

## Transforming Healthcare: The Evolution of Biopharmaceutical Innovation in Mainland China

Over the past few years, biopharmaceutical research has undergone a significant evolution, significantly impacting the pharmaceutical industry and healthcare systems worldwide. This change has been particularly notable in Mainland China, where the government has prioritized the development and innovation of the biopharmaceutical sector as a national strategic initiative. The policies implemented over the past decade have fostered an environment conducive to innovation and have positioned Mainland China as a formidable player in the global biopharmaceutical arena.

The drive for this transformation can be traced back to several key initiatives launched by the Chinese government. Specifically, the 'Made in China 2025' strategy focuses on ten crucial sectors, including biopharmaceuticals. Meanwhile, the 'Healthy China 2030' initiative aims to increase the value of the health service industry to 16tn yuan by 2030. Additionally, the '14th Five-Year Plan for Pharmaceutical Industry Development' also aims to create innovation hubs in ten cities to enhance regional capabilities and promote collaboration within the biopharmaceutical ecosystem.

Mainland China has been committed to reforming its drug review and approval processes, which has been crucial for developing of its biopharmaceutical industry. Since 2015, a series of reforms have aimed to streamline these processes, reduce approval times, and improve patients access to innovative therapies. These reforms include establishment of a marketing authorization holder (MAH) system and a priority review pathway for innovative drugs. The impact of these changes is evident in the increasing number of new drug applications and approvals, in recent years.

As a result of these initiatives, Mainland China now ranks second alobally in terms of innovative drug contributions to the global pipeline, accounting for approximately 23% of new drugs. The country has also become a hub for international clinical trials and collaborations. further integrating itself into the global biopharmaceutical innovation ecosystem. The Clarivate™ data presented in this report illustrates the quantitative growth in drug approvals and highlights qualitative advances in drug development strategies that prioritize patientcentered care and clinical efficacy.

The importance of medical insurance reform cannot be overstated. The establishment of a multi-level medical security system aims to improve access to innovative drugs while ensuring affordability for patients. The National Reimbursement Drug List (NRDL) has been expanded to include numerous innovative therapies, showing a commitment to enhancing patient access while negotiating prices that balance healthcare costs with industry sustainability.

This report thoroughly analyzes the biopharmaceutical landscape in Mainland China over the past decade. It highlights the significant progress made in regulatory reforms, innovation capabilities, and collaborative efforts that have collectively positioned China as a leader in biopharmaceutical development. It is evident that ongoing investment in research and development, along with supportive policies and international collaboration, will be crucial for maintaining this momentum.

The proposed U.S. BioSecurity Act represents a pivotal moment for international biopharmaceutical relations, particularly affecting Mainland China's pharmaceutical industry. While it poses challenges such as increased regulatory scrutiny and potential trade barriers, it also opens avenues for domestic growth and innovation within Mainland China. As both nations navigate this evolving landscape, the longterm impacts will depend on how effectively each country adapts to changing geopolitical realities in the biopharmaceutical sector. The interplay between national security interests and global collaboration will shape the future of pharmaceutical innovation across borders.

The journey so far has been marked by significant achievements and transformative changes. However, stakeholders must remain vigilant and proactive in addressing emerging challenges within this dynamic field. The insights provided here not only celebrate past successes but also serve as a roadmap for future efforts to improve healthcare outcomes for patients domestically and globally. Clarivate is committed to helping all stakeholders achieve these goals.



**Henry Levy** 

President, Life Sciences & Healthcare, Clarivate

Looking ahead, it is evident that ongoing investment in research and development, along with supportive policies and international collaboration, will be crucial for maintaining this momentum.

# How will the pharmaceutical industry operate in the next decade?

The pharmaceutical industry is poised for significant and transformative changes in the upcoming decade, driven by heightened competition. Rapid innovation and intense competition have reshaped market dynamics, leading to more focused and sustainable growth. It's important to acknowledge that the landscape is evolving, and we must adapt to thrive in this new environment.

To create lasting value, companies should prioritize enhancing quality and efficiency while emphasizing product differentiation and cost advantages. The global pharmaceutical market is now heavily influenced by insurance systems, signaling a shift from reliance on out-of-pocket expenses. Notably, the transition towards innovative drugs is gaining momentum in Mainland China as comprehensive medical insurance coverage now favors these groundbreaking treatments over generic options.

As competition in Mainland China intensifies, pharmaceutical companies increasingly explore opportunities in international markets. Venturing into the innovative drug sector requires global engagement to share the high R&D costs of developing new drugs.

Currently, the global pharmaceutical market is dominated by the U.S. (over 40%), Europe (20%), and China (10%). Despite the U.S. and Europe representing more than 40% of global GDP, they only comprise 15% of the world's population. On the other hand, countries involved in the Belt and Road Initiative, including China, represent two-thirds of the global

population and contribute 40% of the global GDP, showcasing immense potential for growth and collaboration.

The size of regional pharmaceutical markets is significantly influenced by GDP and purchasing power, with price playing a pivotal role. Historically, innovative drugs have been associated with high prices, limiting accessibility primarily to economically developed countries.

In many developing countries, the requirement for FDA approval for new drugs may pose challenges due to the high costs associated with clinical trials. This creates barriers to affordability and accessibility for these countries.

As we embark on this new decade, Chinese pharmaceutical companies must prioritize innovation and international expansion. Traditional companies transforming must address the fundamental question of their readiness for innovation. This signifies the need for experience in research and development and the scientific expertise required for innovation. Successful transformations have highlighted the significance of organizational culture in fostering these essential attributes.

Organizational change should not revolve solely around competing with multinational corporations. Instead, it should focus on enhancing internal effectiveness and developing innovative short—and long-term strategies within a unique business framework.

In the past decade, China's pharmaceutical industry has experienced remarkable advancements, including faster review processes, national medical insurance coverage negotiations, centralized procurement bidding, and participation in international regulatory organizations. Efforts such as revising China's Patent Law in 1993 and regulatory reforms in 2015 have contributed to a surge in innovation, marking the beginning of a new era for China's pharmaceutical sector.

As we look ahead to the next decade of innovation, it's crucial to learn from past experiences and remain focused on opportunities rather than succumbing to anxiety about environmental uncertainties. Adopting a forward-thinking mindset can pave a resolute path toward a future filled with promise and growth.



#### Tan Yong

Vice President of China Pharmaceutical Enterprises Association, Publisher of Healthcare Executive

### Data sources

Clarivate has compiled this report using extensive data, proprietary technologies and tools trusted by customers in the global life sciences field.

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## Clarivate contributors

#### Mike Ward

Global Leader of Thought Leadership, Life Sciences & Healthcare, Clarivate

#### Alice Zeng

Senior Consultant, Life Sciences & Healthcare, Clarivate

#### Shuxin Bao

Senior Consultant, Life Sciences & Healthcare, Clarivate

#### Fanney Wu

Consultant, Life Sciences & Healthcare, Clarivate

#### **Boya Zhang**

Healthcare Research & Data Analyst, Life Sciences & Healthcare, Clarivate

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In recent years, there have been significant advances in basic life science research on a global scale, leading to a period of remarkable growth and innovation in the biopharmaceutical industry. This has made the development and innovation of the pharmaceutical sector a strategic priority for many countries.

23%

of the global pipeline for innovative drugs is attributed to Mainland China. Over the past decade, Mainland China's pharmaceutical and healthcare industry has been elevated to a national strategic level, thanks to an actively encouraging and supportive policy environment. The government has issued a series of documents to promote the innovation and upgrading of Mainland China's biopharmaceutical industry. For instance, the 'Made in China 2025' initiative specifically focuses on ten key areas, including biopharmaceuticals and high-performance medical devices. Additionally, 'Healthy China 2030' has set a strategic goal for Mainland China's health service industry to reach 16th yuan by 2030. Furthermore, the '14th Five-Year Plan for Pharmaceutical Industry Development' aims to support approximately 10 cities in building innovation hubs for the pharmaceutical industry. Moreover, the '14th Five-Year Plan for Bioeconomic Development' seeks to enhance original innovation capabilities, strengthen the growth of industrial innovation forces, build high-level biopharmaceutical innovation clusters, and actively integrate into the global biopharmaceutical innovation system.

Against this backdrop, Mainland China has developed a comprehensive biopharmaceutical ecosystem covering regulatory review, medical insurance payment, basic research capabilities, substantial capital investment, and enterprise innovation capabilities to drive Mainland China's biopharmaceutical innovation. This has led to significant achievements and has positioned Mainland China as a major player in the global pipeline of innovative drugs. Mainland China now ranks second in the world for the number of innovative drugs, contributing 23% to the global pipeline. Additionally, Mainland China has been actively involved in international multi-center clinical trials and has engaged in diverse global development collaborations. Clarivate's thorough data analysis aims to showcase the evolving trends and successful outcomes in Mainland China's biopharmaceutical innovation over the past decade. We commend all those who have contributed to Mainland China's biopharma evolution and look forward to continued progress in the coming decade.

# 01 Continuous reform of the drug review and approval process in Mainland China is driving high-quality development of innovative drugs.

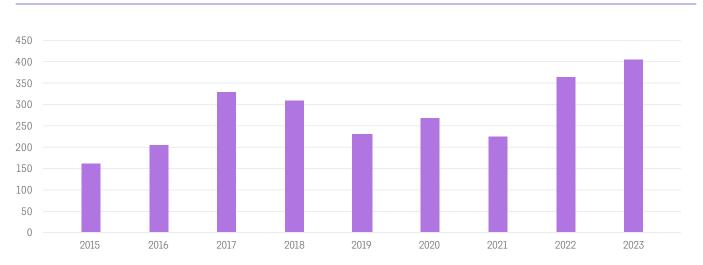
Continuous drug review and approval reform significantly shortens the review and approval time for innovative drugs and promotes rapid development of innovation

Since 2015, the Mainland Chinese government has been implementing a series of reforms to the drug review and approval system to promote innovation in the biopharmaceutical industry. The Opinions of the State Council on the Reform of the System of Evaluation, Review and Approval of Drugs and Medical Devices in 2015 and the Opinions on Deepening the Reform of Review and Approval System to Encourage Innovation of

Drugs and Medical Devices in 2017 have provided strategic guidance for this development. These reforms have focused on combating data fraud, reducing review backlogs, improving standards for new drugs, streamlining the approval process, and promoting innovation in the industry. The reforms have also led to more Mainland Chinese patients gaining access to the latest global therapies at an earlier stage.

Key aspects of the reforms include self-inspection and verification of drug clinical study data, the implementation of a marketing authorization holder (MAH) system, drug registration classification, consistent evaluation of generic drug quality and efficacy, a priority review and approval system, policies to encourage drug innovation, a clinical study registration system, and strengthening of Good Laboratory Practice/Good Clinical Practice.

Figure 1: Number of newly issued regulatory documents on drugs and biological products and medical devices in Mainland China from 2015 to 2023.



Source: Cortellis Regulatory Intelligence™ from Clarivate

## The reform of drug review and approval can be divided into three stages based on the timeline and key achievements:

#### The first stage

The first stage (July 2015 - early 2016) focused on creating a more effective drug regulation and review system. This included eliminating the backlog of drug registration applications, combating data fraud, and ensuring data authenticity and integrity. The pilot program of the MAH system was introduced to enable R&D institutions and researchers with limited production capacity to carry out new drug clinical trial applications or new drug applications. Additionally, the redefinition of drug registration categories brought Mainland China's new drug definition in line with global standards.

#### The second stage

The second stage (2016-2019) aimed to encourage innovation from four perspectives: acceleration of the approval process, clinical trial management, life cycle management, and protection of the rights and interests of innovators. The Mainland China Food and Drug Administration established a list of marketed drugs and a drug patent linkage system, initiated a pilot program for drug patent term compensation, and implemented a clinical trial data protection system. In June 2017, the Mainland China Food and Drug Administration joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), marking a significant step towards aligning with international standards. In addition, comments from the public were solicited forthe Amendment to the Drug Administration Law of the People's Republic of China (Draft for Comments) and the Provisions for Drug Registration (Revised Draft).

#### The third stage

The third stage (from 2020 to present) focuses on encouraging 'patient-centered, clinical value-oriented' R&D strategies, avoiding homogenization, internal competition, and waste of social resources. The National Medical Products Administration (NMPA) launched the Scientific Action Plan for Drug Administration in Mainland China, with the strategic goal of establishing a scientific, efficient, and authoritative drug regulatory system. This plan aims to closely align with international regulatory development standards and accelerate the research and application of new regulatory tools, standards, and methods.

The redefinition of drug

registration categories brought

Mainland China's new drug definition

in line with global standards.

Figure 2: Industry trend in three-year moving median IND approval time, from IND application to IND approval, for NASs in China from 2012 to 2023.

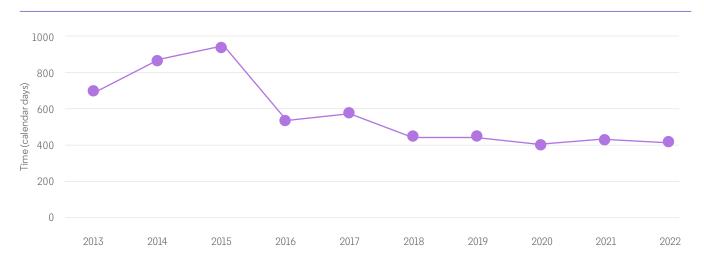


Mainland China — IND submission to IND approval

Data are shown for NASs where the IND approval from the authority was between 2012 and 2023. The value for each year reflects a three-year moving median, e.g., the value shown for 2013 reflects median IND approval time for the years 2012-2014.

 $Source: CIRS* Growth \& Emerging Markets Metrics Program \ an industry \ benchmarking \ program \ providing \ comparative \ data \ and information \ on the regulatory environment in growth \ and \ emerging \ markets.$ 

Figure 3: Industry trend in three-year moving median **approval time**, from NDA submission to NDA approval, for NASs in China from 2012 to 2023.



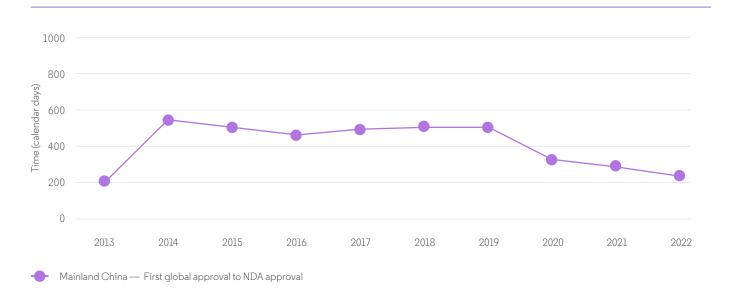
Mainland China — NDA submission to NDA approval

Data are shown for NASs where the NDA was approved by the authority between 2012 and 2023. The value for each year reflects a three-year moving median, e.g., the value shown for 2013 reflects median NDA approval time for the years 2012-2014. Approval time includes both agency and company time.

