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Accessing biopharma innovation in China

Rethinking strategies to play and win in China's rapidly growing and evolving biopharma ecosystem

Introduction

Over the past five years, China has shifted from being the supporting act in the global biopharma ecosystem to being center stage with respect to innovation and deal-making. Chinese government initiatives, such as "Made in China 2025" and the development of innovative biopharmaceutical infrastructure, have fueled a shift to developing innovative first-in-class[1] and best-in-class drugs.[2] At the same time, China has seen regulatory reforms – including accelerated new drug approvals,[3] Research and Development (R&D) subsidies,[4] and an increase in cross-border trial data sharing.[5] These initiatives have been a catalyst for growth in top-tier talent and research institutions[6] that, coupled with lower costs and a large population with diverse disease profiles,[1,7] have created opportunities for global players that substantially evolve the risk/benefit trade-off of engaging in China.

This changing paradigm may require global pharma companies to reassess their positioning and strategies for accessing innovation in China.

Understanding the market as a foundation for success

Regulatory environment: China continues to make significant strides to establish an attractive environment for development, though regulatory risks and geopolitical uncertainties persist.

First, it is important for multinational companies to understand the market and how China has evolved its regulatory framework to attract investment in pharma innovation. By joining international regulatory frameworks like International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017 and updating its pharmacopeia in 2025,[8] China has demonstrated its commitment to global standards, fostering a more favorable environment for international stakeholders.[9] At the same time, cross-ministry policies such as national anti-corruption campaigns in the pharmaceutical sector[10] led jointly by the National Health Commission (NHC), National Medical Products Administration (NMPA), and other ministries, have expanded inspection scope to expand inspection and protect businesses operating in the market. Data protection laws and guidelines have similarly been bolstered, including through the establishment of four mechanisms for cross-border transfers of personal information, namely: (1) a security assessment; (2) the filing of the standard contract for cross-border transfer ("SC"); (3) a personal information protection certification; and (4) exempted scenarios. These measures, alongside clinical standards that are increasingly aligned with global norms, have helped to create a friendlier and more conducive environment for research and trials.[11]

Despite these tailwinds, conducting business in China involves certain risks that require careful assessment. Global players should remain mindful that, even with advances in clinical and data standards, key hurdles persist in data acceptance outside of China, and genetic data and plasma collection. Data acceptance outside of China continues to be a major concern among these matters: western regulators have demonstrated a reluctance to accept China-only data. There's a handful of examples of FDA approvals due to lack of non-Chinese patient data.[12]

Additionally, broader macroeconomic pressures and evolving geopolitical tensions add another layer of uncertainty and volatility that can influence both operations and capital allocation decisions. While China's evolving regulatory and investment climate has become increasingly attractive for multinational participation, navigating the market requires adapting to its unique business dynamics.

