

The Chinese Pharmaceutical Market: Size, R&D, Regulations, Market Access and Innovations

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As China has become the world's second-largest economy and the largest developing country, its economy and market have assumed a prominent position in the Asia-Pacific region. The pharmaceutical industry is an important part of China's national economy, with continuous strong demand, need, and capability for innovation. The industry continues to experience high levels of growth. With China's increasing emphasis on the pharmaceutical industry, and the gradual improvement of healthcare policies, momentum supporting the development of China's pharmaceutical market continues to accelerate. As the sector's market structure continues to become more optimized, the Chinese pharmaceutical market as a whole has shown a stable and positive pattern, and its current advantages and future potential are also attracting increasing numbers of overseas companies to do business in China. This article will analyze the Chinese pharmaceutical market from four aspects: a market overview, the regulatory and reimbursement environment, foreign pharmaceutical companies' strategies in China, and the current state of innovation adoption.

Part I. Chinese Pharmaceutical Market Overview

A. Overview of China's Population, Healthcare, and Economy

Table 1 shows the total population, including those 65+, and projected demographic trends in the next two years. Along with the increase in per capita GDP and improved quality of life, the aging population is increasing year over year and is expected to reach nearly 200 million in 2022. At the same time, healthcare infrastructure, such as the number of doctors and hospital beds per capita, still lags behind that of developed countries. However, with the introduction of incentive policies, the number of certified clinical trial sites in China has increased considerably. With the accumulation of experience in Multi-Regional Clinical Trial (MRCT), there is still room for building continued capability as experienced investigators from China have a growing interest in MRCT and early-stage clinical studies (see Figure 1).

An aging population in China will be a consideration moving forward. As a result, the pharmaceutical industry will be entering an era of growth fueled by changes to China's fundamental demographic structure. With demand for healthcare increasing along with the consumption level, the current prime-age group will become the main consumer base in the future.

Table 1. Overview of China's population, Healthcare, and Economy¹

	2020	2021	2022E	2023E
Total Population (million)	1,395	1,399	1,402	1,404
Population aged 65+ (million)	183.05	190.64	193.90	198.50
Average Number of Doctors/Thousand People	2.30	2.40	2.40	2.40
Average Number of Hospital Beds/Thousand People	4.10	4.10	4.10	4.20
Nominal GDP (USD billion)	14,841	17,305	18,085	18,945
Average per capita GDP, PPP (USD)	17,254	18,784	20,094	21,479

