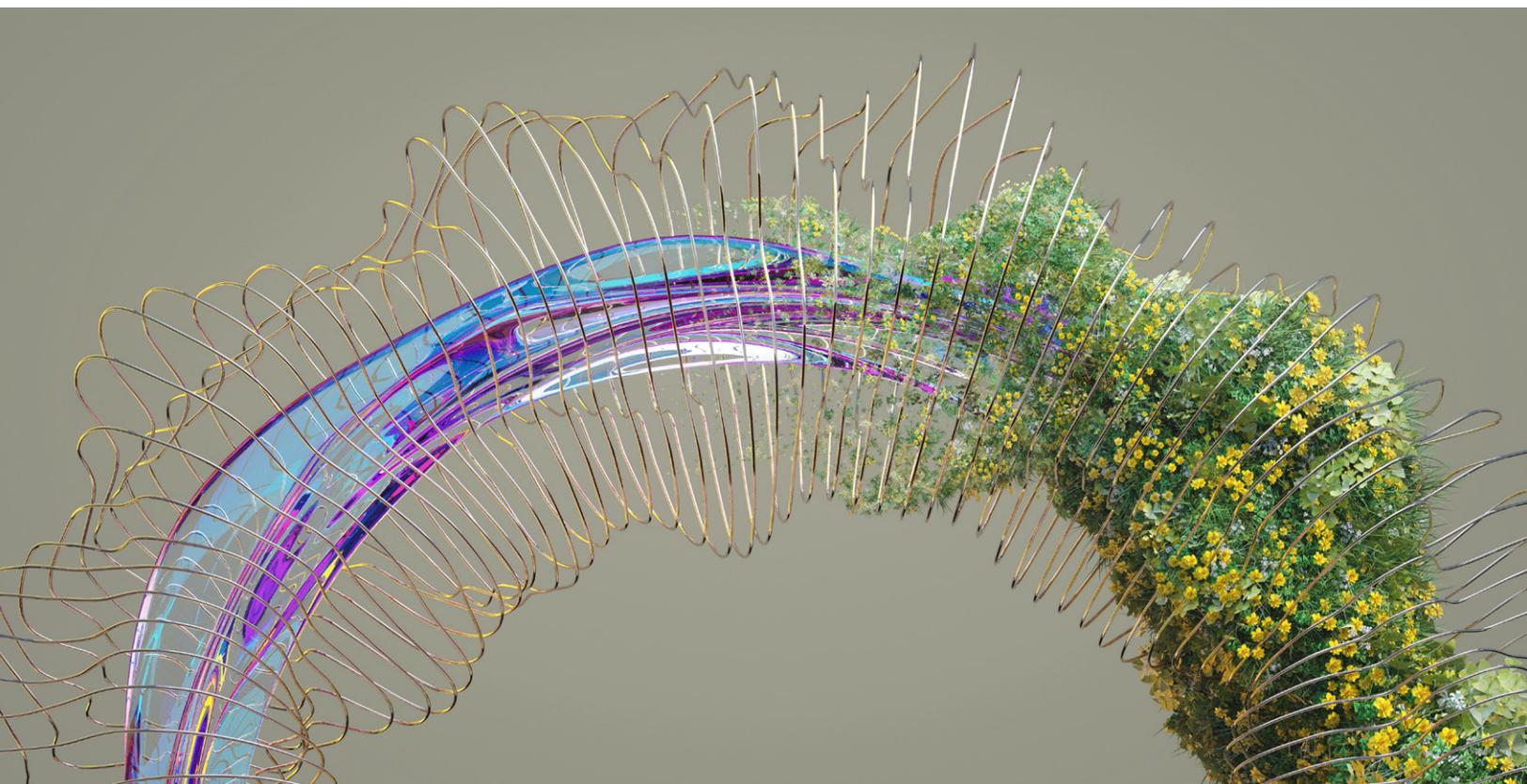


Life Sciences Practice

Vision 2028: How China could impact the global biopharma industry

Biopharmas originating in China will likely have greater influence on the industry by 2028, but regulatory developments and the quality of partnerships will determine how the industry grows.

This article is a collaborative effort by Jeffrey Algazy, Franck Le Deu, Sydnie Li, Fangning Zhang, and Josie Zhou, representing views from McKinsey's Life Sciences Practice.



It's no secret that China has had a growing presence in the global biopharma ecosystem since 2015. Last year, a McKinsey article outlined the key forces behind that emergence.¹ Those forces include regulatory reform, ready financing, and a fast-developing environment for biotech innovation.

Biopharma in China is nearing an inflection point that other Chinese industries, such as consumer electronics, have already passed through. That is, biopharma is no longer an “in China for China only” story, centered on the emergence of a market for innovative drugs in the country. Rather, it is an industry that could have a significant impact on the global biopharma value chain.

In this article, we discuss the impact that China will have on the global biopharma ecosystem by

2028. That's enough time to allow for considerable progress, but not so distant as to be disconnected from current strategy considerations.

To develop a perspective on the global biopharma industry in 2028, we delved into the available data, surveyed executives at some of the world's top biopharma companies, and conducted in-depth interviews with these executives and other market experts (see sidebar “Methodology”).

China's biopharma industry today

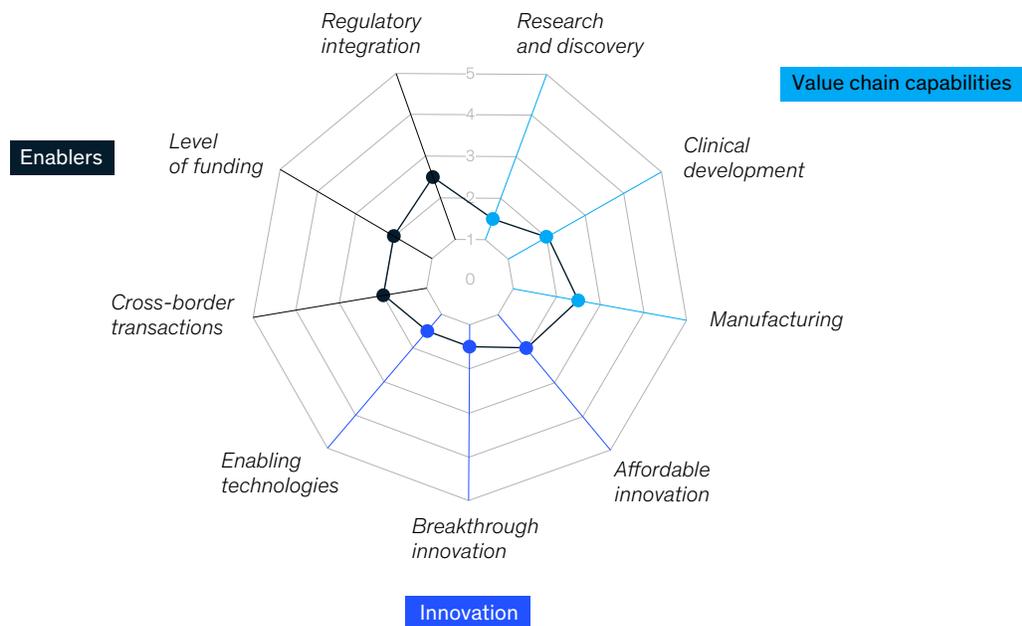
With a strong foundation in manufacturing, the industry has begun to embrace many international standards (Exhibit 1). China's biopharma innovation ecosystem has been evolving rapidly since 2015.

Exhibit 1

China's biopharmaceutical industry has both strengths and weaknesses, with generally low to medium levels of development.