Source: CIRS\* Growth & Emerging Markets Metrics Program an industry benchmarking program providing comparative data and information on the regulatory environment in growth and emerging markets.

<sup>\*</sup> The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to pharmaceutical products.

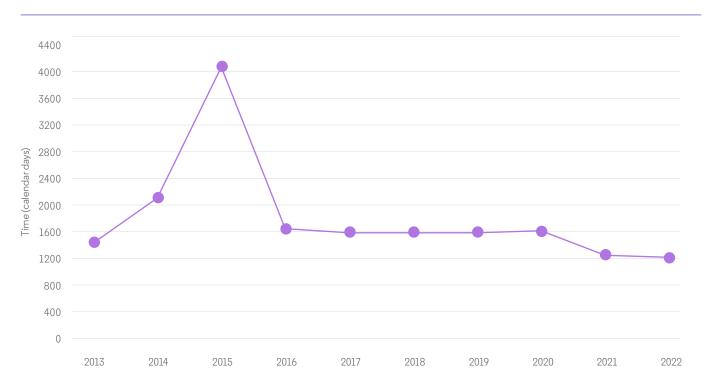
Figure 4: Industry trend in three-year moving median **submission lag**, from first world approval to NDA submission, for NASs in China from 2012 to 2023.



Data are shown for NASs where the NDA was submitted to the authority between 2012 and 2023. The value for each year reflects a three-year moving median, e.g., the value shown for 2013 reflects median NDA submission lag for the years 2012-2014.

 $Source: CIRS* Growth \& Emerging Markets Metrics Program \ an industry \ benchmarking \ program \ providing \ comparative \ data \ and information \ on the regulatory environment in growth \ and \ emerging \ markets.$ 

Figure 5: Industry trend in three-year moving median **roll-out time**, from first world approval to NDA approval, for NASs in China from 2012 to 2023.



Mainland China — First global approval to NDA approval

Data are shown for NASs where the NDA was approved by the authority between 2012 and 2023. The value for each year reflects a three-year moving median, e.g., the value shown for 2013 reflects median NDA roll out time for the years 2012-2014.

 $Source: CIRS* Growth \& Emerging \ Markets \ Metrics \ Program \ an industry \ benchmarking \ program \ providing \ comparative \ data \ and \ information \ on the regulatory \ environment in \ growth \ and \ emerging \ markets.$ 

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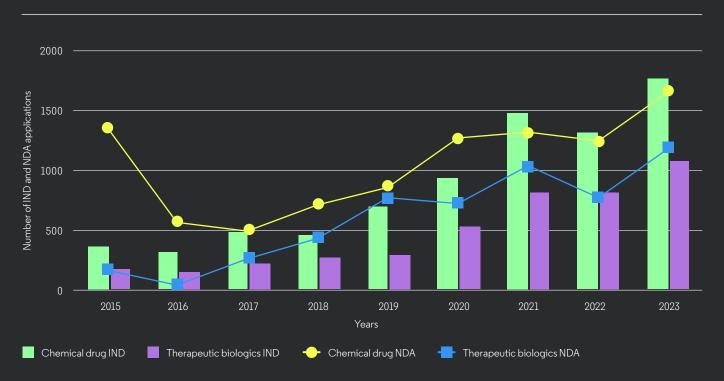
#### Policy dividends from drug review and approval reform continue to be released, accelerating the pace of innovative drug launches

more Class 1 and 2 new drug approvals in 2023 compared to 2018. After introduction of clinical trial data verification in 2015 and the redefinition of new drugs according to international standards in 2016, Mainland China's new drug registration and application process went through a short adjustment period. Starting from 2017, the number of IND and NDA applications gradually increased. According to Clarivate statistics, in 2023, small molecule chemical drugs still made up the majority of IND applications for new drugs in Mainland China, although their proportion slightly decreased.

Simultaneously, due to continuous progress in the development of therapeutic biologics, the number of NDAs for these products increased from 9% in 2015 to 42% in 2023.

Since 2021, the number of new drug approvals has been rapidly increasing. Dozens of innovative drugs are now being approved for marketing each year, which benefits a wide range of patients. In 2023, the number of Class 1 and 2 new drug approvals was 89, which is more than seven times the number approved in 2018 (12 based on approvals).

Figure 6: Number of IND and NDA applications in Mainland China from 2015 to 2023.



As regulatory systems gradually align with international standards, global multinational pharmaceutical companies are actively promoting the faster and earlier entry of their innovative drugs into the Mainland Chinese market. They are striving to achieve simultaneous development and launch. Boehringer Ingelheim's spesolimab (Spevigo) for the treatment of generalized pustular psoriasis in adults was officially approved for marketing in Mainland China in December 2022, only three months later than the approval by the U.S. Food and Drug Administration (FDA)<sup>2</sup>. This was the first innovative drug for the treatment of generalized pustular psoriasis in adults that essentially achieves simultaneous R&D, registration, and approval in Mainland China and globally. In addition, the time difference between Mainland China's approval and the first global approval for Pfizer's JAK3 inhibitor ritlecitinib (LITFULO) capsules<sup>3</sup> and Roche's glofitamab (COLUMVI) was only 4-5 months<sup>4</sup>.

In a recent industry benchmark study report from Clarivate Centre

for Medicines Research (CMR), it was noted that Mainland China has emerged as the world's third largest country for the initial global launch of innovative drugs, following the U.S. and Japan. This share has been increasing steadily over the years. Both local innovative drug companies in Mainland China and multinational companies are choosing Mainland China as the first country for the global launch of their drugs. For instance, in December 2018, the globally first-inclass oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) called roxadustat (EVRENZO), jointly developed by AstraZeneca and FibroGen, was approved for marketing by the NMPA<sup>5</sup>. Similarly, in February 2024, Roche Pharmaceuticals' humanized anti-complement protein C5 monoclonal antibody, crovalimab (PiaSky) injection, was approved for marketing in Mainland China for the treatment of adult and adolescent (≥12 years old) patients with paroxysmal nocturnal hemoglobinuria who have not received complement inhibitor therapy<sup>6</sup>. According to the public announcement by the NMPA, this drug was developed simultaneously worldwide and approved for marketing in Mainland China first.

study report from Clarivate Centre

100

80

60

40

2018

2019

2020

2021

2022

2023

Chemical drugs

Therapeutic biologics

Figure 7: Number of Class 1 & 2 new drugs approved in Mainland China from 2018 to 2023.

Note: The number of new drugs approved is calculated based on the number of approvals for Class 1 and Class 2 chemical drugs and therapeutic biologics in the new registration classification. Statistics do not include traditional Chinese medicine.

Source: Cortellis Regulatory Intelligence™ from Clarivate

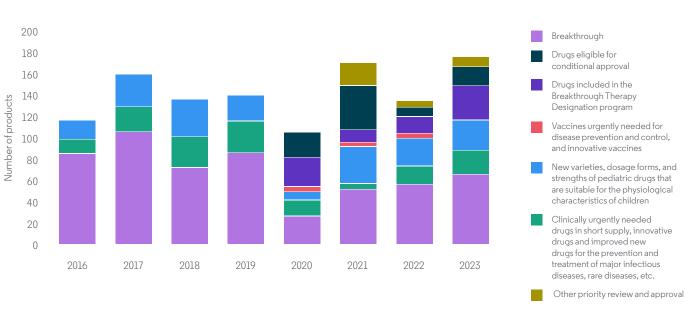
There is also a shift in new drug innovation from being 'new in China' to being 'new globally'.

To promote the review and marketing of urgently needed clinical drugs for treating serious life-threatening diseases, rare diseases, and pediatric drugs, Mainland China has established four special review channels: breakthrough therapy designation, conditional approval, priority review and approval, and special approval procedures. In 2023, the priority review and approval process shortened the technical review from 200 working days to 130 working days and implemented priority arrangements for verification and inspection. From 2019 to 2023, the NMPA approved nearly 40 cell and gene therapy products for clinical trials to treat rare diseases, including seven gene therapy products approved for clinical trials to treat hemophilia. In 2023, three gene therapy products were approved, including the conditional approval of the equecabtagene autoleucel (FOCASO) injection jointly developed by ISAO Biotherapeutics and Innovent Biopharmaceuticals, the approval for launch of inaticabtagene autoleucel (CNCT 19) injection from Juventas,

and the conditional approval of the addition of new indications for axicabtagene ciloleucel (YESCARTA) injection from Fosun Kite.

As Mainland China enters the tenth year of reforming its drug review and approval system, there has been an increase in the number of new drug applications and approvals. There is also a shift in new drug innovation from being 'new in China' to being 'new globally'. The procedures have seen continuous optimization and improvement, resulting in enhanced efficiency. Additionally, various regulatory promotion paths have been established to encourage innovation and focus on addressing unmet clinical needs. These efforts reflect Mainland China's commitment to driving both scientific and technological innovation and systemic innovation. This is expected to support the high-quality development of the biopharmaceutical industry and contribute to the realization of 'Healthy China 2030' and the acceleration of new productivity development.

Figure 8: Special review qualifications granted for approved drugs and vaccines from 2016 to 2023.



Source: 2016-2023 annual drug review reports on CDE website, collated by Clarivate

# 02 Accelerate the construction of a multi-level medical security system and improve the accessibility of innovative drugs

With the continuous advancement of innovative drug development in Mainland China, the country's medical security system also sees ongoing deepening reform. The system is moving gradually from 'full coverage' to 'high-quality' development. The standardized management of the National Reimbursement Drug Listing (NRDL) and the inclusion of innovative drugs in the NRDL through price negotiations demonstrate the remarkable effectiveness of the reform. Continuous improvement of the medical insurance system and related policies has significantly improved patients' access to innovative drugs. At the same time, commercial health insurance is playing an increasingly

important role in the reimbursement of innovative drugs. The Opinions on Deepening the Reform of the Medical Security System in 2020 put forward the clear goal of establishing a multi-level medical security system by 2030, with basic medical insurance as the mainstay, medical assistance as the bottom line, and supplementary medical insurance, commercial health insurance, charitable donations, and mutual medical assistance developing together. Various forms of commercial health insurance are gradually becoming an important part of the diversified payment mechanism for innovative drugs, further improving the affordability and accessibility of innovative drugs<sup>8</sup>.



Accelerate the inclusion of innovative drugs in medical insurance, and further improve the accessibility of innovative drugs with a 'dual-channel' policy

The 2017 edition of the National Reimbursement Drug List (NRDL) increased support for innovative drugs for the first time. It included the most innovative drugs launched from 2008 to 2016 for medical insurance payment. In 2018, the National Healthcare Security Administration (NHSA) was established to integrate various basic medical insurance systems and enhance negotiation capabilities for medical insurance. Since then, the annual adjustment of the NRDL has progressed in an orderly manner in practical exploration and has become increasingly mature and standardized. The latest data from the NHSA shows that since its establishment in 2018, over 700 'lifesaving and critically needed drugs' and innovative drugs have been included in the NRDL. This includes 446 drugs newly added through negotiations, most of which are newly launched in recent years with high clinical value9.

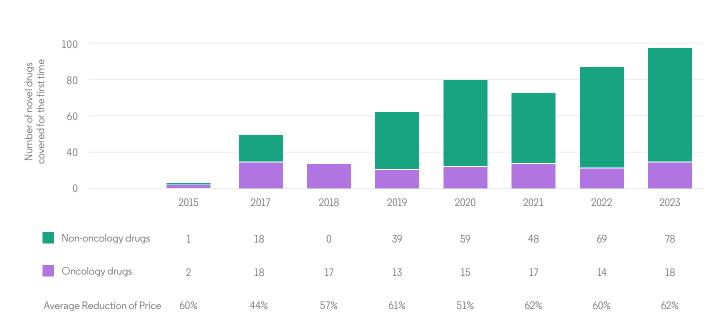
The average price reduction of drugs successfully included in Mainland China's National Reimbursement Drug List (NRDL) through negotiations has reached 50%-60%. According to Clarivate 'China In-Depth Report', analysis of the annual negotiation data released by the National Healthcare Security Administration (NHSA) shows that since 2018, the average price reduction of newly added drugs has been over 50%. In 2023, 143 drugs outside the NRDL were included in negotiations or bidding, and 121 drugs were successfully included, resulting in a success rate of 84.6% and an average price reduction of 61.7%<sup>10</sup>.

In July 2023, the NHSA released the draft Negotiated Drug Renewal Rules and Non-exclusive Drug Bidding Rules for public comment. This is aimed at encouraging sustainable innovation and striking a balance between saving medical insurance funds and supporting the long-term and healthy development of the biopharmaceutical industry. It's the first time since the implementation of national medical insurance negotiations eight years ago that expressions such as 'halving the payment standard' and 'price reduction deduction' have appeared, suggesting that the rules for the renewal price reduction of some drugs may become more moderate.

700+

'life-saving and critically needed drugs' and innovative drugs have been included in the NRDL.

Figure 9: Average price reduction of innovative drugs newly covered by medical insurance from 2015 to 2023.



Source: National healthcare security administration, summarized and collated in Clarivate 'China In-Depth Report'

In addition to the increasing number of innovative drugs covered by medical insurance, the inclusion process is also accelerating. According to data released by the NHSA, the waiting time for new drugs to be included in the NRDL from launch has been shortened from an average of nearly 5 years in the past to just over 1 year now. About 80% of innovative drugs can be included in the NRDL within two years of launch<sup>11</sup>. In 2023, 57 products achieved 'approval and inclusion in the NRDL in the same year'. For instance, the efgartigimod alfa Injection for myasthenia gravis was approved in June 2023 and successfully included in medical insurance through negotiation in December, fully reflecting the country's support for innovative drugs with huge clinical needs<sup>12</sup>.