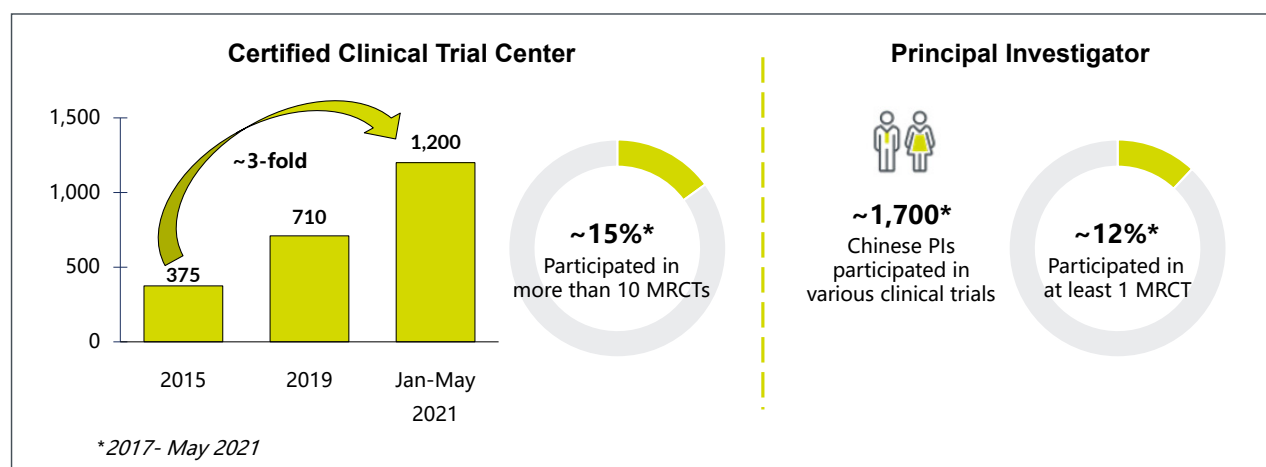


Figure 1: Number of Clinical Study Sites and Principal Investigators in China²

B. Overview of China's Pharmaceutical Market

Figure 2 shows the size of China's pharmaceutical market in 2019 and the expected size in 2024 in terms of therapeutic areas³. It is expected that in 2024, the total value of China's pharmaceutical market will have increased by nearly 36 percent from that of 2019. Given the large market value base (250 billion US dollars in 2019), the future growth prospects of the Chinese pharmaceutical market will continue to be very appealing. In 2019, the five largest therapeutic areas by market size were digestive and metabolic diseases, infectious diseases, central nervous diseases, cardiovascular diseases, and oncology diseases. Each area has a similar market share of ~10-15 percent. In 2024, these five areas will still represent almost 65 percent of the total market, and the oncology market is expected to experience the highest growth and market share as calculated by the compound annual growth rate (CAGR).