China's biopharma industry today

Understanding the chart: The closer an activity's point is to the fifth outermost line (5), the higher its development. The closer an activity's point is to the center (0), the lower its development.



¹ Kiki Han, Franck Le Deu, Fangning Zhang, and Josie Zhou, “The dawn of China biopharma innovation,” McKinsey, October 29, 2021.

Methodology

This article has both quantitative and qualitative sources. The quantitative sources include data from BioCentury, BCIQ, Capital IQ, GBI Research, Pharmaprojects, and the World Intellectual Property Organization (WIPO). In addition, 50 senior executives, most of whom work for biopharma companies, shared insights

for the article. We also sought the views of several private-equity and venture-capital investors. Last, we conducted interviews with about two-thirds of the executives, and the remainder responded to written questions. About half of the participating executives are in China, while the rest are in the West.

We used the responses from these interviews and our own knowledge and experience to assess China's biopharma industry along nine dimensions (exhibit). These dimensions fit broadly into three larger areas: enablers, value chain capabilities, and innovation.

Exhibit

A nine-part framework can assess China's biopharma development.

Enablers	<ul style="list-style-type: none"> ● Regulatory integration Degree of continued integration within global regulatory framework, including application of pro-innovation regulatory changes in China 	<ul style="list-style-type: none"> ● Level of funding Ability to secure financing from both private investors and public markets, including potential to deploy funding outside of China 	<ul style="list-style-type: none"> ● Cross-border transactions Vibrancy of cross-border deal activities at both the asset level and company level
Value chain capabilities	<ul style="list-style-type: none"> ● Research and discovery Capability to contribute to global therapeutic innovation, including scientific breakthroughs of global significance 	<ul style="list-style-type: none"> ● Clinical development Capability to contribute to global clinical development pipeline across therapeutic areas and development stages 	<ul style="list-style-type: none"> ● Manufacturing Capability to supply global needs across modalities, including competitiveness to serve global requirements in quality and cost base
Innovation	<ul style="list-style-type: none"> ● Affordable innovation Scale of global contribution on innovative drugs with validated targets to expand patient access through lower prices and maintaining quality 	<ul style="list-style-type: none"> ● Breakthrough innovation Scale of global contribution on first-in-class or best-in-class assets achieved with scientific breakthroughs that significantly outperform current standard of care 	<ul style="list-style-type: none"> ● Enabling technologies Level of global impact of innovative enabling platforms, including new modalities (eg, cell and gene therapy) and new technology (eg, AI)

The following is an overview of China's status in the most important areas: enablers, value chain capabilities, and innovation.

Enablers

China and China-originated biotechs have made efforts to bolster enablers for industry growth

by improving and following regulatory policies, catching up to global levels of funding, and entering cross-border partnerships and transactions.

Regulatory integration. Since 2015, China has worked to bring its regulatory system more in line with global standards. For instance, it has more than quadrupled the number of reviewers at the Center for Drug Evaluation (CDE) from about 150 to more than 700,² helping to reduce the backlog of drugs that are awaiting approval. In 2021, the CDE introduced guidelines that put additional emphasis on patient centricity and clinical value. China also joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017 and has made a push to implement ICH guidelines. As of July 2022, China was close to implementing all of the initiative's Tier 2 guidelines.³

Level of funding. Chinese biotechs have benefited from a significant inflow of capital. Venture-capital (VC) funding to the sector tripled to \$12 billion in 2018–20 from \$4 billion in 2015–17, according to BCIC, creating a solid foundation for IPOs. As of early 2022, China lagged behind only the United States in the market capitalization of biotech companies that had launched since 2015. To broaden their access to capital, an increasing number of Chinese biotechs have listings on two, or even three, exchanges.

The enthusiasm has abated somewhat. Many biotechs listed since 2018 are trading below or close to their IPO valuations, and the window for financing has narrowed amid declining equity markets and a sense that biotech valuations are inflated.

Cross-border transactions. Between January 2020 and May 2022, Chinese biotechs entered 46 out-

licensing deals with US or European biopharma corporations and 160 in-licensing deals, according to healthcare data provider GBI. Out-licensing deals revolved around two primary models: partnerships with leading multinational biopharmas (partnership model) and tie-ups with medicine platforms that aim to deliver more cost-effective and accessible treatments to patients (medicine platform model).

An example of the partnership model is a 2021 deal in which the US company Seagen picked up ex-Asia rights⁴ to RemeGen's HER2-targeted antibody-drug conjugate (ADC), disitamab vedotin, for \$200 million up front (Exhibit 2). An example of the medicine platform model is the commercialization partnership that Etana Biotechnologies Indonesia has forged with several China-originated biotechs to bring those companies' products to Southeast Asia.

Value chain capabilities

By stimulating research, clinical development, and manufacturing, China has created a conducive environment for biotechs and biopharmas to develop drugs and stimulate the market.

Research and discovery. China has made inroads in innovative basic research and drug discovery, though its contribution to breakthroughs of global significance remains limited. According to *Nature* magazine's 2021 Nature Index, China now hosts eight of the world's top 100 life sciences institutes.⁵ That number is far behind the United States' 51 and Europe's 28, but is very close to the number of top institutes in the United Kingdom and Germany (nine and seven, respectively), the individual European countries with the most appearances in the index.

When it comes to publications, scholars from Chinese institutions ranked second in the world in authorship of biomedical papers from 2015 to

² *Fostering China pharmaceutical innovation system, Report 1: 2015-2020 Review and future outlook*, China Pharmaceutical Innovation and Research Development Association (PhIRDA) and R&D-based Pharmaceutical Association Committee (RDPAC), March 2021.

³ "ICH guideline implementation," International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), accessed July 19, 2022.

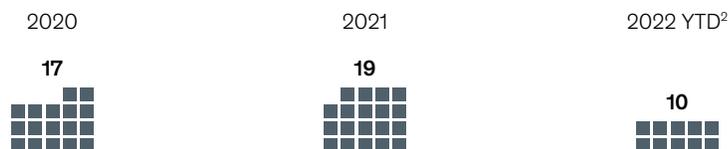
⁴ The rights to develop and commercialize a product outside of certain Asian countries.

⁵ Based on each country's share of articles published in 82 prestigious scientific journals selected by an independent panel of experts and tracked by the *Nature* Index database.

Exhibit 2

There are billions of dollars in outbound licensing deals for China biopharmas.

Out-licensing deals to US or European markets,¹ number of deals



10 of the biggest deals since 2020

Licensor	Licensee	Asset	Target	Most advanced China stage at closing	Upfront, \$ millions	Total deal size, \$ millions
BeiGene	Novartis	Tislelizumab	PD-1	Approved	650	2,200
BeiGene	Novartis	Ociperlimab	TIGIT	Phase 2	300	2,895
RemeGen	Seagen	Disitamab vedotin	HER2	Approved	200	2,600
I-MAB	Abbvie	TJC4	CD47	Phase 1b	200	1,940
Innovent	Eli Lilly	Sintilimab	PD-1	Approved	200	1,026
Junshi	Coherus	Toripalimab	PD-1	Approved	150	1,100 ³
CStone	EQRx	Sugemalimab	PD-L1	Phase 3	146	1,264
Innocal	Biogen	ICP-022 ⁴	BTK	Phase 2	125	930
Jacobio	Abbvie	JAB-3312	SHP2	Phase 1/2	45	885
Allist	Arrivent	Alflutinib	EGFR	Approved	40	805

¹Not including biosimilar and generic.
²Year to date (as of May 2022).
³Also including exercise fee and milestone payments for the licensing of two optional programs (if exercised) beyond toripalimab.
⁴InnoCare licensed autoimmune-related indication to Biogen and kept oncology-related indication.
 Source: GBI SOURCE; Pharma Deals

2020, during which time output grew at a CAGR of 14 percent (Exhibit 3). That said, Chinese authors have a lower share of articles than their global peers in leading journals such as *Cell*, *Nature*, and *Science*. Moreover, their share of what is called “core” research—research that constitutes a scientific breakthrough—has remained low.