Understanding the advancements and innovation driven by Chinese biotech

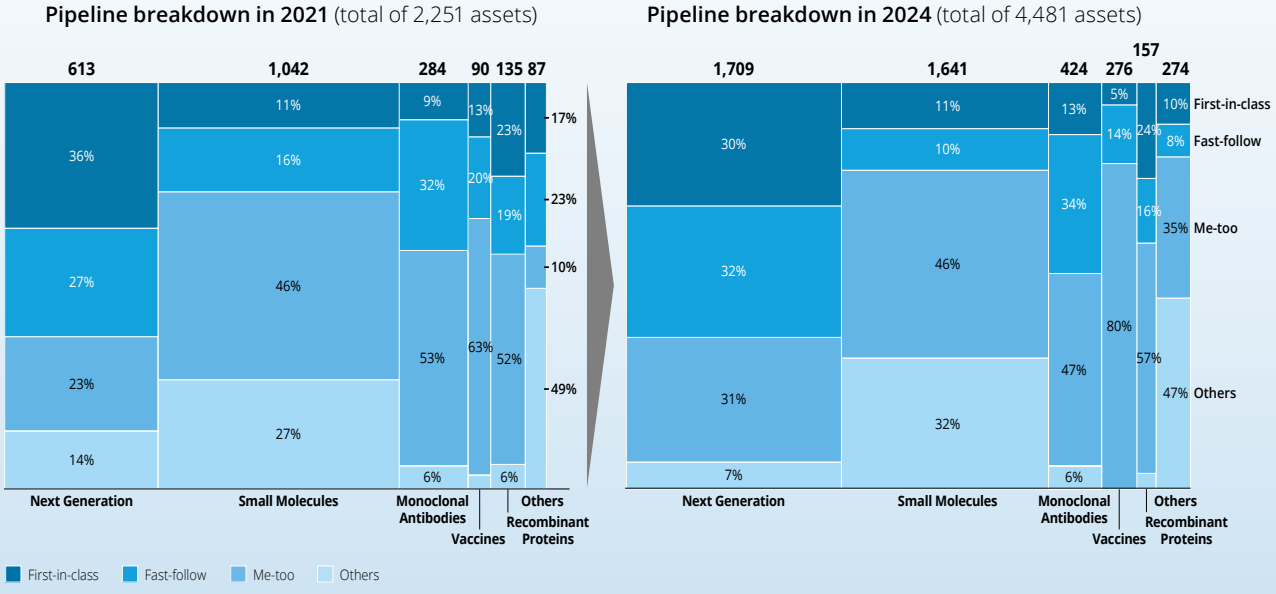
China's biopharma sector has grown into the world's second largest, with it accounting for approximately 31% of the global innovative drug pipeline.[13] This growth is underpinned by substantial government investment, regulatory reforms, and the integration of advanced technologies such as AI, cell and gene therapies, and radioligands. Additionally, Chinese cities like Shanghai[14] and Suzhou[15] have become innovation hubs, hosting thousands of life sciences companies and attracting both domestic and international capital.

China's growth in volume continues to be primarily driven by me-too and fast-follow products, which represent over 60% of pipeline products (Figure 1). However, research is weighted towards next-gen modalities, establishing China as a future leader in these new modalities.[16] By clinical trial volume, China is number one for Anti-body Drug Conjugate ("ADC") biologics globally as well as number two for both Cell and Gene Therapies and Bispecific Antibodies / Polyclonal Antibodies.[17] There is also an upward trend in First-in-class launches from China companies, with the National Medical Products Administration (NMPA) approving 48 domestic first-in-class drugs in 2024.[18,19]

China also continues to demonstrate diversity in therapeutic areas, with oncology (22% of 2024 registered clinical trials), metabolic (17%), and cardiovascular disease (13%) representing the top three development areas.[20]

Based on current trends, China may not necessarily be the global leader for "first-in-class" treatments for now but instead a center for more affordable "best-in-class" treatments.

Figure 1. Pipeline volume by molecule type



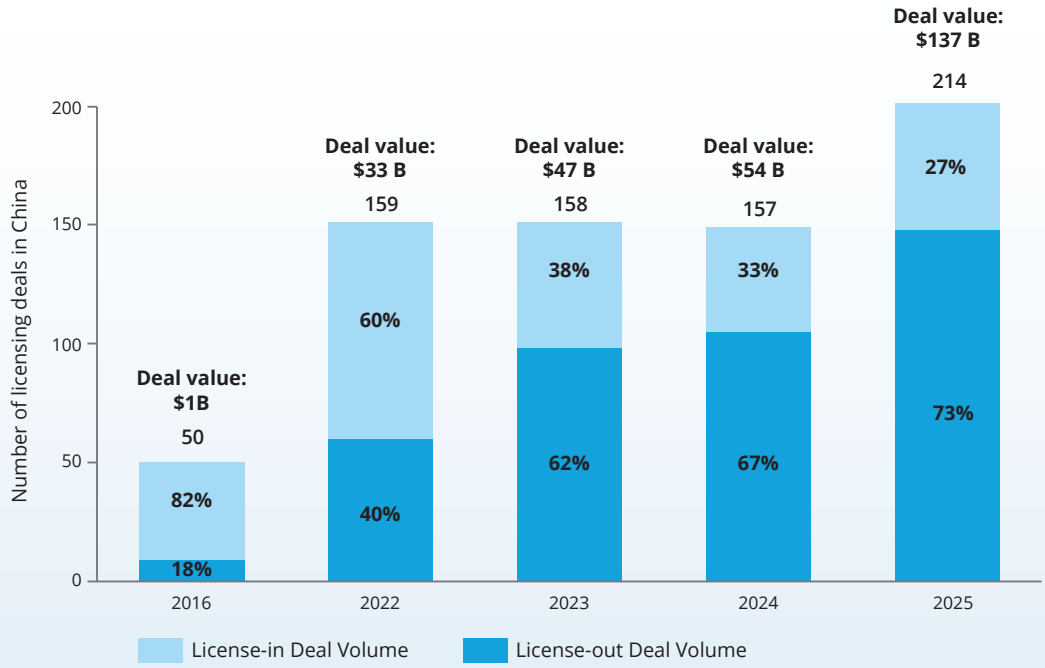
Source: Nature[20]