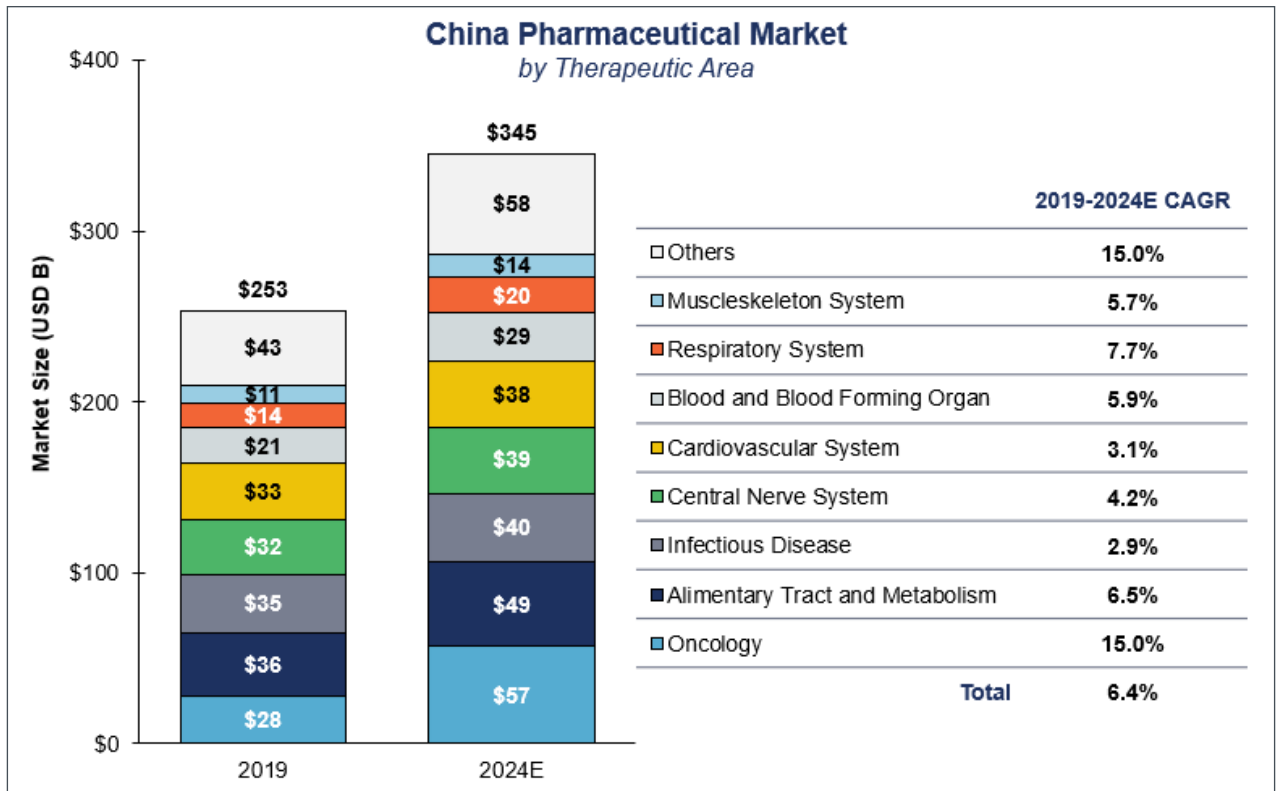


Figure 2: China Pharmaceutical Market by Therapeutic Area (1 USD=6.45330 RMB)³

Figure 3 highlights the size of China's pharmaceutical market broken down by generic and innovative drugs. In 2019, the market size for innovative drugs was about 12 percent larger than that of generic drugs, and it is expected that this gap will further widen in 2024 thanks to the continuous deepening of Chinese regulatory reform and the introduction of favorable policies to encourage companies to produce innovative drugs. Pharmaceutical companies, especially large ones, are also following this trend, increasing their R&D investment in innovative drugs and enriching their R&D pipelines, so that they can excel in the Chinese pharmaceutical market in the future.

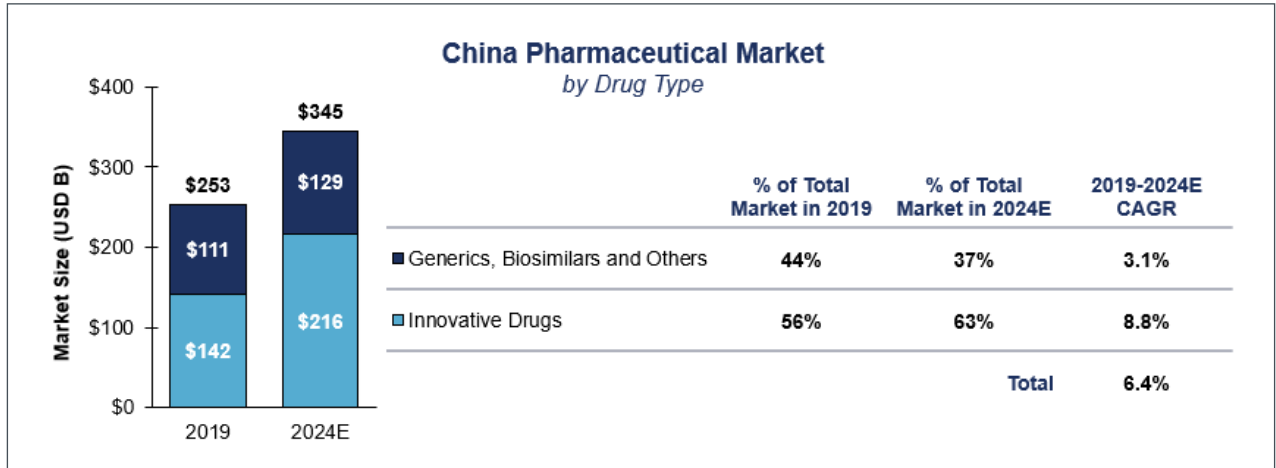


Figure 3: China's Pharmaceutical Market by Drug Type (1 USD=6.45330 RMB)³

(In this chart, innovative drug is defined as the first drug with specific active ingredients to receive approval for its label)

In the past 15 years (Figure 4), the number of R&D pipelines in China has maintained a growing momentum, but the increase is characterized by stages.⁴ Since 2016, the number of R&D pipelines has grown at an exponentially faster rate, attributable to the reform of China's drug review and approval system in 2015.