Clinical development. The number of innovative assets under clinical development in China has

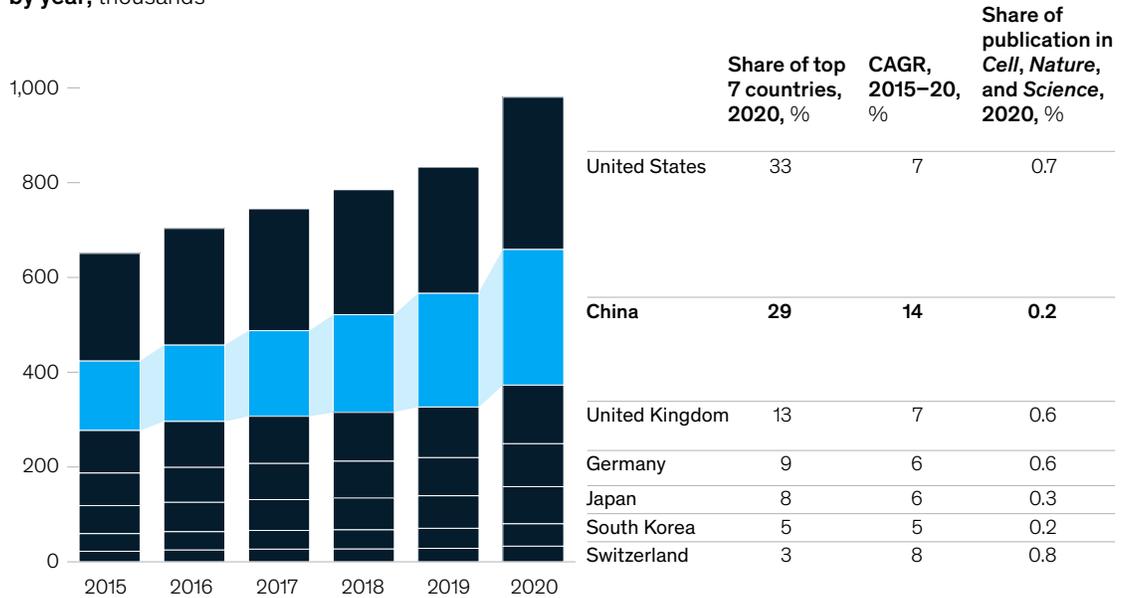
tripled in the past five years (Exhibit 4). Though Chinese biopharmas still mainly focus on continual development and rarely deliver first-in-class innovation, some of them are focusing on unique indications to make their molecules stand out. For example, Impact Therapeutics is trying to differentiate senaparib from two currently available PARP⁶ drugs, olaparib and temozolomide, with the idea that senaparib may work as a first-line maintenance treatment for advanced prostate cancer.

⁶ Poly(adenosine diphosphate-ribose) polymerase.

Exhibit 3

China's contribution to biomedical research is growing.

Biomedical papers by country of author affiliations, by year, thousands

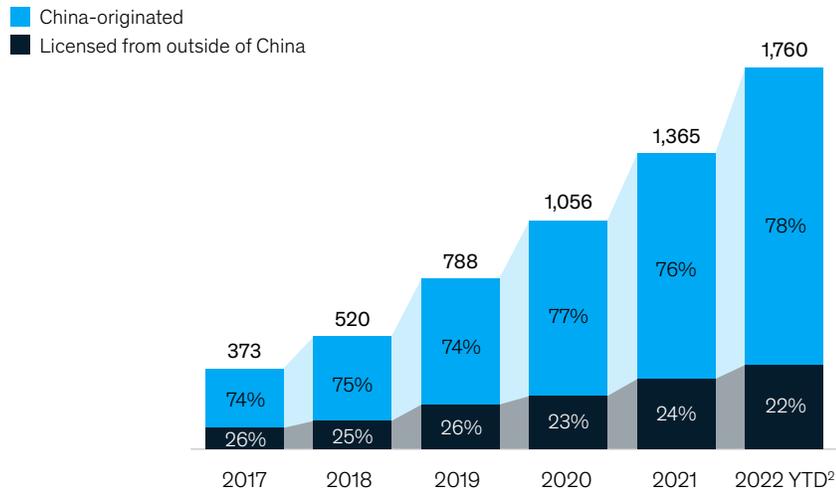


Source: PubMed.gov

Exhibit 4

China's clinical development pipeline is growing quickly.

Innovative assets¹ under clinical development in China, number of assets



¹Innovative assets include both chemical drugs and biologics whose global status is Phase I–III, or pre-registration.

²Year to date (as of May 2022).

Source: Pharmaprojects | Informa, 2021

Biopharmas in China have accelerated innovation. Although many developments and drugs are still in their early stages, they show great promise for the future of the industry in China and the world.

Another China-originated innovation that is already commercialized is BeiGene's zanubrutinib. Sold under the brand name Brunkinsa, zanubrutinib received breakthrough therapy designation, orphan drug designation, and accelerated approval from the US Food and Drug Administration (FDA) in November 2019 for the treatment of mantle cell lymphoma. And Legend Biotech's cell therapy is moving through European and US regulatory systems thanks to Legend's partnership with biopharma company Janssen.

On the whole, however, clinical development remains an area where China-originated biopharma companies are lagging behind. To get their products approved in the biggest markets, China's biopharma companies must get more experience navigating global regulatory pathways. For example, Innovent's sintilimab and Hutchmed's surufatinib were rejected by the FDA due to a lack of multiregional clinical trials that would have been more representative of the US patient population and better aligned to the current standard of care in the United States.

Manufacturing. China has proved itself to be a high-quality, cost-competitive manufacturing hub for small molecules, producing active pharmaceutical ingredients (APIs) and generics that regularly secure approval from the FDA and the European Medicines

Evaluation Agency (EMA). Chinese contract development and manufacturing organizations (CDMOs) are also extending their services into biologics, even as homegrown biotechs begin to develop the capability and capacity of independent biologics to secure quality and supply. China's top CDMOs and biotechs⁷ now account for about 7 percent of the world's monoclonal antibody (mAb) capacity. Many CDMOs are in the process of improving their manufacturing capabilities to bring them up to par with those of global leaders (see sidebar "China's expanding position in contract research, development, and manufacturing").

Innovation

Biopharmas in China have accelerated innovation. Although many developments and drugs are still in their early stages, they show great promise for the future of the industry in China and the world.

Affordable innovation. One of the first waves of these assets—which use new molecules to provide low-cost alternatives to first-in-class drugs as part of a “me too or me better” strategy—has reached the commercial stage in China and is coming to the attention of global markets. In 2021, approvals for new-drug applications from local players in China surpassed those from multinational companies (MNCs) for the first time (Exhibit 5).

⁷ This analysis is based on publicly available information about the top three China-originated CDMOs and top 20 biotechs (by market cap in 2021).