Note: [1] including drugs forming part of FDCs and those lacking sufficient information for categorization;[2] those not fitting into any existing categories.; drugs with novel targets or novel mechanisms of action (MOAs) were defined as either first-in-class or fast-follower based on whether or not they have class-leading clinical development status worldwide; drugs with the same targets and similar MoAs as already-approved drug classes were considered me-too. Source: Nature, Deloitte Research

Understanding deal-making activity and common deal structures

Parallel to the growth in development has been a change to both the scale and nature of deal-making activity in China as companies looked to take part in the evolving ecosystem. The number of annual global drug licensing deals involving Chinese companies rose from 50 in 2016 to 214 in 2025, accompanied by a 4x increase in total deal value for Chinese biopharma assets (Figure 2). In 2025, total deal value for Chinese biopharma assets reached approximately USD 137 billion (Figure 2). Three quarters of these licensing deals now involve the out-licensing of China-originated assets (e.g., therapies discovered and initially developed domestically, but commercialized by global collaborators), particularly in high-value areas such as oncology, rare disease, and immunology, indicating the growing international demand for China innovation.[21]

Figure 2: China growth in licensing activity (2016-2025)



Source: Deloitte analysis of Pharmcube, accessed on January 21

A wide range of players, from institutional investors to established Biopharma companies, have continued to make deals in China; however, the deal approaches that global biopharma companies leverage have changed over time. Based on Deloitte experience working with global biopharma clients, we have seen an increase in companies leveraging traditional out-licensing (typically of commercial rights outside of China) and M&A as well as innovative incubator and venture capital models to access innovation as part of "China for Global" strategies, as opposed to the more historic focus on "China for China" in-licensing deals.

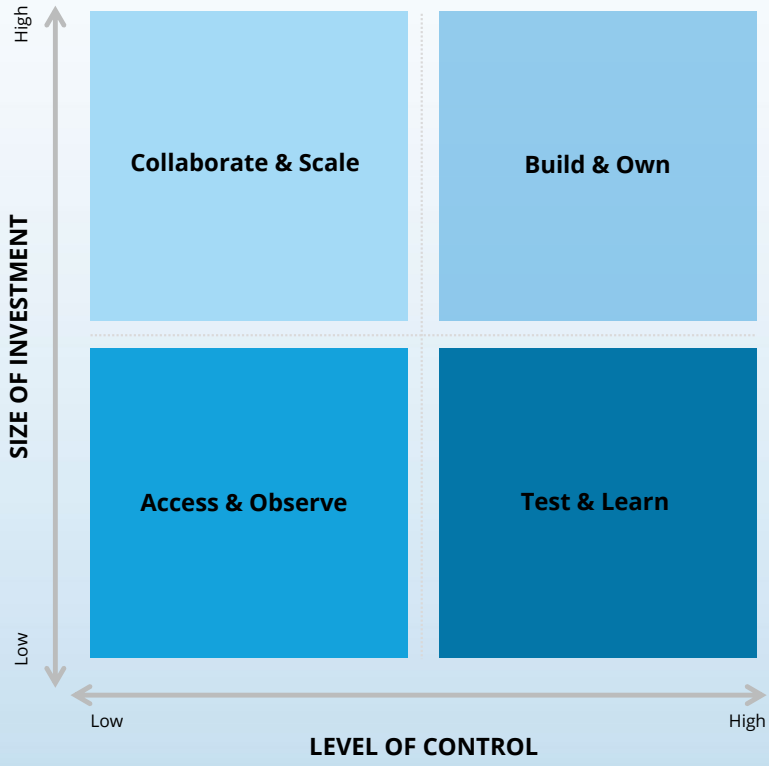
While there continues to be a robust pipeline for deal activity, the increase in participants, deal approaches and deal volume highlight increasing competition to access the quality opportunities, necessitating thoughtful strategy to prevent overvaluing assets and mitigate other risks.