In 2021, the government issued Guidance on Establishing and

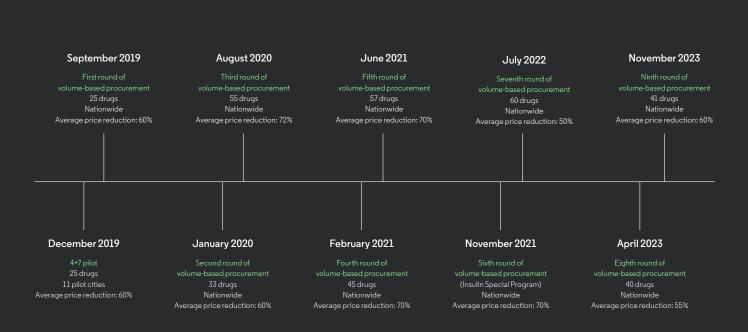
Perfecting the Double Channel Management Mechanism for Drugs Priced Through Government Negotiations to improve access to innovative drugs through medical insurance. The goal was to address the issue of patients having medical insurance but unable to access necessary medications. The guidance establishes a 'dual-channel' system, allowing patients to purchase negotiated drugs at specific hospitals or pharmacies and seek reimbursement using a doctor's prescription. Both channels follow the same payment policy. This system focuses on ensuring access to high-value, urgently needed, and costly drugs. It also includes retail pharmacies supplying negotiated drugs and ensures that they follow the same reimbursement policy as medical institutions. This aims to improve patients' access to innovative drugs priced through government negotiations.

#### Continuously increase medical insurance expenditure on innovative drugs and standardize and improve the efficiency of medical fund utilization

Since the launch of the Pilot Program for Centralized Drug Procurement Organized by the State in November 2018, the NHSA has conducted nine rounds of centralized volume-based drug procurement (referred to as 'collective procurement'), covering a total of 374 drugs. This initiative has resulted in an average price reduction of over 50%. As a result, it has significantly eased the financial burden on patients and saved substantial funds for the medical insurance system.

Furthermore, it has created opportunities for the inclusion of more innovative drugs. The first nine rounds of collective procurement have achieved 'cost reduction and volume increase'. Additionally, innovative drugs included in the NRDL from 2017 to 2023 have seen 'increases in both volume and revenue<sup>13</sup>. Official data from the NHSA indicates that national medical insurance expenditure on innovative drugs has surged from 5.949bn yuan in 2019 to 48.189bn yuan in 2022, marking a sevenfold increase.

Figure 10: Timeline and average price reduction of volume-based procurement programs from 2018 to 2023.



Source: National healthcare security administration, summarized and collated in Clarivate 'China In-Depth Report'

The NHSA has been working to reform medical insurance payment methods to control costs at hospitals. It promotes the use of Diagnosis-Related Groups (DRG) and Disease Intervention Packet (DIP) payment methods for all eligible medical institutions providing inpatient services. The NHSA formulated the Three-Year Action Plan for DRG/ DIP Payment Method Reform to achieve full coverage of disease types and medical insurance funds by the end of 2025. This reform aims to improve the efficiency of medical insurance fund utilization.

New rules have been introduced to support the implementation of new clinical technologies and ensure adequate treatment for critically ill patients as part of the reform of payment methods. These rules include the 'exceptional payment' rule. which allows eligible new drugs and technologies to be excluded from the disease-based payment standards, and the 'special case discussion' rule for severe cases with significantly higher costs than the average for the disease. On July 13, 2022, the Beijing Medical Insurance Bureau launched a pilot program to manage new drugs

and technologies that are excluded from the CHS-DRG payment. This payment method clarifies that innovative drugs, medical devices, and medical services can be paid separately based on actual costs rather than through the DRG system. As the DRG pilot program is rolled out nationwide, provinces like Henan, Shaanxi, Guangdong, and Jiangsu have successively defined the scope of outpatient special drugs. They have implemented preferential policies for innovative drugs launched in recent years, such as no deductibles, no maximum limits, exclusion from DRG and drug proportion assessments.

These 'preferential' policies have a dual purpose. First, they help innovative drugs be used in clinical settings without being restricted by cost-control measures imposed by medical insurance when they enter the market. Second, they allow for the collection of real-world data on these drugs, including their clinical effectiveness, safety, and economic aspects, during their actual clinical use. These data then help to integrate these innovative products smoothly into new medical insurance payment methods.

New rules have been introduced to support the implementation of new clinical technologies and ensure adequate treatment for critically ill patients as part of the reform of payment methods.

#### Commercial health insurance is gradually becoming a crucial component of diversified payment mechanisms for innovative drugs

Since its establishment, the NHSA has achieved significant progress in alleviating the financial burden of medical expenses on patients. By negotiating prices, it has successfully added many high-value innovative drugs to the National Reimbursement Drug List (NRDL), including medications for cancer, rare diseases, and chronic illnesses. It's important to note that the annual treatment costs for all drugs currently on the NRDL do not exceed 300,000 yuan within the defined payment scope.

The prices of negotiated drugs are compared with those in various countries and regions to ensure they do not exceed the lowest international benchmark. Specifically, the payment standards for drugs in different therapeutic areas are as follows: non-oncology drug pricing is set at less than 1-1.5 times the per capita GDP, while oncology drug pricing is less than 3 times the per capita GDP (in 2023, Mainland China's per capita GDP was 13,160 USD, approximately 93,000 RMB).

This means that inclusion in the NRDL, which is oriented towards 'basic coverage,' becomes a challenge for certain high-priced innovative drugs.

On July 5, 2024, the State Council Executive Meeting reviewed and adopted the Implementation Plan for Full-Chain Support of Innovative Drug Development (referred to as the 'Plan'). The Plan emphasizes the coordinated use of commercial insurance and other policies to drive breakthroughs in innovative drug development. This represents another important positive signal for innovative drugs and devices, commercial health insurance. and commercial insurance fund investment, following the clear objective set forth in the Opinions on Deepening the Reform of the Medical Security System in March 2020. The objective aims to 'strive to build a multi-level medical security system by 2030, with basic medical insurance as the mainstay, medical assistance as the bottom line, and supplementary medical insurance, commercial health insurance, charitable donations, and mutual medical assistance developing together.' Additionally, the 14th Five-Year Plan for National Health, issued by the State Council in April 2022, encourages synergistic development between the medical and pharmaceutical industries and the insurance industry.



Due to various policies, commercial health insurance has become an important aspect of the diverse payment system. Currently, many types of commercial insurance cover innovative drugs. Welfare Insurance, also known as city-customized commercial medical insurance, has been implemented nationwide since 2020. By 2023, over 90% of Welfare Insurance products will include coverage for special drugs, with domestically marketed innovative oncology drugs being the core drugs in the Welfare Insurance drug list. In 2023, the number of included drugs reached 550, with 246 of them being innovative oncology drugs marketed in Mainland China. In recent years, the Boao Lecheng pilot zone in Hainan has pioneered the 'Medical Insurance + Commercial Insurance' model and launched the 'Lecheng Global Special Drug Insurance'. This provides a payment quarantee through commercial insurance for foreign special drugs not included in the NRDL, with the implementation of pilot policies such as the 'Four Permissions' in Boao Lecheng.

Commercial insurance channels have played a vital role in providing coverage for innovative drugs used to treat rare diseases and hematological neoplasms, which are associated with high treatment costs and limited accessibility. Recently, non-solid

tumor innovative therapies like CAR-T products have been included in special drug coverage by commercial medical insurance. Specifically, elmacabtagene autoleucel and axicabtagene ciloleucel have been included in 62 and 75 commercial medical insurance programs. respectively. According to Clarivate 'CAR-T Cell Therapy — China Indepth Report,' experts believe that the unique nature of CAR-T cell therapy, as a one-time treatment, makes it unsuitable for traditional drugs' annual treatment cost framework. Therefore. innovative payment models such as pay-for-efficacy or patient-specific limits are considered more suitable reimbursement methods for these therapies. In January 2024, Fosun Kite launched the first value-oriented payfor-efficacy program for axicabtagene ciloleucel (Yescarta) in Mainland China. Under this program, if a patient receiving Yescarta does not achieve a complete response within three months of treatment, the company will refund half of the treatment cost (600,000 yuan). This marks the first program for a bio-innovative drug to be paid for based on its therapeutic value in Mainland China, representing a significant attempt at an innovative drug payment model. This initiative provides a reference path for the future promotion of innovative drugs and seeks to strike a balance between meeting patient needs and improving drug accessibility.

Commercial insurance channels have played a vital role in providing coverage for innovative drugs used to treat rare diseases and hematological neoplasms, which are associated with high treatment costs and limited accessibility.

# 03 Investment in basic research continues to increase, and sources of innovation are gradually being activated, but there is still much room for improvement<sup>14</sup>

The global scientific and technological revolution and industrial transformation lead to increased international competition in basic research.

Scientific exploration is expanding in both macro and micro directions while cross-integration is accelerating. Guided by the National Innovation-Driven Development Strategy Outline, the 13th Five-Year Plan for Bio-industry Development, and the 14th Five-Year

Plan for Bioeconomic Development <sup>15</sup>, Mainland China's basic research in biomedicine has shifted from the initial system establishment to a stage of rapid development over the past decade. This is due to Mainland China's significant increase in investment in basic research. Mainland China's overall R&D investment has grown 3.5 times compared to a decade ago, contrasting with the 1.5 times growth in the U.K. and

1.3 times growth in the United States. Currently, Mainland China's R&D investment exceeds the total investment of the entire European Union and is rapidly approaching the U.S. level. In the foreseeable future, the overall level of scientific research investment in the Asia-Pacific region, with Mainland China as the core of influence, is expected to become a leading factor in technological innovation.

Figure 11: Gross expenditure on research & development (GERD).



Source: Global Research Report: Mainland China's research landscape, ISI, Clarivate

Between 2007 and 2011, Mainland China's publication records in clinical medicine, life sciences, and other disciplines were not broad. However, from 2017 to 2021, Mainland China has not only surpassed the United States in publication output in pharmacology but is also strongly challenging the leading position of the United States in molecular biology.

Although Mainland China currently contributes a relatively small share of global research activities in the medical field, its contribution is expected to increase significantly in the future due to continuous increases in investment and technological advantages. Mainland China's growing technological strength is likely to lead to major innovation in the field

of molecular biology, effectively complementing research approaches in Europe and North America. The rise of Mainland China's biomedical research capabilities and its potential to deliver outstanding research will have a broad and profound impact on the global research landscape.

Mainland China's research activities remain largely domestic, with 70% to 80% of research papers having no international collaboration. In contrast, the proportion of U.S. publications without international collaboration is currently less than 60%, while the U.K. and E.U. economies typically have proportions of less than 40%. Although research and external collaboration in the

fields of biochemistry, molecular biology, and medicine are gradually expanding, the share of Mainland Chinese co-authorship in biomedical research papers in Europe and the United States is very low. This is mainly because Europe and the United States have long maintained their own strong research capabilities and leading positions in these fields.

Additionally, data from Clarivate show that Mainland China is gradually and more frequently collaborating with a wide range of countries/regions around the world. The United States remains Mainland China's primary partner, but research collaboration with emerging economies in the Middle East and countries along the 'Belt and Road' is also becoming increasingly close.

Table 1: Share of global papers (articles and reviews) published in journals indexed in subject categories in the Web of Science (2017 2021) for Mainland China, the U.S. and the E.U., and the percentage of their output on which the U.S. and the E.U. collaborate with Mainland China.

	Share (%) of Global output			Share (%) co-authored with Mainland China	
Subject category	Mainland China	United States	European Union	United States	European Union
Cell biology	32.6	29.9	12	15.7	3.5
Oncology	30.9	29.6	18	10.6	2.6
Applied chemistry	39.6	8.6	48.7	29.4	4.9
Integrative and alternative medicine	41.3	10.3	50.7	17.3	6

Source: Global Research Report: China's research landscape, ISI

Mainland China is currently prioritizing incremental innovation breakthroughs and advances in emerging 'technology areas' rather than pursuing major breakthroughs in the field of biomedicine. Gene-editing and synthetic biology are among the key areas of basic research in Mainland China. In the field of gene-editing technology, Mainland China has published a similar volume of papers as the United States and significantly more than the United Kingdom, Germany, and Japan. Mainland China's Category Normalized Citation Impact (CNCI) is higher than the global average, and other key indicators rank among the top three in the world. Clarivate Citations From Patents, which connects basic research with industrial applications, indicate that papers in the field of gene-editing

from Mainland China have been cited by patents over 4,000 times. Although a significant gap exists with the United States, Mainland China holds the second position globally.

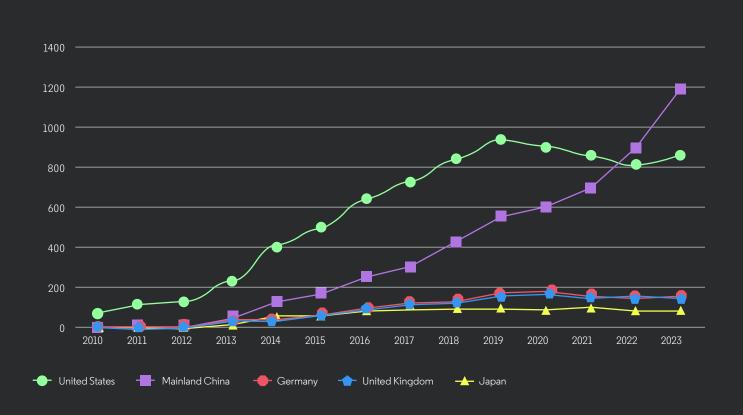
Gene-editing and synthetic biology are among the key areas of basic research in Mainland China.

Table 2: Top 5 Countries in global gene editing publications from 2015 to 2023.

Country	Number of Papers from 2015 to 2023	Number of Citations	Category Normalized Citation Impact (CNCI)	Percentage of Highly Cited Papers	Number of Patent Citations
United States	7189	334780	1.280237905	5.38	21691
Mainland China	5282	146178	1.075178285	3.92	4477
United Kingdom	1307	40334	1.050812012	2.91	1303
Germany	1265	45866	1.100862609	4.03	3289
Japan	983	31717	0.709595015	3.05	1845

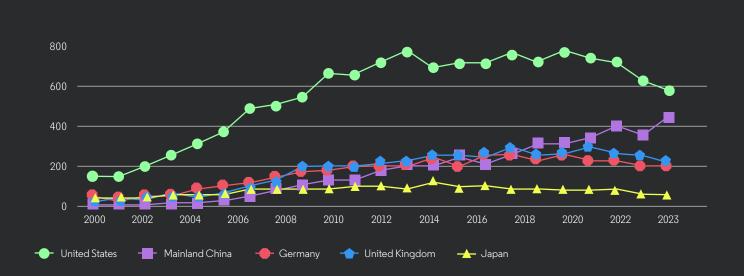
Source: Web of Science™, Clarivate

Figure 12: Number of gene editing publications in major countries from 2010 to 2023.