China's expanding position in contract research, development, and manufacturing

Chinese contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs) are an important part of China's biopharma initiatives. Some prominent CROs and CDMOs—such as Asymchem, Pharmaron

Beijing, and WuXi AppTec—received more than three-quarters of their revenues from non-China customers in 2021.

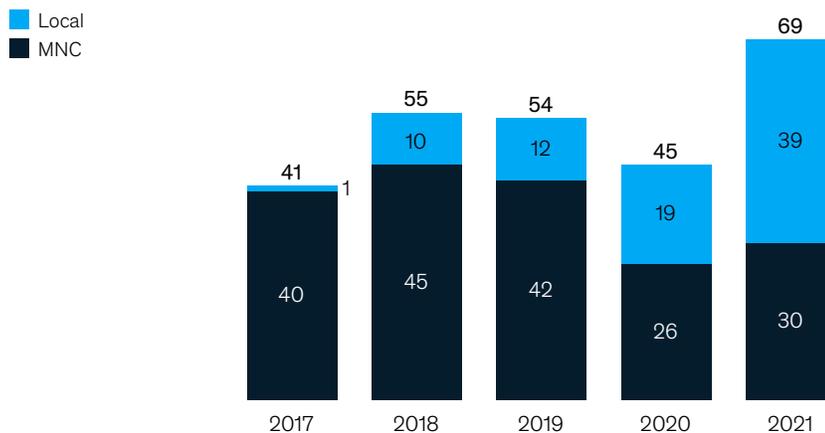
Some CROs and CDMOs are also expanding their geographical footprint.

A case in point is the decision by Shanghai-based CRO dMed to merge with Clinipace, a clinical research organization based in Raleigh, North Carolina.

Exhibit 5

Local drug approvals bypassed those of multinational corporations (MNCs) in 2021 and began to generate sizable revenue.

NDA approvals for innovative drugs, 2017–21¹



Notable examples² by commercial launch year, 2021 revenue, \$ millions



Note: References to specific products or organizations are solely for illustration and do not constitute any endorsement or recommendation.
¹New-drug application, including both innovative chemical drugs and biologics (class 1: innovative drugs that have not been marketed in China or overseas; class 5.1: original drugs and modified drugs that have been marketed overseas; class 3.1: biologics that have been marketed overseas).
²Includes only products launched in or after 2018.
³Estimated based on percentage of sintilimab's revenue contribution to Innovent's total product revenue.
 Source: Company annual reports 2021; GBI SOURCE

Whether the me-too and me-better drugs will become accessible outside of the home market and to patients worldwide is an open question. The challenge is evident in some recent FDA decisions to reject assets with exclusively Chinese clinical data.

Breakthrough innovation. Historically, most China-originated biopharmas have concentrated on a small pool of derisked mechanisms of action (MoAs) because that's what was in their pipelines, but this is beginning to change. More China biopharmas today are working on first-in-class MoAs, and some are at a more advanced stage of clinical development. In addition, a small fraction of

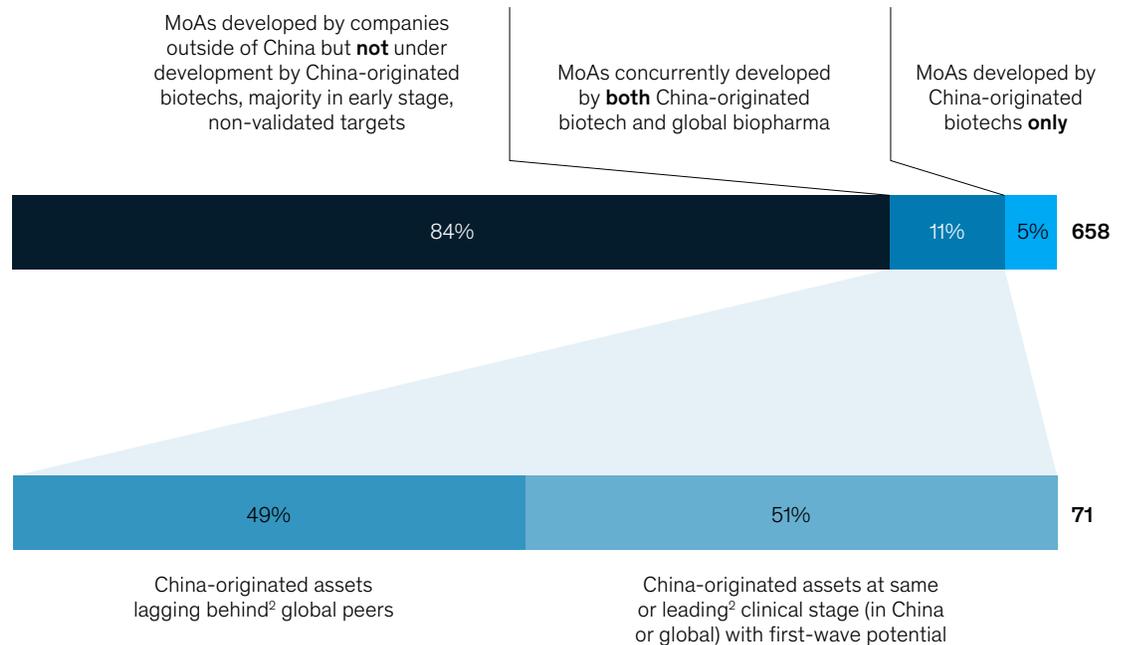
Chinese players are pursuing unique MoAs, albeit with uncertain potential (Exhibit 6). What happens as the China-originated therapies get deeper into the clinical pipeline will be an interesting development to see.

Enabling technologies. In 2021, several China-focused companies developed drugs using bispecific antibody or ADC platforms. Harbour BioMed was one of them; it used its proprietary platform to develop a bispecific antibody targeting CLDN18.2xCD3 and licensed it to AstraZeneca. Other young platform companies have positioned themselves to work in different modalities, such

Exhibit 6

China-originated biotechs have started to develop assets with global first-wave potential.

Global clinical-stage oncology mechanisms of action (MoAs)¹ breakdown by company origin



¹Including MoAs in Phase I–III and pre-registration stages, excluding MoAs with launched products. MoA numbers are counted by modality and target pairs. For small molecule, ADC, and mAbs, the MoA counts are evaluated using each single targets; for multivalent mAbs and CGT, the MoA counts are evaluated using the target combinations.

²Comparison based on most advanced global status (China and ex-China status combined).
Source: Pharmaprojects | Informa, 2021

as cell therapy, gene therapy, and messenger RNA (mRNA).

In addition, local AI-driven drug discovery (AIDD) companies, such as Insilico Medicine and XtalPi, are emerging as a key part of the value chain. This is evident in the attention they're getting from biopharma companies—attention that hasn't been lost on investors. Of the 20 largest pre-IPO

rounds of funding involving AIDD companies in 2021, seven involved companies in Greater China (Exhibit 7).

The capital that's flowing into AIDD is impressive, but this area of biopharma remains in a very early stage. Like their peers elsewhere, China's AIDD companies still need to develop the ability to integrate with pharmaceutical

Exhibit 7

There is strong funding for AI-driven drug discovery (AIDD) startups in China.