Rethinking strategies to gain access to Chinese innovation

Successfully accessing innovation

As China cements its position as a global innovation hub, biopharma companies are rethinking how they participate in its ecosystem. The choice is increasingly not whether to participate, but how to do so in a way that balances control, speed, and risk. Four strategies are emerging, each with their own unique advantages, based on level of investment, risk appetite, and strategic ambition.

Figure 3: Strategies for accessing Chinese innovation



Source: Deloitte Global

Figure 4: Build and own

Building local presence fosters favorability amongst local participants and regulators. Though this approach requires a significant time horizon and long-term commitment, these participants may see advantages in market access for commercialization and tap directly into the advantages of cost-effective R&D in China.

	Clinical development & R&D capabilities	Enhancing operational efficiency through local CROs
Rationale	• Regulatory relationship building • Patient Recruitment speed • Reduced trial costs and timelines • Guarantees design, data, regulatory control	• Fast, low-risk China access • Rapid proof-of-concept validation • Cost-efficient CRO operations • Broader site/patient reach leveraging CRO network
Success Factors	• Register entity, secure licenses • Hire local leadership teams and build alliances with NMPA regulators • Onboard and train staff; introduce digital tools • Prioritize experienced multinational trial site activation • Establish compliant data systems and align protocols with global and Chinese standards • Implement automated audit trails and local retention	• Establish scorecards for vendor selection/ monitoring, select and vet CRO • Define governance and roles; assign local experts for oversight • Define contract scope and milestones • Establish approach to monitor CRO's compliance and define milestone-based payments • Establish joint SOPs and staff rotations for best practices • Implement routine audits, real-time monitoring to ensure compliance

Figure 5: Collaborate and scale

Leveraging local biopharma participants enables speed and comparative flexibility to react to changing market circumstances while accessing local know-how and channels via the established partner. However, loss of control is the trade-off for this flexibility. Having a trusted collaborator is essential for success.

	Expand through licensing	Strengthen through strategic partnerships
Rationale	• Rapid, cost-effective entry into China • Limit risk with milestone-driven deals • Leverage collaborator scale / local presence while maintaining flexibility	• Enable co-ownership (such as co-development and JV) and influence over a portfolio of assets • Platform-based collaborations to scale across multiple assets and capabilities • Combine complementary strengths together (e.g., innovation vs. clinical development) to unlock greater value • Preserve optionality to deepen collaboration or move toward acquisition
Success Factors	• Conduct diligence on IP, supply chain, liabilities, approval pathways and regulatory hurdles • Ensure strategic asset fit and ex-China reimbursement viability • Align governance on China/global rights and stand-up and ensure streamlined plans for tech transfer • Establish transparent, multi-level stakeholder engagement, including continuous collaborator management and compliance oversight • Engage international regulatory bodies to ensure approval pathway	• Clear data & IP ownership: Define boundaries upfront to protect long-term value and avoid disputes • Aligned incentives & governance: Establish robust governance mechanisms to ensure decision rights, accountability, and execution discipline • Partner interest protection: Balance control vs. autonomy to safeguard both parties' strategic interests • Cultural & operating fit: Ensure ways of working are compatible to enable effective collaboration at scale

Figure 6: Test and learn

Investing internal development capabilities to support co-development or collaborations with existing biotech companies and research institutions allows for relationship building without investment in a major on-the-ground footprint.