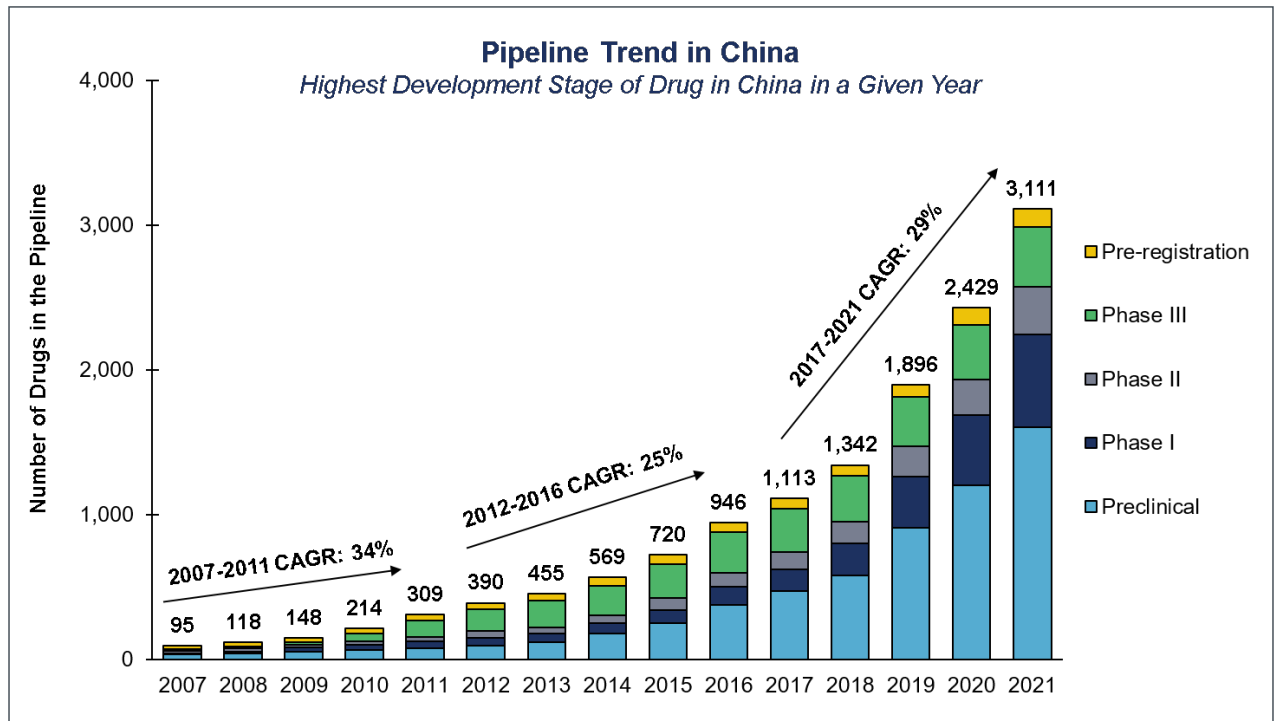


Figure 4: Pipeline Trend in China Over the Past 15 Years

Part II. R&D Pipelines and Clinical Trials

A. Oncology Drugs

Oncology comprises a high market share of resources for new drug research and development in China. 10 types of cancer occur with the highest incidence in China (Figure 5). include: Lung, gastric, liver, esophagus, and colon cancer had the highest mortality rates in 2020, with more than 2 million new cases and accounted for 65 percent of total cancer deaths (see Figure 5).