Global top 20 AIDD companies by pre-IPO funding¹

● Companies with headquarters in Greater China ● Companies with headquarters in ex-Greater China

Company	Headquarters	Funding, \$ millions	Company	Headquarters	Funding, \$ millions
XtalPi	Greater China	786	Schrodinger	United States	216
Insitro	United States	743	Atomwise	United States	177
Exscientia	United Kingdom	601	Xbiome	Greater China	124
Relay Therapeutics	United States	520	AccutarBio	Greater China	114
Recursion	United States	483	StoneWise	Greater China	110
BenevolentAI	United Kingdom	351	Standigm	Korea	72
Insilico Medicine	Greater China	316	Innoplexus	European Union	64
Owkin	United States	254	Zilliz	Greater China	56
Deep Genomics	Canada	241	Engine Biosciences	United States	53
METIS	Greater China	236	Evaxion Biotech	European Union	41

7
of global top 20
originated from China

31%
funding share
by Chinese players

Note: References to specific products or organizations are solely for illustration and do not constitute any endorsement or recommendation.
¹As of May 2022.
 Source: Crunchbase; McKinsey analysis based on PitchBook data

R&D expertise, secure clinical validations, and replicate efficiency improvements to other modalities and MoAs.

Pivotal factors for China’s biopharma development in the coming years

Four interrelated factors will determine China’s impact on the global biopharma value chain in the next five to ten years (Exhibit 8).

Integration into global regulatory and health systems

Integration is the most obvious step that biopharmas must take as China-sourced innovative therapies seek to reach patients worldwide.

China-originated biopharmas face many challenges in navigating overseas regulatory systems and institutions. The first challenge is to provide clinical data that meet thresholds that are already in place. Western regulators typically ask for patient populations that reflect their own region’s demographics, which limits the value of China-only trials. Another challenge for China-originated biopharmas revolves around data and rigor. The clinical practices and trial data of China-originated biotechs must fully meet the FDA and EMEA’s requirements on data disclosure and data security as well as consider the evolving standard of care in specific indications.

China’s implementation of the remaining ICH guidelines—an effort that is supposed to conclude shortly—would be an important milestone. Still, in the current geopolitical climate, it remains to be seen whether China’s transition to tighter regulations and global practices will be accepted by overseas regulators and other healthcare ecosystem stakeholders.

Another component of integrating with global health systems is understanding the systems of payers, pharmacy benefit managers, physicians, and patients elsewhere. Without this understanding, China-originated biopharmas will not be able to gain broad acceptance for their innovations.

Evolution of the local access environment

The first market that must work for Chinese biopharma companies is the Chinese market itself. For this to happen, it’s not enough for a domestic company’s innovative new drug to receive approval in China—the drug must also be accessible to patients.

This can happen in three ways. First, the demand for a drug can be so high that patients are willing to pay for it out of pocket. Second, the drug can be covered by commercial health insurance plans. Third, and arguably most important, the drug can be added to the National Reimbursement Drug List (NRDL). China is now updating the NRDL annually, which is good news, but the rewards for innovation

Exhibit 8

Developing these four areas will determine how far China’s biopharma industry can go.

1

Integration into global regulatory and health systems to play a pivotal role in determining whether China-sourced innovative therapies can reach patients worldwide

2

Evolution of the local access environment to further reward China-originated innovation

3

Upstream innovation capabilities (basic research, translational research, discovery) and ecosystem to drive scientific breakthroughs at scale

4

Organizational adaptiveness toward global companies’ practices as more venture outside of home market

are not yet sufficient to guarantee increasing R&D investments by local biotech companies. This remains a counterweight to what might otherwise be the positive effects of the NRDL's expansion.

Upstream innovation capabilities

China is making good progress in improving its life sciences institutions and related academic talent pools, but the country still has work to do to be on par with the world's leading seats of biopharma research. The country continues to face hurdles in the pace and scale of scientific breakthroughs and in a lack of mature ecosystem mechanisms to transfer these research and intellectual property advances into the biopharma pipeline.

Organizational adaptiveness

If China-originated biopharmas are to succeed in building businesses with truly global footprints—able to get funding from investors in different countries and to operate wherever they want to—they will have to adapt their operating models, embrace diverse working practices, and attract talent from all over the world.

Three growth scenarios: Continued momentum, stunted, and transformative

We see three basic impact scenarios: continued momentum, stunted, and transformative. Of these, we believe the “continued momentum” scenario is most likely, so we have devoted the most space to it in our analysis below. The “stunted impact” and “transformative impact” scenarios are more extreme views of 2028, and neither is likely to materialize in its entirety. Both, however, provide pointers that may be useful on the trajectory of specific industry segments within China's biopharma sector.

1. Continued-momentum scenario

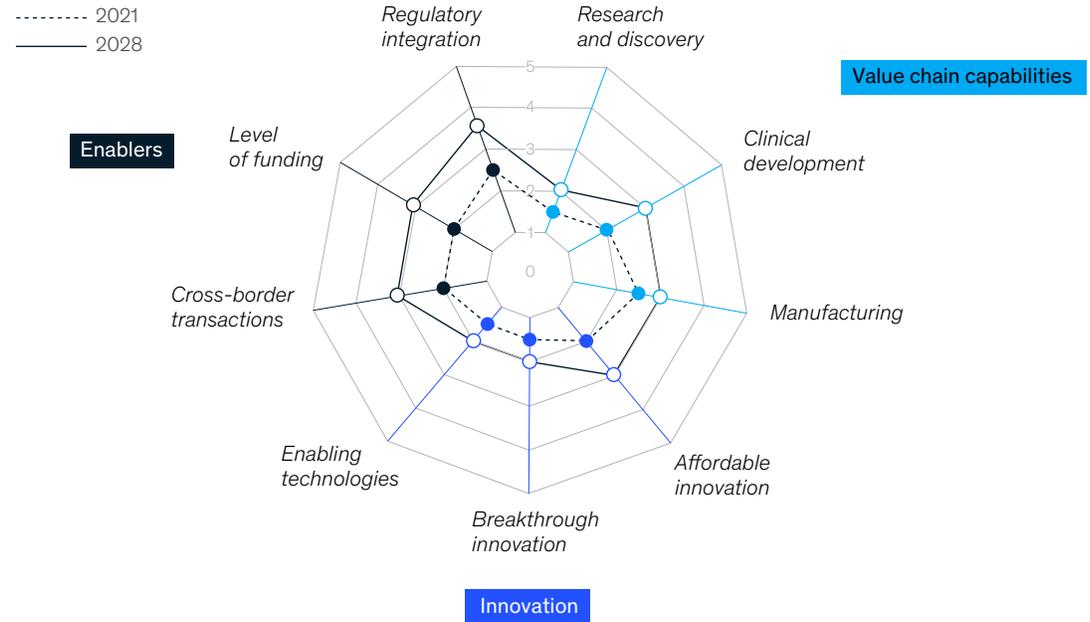
Under this scenario, China's integration into the global biopharma value chain will, overall, continue to progress at its current strong pace. But progress won't be uniform; some value chain capabilities, such as manufacturing, will evolve rapidly, while others, particularly the innovation dimensions, will move more slowly. In this scenario, discovery, development, and manufacturing are further integrated into the global biopharma industry value chain, driving the emergence of China-originated global leaders in certain areas (Exhibit 9).

China is making good progress in improving its life sciences institutions and related academic talent pools, but the country still has work to do to be on par with the world's leading seats of biopharma research.

Under the continued-momentum scenario, most activities will achieve medium development by 2028.

Development in 2028 under continued-momentum scenario

Understanding the chart: The closer an activity's point is to the fifth outermost line (5), the higher its development. The closer an activity's point is to the center (0), the lower its development.



Selected China-originated biotechs will continue to increase their capabilities and scale in this scenario and expand to new regions. Indeed, this is already happening, as shown by recent moves from China to the United States and Europe by BeiGene, Hengrui, Hutchmed, Innovent, Legend Biotech, and Zai Lab. Members of this early wave of China-originated biotechs are globalizing their investor bases, operations, talent pools, and cultures.