	Joint development	Collaborative research projects
Rationale	• Access to local innovation with top local biotechs • Share investment and development risks • Flexibility to shape relationship and development scope	• Cost-effective access to innovation • Tailor research to China-specific needs • Experiment with new, high-risk platforms • Leverage universities for sourcing, collaboration and scientific networks
Success Factors	• Establish joint governance and integrated teams, including performance milestones and escalation protocols • Align regulatory strategy and milestones • Enable transparent cross-border data sharing, including IP management systems • Align on resources required upfront and embed personnel for integration and adaptation • Codify step-out mechanisms for value protection	• Finalize clear legal and IP frameworks, including future-proof data security protocols • Ensure regulatory readiness and adaptability and allow for real-time project review with agile adjustments • Establish joint scientific review committees and stakeholder engagement approach • Secure ethics and institutional approvals • Implement joint accelerators advancing discoveries to translation

Figure 7: Access and observe

Tapping into early-stage innovators allows for a smaller investment while maintaining access to the local innovation scene. Partner-led incubators such as Lilly's Catalyst360 and Sanofi's Intrepid Labs build early relationships with startups through funding, lab space, and technical support. However, revenue upside remains less certain in these arrangements.

	Venture funding	Start-up accelerators
Rationale	• Early pipeline access • Influence research priorities, with minimal investment • Build ecosystem of relationships with key industry participants	• Early pipeline access at minimal risk and investment • Deep partnership building and capability knowledge exchange • Ability to pursue proof-of-concept, validating impact before scaling
Success Factors	• Conduct detailed diligence and align opportunities with business objectives • Structure investment around proven, high-impact solutions • Monitor and address regulatory requirements • Reinforce governance and proactive operational engagement for strong compliance and optimal results • Manage collaboration portfolio for maximum value and ensure flexibility for rapidly changing business aspects	• Embed teams and establish clear partnership agreement roles and expectations to deepen collaboration and speed outcomes • Enable open access and mentorship for faster innovation and development of local talent • Align early on IP and governance for smooth execution • Fast-track commercial readiness with targeted skills • Establish strong controls through clear policies, risk management and identify internal champions to drive collaboration initiatives

Source: Deloitte Global

High investment strategies:

- **Own and build:** Investing deeply into building a China footprint allows for long-term relationship building and favorability amongst local participants and regulators. Though this approach often requires a significant time horizon and long-term commitment, these participants typically see advantages in market access for commercialization and tap directly into the advantages of cost-effective R&D in China.
- **Collaborate and scale:** Leveraging local biopharma participants helps enable speed and comparative flexibility to react to changing market circumstances while accessing local know-how and channels via the established collaborator. However, loss of control is the trade-off for this flexibility. Having a trusted collaborator can be important for success.

Low investment strategies:

- **Access and observe:** Tapping into early-stage innovators allows for a smaller investment while maintaining access to the local innovation scene. Collaborator-led incubators are often used to build early relationships with startups through funding, lab space, and technical support. However, revenue upside remains less certain in these arrangements.
- **Test and learn:** Investing internal development capabilities to support co-development or collaborations with existing biotech companies and research institutions allow for relationship building without investment in a major on the ground footprint.

The strategy a given company chooses to deploy is often based on existing footprint; companies with smaller footprints today will likely choose to begin with lower investment strategies. These strategies, of course, are dynamic, with companies moving across approaches and often approaching multiple in parallel.

Regardless of path, success rests on three enablers:

1. Clarity on China's role within an organization's global strategy and overall portfolio strategy
2. Local know-how and boots on the ground – via trusted relationships or in-market capabilities and footprint
3. Institutional confidence and organizational agility to navigate evolving policy and geopolitical dynamics

Engaging with China's innovation ecosystem is no longer a tactical move—it's a strategic choice. Companies that align internal capability with external collaboration are more likely to access China's scientific strength and potentially convert it into a lasting global advantage.

