.

167. https://www.gio.zone/wp-content/uploads/2024/03/CAMS-Data-elements-Digital-Health-1.pdf

168. "NDA Marries Data Elements x and AI Plus," Trivium, April 17, 2026, https://triviumchina.com/2026/04/17/nda-marries-data-elements-x-and-ai-plus.

169. Winston Ma, "China's Approach to Data and AI Is Changing. Here's What That Means," World Economic Forum, January 11, 2024, https://www.weforum.org/stories/2024/01/chinas-data-and-ai-approach-is-changing-heres-what-that-means.

170. One example is the March 2026 launch in Beijing of the World Data Organization, presented as a platform to support international data-governance standards, promote trusted cross-border data collaboration, and explore mechanisms that could reduce barriers to compliant data exchange. See: "World Data Organization Established in Beijing," State Council of the People's Republic of China (XinHua), March 31, 2026, https://english.www.gov.cn/news/202603/31/content_WS69cb2a94c6d00ca5f9a0a2db.html.

171. "Guójiā shùjù jú yǐ xīn shè guójì shùjù zhìlǐ hézuò sī" 国家数据局已新设国际数据治理合作司 [The National Data Administration has established a new Department for International Data Governance Cooperation.], 21st Century Business Herald, March 28, 2026, https://www.21jingji.com/article/20260328/herald/132c1debdc0513d11420ed58d07ce778.html.

might make China data more available for certain types of research, even if the sources are limited and contained."[172]

## Long-Term: Managed openness within a sovereignty-centered system

Over the long term, China aims to build a comprehensive cross-border data governance model covering the full data lifecycle, from collection and processing to transfer and trading. This system will combine domestic control with selective international integration. This trajectory aligns with China's "dual circulation" strategy.[173] In essence, Beijing will optimize domestic data flows to support economic development and technological innovation, while selectively permitting cross-border flows where they align with national interests (Figure 4).

China is also likely to play a more active role in shaping international data governance standards while maintaining core principles of sovereignty and state oversight. China's 2022 "Twenty Measures on Data" state that China should "actively participate in the formulation of international rules governing cross-border data flows," while ensuring security across the full process of data provision, circulation, and use.[174] More recent 2026 planning guidance similarly calls for aligning with "high international standards" in areas including finance, healthcare, education, and cross-border data flows, while balancing development and security.[175] These signals suggest China seeks a larger role in shaping global digital rule-making while maintaining its core positioning on data sovereignty and security. The long-run trajectory will be toward a more mature, layered regime in which some categories of data move through more standardized channels, while politically and strategically sensitive data remain subject to tighter gatekeeping.

AI is likely to matter even more in the long run because it raises both the economic value and strategic sensitivity of data. In the long term, this suggests the PRC will aim to maintain participation in global AI value chains, while treating data flows relevant to AI as matters of national security and central to data sovereignty, and subject to more stringent oversight than flows related to ordinary digital trade.

172. "China Launches World Data Organization," Trivium, March 31, 2026, https://triviumchina.com/2026/03/31/china-launches-world-data-organization/; Guancha: 世界数据组织在北京正式成立 已汇集会员超200个; Weixin: 国家数据局已新设内设机构

173. Hung Tran, "Dual Circulation in China: A Progress Report," Atlantic Council, October 24, 2022, https://www.atlanticcouncil.org/blogs/econographics/dual-circulation-in-china-a-progress-report/.

174. See: "China Unveils Measures to Build Basic Systems for Data," State Council of the People's Republic of China (XinHua), December 19, 2024, https://english.www.gov.cn/policies/latestreleases/202212/19/content_WS63a17f7dc6d0a757729e49bd.html; "China has a New Plan to Strengthen its Data Economy," *China Briefing*, January 23, 2023, https://www.china-briefing.com/news/china-has-a-new-plan-to-strengthen-its-data-economy/; "Remarks by the Chinese Delegation at the Global Roundtable on ICT Security Capacity-Building," Permanent Mission of the People's Republic of China to the UN, May 10, 2024, https://un.china-mission.gov.cn/eng/chinaandun/disarmament_armscontrol/202405/t20240511_11303055.htm.

175. National Development and Reform Commission, *Report on the Implementation of the 2025 Plan for National Economic and Social Development on the 2026 Draft Plan for National Economic and Social Development,* March 5, 2026, https://npcobserver.com/wp-content/uploads/2026/03/2026-NDRC-Report_NON-FINAL_EN.pdf.