On average, the executives we surveyed believe that by 2028, China-headquartered companies will account for eight of the top 50 global pharmaceutical companies by prescription medicine (Rx) sales (if generics are included). That would be twice the representation that China had in 2020 but still less than what Japan has today (nine companies). The executives expressed some

doubts about the reception that China-originated affordable innovation would get in the United States and European Union, with only one-third of executives saying they believe Chinese innovations will penetrate those markets at scale. China's affordable innovations are likely to have more acceptance in Southeast Asia, the Middle East, and Latin America.

As for breakthrough innovations, we expect that by 2028, a handful of China-originated biotechs will have strong enough pipelines that some of their innovations will be in drugs that have received, or are close to receiving, FDA approval. Such breakthroughs from China-originated biotechs are likeliest in the areas of oncology, small molecules, and mAbs. While some biotechs may try to commercialize these assets on their own, others will

enter codevelopment and copromotion deals with global biopharmaceutical partners.

We have identified three enablers, three value chain opportunities, and three innovations that fall under the continued-momentum scenario:

Regulatory reform and integration advances.

Under a continued-momentum scenario, the healthy trajectory of regulatory developments will continue, and global regulatory integration will encounter no major barriers. For this to happen, Chinese companies must make significant changes. The FDA has already signaled that its approvals will depend on data from multiregional trials; it's possible that EU regulators will do the same. In the meantime, Chinese companies should be incubating the ability to operate in several markets and developing the expertise to deliver data packages that can survive intense regulatory scrutiny. Multiregional clinical trials will mean higher costs for China-originated biopharma companies, which could lead to more partnerships to share development costs and risks.

Level of funding. An ongoing market downturn has affected the fortunes of many early-stage companies, forcing them to focus on short-term cash preservation, prioritize their various initiatives, and find faster routes to differentiation. History suggests the difficult funding environment won't last indefinitely and that better days will return. When they do, companies with portfolios or technology platforms that focus on highly unmet therapeutic needs will have the best access to financing and will be able to scale.

Our interviews reflected this optimism about funding. Virtually none of the executives cited insufficient funding as a source of uncertainty in the next five to ten years. Even China's *14th five-year plan for the development of the pharmaceutical industry*, released amid capital market volatility in 2022, calls for biopharma R&D spending to grow more than 10 percent per year through 2025.⁸

Cross-border transactions. The vibrant asset transaction activity of the past few years continues under the continued-momentum scenario, enabled by a broadening of differentiation-focused pipelines and an increase in MNCs' familiarity with China-originated biotechs. Our interviewees support this view. They see more significant cross-border transactions taking place in the next three years. About half of the interviewees expect that China's innovation landscape will consolidate in the years ahead. A more differentiated pipeline of novel modalities, pursuing a wider set of targets, will likely mean an increase in cross-border deal volume and quality.

Slow progress in research and discovery. China's biopharma companies have the most work to do in research and discovery, according to the executives we interviewed. Our respondents gave these areas the lowest scores, both for current value chain capabilities and for China's likely capabilities in 2028 (Exhibit 10). However, both areas are gaining strength, according to our respondents, who also anticipate additional developments that underpin scientific breakthroughs and biology-based translation.

We agree that China will continue to make progress in research and discovery, but we also believe that early-stage discovery capabilities will take time to mature. China's biggest impediments to developing leadership in this area are a lack of a talent pool to effectively transfer innovation from academia to industry and weak collaboration among scientists, medical, and industry professionals.

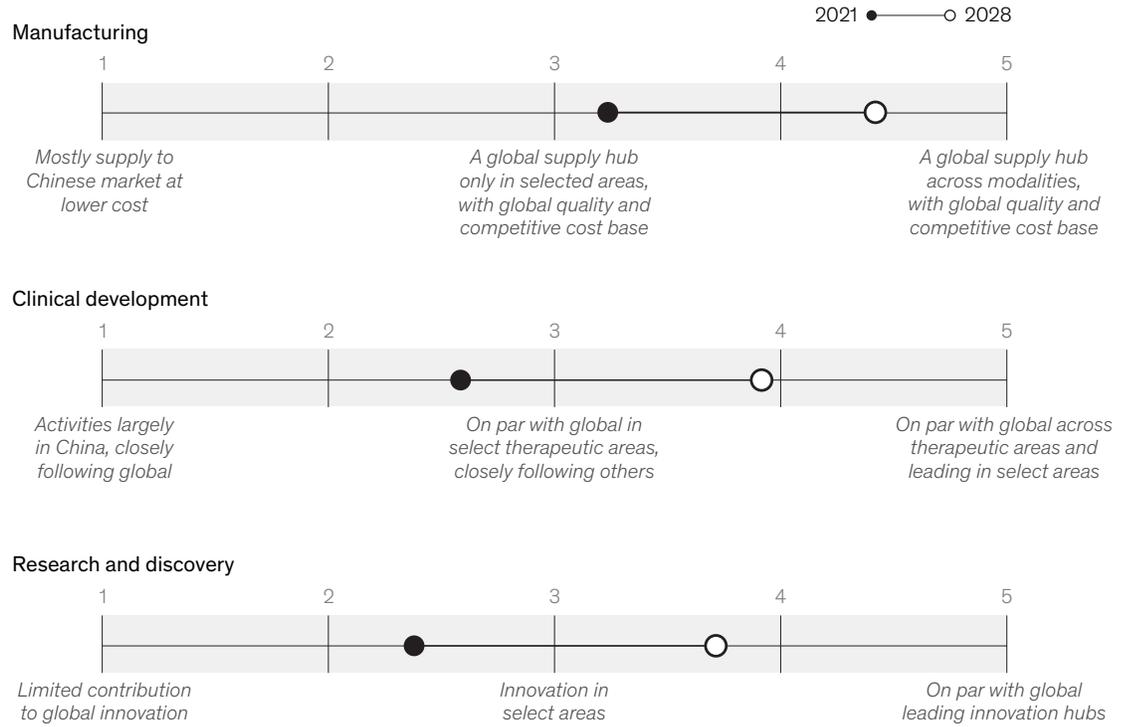
Rapidly maturing clinical-development capabilities. China-originated biopharmas are catching up quickly with global peers in selected therapeutic areas, and their late-stage development capability is improving, especially in areas where they're using a fast-follower strategy. However, China still lags behind in early-stage explorative clinical development and novel trial design. The executives we surveyed

⁸ Hilton Yin, "New trend of China's pharmaceutical industry as indicated in the 14th Five-Year Plan of Pharmaceutical Industry Development Plan," Dentons, May 9, 2022.

Exhibit 10

Value chain capabilities are projected to moderately improve by 2028 under the continued-momentum scenario.

How would you rate China’s capability in manufacturing, clinical development, and research and discovery in 2021 and by 2028? Average score on a scale of one to five, n = 33



Source: McKinsey Impact of China Biopharma on Global Survey, 2021, n = 33

see the early development of innovative assets improving over time and expect China to close the gap with overseas leaders in therapeutic areas beyond oncology.

Increased manufacturing capability. The executives we interviewed see China cementing its position as a global supply hub by expanding into small molecules and additional modalities. In effect, they said that manufacturing—a top capability today—will continue to advance, remaining the biopharma

industry’s most advanced capability in 2028. One sign of continued progress will be in biologics, with China’s top CDMOs and biotechs⁹ expected to double their capacity to manufacture mAbs from 2021 to 2023.