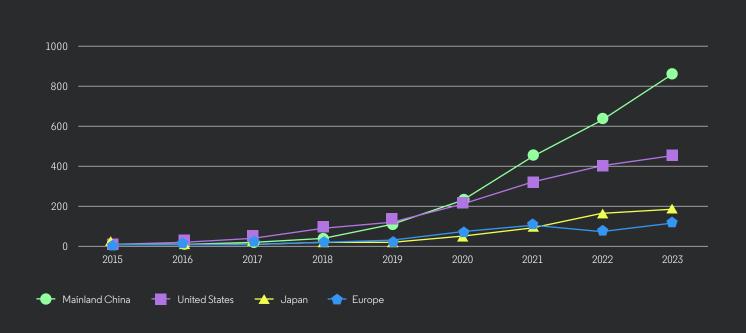
Source: Web of Science™, Clarivate

Figure 13: Number of synthetic biology publications in major countries from 2000 to 2023.



Source: Web of Science™, Clarivate

Figure 14: Number of CRISPR Patents Granted from 2015 to 2023.



Source: Derwent Innovation™, Clarivate

Over the past decade, Mainland China has made significant progress in basic research in biomedicine, resulting in a rapid increase in the number of high-quality papers and patents. Research in cancer and drug resistance prevention and control has yielded fruitful results. Although Mainland China still lags in basic research related to biomedicine, the country strives to close this gap by strengthening top-level planning, improving investment mechanisms, and enhancing supporting conditions. Efforts are being made

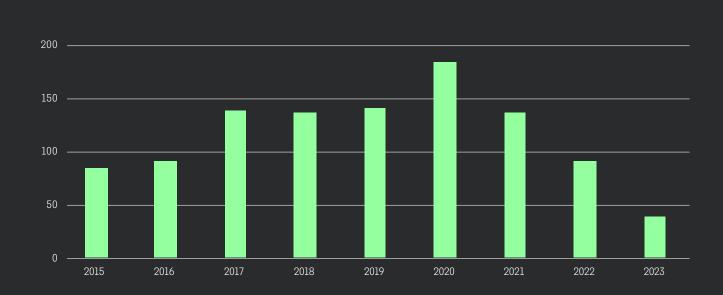
to expand the breadth and depth of basic research, promote industry-university research cooperation, and integrate emerging technologies such as gene editing, synthetic biology, artificial intelligence, and big data. Mainland China also focuses on cultivating local talents, improving education levels, and enhancing scientific research capabilities<sup>16</sup>. With these efforts, Mainland China aims to achieve breakthroughs in biomedicine research and influence global scientific progress, benefiting patients worldwide.

# 04 A preliminary map of innovative industrial clusters has been formed, and efforts are being made to move to catch the world leaders

Over the past two decades, programs aimed at attracting talented individuals in innovation, increased domestic investment in the biopharmaceutical field, and a more favorable domestic innovation environment have led to many overseas scientists returning to Mainland China to start their own businesses. This has fuelled a strong entrepreneurial spirit in the biopharmaceutical industry and has given rise to numerous innovative biotechnology companies. With the support of capital and policy incentives,

some of these companies have grown rapidly and evolved into leading biopharmaceutical companies, driving innovation and development in the industry. Since 2015, the growing number of biopharmaceutical and biotechnology companies and the innovative transformation of traditional generic drug companies have marked a shift from 'Made in China' to 'Created in China.' This has led to gradually forming new innovative industrial clusters alongside the traditional API and generic drug industry map.

Figure 15: Number of new Chinese biopharmaceutical and biotechnology companies with active pipelines from 2015 to 2023.



Source: Cortellis Competitive Intelligence™, Clarivate

Compared to the United States, Europe, and Japan, Mainland China's biopharmaceutical innovation clusters have formed and developed relatively late. Currently, these clusters exhibit typical development characteristics, with cities rich in innovation resources serving as the core. Many innovative pharmaceutical and biotechnology companies are gathering in these cities, gradually spreading to surrounding areas to form a complete and systematic bioindustrial ecosystem. This achieves a regional cluster effect greater than the sum of its parts, serving the country's major regional strategies and promoting the development of clusters towards a high-end, international, and platform-oriented direction.

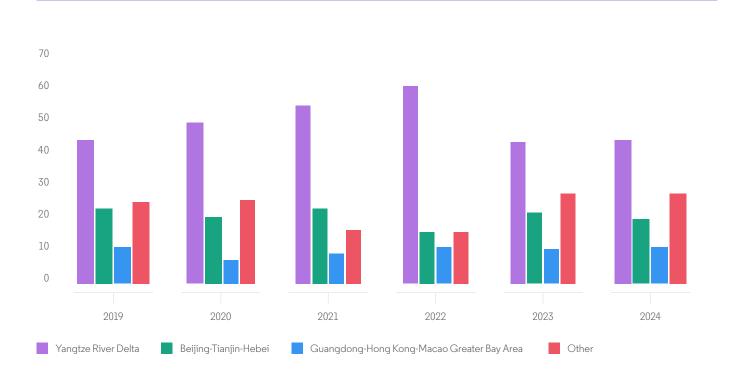
From a geographical distribution perspective, after a decade of development, Mainland China has established biopharmaceutical innovation clusters centered around the Yangtze River Delta region, Beijing-Tianjin-Hebei region, and Guangdong-Hong Kong-Macao Greater Bay Area:

- Yangtze River Delta region:
   Shanghai, Suzhou, and Hangzhou are the core driving forces of innovation in this cluster, leading China's biopharmaceutical innovation and moving towards a world-class biocluster.
- Beijing-Tianjin-Hebei region:
   Beijing is the innovation center of this cluster, which relies on abundant scientific research resources and basic research capabilities to drive the development of Tianjin, Shijiazhuang, Jinan, and other cities around the Bohai Rim.

 Guangdong-Hong Kong-Macao Greater Bay Area: Guangzhou and Shenzhen are the innovation drivers in this preliminary innovation cooperation region, with Hong Kong, Macao, and Zhuhai providing support.

Mainland China's biopharmaceutical innovation industry is mainly driven by three major innovation clusters, with further growth in the central and western regions. The industry is progressively moving from east to west, for example, in the Chengdu-Chongqing economic circle, creating a competitive and collaborative environment for regional coordinated development. This enhances overall innovation capacity, leadership, and collaboration, providing strong support for the sustainable development of the biopharmaceutical industry.

Figure 16: Regional distribution of Mainland China's Top 100 biopharmaceutical innovation companies from 2019 to 2024\*.



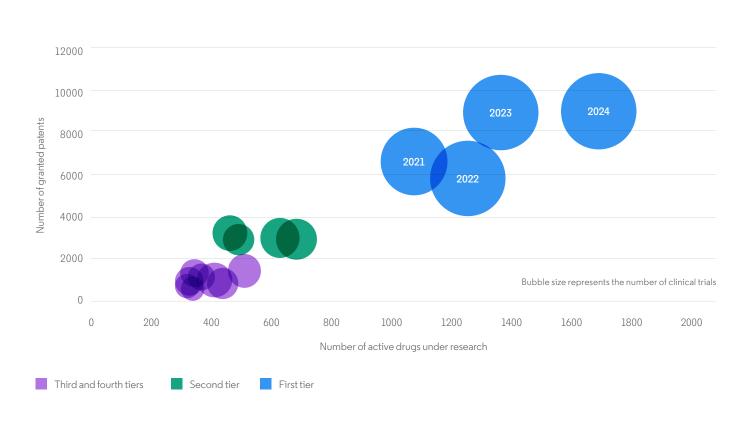
Note: Distribution area is calculated based on business registration

Source: '2024 List of China's Top 100 Pharmaceutical Innovation Enterprises', Clarivate & Healthcare Executive

When assessing innovation strength, Mainland China's biopharmaceutical innovation is primarily concentrated in the top 25 companies in the China Pharmaceutical Innovation Ranking. There is a notable gap in innovation assessment data compared to other companies. The leading innovation companies demonstrate stable and strong revenue performance, with continuous increases in

innovation investment and a rich pipeline layout. These companies include traditional generic drug companies that have transitioned into innovative drug companies, biotechnology companies that have expanded into biopharmaceutical companies, and specialized companies focusing on specific technologies, technology platforms, business models, or niche markets.

Figure 17: Innovation capabilities of different tiers of China's Top 100 innovative biopharmaceutical companies in 2024.



Source: Cortellis Competitive Intelligence™, Cortellis Clinical Trials Intelligence™, Derwent Innovation™, '2024 List of China's Top 100 Pharmaceutical Innovation Enterprises', Clarivate & Healthcare Executive

Table 3: List of Mainland China's Top 25 Innovative Biopharmaceutical Companies in 2024 (in no particular order).

- Hengrui Pharma
- BeiGene
- Sino Biopharm
- · CSPC
- Innovent Biologics
- RemeGen
- Hansoh Pharma
- Akeso Inc
- BIOKIN Pharmaceuticals
- Qilu Pharmaceutical
- Henlius
- Hutchmed
- Shanghai Pharmaceuticals Holding

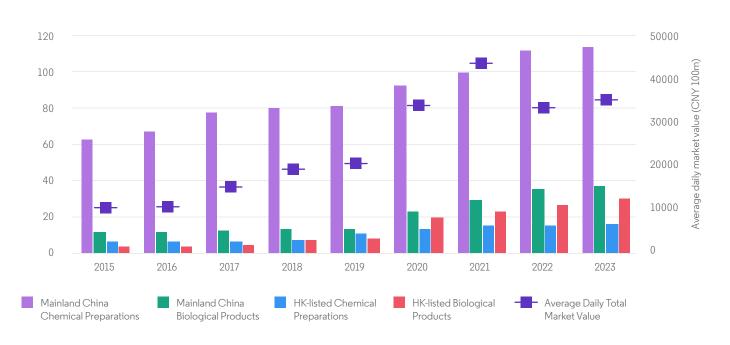
- Sinopharm CNGB
- Fosun Pharmaceutical
- Zai Lab
- Betta Pharmaceuticals
- Luye Pharma
- Junshi Biosciences
- Hisun Pharmaceutical
- Tasly
- Kelun Pharmaceutical
- Lunan Pharmaceutical
- HEC Pharmaceutical
- · Simcere Pharmaceutical

 $Source: '2024 \ List of \ China's \ Top \ 100 \ Pharmaceutical \ Innovation \ Enterprises', \ Clarivate \ \& \ Healthcare \ Executive$ 

The number of listed companies in biopharmaceutical chemical preparations and biological products in Mainland China was 197 in 2023, 2.37 times the 83 listed in 2015. From 2018 to 2021, significant global capital flowed into Mainland China's biopharmaceutical industry. This was facilitated by new financing and exit channels (such as the Hong Kong Stock Exchange 18A and Mainland China's Science and Technology Innovation Board) as well as the impact of the pandemic. These factors drove rapid growth in the average daily market value of listed companies in this field, reaching a peak of nearly 4.44tn yuan

in 2021, which is 3.53 times the average daily market value in 2015. However, since 2022, the capital market has undergone significant adjustments. In 2023, the total market value of listed companies in this sector shrank to 3.54tn yuan, with a loss of 896bn yuan compared to 2021. Both internal and external factors contributed to these changes in financing conditions, including the cooling down of global biotechnology enthusiasm, adjustments in expectations by listed companies, and increased uncertainty in realizing the full commercial value of innovative drugs.

Figure 18: Number and average daily total market value of listed companies in chemical preparations and biological products in Mainland China from 2015 to 2023.



Note: Mainland China includes Mainland China and the Hong Kong Special Administrative Region

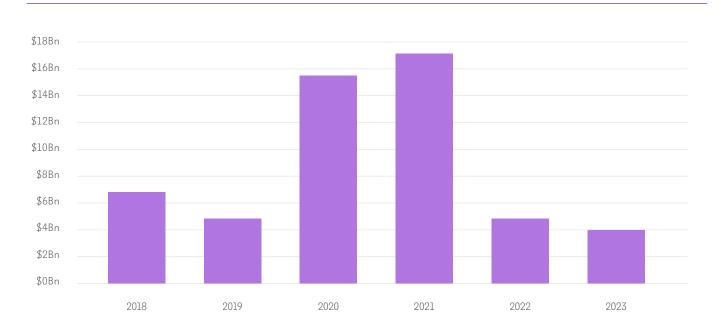
Source: Wind, Healthcare Executive and Clarivate

## Mainland Chinese enterprises have demonstrated remarkable resilience and innovation.

In the face of a challenging global economic cycle and financing environment, the growth rate of R&D expenditure of listed companies in chemical preparations and biological products in Mainland China has slowed down in the past three years. However, Mainland Chinese enterprises have demonstrated remarkable resilience and innovation. Despite implementing various cost control measures, they have significantly increased investment in innovative R&D, reaching a total

of 113bn yuan in 2023, which is 44.7 times the amount of 252.8m yuan in 2015. This has provided a strong driving force for the continuous innovation of Mainland China's biopharmaceutical industry. In 2023, only one enterprise had an R&D expenditure exceeding 10bn yuan, and only 21 had an R&D expenditure exceeding 1bn yuan. This still indicates a significant gap from the global benchmark level of R&D investment for innovative pharmaceutical companies.

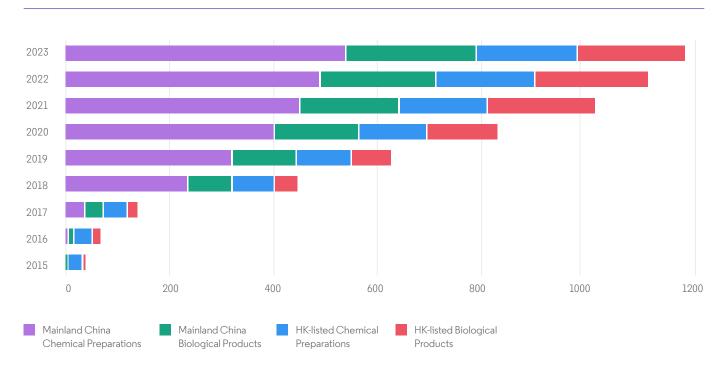
Figure 19: Trends in Asian biopharmaceutical financing from 2018 to 2023.



Mainland China includes mainland China and the Hong Kong Special Administrative Region

Source: BioWorld Asia, Clarivate

Figure 20: R&D expenditure of listed companies in chemical preparations and biological products in Mainland China from 2015 to 2023.



The R&D expenditure of companies listed in both Mainland China and Hong Kong stock markets are all counted as companies listed in Mainland China, and are not counted repeatedly in Hong Kong stock market.