## **Figure 4:** China's near-, medium-, long-term data policy directions

Continue refining the regime, facilitate lower-risk and strategically beneficial transfers, and maintain strong control over high-sensitivity and national security-relevant data.

**BOTTOM LINE** *China is moving toward a more differentiated and conditional cross-border data governance model that facilitates selected lower-risk and strategically beneficial health-data transfers while maintaining strict control over genomic, important-data, AI-relevant, and national-security-sensitive datasets.*

| NEAR-TERM | MEDIUM-TERM | LONG-TERM |
|---|---|---|
| **Now–2 Years** | **2–5 Years** | **5+ Years** |
| *Refinement, selective easing, controlled facilitation* | *Differentiation, institutionalization, post-transfer oversight* | *Managed openness with a sovereignty-centered system* |
| 01 **Refine implementation** Policy focus on refining the existing cross-border data regime. | 01 **Risk-, sector-, and location-based differentiation** Sector-specific rules emerge, for example autonomous vehicles. FTZ negative-list models expand, including Shanghai citywide and Hainan Free Trade Port.data regime. | 01 **More integrated lifecycle governance** Across collection, storage, transfer, use, and post-transfer supervision. |
| 02 **Expand FTZ negative-list pilots** Beijing, Shanghai, Tianjin, and Hainan pilots already in use; plan to replicate and scale. | 02 **Negative-list mechanisms expand** Data not on the negative list may flow abroad without extra filings or declarations. | 02 **Selected international integration** Selected forms of international biomedical and health-data collaboration permitted through structured, state-visible, and institutionally supervised channels. |
| 03 **Pilots with progress in pharmaceuticals** CAC highlights particular progress in the pharmaceutical sector. | 03 **Enhanced post-transfer oversight** Exemptions for some transfers, while requiring remedial action after incidents and regulator reporting. | 03 **Continued emphasis on data sovereignty** Core principle guiding China's data governance approach. |
| 04 **Develop more sector-specific guidance** NDRC to develop industry-specific rules. Recent examples: financial data April 2025, automobile data February 2026. | 04 **Institutional ethics governance expands** Scientific ethics committees play a larger role in biomedical and genetic-data oversight. | 04 **More standardized channels** For approved data categories, alongside continued oversight. |
| 05 **Selective facilitation for lower-risk transfers** Exemptions for contract performance, HR management, emergencies, and limited volumes of non-sensitive data. | 05 **More internal compliance obligations** Designated compliance personnel, internal approval procedures, multi-year transfer logs. | 05 **Tighter controls on high-sensitivity data** Genomic, population-scale, important-data, and national-security-relevant datasets remain tightly governed. |
| 06 **Important data remains tightly controlled** Definition remains flexible and vague; scope can expand with geopolitical and biotech competition. | 06 **Development of AI-ready sectoral datasets** State-led creation of high-quality, standardized datasets to support AI training and applications. | 06 **Greater PRC role in global rulemaking** China seeks a larger role in international data governance frameworks. |
| | 07 **Stronger linkage between data governance and AI policy** Data systems built to enable circulation and use while ensuring security. | 07 **AI-relevant data treated as high-priority policy and governance assets** AI-relevant health, genomic, and population-scale datasets increasingly function as high-priority policy and governance assets. |

| CROSS-CUTTING THEMES |
|---|
| **Risk-based classification** Lower-risk data faces easing; higher-risk data faces continued control. |
| **Location-based pilots** FTZs lead innovation with negative lists and flexible mechanisms. |
| **Sector-specific rules** More industries will receive tailored requirements. |
| **From approvals to oversight** Partial shift from front-end approvals toward audits, ethics review, institutional compliance, and post-transfer supervision. |
| **Data systems for AI** State-supported high-quality datasets and controlled data circulation increasingly support AI development. |
| **Sovereignty first rules** Security and national interests remain the organizing principle. |
| **Conditional governance model** Cross-border access increasingly permitted through supervised, differentiated pathways. |

Note: May 2026 HGR revisions remain draft and directional pending finalization.

## Recommendations for MNCs to Build Resilience in the Face of Potential Future Regulatory Changes

China's health and data governance system now prioritizes domestic control, policy alignment, and strategic value of data, while still allowing targeted collaboration in areas that support national goals. For foreign MNCs operating in China, the practical implications of China's health-data regime differ significantly depending on the type of data involved, the sector, the geographic location, and whether AI systems are part of the workflow. Still, several broad operational principles emerge from the current regulatory environment.