Affordable innovation will catch on in selected markets. China-originated biopharmas are already pushing to get wider international distribution for products in this category. This is certainly one of the reasons why Jiangsu Hengrui Pharmaceuticals, one

⁹ This analysis is based on publicly available information about the top three China-originated CDMOs and top 20 biotechs (by market cap in 2021).

of the largest biotech companies in China, is basing its recently launched Luzsana Biotechnology unit in New Jersey, a state with a high concentration of pharmaceutical companies. The experts we interviewed generally don't expect affordable innovation from China to enter EU or US markets at scale by 2028. Their doubts reflect a perception about complex stakeholder dynamics—in particular, the expectation that powerful incumbents would create resistance.

Chinese innovation will likely get a better reception in developing economies—specifically Southeast Asia, the Middle East, Africa, and Latin America. These are all highly populous places where access to innovative drugs is still limited by cost and other factors. Fast-follower or me-too and me-better therapies are an attractive proposition for local payers and patients in these places. The distribution of affordable medications in these regions could, of course, be handled directly by the China-originated developer of the medications. But it wouldn't have to be. A partnership with a multinational pharma company or an emerging platform player, such as Etana or US-based EQRx, could also handle distribution.

Few and sporadic breakthrough innovations.

Despite holding overall positive views about future innovation in China, our experts are less sure of China's ability to develop a reputation for disruptive breakthrough therapies by 2028. The real question in our respondents' minds is whether, six years from now, any of the high-profile breakthrough innovations in the European Union or United States will be China-originated. Survey and interview results revealed a clear divide between Chinese and non-Chinese executives in answering this question. Two-thirds of the Chinese executives we talked to said they think they and other China-originated companies will have best-in-class or first-in-class biopharma assets in Western markets by 2028, but fewer than a third of non-Chinese executives expect this to happen.

Still, Chinese and non-Chinese executives agreed that China could stand out for its

innovations in oncology, monoclonal antibodies, and small molecules.

The wait for innovative technology platforms. It's still early days for China-originated technology start-ups in the drug R&D space. But some companies in China are making strides and could end up on the forefront of technology-enabled drug discovery and development. AI drug development, cell and gene therapy, and mRNA show particular promise.

2. Stunted-impact scenario

The likelihood of a stunted-impact scenario has increased over the past year. Understanding this scenario is important given its implications for patients worldwide.

This scenario would come about if geopolitical relations deteriorate to a point where key enablers, notably regulatory integration, take a step backward (Exhibit 11). If this happens, China's access to major global biopharma markets will become much more limited. The FDA or EMEA might stop recognizing China-based trial data, in effect precipitating a return to pre-2017 conditions—that is, when China wasn't part of the ICH and approvals in China required China-based trials. As a result, other countries might similarly decide not to recognize China-based trial data. VC funding dries up in this scenario, and MNCs significantly scale back their investments in the China market. The development of value chain capabilities is constrained to a narrow scope of services, such as the provision of APIs.

This is an adverse scenario for all involved, with predictable consequences for each set of stakeholders:

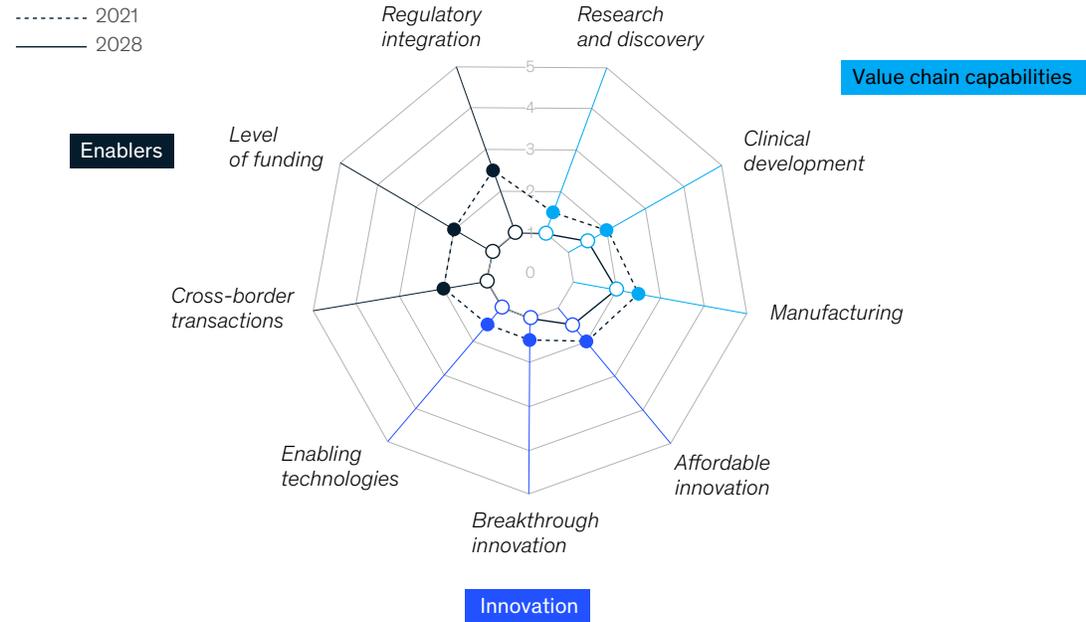
China's patients and biopharma industry.

In China, MNCs would make investments less of a priority, which would significantly reduce access to innovative drugs for Chinese patients. The domestic industry's ability to innovate would stall, and any hopes of globalization for local industry participants would be delayed indefinitely.

Under the stunted-impact scenario, all activities will have low to very low development by 2028.

Development in 2028 under stunted-impact scenario

Understanding the chart: The closer an activity's point is to the fifth outermost line (5), the higher its development. The closer an activity's point is to the center (0), the lower its development.



Patients elsewhere and overall biopharma development. In the rest of the world, industry participants—both small biotechs and larger biopharmas—would lose access to China’s development and manufacturing platforms, negatively affecting the cost and speed of innovation-driven programs. As a result, patients worldwide would lose out on broader access to both more affordable innovative medicines and China-originated novel-mechanism drugs. This would have a disproportionate impact on regions with limited drug access and rapid population growth, such as Africa and Southeast Asia.

3. Transformative-impact scenario

In our most positive scenario, China’s integration into the global biopharma ecosystem accelerates,

and China-originating biopharmas become MNCs with global footprints. Transformative impact is the least likely of all our scenarios, but the implications—greater innovation and greater access to affordable medicines all over the world—are so far-reaching that this scenario deserves a bit of attention.

In this scenario, China grows into a leading hub for high-quality, cost-competitive innovation, meeting global needs across therapeutic areas and modalities, including cell and gene therapies. In some areas, such as contract research organization or contract development and manufacturing organization service provision, China assumes global leadership, leveraging its scale and process optimization capabilities to nurture more dynamic biotech clusters. The increased standing of its biotech industry makes partnerships with

global counterparts a common occurrence and enables China-originated companies to make more acquisitions of non-China companies, especially small and medium-size enterprises. China-originated innovations also get the widest distribution under this scenario (Exhibit 12).

An integrated China biopharma industry—one seen as equal, from a regulatory standpoint, to counterparts in the European Union, Japan, the United Kingdom, and the United States—would enhance competition. Patients would benefit from a stronger pipeline of breakthrough drugs as China brings its own innovation strengths, complementing those of the European Union and the United States. High-quality innovative treatments would end up in the hands of a larger global patient pool, creating

positive impact on healthcare in the developed world and transforming access conditions in developing markets. Realizing the transformative-impact scenario would enable the industry to fulfill its collective purpose on a much wider scale, but geopolitical trends and conditions make this scenario rather unlikely.