Translating access into advantage

China's transformation into a biopharma innovation hub can help to redefine how global pharmaceutical companies compete for science, speed, and scale. The country now offers differentiated assets, clinical efficiency, and digital sophistication, but competition for access is accelerating. Companies that do not invest in local insight and evaluation may risk losing visibility into the most promising innovation. Yet even as reforms have improved predictability, risks remain, including data protection, IP enforcement, and an evolving geopolitical landscape. The right stance, therefore, is one of cautious optimism, to lean into China's growth potential but engage with structured diligence and strategic control.

For companies that engage with structured strategy, China may offer tangible ways to create global advantage:

- **Deepen local relationships:** Strengthen ties with universities, hospitals, and regulators to maintain access to emerging science.
- **Leverage trial efficiency:** Use China's Phase 1 and proof-of-concept infrastructure to help accelerate early development and "fail fast."
- **Apply AI and digital insights:** Translate lessons from China's AI-driven R&D ecosystem to global discovery programs.
- **Enhance market sensing:** Use advanced analytics and Generative AI (GenAI)-enabled forecasting to stay ahead of policy and competitive shifts.

Executed effectively, these strategies may turn engagement in China's ecosystem into measurable improvements in R&D productivity, speed, and innovation output.

Capturing value in China requires disciplined collaborator selection and strong governance. Alignment on data integrity, regulatory standards, and technical capability remains essential.

China's BD deal structures are rapidly evolving from asset-based licensing models toward deeper strategic partnerships, such as Co-Co models (co-development, co-commercialization, and profit sharing) and New-Co structures (jointly established entities). This shift reflects not only MNCs' move from asset acquisition to capability building, but also Chinese biotechs' increasing ambition to leverage partnerships for global expansion. However, deeper collaboration significantly increases operational complexity, particularly across data sharing, IP ownership and governance, and CMC and supply chain coordination. Companies will need to establish more sophisticated governance and operating models to enable cross-border, cross-functional integration. Going forward, the ability to effectively manage these complex partnership structures will be a critical determinant of BD success. Meanwhile, cross-border investment scrutiny and potential US technology-transfer restrictions, including Committee on Foreign Investment in the United States (CFIUS) reviews, underscore the need for adaptive compliance.[22] While we've seen a small number of Chinese companies be successful at globalizing, many still depend on multinational relationships to scale internationally providing ongoing opportunities for win-wins.[23]

Watch-outs and lessons learned

Given the risks inherent to the China market, companies should carefully evaluate different strategies and preemptively deploy mitigation solutions. Challenges we have seen many organizations face in accessing innovation in China can offer valuable lessons learned. Strategies may be less successful when:

- Global commercialization is not factored into R&D approach, leading to unforeseen development costs and/or lack of acceptance in foreign markets
- Global oversight and compliance pull-through mechanisms of local sites and collaborators are weak, leading to violations and reputational damage
- Lack of resilience in supply chain management, leading to future scalability challenges
- Deal decisions are driven by hype instead of alignment to long-term portfolio strategy, leading to dyssynergies and eventual divestment

Proper vetting, trust-building with local participants, and connection of China business development with broader organization strategic priorities are important to help mitigate downside risk and allow for success in China.

Conclusion

China's ascent as a biopharma innovator is no longer peripheral—it's central to the global innovation landscape. Access to the ecosystem alone may not create advantage; the differentiator lies in how effectively companies combine local presence, trusted relationships, and strategic agility.

Those that act early, evaluate rigorously, and execute with discipline are likely to be a part of in China's growth and help define the next era of global biopharma innovation.

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Acknowledgements

A special thank you to **Michiel ten Broeke**, **Ahmad Firdaus**, **Nick DeSimone**, **Alexandra Witt**, **Tingting Wu**, and **Bill Shen** for their support throughout the development of this paper.

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