*Differentiate among types of health data*

Not all health data carries the same regulatory or political sensitivity. Routine clinical-trial data and certain imaging datasets increasingly move through approved channels, especially in oncology and multinational pharmaceutical trials. By contrast, genomic data, multimodal datasets combining genomic and behavioral information, and population-scale datasets remain significantly more sensitive because regulators link them to biotechnology competition, AI development, and national security. The most difficult compliance environments are likely to involve: multimodal AI-training datasets, integrated patient-level longitudinal records, genomic and sequencing datasets, real-world evidence platforms operating across borders, and foundation-model training environments involving sensitive medical data.

*Understand which regulators matter for which activity*

China's health-data system remains fragmented across multiple regulatory authorities with overlapping jurisdiction.

- The CAC primarily oversees outbound data-transfer assessments, cybersecurity reviews, and implementation of the PIPL and DSL.
- Previously under MOST management, NHC now oversees the HGR regime, genomic collaboration approvals, and foreign participation in genetic-resource activities.
- NHC and hospital systems govern clinical records, health-data governance, ethics review, and hospital information systems.

Provincial governments and FTZ authorities increasingly shape implementation through pilot mechanisms, negative lists, and localized experimentation.

Successfully navigating an evolving regulatory regime will depend on regulatory alignment, local partnership, and operational flexibility across jurisdictions. Fortunately for multinationals, China still needs international collaboration to meet its long-term healthcare sector goals,[176] and this means opportunities for cooperation continue despite persisting and rising geopolitical tensions.

*Assume localization by default*

Companies should assume that sensitive health data, especially identifiable patient data, imaging datasets, genomic information, and multimodal AI-training datasets, will need to remain stored and processed within China unless a clear approved pathway exists for export. MNCs have begun to consider more China-localized data stacks paired with other privacy-enhancing approaches, or restructuring workflows to minimize cross-border transfer dependence.[177]

Techniques, such as federated learning (in which an AI model trains across multiple locations without centralizing the underlying data), domestic model training, trusted research environments, localized inference infrastructure, and use of synthetic data (artificially generated data designed to statistically resemble real-world data) can support collaboration without transferring raw data and align with emerging PRC approaches sometimes described as making data "usable but not visible."[178] China has begun advancing pilot initiatives around trusted data spaces and privacy-preserving data-sharing frameworks in healthcare, suggesting these models have emerging government support.[179]

*Build around Chinese institutional partners*

China's system places high value on institutional relationships, local trust, and embedded presence, which have direct im-

176. Lizzi C. Lee and Jing Qian, "China's Biotech Boom: Why the Nation Must Collaborate to Stay Ahead," *Nature*, February 10, 2026, https://www.nature.com/articles/d41586-026-00387-1.

177. See: Lee and Qian, "China's Biotech Boom."

178. Echo H. Wang et al., "Crossing Borders Securely: Synthetic Data and Federated Networks for Privacy-Preserving Access to Real-World Data and Emerging Use Cases," *npj Digital Medicine* 8, No. 1758 (December 2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12705744/; Nicole Rieke et al., "The Future of Digital Health with Federated Learning," *npj Digital Medicine* 3, No. 119 (202o), https://arxiv.org/abs/2003.08119; Jessie Zhang, "Trusted Data Spaces: New Path to Managing Medical Data Risks," *China Business Law Journal* (December 2025), https://law.asia/trusted-data-spaces-managing-medical-data-risks/

179. Zhang, "Trusted Data Spaces"; Lee and Qian, "China's Biotech Boom."

pacts on business outcomes. As one expert in China's healthcare sector put it, "trust, reputation and alignment with local interests shape everything—from access to clinical sites and patient data, to regulatory timelines and hospital partnerships. Those who prioritize relationships first and profit second will be best positioned to navigate complexity and thrive."[180]

Successful collaboration generally depends on strong Chinese institutional partners. These often include top-tier hospitals, local affiliates, contract research organizations, research institutes, or state-linked healthcare entities capable of interfacing with regulators and ethics committees. In many cases, these institutions formally control or steward the underlying datasets and serve as the primary interface with authorities. Institutional trust, existing regulator relationships, and operational familiarity with provincial implementation practices often determine whether projects move forward efficiently.[181]