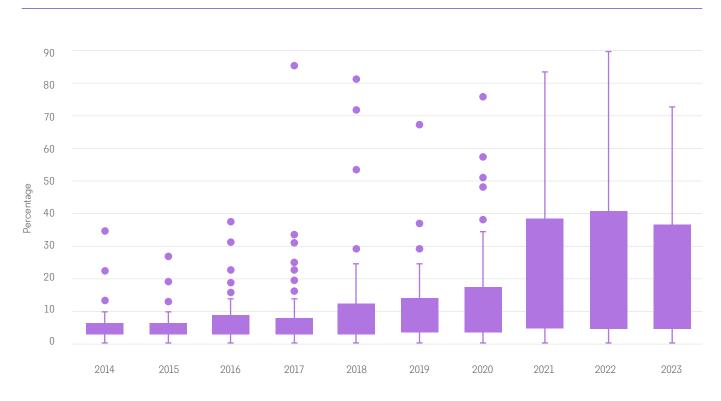
Source: Wind, Healthcare Executive and Clarivate

R&D expenditure as a percentage of revenue for enterprises has been continuously increasing from 2015 to 2020. The average R&D expenditure has consistently been maintained at 10% over the past three years. This level is lower than the global benchmark for biopharmaceutical R&D investment. However, most of the top 25 companies among Mainland China's top 100 innovation companies have maintained an R&D expenditure of 20% or higher. This is consistent with the average 20% R&D expenditure of leading global biopharmaceutical companies, as reported in Clarivate CMR Global R&D Performance Report 2022. Additionally, unprofitable Mainland Chinese biotechnology companies in the special development stage have

R&D expenditures exceeding 300%, contributing to the strong growth of innovation activities in Mainland Chinese biotechnology companies.

Regarding industrial cluster development, innovative Mainland Chinese biopharmaceutical companies have moved into a period of steady adjustment after a period of rapid growth. Despite facing numerous uncertainties, these companies remain committed to innovation. They continue to invest in innovative research and development and integrate internal and external resources while actively participating in the global biopharmaceutical innovation system with a more open mindset.

Figure 21: Percentage of R&D expenditure to revenue of listed companies in chemical and biological products in Mainland China from 2015 to 2023.



Source: Wind, Healthcare Executive and Clarivate

# 05 Innovation achievements have been successful due to perseverance, and now is the perfect time to cultivate a global perspective

Due to policies, talent, environment, and capital, Mainland China's new drug research and development is rapidly advancing. The number of innovative drug pipelines under research has been increasing yearly, and some tracks have the highest number of pipelines under research worldwide. The types of innovation have expanded beyond small molecules and monoclonal antibodies to diverse emerging therapies and technical fields, some of which are world-class. New drug R&D efforts focus on oncology, anti-infectives, neuropsychiatry, and other areas with high unmet needs.

The innovation model has shifted from rapid follow-up innovation (Me-Too/ Me-Better) to gradual combinatorial innovation, aiming to achieve firstin-class drugs as soon as possible. In the global innovation context, innovation cooperation is increasingly active, with a significant increase in the number of overseas clinical trials, a continuous rise in the number and value of authorized licensing transactions, and more diverse forms of cooperation. Mainland China's 'gradual' innovation has incrementally been deeply integrated into the global innovation ecosystem and is playing an increasingly important role.



## The number of innovative drug R&D pipelines has increased significantly, and they are more diverse

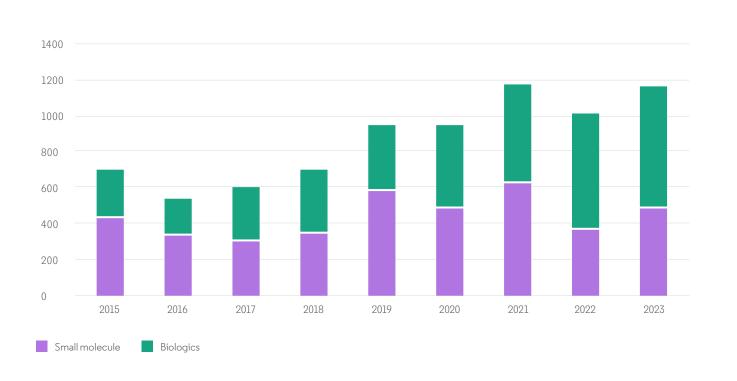
In recent years, domestic investment in the research and development of new drugs has significantly increased, leading to a substantial rise in the number of new innovative drug pipelines globally. For instance, in 2023, there was a 60% increase compared to 2015, accounting for about 27% of the global new pipelines, a significant jump from the 14% globally in 2015.

The focus of innovative R&D has shifted from small molecules to biologics, with the proportion of biologics increasing from about 40% in 2015 to 58% in 2023.

Notably, the number of antibody drug conjugate (ADC), bispecific antibody, and CAR-T pipelines has increased by seven, five, and four times, respectively. Additionally, emerging therapies such as siRNA, exosomes, CAR-NK, and mRNA have entered late stages of development.

As of July 2024, 86 new drugs under active research in Mainland China have received special designation from the U.S. FDA (breakthrough therapy, priority review, orphan drug, fast track).

Figure 22: Number of new innovative drug R&D pipelines in Mainland China from 2015 to 2023.

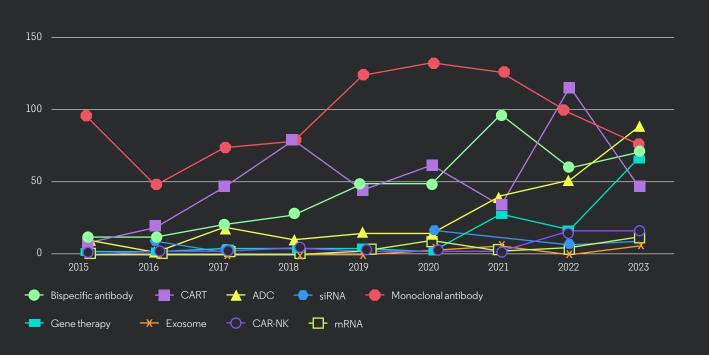


Source: Cortellis Competitive Intelligence™, Clarivate

ADC technology, an increasingly important modality in the field of oncology, has garnered significant attention globally and in Mainland China. The number of ADC R&D pipelines in Mainland China has increased significantly since 2020, surpassing monoclonal antibodies and bispecific antibodies in 2023 to become the most actively pursued R&D track. With domestic new drug R&D companies conducting in-depth research on targets, payloads, linkers, and the optimization and transformation of mainstream technology platforms, various unique and differentiated technology platforms have emerged.

These include the acidic stability linker modification of BIOKIN Pharmaceuticals, the OptiDC technology platform of Kelun-Biotech, the TMALIN® ADC technology platform of MediLink Therapeutics, and the DITAC technology platform of Duality Biologics. These technology platforms have garnered widespread attention from 2023 to 2024, and successful collaborations with major multinational pharmaceutical companies have been established. Bispecific antibodies, cell and gene therapies, and radiopharmaceuticals are also emerging as focal areas of interest.

Figure 23: Number of new innovative therapy pipelines in Mainland China from 2015 to 2023.



Source: Cortellis Competitive Intelligence  $^{\text{\tiny{TM}}}$  , Clarivate

Table 4: Major milestones of innovative drugs in Mainland China.

Year	Company	Milestone event
2011	Betta Pharmaceuticals	lcotinib, the first small molecule targeted anticancer drug with completely independent intellectual property rights in Mainland China, was approved for marketing <sup>17</sup>
2018	Junshi Biosciences	Toripalimab, the first PD-1 monoclonal antibody independently developed by Mainland China was approved for marketing in Mainland China <sup>18</sup>
2019	BeiGene	Zanubrutinib, a BTK inhibitor independently developed by Mainland China, became the first original innovative drug to approved by the U.S. FDA <sup>19</sup>
2021	RemeGen	Disitamab Vedotin, the first ADC drug independently developed by Mainland China, was approved for marketing in Mainland China <sup>20</sup>
2021	Fosun Kite	The first technology-introduced CAR-T product, Yescarta® (axicabtagene ciloleucel injection) was approved for marketing in Mainland China <sup>21</sup>
2022	Legend Biotech	Cilta-cel, the first CAR-T product independently developed in Mainland China, was approved for marketing in the United States $^{22}$
2022	Akeso Inc	Cadonilimab, the first bispecific antibody independently developed in Mainland China, was approved for marketing in Mainland China <sup>23</sup>
2023	Junshi Biosciences	Toripalimab became the first innovative biologic drug independently developed and manufactured in Mainland China approved for marketing by US FDA <sup>24</sup>
2023	BeiGene	Zanubrutinib, a BTK inhibitor independently developed by China, achieved over US\$1bn in global sales, making it the first blockbuster drug 'developed in Mainland China <sup>25</sup>
2024	Akeso Inc	Ivonescimab injection, the world's pioneering bispecific antibody drug, was approved in Mainland China $^{\rm 26}$
2024	Chinese innovative drug companies	The excitement will continue

Source: Cortellis Competitive Intelligence  $^{\text{\tiny{TM}}}$ , Clarivate

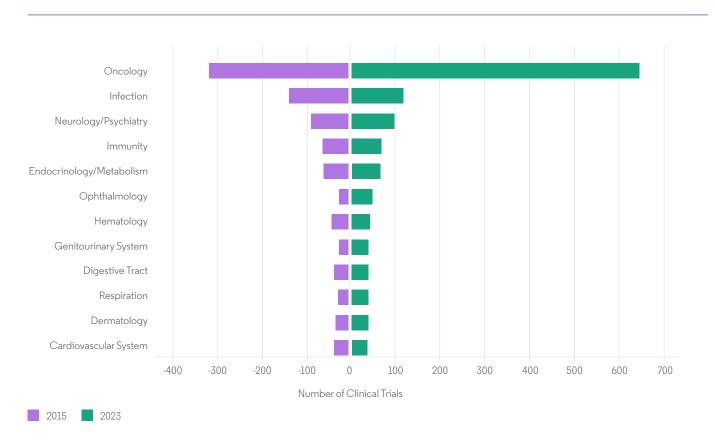
## R&D focus is primarily on oncology, infection, and neuropsychiatry, with increasing activities in other areas with high unmet needs

Over the past decade, pharmaceutical R&D in Mainland China has primarily focused on three main areas: oncology, infection, and neuropsychiatry.

Notably, the proportion of oncology pipelines under research has increased significantly, from 38% in 2015 to 51% in 2023. This reflects the rapid development of targeted therapies, immunotherapies, and new therapy innovation strategies. Furthermore,

there has been continued growth in ophthalmology pipelines, particularly in the field of retinal disorders such as age-related macular degeneration (AMD) and diabetic macular edema (DME), where there are significant unmet clinical needs. Additionally, numerous advances have been made in developing common ophthalmologic treatment drugs for xerophthalmia, glaucoma, and myopia.

Figure 24: Comparison of disease areas focused by new R&D pipelines in 2015 and 2023.

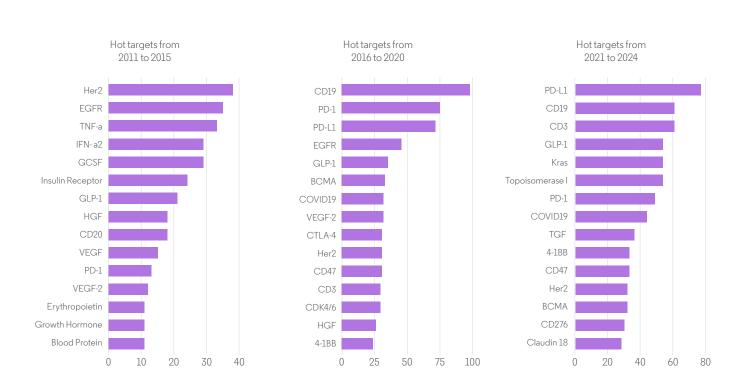


Source: Cortellis Competitive Intelligence™, Clarivate

## Innovation model shifts from me-too to combination innovation, moving towards original innovation

Due to the enhancement of R&D capabilities and the growing experience of Mainland Chinese enterprises, the R&D innovation model has shifted from me-too/ me-better, imitating or improving existing products, in the fastfollowing stage, to a combination of technological innovation and differentiated development.

Figure 25: Popular targets in Mainland China from 2011 to June 2024 .



Hot targets refer to the targets corresponding to the R&D pipelines under development. For example, the popular targets from 2011 to 2015 are the targets corresponding to the active R&D pipelines in Mainland China collected by Cortellis Competitive Intelligence during the period from 2011 to 2015.

Source: Cortellis Competitive Intelligence™, Clarivate

## Three stages of innovation model:

#### Me-too stage

Between 2011 and 2015, the focus was on well-established blockbuster drugs with significant market sales, which had a delay of 5-6 years between their development and global approval. The popular pipelines mainly consisted of multi-target tyrosine kinase inhibitors (TKIs), and the biopharmaceuticals were primarily insulin and cytokine drugs.

#### Fast-follow stage

From 2016 to 2020, there was intense competition for the existing market, with research and development moving forward from marketed drugs to Phase 3, Phase 2, Phase 1, and even preclinical stages. This shift led to increased uncertainty and risks. Additionally, original drugs were launched more quickly in Mainland China, and domestic enterprises obtained licenses, shortening the time for follow-up. For example, after nivolumab (OPDIVO, referred to as 'O drug') was approved for marketing in the U.S. in 2014, many domestic PD-1 drugs had already begun clinical trials. In 2018, the O drug was approved for marketing in Mainland China, and in the same year, Junshi Biosciences' toripalimab (LOQTORZI) became the first domestic PD-1 monoclonal antibody to be approved for marketing. In May 2019, Hengrui Medicine's camrelizumab (AiRuiKa) was also approved for marketing.

#### Combination innovation stage

From 2021 to 2024, the focus shifted to combining validated targets and technology platforms to improve research and development success rates. This model included combining validated targets and technology platforms, as well as validated targets and cutting-edge targets. For example, the research and development direction of PD-1 and PD-L1 shifted from monoclonal antibodies to the development of bispecific antibodies or ADCs.

## The number of clinical trials has increased significantly, and the clinical development of innovative drugs has become more efficient and effective

Since the drug review and approval system reform in 2015, several policies have been gradually implemented and continuously refined to optimize clinical study management.