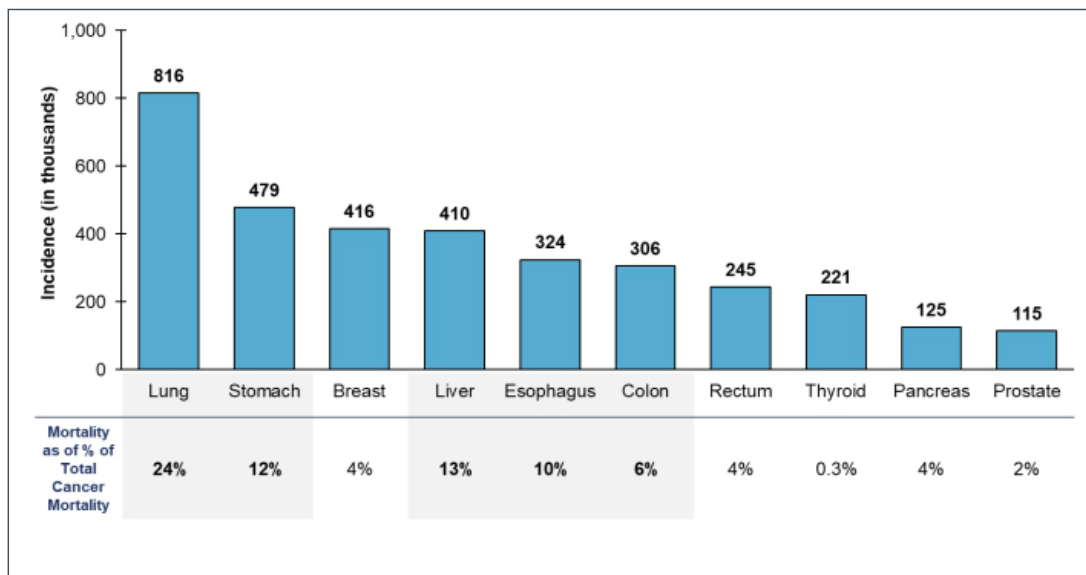


Figure 5: Top 10 Deadliest Cancers in China in 2020⁵

China's oncology drug market is projected to reach US\$57 billion in 2024 and the growth rate is expected to be higher than historical levels, driven by three main factors⁶:

- › **A Significant Increase in the Number of Patients:** In 2020, 4.6 million new cancer cases accounted for about a quarter of the global incidence of cancer. Due to an aging population, environmental pollution, unhealthy lifestyles, and improvements in diagnostic technology, the number of new cancer patients is expected to increase to 5.2 million by 2025.
- › **Huge Unmet Need for Cancer Treatment:** Although more and more new oncology therapies have been approved by the National Medical Products Administration (NMPA) in recent years, the gap between China and developed countries for available anti-cancer therapies is evidenced by 2021 data in which 43 targeted small molecule drugs are available in China compared to 107 in the US.

- › **Oncology drugs as a key therapeutic area in National Reimbursement Drug List (NRDL) first-time listing:**
 In 2021, oncology drugs were the largest category of NRDL listings of novel drugs, accounting for ~26 percent of all the listings. Including novel oncology drugs as Class B drugs reduce patients' out-of-pocket expenses.