Partnership models should tailor to specific objectives. Models can include equity-based partnerships,[182] project-based collaborations,[183] capacity-building and exchanges,[184] licensing arrangements, and embedded, long-term local presence.[185] Several partnership models exist, with tradeoffs for each type. For example, equity-based partnerships (i.e., joint ventures, acquisitions, co-funding arrangements, etc.) are beneficial in terms of better ensuring strategic alignment and signaling long-term commitment, as well as gaining local insights and engaging in shared risk not available with other partnership models. However, these processes are time-consuming, costly, and often require significant financial and human resource investments. Meanwhile, project-based collaborations (more common for global research projects) are much less costly and much quicker to launch. However, questions around intellectual property and data ownership and dependence on local execution of the project may come with significant downsides.[186]

*Expect iterative and ongoing engagement*

Although the post-2024 CAC regime has become more proceduralized, firms still report substantial uncertainty around the important data classification, scope determinations, and

180. See: Ruby Wang, "Biotech in China: Four Important Truths That Everyone Isn't Talking About," China Health Pulse, March 26, 2025, https://www.chinahealthpulse.com/p/biotech-in-china-four-important-truths.

181. This reliance on Chinese institutional partners also creates strategic and compliance challenges for multinational companies. Many of the entities best positioned to secure approvals, manage sensitive datasets, and navigate provincial implementation processes maintain close relationships with state authorities, public hospitals, or state-affiliated research ecosystems. From a U.S. government perspective, these partnerships may raise concerns related to data security, technology transfer, sanctions exposure, export controls, human rights due diligence, or broader geopolitical risk. As a result, multinational firms increasingly face a dual compliance problem: satisfying Chinese localization, partnership, and regulatory requirements while also ensuring alignment with evolving U.S. and allied restrictions on sensitive data, biotechnology collaboration, and engagement with certain Chinese entities.

182. Examples: https://www.prnewswire.com/news-releases/medimmune-and-wuxi-apptec-announce-joint-venture-to-develop-novel-biologic-for-chinese-market-169142866.html; https://firstwordpharma.com/story/4600659; "GSK and Zhifei Announce Exclusive Strategic Vaccine Partnership in China," release, GSK, October 9, 2023, https://www.gsk.com/en-gb/media/press-releases/gsk-and-zhifei-announce-exclusive-strategic-vaccine-partnership-in-china/; "Merck and Kelun-Biotech Announce Exclusive License and Collaboration Agreement for Seven Investigational Antibody-drug Conjugate Candidates for the Treatment of Cancer," release, Merck, December 22, 2022, https://www.merck.com/news/merck-and-kelun-biotech-announce-exclusive-license-and-collaboration-agreement-for-seven-investigational-antibody-drug-conjugate-candidates-for-the-treatment-of-cancer/.

183. Examples: https://www.beijing.gov.cn/ywdt/gzdt/202301/t20230118_2902294.html; https://asiasociety.org/policy-institute/chinas-human-genetic-resources-rules-and-clinical-trials; "Pfizer Enters into Exclusive Licensing Agreement with 3Sbio," release, Pfizer, May 19, 2025, https://www.pfizer.com/news/press-release/press-release-detail/pfizer-enters-exclusive-licensing-agreement-3sbio.; https://investors.biontech.de/news-releases/news-release-details/biontech-and-fosun-pharma-collaborate-covid-19-vaccine; https://www.roche.com/media/releases/med-cor-2023-11-05.

184. See, for example: "GE yīliáo kèhù péixùn kèchéng fāng'àn" GE医疗 客户培训课程方案 [GE Healthcare Customer Training Course Program] GE HealthCare, accessed June 1, 2026, https://smartmart.gehealthcare.cn/Training/Training.html; "Zhuānjiā jiědú" 专家解读 "Fēnjí zhěnliáo shíshī wǔ bù zǒu, jīcéng yīliáo nénglì tíshēng shì guānjiàn" 分级诊疗实施五步走，基层医疗能力提升是关键 [Expert Analysis: A five-step approach to implementing tiered diagnosis and treatment: enhancing primary healthcare capacity is key.], PCB Basic Medical Business Unit, January 4, 2018, https://edu.gehealthcare.cn/mobile/thread/1489; Shine, "Roche Diagnostics China Signs Two Memoranda of Understanding to Advance Digital Healthcare Innovation in China," City News Service, March 16, 2026, https://www.citynewsservice.cn/articles/shanghaidaily/news/roche-diagnostics-china-signs-two-memoranda-of-understanding-to-advance-digital-healthcare-innovation-in-china-xm5gpb0k.