These policies include promoting tacit approval of clinical trials, accepting data from overseas clinical trials, and encouraging

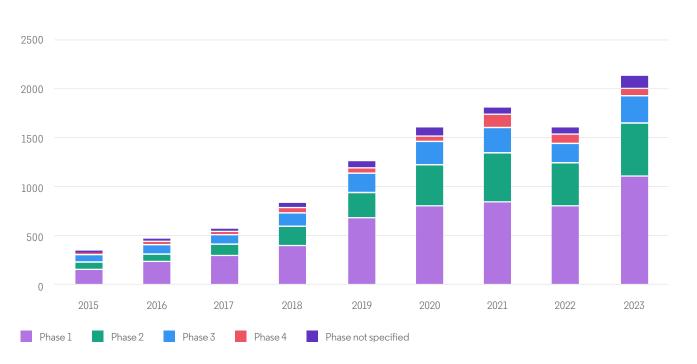
simultaneous R&D and registration of innovative drugs from overseas within Mainland China. As a result, the number of clinical trials conducted by Mainland Chinese enterprises has significantly increased. Clinical trials have become more standardized, regulated, and internationalized, improving speed and quality.

## The overall number of clinical trials conducted by Chinese enterprises has shown an increasing trend

According to Cortellis Clinical Trials Intelligence<sup>™</sup>, from 2015 to the first half of 2024, the total number of commercialization-related clinical trials conducted by Mainland Chinese enterprises reached 11,113, with approximately 82% conducted solely in Mainland China. In 2018, Mainland China officially launched the tacit approval system for clinical trials, leading to a rapid and substantial increase in the number of clinical trials. In 2023, the number of commercial development-related clinical trials led by enterprises reached 2,078, which is 7.5 times that of 2015.

A comparison of the number of clinical trials in different phases in 2015 versus 2023 shows that the increase in the number of Phase 1 clinical trials in 2023 (710%) was 10% and 44% higher than that of Phase 2 (645%) and Phase 3 (494%) clinical trials, respectively. The preclinical development capabilities of Mainland Chinese enterprises for innovative drugs are improving, effectively promoting the rapid growth in the number of early-phase clinical trials.

Figure 26: Distribution of numbers of clinical trials conducted by Mainland Chinese enterprises from 2015 to 2023 by phase.



Data coverage timeframe is based on the start dates of clinical trials from January 1, 2015 to December 31, 2023.

Note: Clinical phase classification is defined as follows: Phase 3 includes Phases 3, 3a, 3b, and 2/3 (enrollment of 300 or more); Phase 2 includes Phases 2, 2a, 2b, 1/2 (enrollment of 100 or more), and 2/3 (enrollment of less than 300 or not specified); Phase 1 includes Phases 1, 1a, 1b, 1/2 (enrollment of less than 100 or not specified), and Phase 0.

Source: Cortellis Clinical Trials Intelligence™, Clarivate

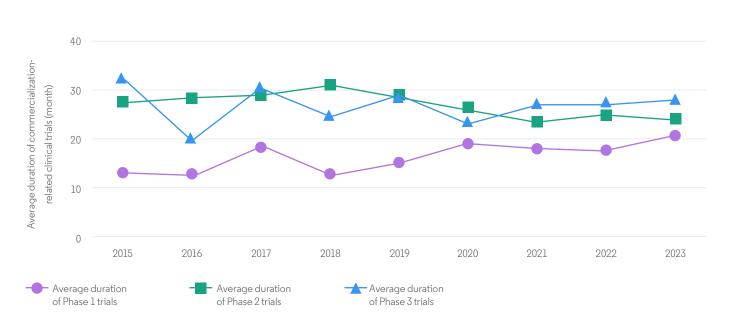
## Participant recruitment has accelerated, and clinical efficiency has gradually improved

Recruitment for innovative drug clinical trials has been speeding up. Over the past decade, the demand for participants has grown nearly 10% due to the increase in the number and scale of trials. The pace of participant recruitment significantly impacts the speed of clinical trials and the time it takes to bring products to market<sup>27</sup>.

According to the analysis of Cortellis Clinical Trials Intelligence data, the average duration of clinical trials conducted by Mailand Chinese enterprises has slightly decreased, and the speed of participant recruitment has increased significantly. Indeed, in the past three years, the pace of participant recruitment for Phase 3 clinical trials has increased by up to 25%. In recent years, the national promotion of digital empowerment and the application of AI technology has accelerated the speed of participant recruitment and improved clinical efficiency. The outbreak of he should read the COVID-19 pandemic fostered the accelerated integration of digital and information technology into clinical research.

New policies, such as the Guiding Principles for the Management of Clinical Trials of Drugs During the COVID-19 Epidemic and the Guiding Principles for the Implementation of Patient-centric Clinical Trials (Draft for Comments), have proposed several application scenarios for patient-centric new technologies, new methods, and new models, including the use of internet platforms for recruitment and intelligent recruitment based on big data of patient information<sup>28</sup>.

Figure 27: Average duration of commercialization-related clinical trials in Mainland China from 2015 to 2023.

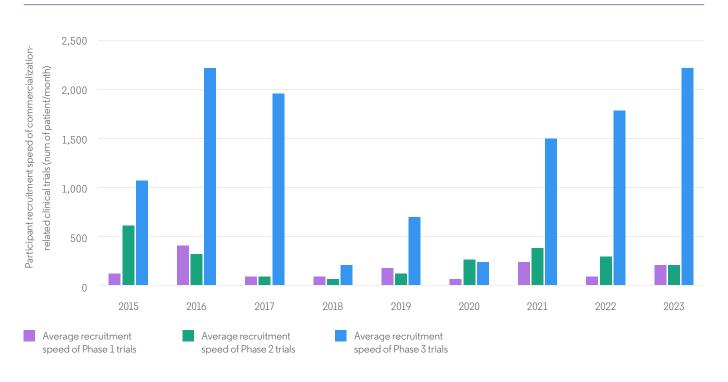


Data coverage timeframe is based on the completion dates of clinical trials from January 1, 2015 to December 31, 2023.

Note: Clinical phase classification is defined as follows: Phase 3 includes Phases 3, 3a, 3b, and 2/3 (enrollment of 300 or more); Phase 2 includes Phases 2, 2a, 2b, 1/2 (enrollment of 100 or more), and 2/3 (enrollment of less than 300 or not specified); Phase 1 includes Phases 1, 1a, 1b, 1/2 (enrollment of less than 100 or not specified), and Phase 0.

Source: Cortellis Clinical Trials Intelligence  $^{\!\scriptscriptstyle\mathsf{TM}},$  Clarivate

Figure 28: Participant recruitment speed of commercialization-related clinical trials in Mainland China from 2015 to first half of 2024.



Data coverage timeframe is based on the completion dates of clinical trials from January 1, 2015 to December 31, 2023.

Note: Clinical phase classification is defined as follows: Phase 3 includes Phases 3, 3a, 3b, and 2/3 (enrollment of 300 or more); Phase 2 includes Phases 2, 2a, 2b, 1/2 (enrollment of 100 or more), and 2/3 (enrollment of less than 300 or not specified); Phase 1 includes Phases 1, 1a, 1b, 1/2 (enrollment of less than 100 or not specified), and Phase 0.

Source: Cortellis Clinical Trials Intelligence  $^{\!\scriptscriptstyle\mathsf{TM}}$  , Clarivate

## Chinese companies have gained global recognition for the quality of their clinical research

In recent years, numerous Mainland Chinese companies have used clinical trial data from both Mainland China and overseas to support marketing approvals in foreign countries and regions. Examples include zanubrutinib (BRUKINSA), ciltacabtagene autoleucel (CARVYKTI), benvitimod (VTAMA), toripalimab (LOQTORZI), fruquintinib (FRUZAQLA), and efbemalenograstim alfa.

Mainland Chinese companies are continuously learning and growing, conducting in-depth exploration in clinical research, employing advanced clinical trial design methodologies, ensuring data integrity and accuracy, and enhancing data quality.

As a result, they have earned recognition from the FDA and globally.

## Improving clinical development efficiency: international multi-center clinical trials emerge as a new trend

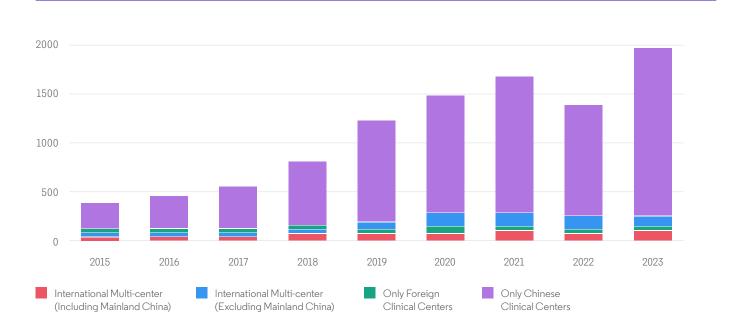
Ten years ago, Mainland Chinese companies conducted few overseas clinical trials for new drugs. Limited experience in clinical development strategy research, unfamiliarity with overseas registration requirements for clinical trials, and a lack of clinical development capabilities within their teams led most Mainland Chinese companies to prefer conducting clinical trials in the familiar domestic market. However. with the continuous enhancement of Mainland China's innovative drug development capabilities and increasing pressure on the return on

investment in innovative drugs, most Mainland Chinese innovative drug companies have begun to consider international multi-center clinical trials (MRCT) as their first step towards internationalization since 2018. This trend has gradually become prominent in Mainland China's new drug development landscape.

By employing a consistent scientific design, companies can simultaneously obtain global clinical trial evidence in multiple countries/regions, better supporting drug registration applications in multiple countries.

This approach also saves resources, shortens the time to market globally. and allows local biotechnology companies to obtain clinical data recognized by mature markets through MRCT, demonstrating their R&D strength and product potential to attract overseas licensing, collaboration, or M&A opportunities. For example, BeiGene's zanubrutinib and tislelizumab (TEVIMBRA), Hengrui Medicine's fluzoparib (AiRuiYi), and Dizal Pharmaceutical's savolitinib (ORPATHYS) have been the focus of international multi-center clinical trials<sup>29</sup>.

Figure 29: Distribution of clinical trial centers in Mainland China and internationally for commercialization-related clinical trials conducted by Mainland Chinese companies.



Data coverage timeframe is based on the time of being recorded in Cortellis Clinical Trials Intelligence from January 1, 2015 to December 31, 2023.

Source: Cortellis Clinical Trials Intelligence™, Clarivate

Based on the analysis of the sample data, it was observed that the growth rate of Phase 1 and Phase 2 commercialization-related clinical trials conducted by Mainland Chinese companies overseas after 2017 was relatively fast, while the growth rate of Phase 3 trials was relatively slow.

This trend is linked to the attrition rate of clinical drug R&D and aligns with expectations. After 2021, there was a decrease in the number of clinical trials in all phases, possibly due to the impact of the COVID-19 pandemic on the normal conduct of clinical trials.

Figure 30: Distribution of different phases of commercialization-related clinical trial conducted by Mainland Chinese companies overseas.



 $Data\ coverage\ time frame\ is\ based\ on\ the\ time\ of\ being\ recorded\ in\ Cortellis\ Clinical\ Trials\ Intelligence\ from\ January\ 1,\ 2015\ to\ December\ 31,\ 2023.$ 

Source: Cortellis Clinical Trials Intelligence™, Clarivate

# The global synchronized R&D strategy is making progress, and early preparations are being made for international product launches

According to Clarivate analysis,
Mainland Chinese companies,
which used to participate in international
multi-center trials only during Phase 3,
are now getting involved in such trials
as early as Phase 2 and even Phase 1.
This is especially true for innovative
therapies and new technologies like
CAR-T therapy. Early participation in
overseas clinical trials benefits research

institutions and pharmaceutical R&D personnel. It allows them to engage with foreign investigators and regulatory agencies early, which helps deepen understanding of the project for all parties involved. Additionally, it can contribute to designing more reasonable and effective Phase 3 clinical trials, ultimately improving the success rate of the studies.

## Chinese companies are exploring global expansion and developing international multi-center clinical development strategies

Conducting overseas clinical trials is crucial for innovative drugs to go global. Effectively formulating clinical development and registration strategies can improve drug development efficiency, save time for global market launch, and reduce development investment. This is essential for marketing applications in multiple countries or regions, resulting in higher company returns. Mainland Chinese companies have been working on innovative international multi-center

clinical development strategies in the past decade. For example, BeiGene initiated the first-in-human clinical trial of zanubrutinib in Australia in August 2014. The Phase 1 clinical data from Australia supported the Phase 2 and pivotal clinical trials in Mainland China and the United States. Later, the data from the pivotal Phase 2 clinical trial in Mainland China further supported the marketing applications and approvals in the United States, Mainland China, and subsequently in many other countries<sup>30</sup>.

## Australia is ideal for Chinese companies to conduct clinical trials overseas

Mainland Chinese pharmaceutical companies are increasingly conducting clinical trials of new drugs overseas. with the United States, Australia, Europe, and Japan being the main regions for such research. Due to their high global share of the pharmaceutical market and standardized drug registration processes, mature markets are preferred for the international launch of innovative drugs. However, it is worth noting that Australia has gradually become a preferred destination for many innovative Chinese pharmaceutical companies to conduct international multi-center clinical trials. The Australian government provides substantial R&D expenditure

tax incentives, and its regulatory environment is also very supportive of the development of the clinical trial industry, making it an ideal place for clinical trials with advantages in research quality, speed, and cost-effectiveness. Among the companies conducting clinical trials in Australia, biotechnology companies account for about 40%. In addition, Phase 1 clinical trials account for the highest proportion (62%). Phase 1 clinical trials in Australia only require filing, and it takes only 3-4 months from filing to the first-in-human trial. This aligns with companies' demands for speed, cost-effectiveness, and quality<sup>31</sup>.

Figure 31: Geographical distribution of overseas clinical trials conducted by Mainland Chinese enterprises.



Data coverage timeframe is based on the time of being recorded in Cortellis Clinical Trials Intelligence™ from January 1, 2015 to June 30, 2024.

Source: Cortellis Clinical Trials Intelligence™, Clarivate

# 06 'Bring in and go global', extensively and deeply integrate into global innovation cooperation

2015 was a turning point for new drug development in Mainland China, as traditional companies shifted their focus to innovation and increased investment in the biopharmaceutical field. This led to the emergence of a new wave of Biotech companies. The research and development (R&D) and innovation capabilities were just starting, but the demand for innovative drugs in the market was growing. This led to increased competition in the industry, with high-quality R&D assets becoming the focus, leading to

numerous in-licensing transactions. These transactions not only filled the product R&D pipelines of companies but also became crucial for Biotech companies to secure financing.