Capitalizing on China’s probable momentum

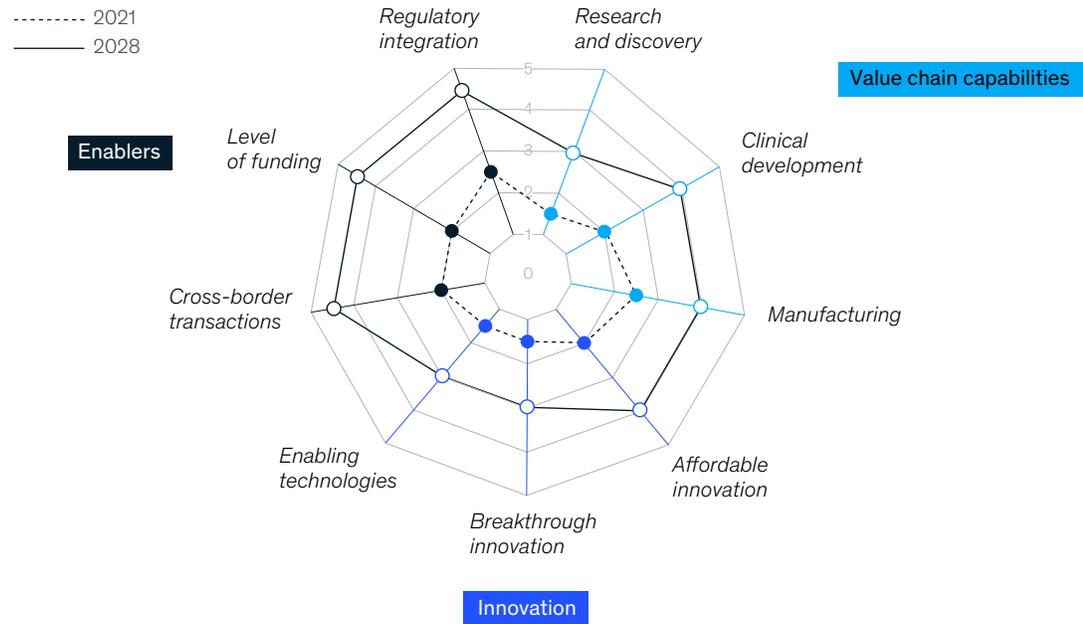
For now, every party with a stake in China’s biopharma ecosystem can proceed on the assumption that the continued-momentum scenario will materialize. The realization of this scenario would be important for biopharma companies

Exhibit 12

Under the transformative-impact scenario, most activities will achieve high to very high development.

Development in 2028 under transformative-impact scenario

Understanding the chart: The closer an activity’s point is to the fifth outermost line (5), the higher its development. The closer an activity’s point is to the center (0), the lower its development.



For now, every party with a stake in China's biopharma ecosystem can proceed on the assumption that the continued-momentum scenario will materialize.

everywhere, not just in China. Here's how MNCs and China's biopharmas should prepare.

What MNCs should do

MNCs will play an important role in the growth of China-originated biopharmas and the industry itself. MNCs stand to gain from the future of the pharmaceutical industry in China by committing to the following steps:

Improve the capability to forge local partnerships.

The decrease in biotech funding, coupled with China-originated biopharmas' goal of getting their product portfolios in front of a more global audience, makes the next few years an excellent time for partnerships. To have a chance to do deals with the most promising companies and to expand their reach into the local innovation ecosystem, MNCs should build on-the-ground capabilities or elevate the capabilities they already have. This will help them identify and assess attractive partnership opportunities early on. MNCs should also accelerate their decision making so that when a good opportunity comes along, they can pounce on it.

Adopt a flexible operating model in China. The many biopharma MNCs that have increased their presence in China must find the best ways to operate there. These ways won't be the same for every global biopharma. Growth objectives, the

competition for talent, value chain complexity, and, of course, the ongoing COVID-19 pandemic (with its impact on cross-border travel and on executives' willingness to relocate) all create a challenging environment. Companies will need to make careful choices based on their own aspirations for China in the context of their overall businesses.

Act with urgency. Now is not the time to take a "wait and see" approach. Global biopharmas should reevaluate their strategies in China and start aligning their organizations to tap local innovation and accelerate their involvement in China's burgeoning innovation ecosystem. They mustn't stand still.

What China's biopharmas should do

China-originated biopharmas have come a long way in recent years, but they still have a long way to go to catch up with the biopharma industries of some other countries. China-originated biopharmas can continue their growth and global influence by taking the following actions:

Navigate near-term capital market challenges.

Recent market volatility underscores the need for biotechs to be more disciplined about allocating capital.¹⁰ For some companies, the next two or three years will feel like a fight for survival. Companies facing cash constraints may need to reprioritize

¹⁰Olivier Leclerc, Werner Rehm, Lydia The, and Peter Wright, "How biotechs can rethink their strategies after the market downturn," McKinsey, May 11, 2022.

their portfolios, enter partnerships to share development and commercialization costs, or delay major investments. By conserving cash, companies can continue to develop the assets already in their pipelines without giving up their ability to place strategic long-term bets.

Shift the focus to unmet patient needs. Chinese biopharmas' emphasis on mature MoAs reflects their generally risk-averse approach to clinical development. It has also often left China-originated biopharmas in crowded therapeutic areas, limiting their ability to have an impact on patients' lives. In the future, companies should pay much more attention to unmet medical needs. This could take many different forms—for instance, targeting a novel mechanism or adopting a differentiated development strategy. Clinical differentiation backed by robust data is essential to securing sustainable advantage.

Find viable globalization pathways. Chinese biopharmas that want to go global via partnerships with MNCs must first articulate what they want to get out of those partnerships. Should they aim to learn about Western markets so their efforts in those markets can be more successful? Do they want to leverage a partner's financial muscle and existing operation, or is their goal to fill in their own capability gaps? Answering these questions will help Chinese companies draw up short lists of the best potential partners.

Jeffrey Algazy is a senior partner in McKinsey's New Jersey office, **Franck Le Deu** is a senior partner in the Hong Kong office, **Sydney Li** is an associate partner in the Beijing office, and **Fangning Zhang** and **Josie Zhou** are partners in the Shanghai office.

The authors wish to thank Kiki Han, Rufus Ng, Menglu Qian, Yinying Ren, Yi Shao, Guang Yang, Peiheng Zhang, Alex Zhao, and Kexian Zhu for their contributions to this article.

Designed by McKinsey Global Publishing
Copyright © 2022 McKinsey & Company. All rights reserved.

Partnering won't be central to every China biopharma's strategy. The companies that are more interested in organic market development will need a multimarket culture, a globally scalable operating model, and a sound approach for attracting global talent. They will also need a strong corporate brand.

China's biopharmaceutical industry has made great strides in some crucial areas, including manufacturing and its clinical development pipeline. Many China-originated companies have secured the growth capital they need or entered partnerships with mature Western biopharma companies. Some have even built facilities in the biopharma hot spots of Europe and the United States. This growth has assuaged any doubt about their aspiration to reach global patients.

Regulatory issues and geopolitical uncertainty could still get in the way, causing China's biopharma industry to stall or move backward over the course of this decade. But our most likely scenario predicts that China-originated biopharmas will build on their accomplishments and become bigger contributors to the global biopharma ecosystem by 2028. This would also mean more innovation globally and more benefits for patients throughout the world.