185. Examples, among many others: Huaxia, ed., "GE HealthCare Expands in China with New R&D Center," XinHua, December 16, 2025, https://english.news.cn/20251216/bb5802572dbb4ae59e9c9d05c2f353ae/c.html; "Pharma Partnering in Asia," Roche, accessed June 1, 2026, https://www.roche.com/innovation/partnering/pharma/asia.

186. See: Wang, "Biotech in China: Four Important Truths."

documentation requirements. Publicly available guidance now includes standardized filing templates, formal completeness checks, published review timelines, and expanded exemptions.

However, implementation still appears highly relationship-driven and iterative in practice. China's regulatory system often relies significantly on ongoing engagement and coordination, from local pilot zone engagements at the working level to central authorities. Approval processes often depend on iterative dialogue. Successful business outcomes are often the result of continuous regulatory engagement, including early-stage consultation on data export and trial design, coordination across local and national authorities, and dedicated in-country teams to manage government relations.[187]

Companies should expect extensive pre-filing consultation, multiple rounds of documentation revision, and coordination across legal, compliance, technical, ethics, and hospital stakeholders. The goal should be sustained engagement rather than transaction-oriented. For example, a cadence of bi-monthly check-ins at the working level to update on progress and thank local teams for their assistance can better equip these teams to make bigger "asks" higher up the bureaucratic chain when needs arise. For example, pilot programs such as FTZs and "green channel" mechanisms provide faster approvals when firms engage proactively.[188]

*Plan for regulatory divergence and operational decoupling*

US and Chinese policies on health data, biotechnology, and sensitive information are diverging, increasing global data fragmentation and hindering opportunities for cross-border collaboration.[189] The United States has introduced restrictions affecting bulk sensitive data transfers and biotechnology collaboration,[190] while China treats certain health, genomic, and related biodata as strategically sensitive and subjects many transfers to security review.[191]

Firms could consider parallel operating structures, including separate data environments for China and global operations, distinct clinical trial strategies and data pipelines, and flexible manufacturing and R&D footprints across jurisdictions. These approaches, while potentially improving regulatory resilience and operational continuity, are often resource-intensive and may require substantial investments in infrastructure, compliance, staffing, legal coordination, and duplicative operational capacity. Elements of this shift are already visible, with many multinationals expanding localized R&D, manufacturing, and data-handling infrastructure in China to manage regulatory fragmentation and improve resilience across jurisdictions. For example, recent analyses have found a broader shift by foreign life sciences firms toward localization strategies in response to regulatory, supply-chain, and geopolitical risk.[192]

187. Hanshuo Zhou, Xiaoyun Wang, and Taige Shi, "China's Digital Healthcare: Structuring Compliance for AI-Enabled Clinical Infrastructure: Regulatory Landscape of China's Digital Health Sector," Chambers and Partners, June 26, 2025 [update], https://practiceguides.chambers.com/practice-guides/digital-healthcare-2025/china/trends-and-developments.

188. Example: https://www.beijing.gov.cn/ywdt/gzdt/202402/t20240229_3575133.html

189. Lee and Qian, "China's Biotech Boom."

190. Combined Notice of Filings, 89 Fed. Reg. 107138 (Dec. 31, 2024).

191. Ministry of Science and Technology of the People's Republic of China, "Regulations of the People's Republic of China on the Management of Human Genetic Resources – 2019," (entry at note 1).

192. See: Zhao Ruixue, "Foreign Firms Deepen Roots, Strive for Localization," Invest in China, May 30, 2025, https://investinchina.chinaservicesinfo.com/s/202505/30/WS683970a4498eec7e1f738a65/foreign-firms-deepen-roots-strive-for-localization.html; Helen Chen and Grace Wong, "Going Local: Strategic Considerations for Medtech Manufacturers in China," LEK, April 4, 2023, https://www.lek.com/insights/medtech/going-local-strategic-considerations-medtech-manufacturers-china-0; Sun Chau Siu et al., "Access the Chinese Market with a Localization Strategy," BioProcess International, January 29, 2025, https://www.bioprocessintl.com/bioregions/access-the-chinese-market-with-a-localization-strategy; Cyberspace Administration of China, "Q&A on Data Cross-Border Security Management Policies – 2025," (entry at note 153).

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