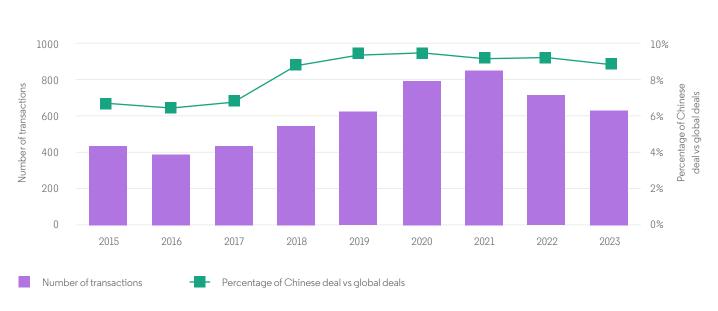
Over time, Mainland Chinese R&D and innovation capabilities have rapidly improved, especially in terms of engineering. Mainland China has become an incubator for innovative drugs, attracting both domestic and overseas companies. This has led to a surge in asset transactions, followed by mergers and acquisitions.

# Mainland Chinese biopharma companies are increasingly active in deals, with a significant increase in the volume of service-type transactions

In the past decade, the number of transactions by Mainland Chinese biopharmaceutical companies has steadily increased, reaching 770 in 2021, up from about 400 in 2015. Despite economic fluctuations, the number of transactions has remained around 600.

From a global perspective, the proportion of transactions involving Mainland Chinese companies has risen from about 6.5% in 2015 to around 9% in the past five years. This indicates a continuous increase in transaction activity and cooperation among Mainland Chinese biopharmaceutical companies.

Figure 32: Transactions involving Mainland Chinese biopharma companies from 2015 to 2023.

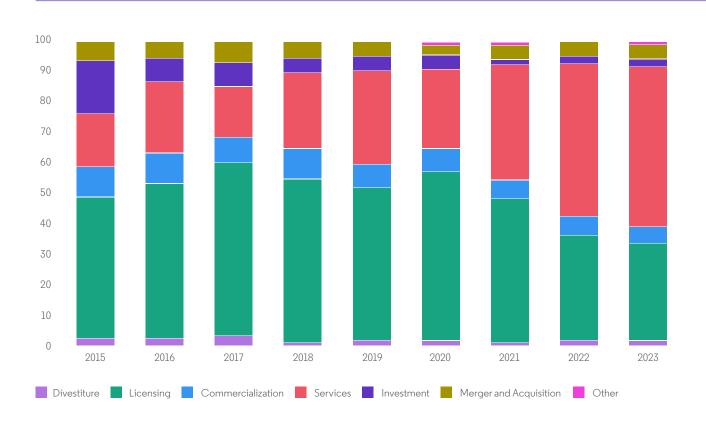


Source: Cortellis Deals Intelligence $^{\mathsf{TM}}$ , Clarivate

The structure of biopharmaceutical transaction types in Mainland China has changed significantly over the past decade. In 2024, service-based transactions made up the largest proportion of transactions at 55%, compared to only 17% in 2015.

A decade of innovation and development in the biopharmaceutical industry has not only transformed biopharmaceutical companies but also spurred the growth of research and development (R&D) supporting service companies.

Figure 33: Analysis of number of transactions involving Mainland Chinese biopharmaceutical companies from 2015 to 2023 by type.



Transaction types include M&A (including 50%-100% acquisitions, mergers, and reverse acquisitions); licensing includes licensing agreements and joint ventures (JVs); divestiture includes acquisitions of products or business units; investment includes equity acquisitions of less than 50%, grants, loans, and other investments; commercialization includes distribution, supply, and co-promotion; services include contract services; other includes buybacks, spin-offs, and carve-outs.

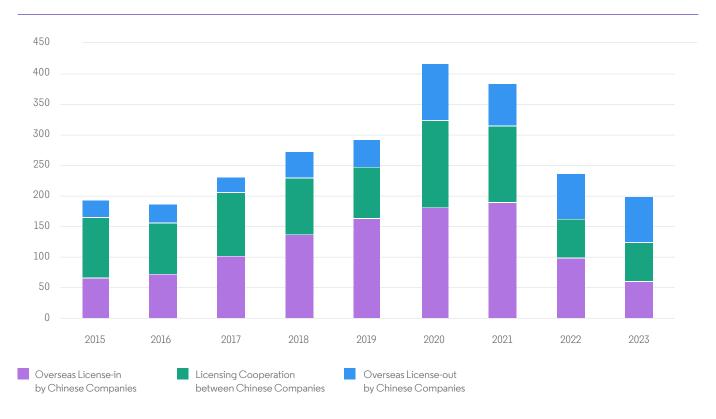
Source: Cortellis Deals Intelligence  $^{\text{\tiny{TM}}}$ , Clarivate

## Licensing transactions support the total transaction value

Over the years, Mainland Chinese companies have been primarily involved in licensing transactions. In 2015 these transactions accounted for approximately 47% of the total, but this proportion gradually decreased to 30% in 2023. Despite the decline in proportion, the number of licensing transactions saw significant growth, reaching its peak in 2020 and then gradually declining to the 2015 level from 2021 to 2023.

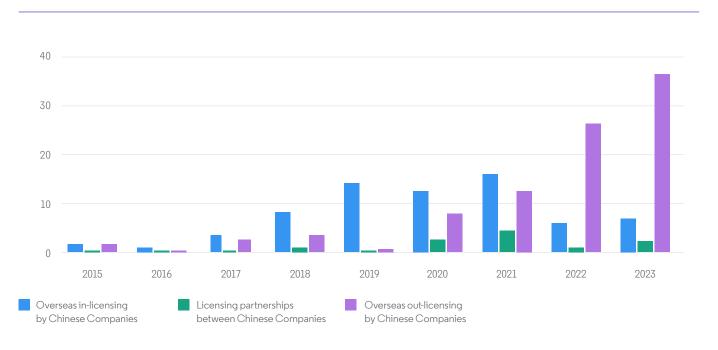
In terms of transaction value, the total value of publicly disclosed licensing transactions by Mainland Chinese companies in 2023 exceeded \$36bn, which is 13 times higher than the \$2.6bn 2015. Furthermore, there have been 'mega deals' in recent years, with single transaction values surpassing the total transaction value for the entire year of 2015.

Figure 34: Number of licensing transactions by Mainland Chinese companies from 2015 to 2023.



Source: Cortellis Deals Intelligence  ${}^{\text{\tiny{TM}}}$ , Clarivate

Figure 35: Value of licensing transactions by Mainland Chinese companies from 2015 to 2023.



Source: Cortellis Deals Intelligence™, Clarivate

## Chinese innovation: From 'bringing in' to 'going global'

In recent years, Mainland Chinese biopharmaceutical companies have been engaging in significant international transactions involving the licensing of innovative drugs. These transactions have seen substantial growth in both the number and value of deals. Chinese companies have been acquiring rights to develop and commercialize innovative drugs from international developers, while also granting international companies access to their own innovative drug assets.

For instance, Zai Lab signed a cooperation agreement with Tesaro on the eve of niraparib's Phase 3 clinical trial results, making a U.S.\$15m down payment to obtain the drug's development and commercialization rights in Mainland China. Subsequently, niraparib received FDA approval in the following year, and Zai Lab obtained marketing approval for the drug in Mainland China<sup>32</sup> in December 2019, just over three years after its introduction.

In 2019, Everest and Immunomedics brokered a landmark transaction for the Trop-2 inhibitor sacituzumab govitecan, with a down payment of \$65m<sup>33</sup>. However, with the improvement of capabilities in innovation and R&D of domestic innovative drug companies and the advancement of their independent R&D projects, the enthusiasm of domestic biopharmaceutical companies for in-licensing has waned, leading to a decline in the number of transactions since 2022, amid global economic fluctuations and controversies over business models.

Conversely, Mainland Chinese companies have also been engaging in outbound licensing transactions, allowing international companies to access their innovative drug assets. These transactions have seen significant growth, with the total transaction amount of out-licensing deals exceeding \$35bn in 2023.

In 2017, BeiGene and Celgene (later acquired by BMS) signed a \$1.393bn overseas licensing agreement for the PD-1 inhibitor tislelizumab, setting a record for Mainland China's single-product out-licensing at that time<sup>34</sup>. At the end of 2017, Legend Biotech and Johnson & Johnson reached a cooperation

agreement on the BCMA CAR-T therapy ciltacabtagene autoleucel, with a down payment of \$350m<sup>35</sup>.

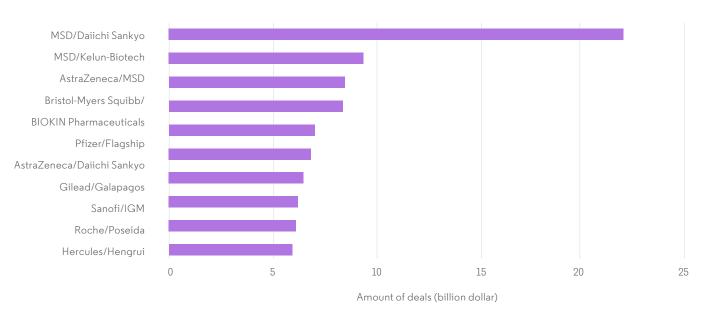
Since 2020, the number of overseas out-licensing transactions involving Chinese innovative drugs has remained at around 50 per year. The total transaction amount in 2020 reached \$7bn, which had doubled from the previous year. There was rapid growth in the following years, with out-licensing transactions totalling more than \$35bn in 2023.

In 2022, Kelun-Biotech and MSD signed three contracts in a row, with a total transaction value of more than \$11.8bn, including one transaction valued at \$9.475bn<sup>36</sup>. In 2023, BIOKIN Pharmaceuticals' subsidiary, Systlmmune, reached a deal with BMS for a total price of \$8.4bn, with BMS acquiring global rights to BIOKIN Pharmaceuticals' HER3 x EGFR bispecific antibody outside of Mainland China. The upfront payment of up to \$800m set a record for an out-licensing deal by a Chinese company, as well as being the largest licensing transaction in BMS's history<sup>37</sup>.

Recent transaction cooperation fully demonstrates that the innovation, R&D strength, and quality of some Mainland Chinese biopharmaceutical companies have reached an internationally advanced level, and the commercial value of their assets has been highly recognized by international peers. These transactions highlight the growing international recognition of Mainland Chinese biopharmaceutical companies' innovation and R&D capabilities, positioning them at an internationally advanced level in the global biopharmaceutical market.

Mainland Chinese companies have also been engaging in outbound licensing transactions, allowing international companies to access their innovative drug assets.

Figure 36: Top 10 global biopharmaceutical licensing transactions by total amount.



Source: Cortellis Deals Intelligence™, Clarivate (data cutoff: June 30, 2024)

## Deepen global presence, integrate into global innovation, and actively seek M&A opportunities

Over the past few years, Mainland Chinese biopharmaceutical companies have been actively acquiring overseas assets and technologies to bolster their global innovation strategy. This move has been facilitated by favorable macroeconomic conditions and a more relaxed domestic and international environment. For instance, Grand Pharma acquired OncoSec, a U.S.-based biotech company, in 2022, securing the rights to market its tumor immunotherapy product in Mainland China and other Asian regions.

Similarly, Sino Biopharm completed the acquisition of F-star, a U.K.-based bio-tech company, in 2023, gaining access to its innovative oncology drugs and R&D platform.

At the same time, global pharmaceutical giants are also seeking M&A opportunities with small and medium-sized biotech companies to fill gaps in their R&D pipelines. This has led to notable acquisitions, such as AstraZeneca's agreement with Gracell in 2023 to explore cell therapy in autoimmunity, Genmab's acquisition of ProfoundBio to strengthen its clinical pipeline, and Novartis's acquisition of SanReno to expand its presence in nephropathy.

These M&A activities reflect a trend of collaboration and consolidation in the biotech industry, with Mainland Chinese companies playing an increasingly important role in the global biopharmaceutical landscape.

# 07 Innovative insights: the future is now, and the only constant is change: perseverance leads to a promising future

Mainland China has the world's second-largest healthcare market, accounting for approximately 15% of the global market, with growing medical needs and vast market potential. Surfing the new wave of the global biotechnology revolution, Mainland China's biopharmaceutical industry is rapidly evolving in research and development, regulation, payment, and market access.

Mainland Chinese biopharmaceutical innovators are adopting suitable approaches and driving innovation in areas such as technology, business models, management, and collaboration at pace.

They are gradually integrating deeply into the global biopharmaceutical innovation ecosystem and striving to achieve a perfect fusion of 'science' and 'business.'



In this rapidly evolving and uncertain new cycle, guided by the national 14th Five-Year Plan for Bioeconomic Development, we believe the following points deserve attention:

## Enhance R&D economic efficiency and achieve exceptional market launch

The rapid pace of innovation and the increasingly challenging market environment necessitate that Mainland Chinese biopharmaceutical companies continuously enhance their research and development and business models to succeed in a highly competitive and complex market. We believe that the keys to success include:

- Identifying investment targets with a high likelihood of success at relatively low project cost and risk;
- Utilizing technology to streamline clinical trials, as competition for patient recruitment is intense, and there are significant rewards for being the first to market;
- Integrating evidence generation and access strategies to create value in an increasingly diverse and competitive range of medical conditions.

The competitive market environment among biopharmaceutical companies has heightened the importance of reducing time-to-market, increasing the probability of technical and regulatory success, and intensifying the competitive pressure to balance trial costs and label breadth. Achieving this balance requires technology and proprietary knowledge, widespread adoption of biomarkers during development, identification of participants and accelerated recruitment, expansion of the reach of trial networks, and synthetic cohorts and adaptive trials to reduce the number of patients.

High-quality, real-world data help generate evidence beyond the scope of randomized controlled trials. Real-world data also support the design and execution of outcome-based payment contracts when innovative drugs offer differentiated clinical value across multiple indications, breaking away from the traditional one-size-fits-all pricing model.

High-quality, real-world data help generate evidence beyond the scope of randomized controlled trials.

## Asset value reconstruction and recreation

The global pharmaceutical policy and regulatory landscape is undergoing significant changes. The U.S. Inflation Reduction Act (IRA) will majorly impact the global biopharmaceutical ecosystem and value chain. The E.U.'s pharmaceutical legislation reform package is progressing as planned. Mainland China is also continuously improving its regulatory review and approval processes and policies for the pricing and payment of innovative drugs. Innovative Mainland Chinese drug companies aiming for the global biopharmaceutical market must closely monitor and deeply understand regulatory intelligence, expertise, and regional priorities, even during the innovative drug development stage. They must keep track of regulatory policy changes in key regions/markets, adjust their pharmacovigilance and regulatory strategies, ensure rapid, efficient, cost-effective pipeline development, and avoid potential compliance risks.

The U.S. IRA directly impacts the U.S. drug pricing structure, which in turn may influence innovative drug development strategies and begin to reshape the global innovative drug R&D ecosystem as companies reassess the expected return on investment

(ROI) of their new assets. It will also impact the pipeline development strategies and asset value assessments of Mainland Chinese innovative drug companies currently primarily focused on validated targets.

The pricing of new drugs in Mainland China is expected to move towards a more rational evaluation of their value and determination of prices. This means that companies producing innovative drugs must actively gather and produce evidence to support their products throughout the drug development process. This evidence should come from scientific research, real-world data. internal analyses, and consultations with experts in the field. This preparation is crucial for successful negotiations on pricing with national health insurance and pricing and reimbursement in other countries around the world.

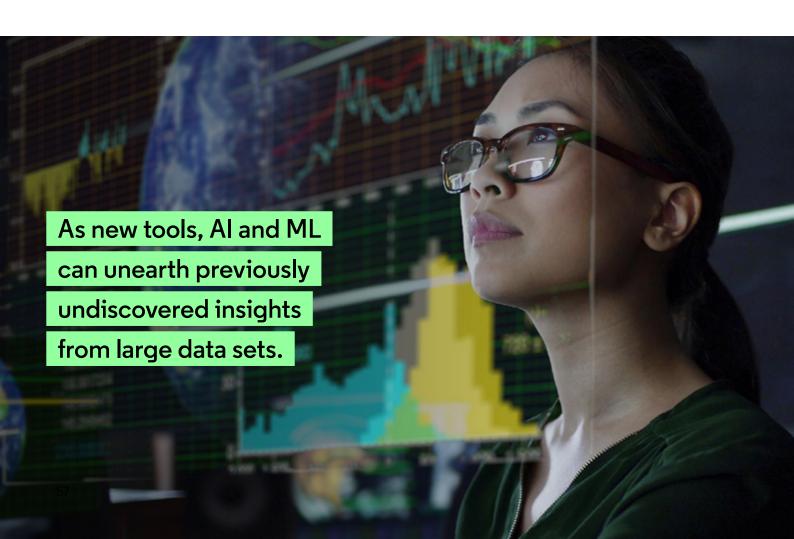
As a result, companies developing innovative drugs at all stages must adapt to the rapidly changing regulations and policies. They will need to continually develop strategies and methods for evaluating the value of their drugs, setting prices, and creating innovative business models from the early stages of development through to commercialization.

The pricing of new drugs in Mainland China is expected to move towards a more rational evaluation of their value and determination of prices.

## Artificial intelligence and machine learning empower drug discovery and development

Real-world examples increasingly demonstrate how artificial intelligence (AI) and machine learning (ML) are transforming innovative new drugs' discovery, development, and delivery. To realize the potential of these technologies, biopharmaceutical companies will need to train these tools with the most robust and highest-quality data available and acquire the expertise to manage them. As new tools, Al and ML can unearth previously undiscovered insights from large data sets. Their widespread application not only has the potential to accelerate product launches but also to address the unmet needs of diverse patient populations, including patients with rare diseases, diseases with unclear characteristics

(such as neurological diseases), and those who can benefit from precision medicine (such as cancer patients). Furthermore, the biopharmaceutical industry is no longer solely reliant on serendipitous discoveries of drug repurposing opportunities across different diseases. Instead, it delves deeper into the connections between mechanisms of action, drug targets, and various interactions to improve drug development efficiency. Demonstrating research value upfront and determining whether a potential treatment represents a transformative leap or merely an improvement over the current standard of care has also attracted the attention of investors and regulatory agencies.



## Strategic collaboration for mutual success

Global pharmaceutical companies have a long history of collaborating with biotechnology firms to supplement their expertise. technology, agility, and resources. Their goal is to discover new avenues for profitability and enhance patient outcomes. Many of the top 50 global pharmaceutical companies are exploring partnerships with independently developed innovative drug pipelines in Mainland China. In the future, Mainland Chinese innovative drug companies will have numerous opportunities to partner with or be acquired by global pharmaceutical companies in order to further develop their assets and drive continuous innovation.

Innovative Mainland Chinese drug companies must maintain a strategic focus on global innovation and determine how to leverage their platforms and assets to address industry gaps and unmet medical needs. Clearly defining the form and content of cooperation and establishing unique advantages will be essential for standing out in the competition among different pipelines targeting the same goals. Large pharmaceutical companies may also prefer 'specialized, refined, distinctive, and innovative' biotechnology firms that tackle specific cutting-edge technologies and issues.

During the evaluation process for potential partnerships, innovative drug companies must demonstrate that their assets have a high success rate in regulatory approval, market access, medical insurance reimbursement, and marketing promotion to increase asset valuation and improve collaboration opportunities. Ultimately, scientific breakthroughs alone are not sufficient to guarantee market success.

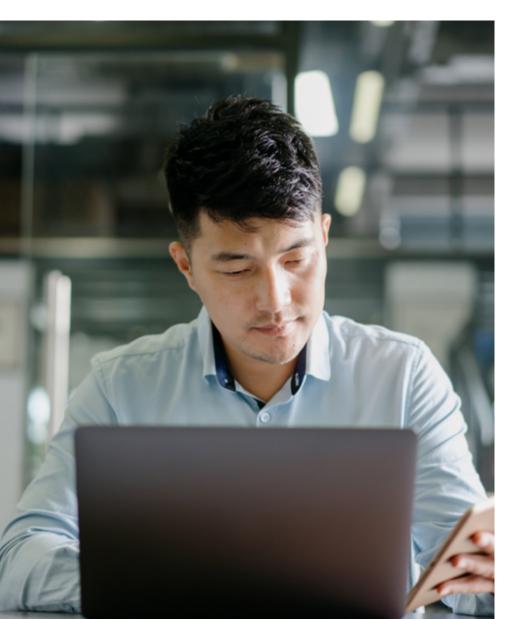


## The potential impact of proposed U.S. BioSecurity Act

The proposed U.S. BioSecurity Act could have significant implications for the Chinese pharmaceutical industry, particularly in the context of increasing global scrutiny over biopharmaceutical supply chains and national security concerns. The proposed BioSecurity Act emphasizes the importance of U.S. domestic production and supply chain security in the biopharmaceutical sector. As a result, it may lead to increased tariffs or restrictions on imports from countries deemed high-risk, including Mainland

China. This could hinder the entry of Chinese pharmaceutical products into the U.S. market, impacting revenue streams for Mainland Chinese companies that rely on exports. Moreover, if U.S. companies are incentivized to source materials domestically or from allied nations, this could further isolate Mainland Chinese firms from critical markets.

The Act is also likely to introduce more rigorous regulatory requirements for foreign pharmaceutical companies operating in the U.S. This could mean that Mainland Chinese firms will face heightened scrutiny regarding their manufacturing practices, data integrity, and compliance with safety standards. Such regulations could increase operational costs and complicate market entry strategies for Chinese pharmaceuticals aiming to enter or expand within the U.S. market. The BioSecurity Act may also limit opportunities for collaboration between U.S. and Chinese firms in research and development initiatives.



Nevertheless, while the proposed U.S. BioSecurity Act presents several challenges, it also offers an opportunity for the Mainland Chinese pharmaceutical industry to strengthen its domestic market capabilities. With increased focus on self-sufficiency and domestic innovation, Mainland China could accelerate its efforts to develop a robust biopharmaceutical ecosystem that reduces reliance on foreign markets. Investment in local research and development initiatives could position Mainland Chinese firms favorably in a changing global landscape.

Many of the top 50 global pharmaceutical companies are exploring partnerships with independently developed innovative drug pipelines in Mainland China.

## 08 The Next Decade: Insights from China BioPharma tycoons

Standing at the juncture of a decade of innovation in China, looking ahead to the next ten years of Chinese biopharmaceutical development, Clarivate close partner Healthcare Executive has exclusively interviewed several company leaders and scientists who have achieved outstanding

innovation results in the past decade. These interviews aim to contribute insightful thoughts for the high-quality development of the upcoming decade.

The following is an excerpt from the series of interviews conducted by Healthcare Executive.

## Fu Wei, CEO of C-Bridge.

The end of an era often signifies the end of its irrationality, chaotic competition, and unsustainable profitmaking models. However, for those who operate with integrity, the era never changes. It is just that the melody of the era returns to common sense, to the market, to competition, and to value creation. In the new cycle, merely discovering value is not enough; it is more important to engage in activities that create value. All businesses need to return to value investing.

The dynamics between capital and enterprises are shifting in Mainland China. The frenzy of chasing fleeting trends and engaging in fierce competition for every perceived opportunity is giving way to more rational and focused competition. While specialization and niche expertise remain important, there's a growing recognition of the significant economic

contributions made by consolidating industry leaders into powerful entities. By integrating similar enterprises and streamlining sales forces, companies can enhance profitability and bolster their overall strength. This, in turn, enables larger-scale investments in R&D pipelines, paving the way for sustained, long-term profit growth.

Investors, having learned from past setbacks, are also arriving at a more rational consensus. They are realizing that instead of blindly following trends and engaging in redundant development, it is more prudent to focus on integrating and optimizing existing resources. By breaking free from inertial thinking and returning to the fundamental logic of business — embracing common sense, market principles, healthy competition, and genuine value creation — the path forward becomes clear.

## Zhang Lianshan, Director and Deputy General Manager of Hengrui Medicine

In the future, domestic innovative drugs must compete with those meeting international standards, which is already the consensus of the industry.

To keep up with the pace of global innovation, we must follow the principle of 'patient-centricity'. Secondly, it is important to combine the company's own R&D fields and market demands. The establishment of differentiated competitive advantages is not only a test of a pharmaceutical company's forward-looking strategic vision to select differentiated projects but also a test of the quality and efficiency of clinical trial progression. For companies, the challenges they must face are not only the reliability and accuracy of clinical trials but also the speed at which these trials are advanced. Both are key factors

in determining the success of new drug development. The future development potential of the Chinese pharmaceutical industry is huge, especially in terms of technological innovation and market expansion. However, continuous innovation requires stable financial support and market returns. Companies need to ensure the sustainability of capital investment through effective market operations. State support should be concentrated mainly in the initial stages to create a favorable R&D environment for companies. China's drug innovation needs the investment of Chinese capital and the development of Mainland China's basic research. What Hengrui has to do is to focus on global cutting-edge projects and product portfolios based on Hengrui's own characteristics.



## Su Weiguo, CEO and Chief Scientific Officer of Hutchmed

No matter how fast a company runs, if the direction is wrong, it will get farther and farther away from the goal.

Biotech needs to learn to 'walk before running.' If one emphasizes running fast from the beginning, the possibility of falling will be very high. No matter how fast a company runs, if the direction is wrong. it will get farther and farther away from the goal. Business operations require long-term strategies. Nowadays, Mainland China's leading biotech companies have developed to the stage where they need to think about how to grow bigger and stronger, internationalize more products, and enhance international competitiveness. But the new stage brings new risks, so Hutchmed and its peers in biotech are exploring how to achieve steady and sustainable development for the company. Corresponding to this goal is how to do a good job in MRCT, achieve simultaneous registration in Mainland China and overseas, and reduce the cost of clinical research. From a translational perspective,
Mainland Chinese pharmaceutical
companies, leveraging their
remarkable efficiency and abundant
clinical resources, have essentially
caught up with their global
counterparts in translation of known
targets. However, when it comes to
fundamental technologies, Mainland
China's biopharmaceutical innovation
industry, being a relatively recent
entrant, still needs to strengthen its
original innovation capabilities through
further accumulation of basic research.

The future of the innovative drug industry is incredibly promising. In the translation of known targets, Mainland China is well-positioned to leverage its domestic resources and supportive policies to keep pace with, or even lead, the global race. Simultaneously, in the exploration of novel targets, mechanisms, and technologies, steady progress in basic research will pave the way for Mainland China's continued growth and maturity in this exciting field.

## Lu Xianping, Founder and Chairman of Chipscreen Biosciences

The Chinese pharmaceutical industry has transitioned from its initial stage of ecological construction to a new stage of ecological evolution.

In an interconnected ecosystem of the pharmaceutical industry, market guidance, policy support, and incentives from the payment side are all indispensable and crucial for driving the R&D of innovative drugs. Only through continuous deepening of reforms can all parties, in a spiraling upward trajectory, navigate the current temporary downturn, rejuvenate, and enter a new era of development.

The current environment for innovative drug development is like 'frying fish on the palm of your hand'. Low anticipated returns from payers and investors have placed entrepreneurs in a difficult position. This challenging environment compels companies to deeply reflect on their future development strategies.

Entrepreneurs need to remain both sensitive and cautious, while also demonstrating sufficient skill and determination to navigate these challenges.

At the current juncture, Mainland Chinese pharmaceutical companies should proactively engage in global competition and strive to become truly globalized enterprises. This requires not only alignment with international standards in technology and management but also a global vision and strategic thinking. While domestic research and development capabilities have gained international recognition, it is worth noting that many products licensed to multinational corporations have been difficult to achieve successful launches. This highlights the need for companies to go beyond technological innovation and delve deeper into understanding the demands and operational dynamics of international markets. Furthermore, when pursuing globalization, in addition to considering whether their shareholder background supports their internationalization strategy, companies must also closely monitor the potential impact of global supply chain restructuring on their operations.

Entrepreneurs need to remain both sensitive and cautious, while also demonstrating sufficient skill and determination to navigate these challenges.

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### Maqda Bujar

Associate Director, Research Analytics, Center of Innovation Regulatory Science, Clarivate

### Hozana Castillo

Solutions and Consulting Manager, Life Sciences & Healthcare, Clarivate

### Ruchita Kumar

Senior Manager, Healthcare Research & Data Analytics, Clarivate

## **Huang Tingying**

Customer Success and Consulting Manager, Academic Research and Government Business, Clarivate

#### Adem Kermad

Senior Research Analyst, Center of Innovation Regulatory Science, Clarivate

## Zhao Hanyu

Regional Marketing Manager, Life Science & Healthcare, Clarivate

## Li Jingzhi

Executive Editor-in-Chief, Healthcare Executive

### Liu Yan

Regional Marketing Director, Academic Research and Government Business. Clarivate

## Zeng Shuwei

Business Solution Consultant, Intellectual Property, Clarivate

## Sun Xiaolong

Project Manager, Healthcare Executive

### Lv Hanmeng

Central Marketing Director, Healthcare Executive

### Chu Lei,

Senior Researcher, E-Pharma Industry Research Institute

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