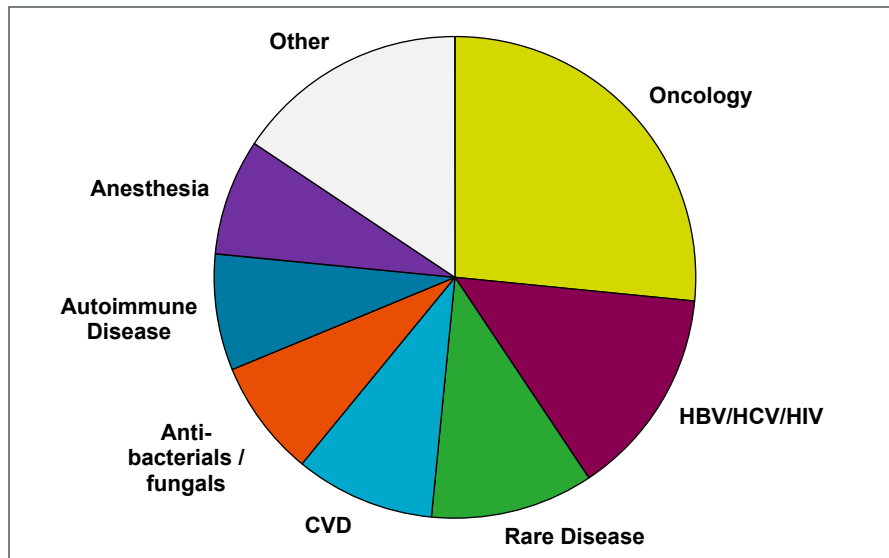


Figure 6: First-time NRDL Listings by Therapeutic Area in 2021⁷

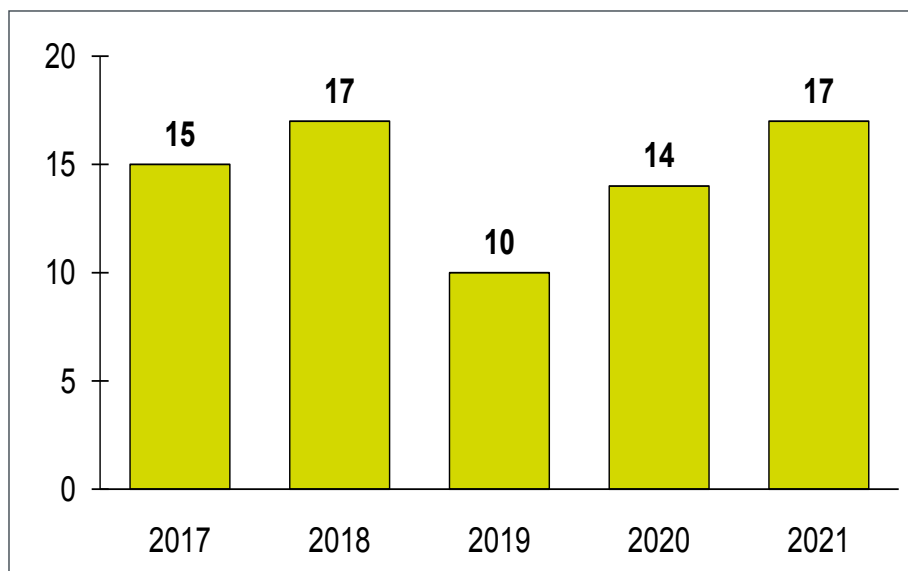


Figure 7: Number of First-time NRDL Listings of Novel Oncology Drugs⁸

B. Rare Disease Drugs

Because rare diseases impact a relatively small number of patients, the pressure on R&D competition may have been less in the past. But, Chinese regulatory authorities have accelerated the introduction of incentive policies to encourage companies to develop drugs for rare diseases. In China, rare diseases are recognized in the National Rare Diseases List. In May, 2018, the National Health Commission of China released the First List of Rare Diseases in China, which covers 121 diseases that affect up to 3 million patients. The current Chinese rare disease drug market is valued at close to US\$1 billion and is projected to grow at a speed of about 40 percent (see Figure 8), mainly attributed to the following three factors⁹:

- › **Large Patient Population:** In May 2018, China's National Health Commission and four other departments jointly released China's first Rare Disease List, covering 121 diseases that affect more than 3 million patients¹⁰.
- › **Inclusion of Rare Disease Drugs by NRDL Hit New High in 2021:** In 2021, there were seven first-time NRDL listings of novel drugs for rare diseases. This has been the largest intake of novel drugs for rare diseases to NRDL since 2019.
- › **NMPA Accelerated Approval:** From 2018 to 2020, NMPA announced three lists of overseas new drugs urgently needed for clinical use, including rare disease drugs, which qualify for priority review and approval.

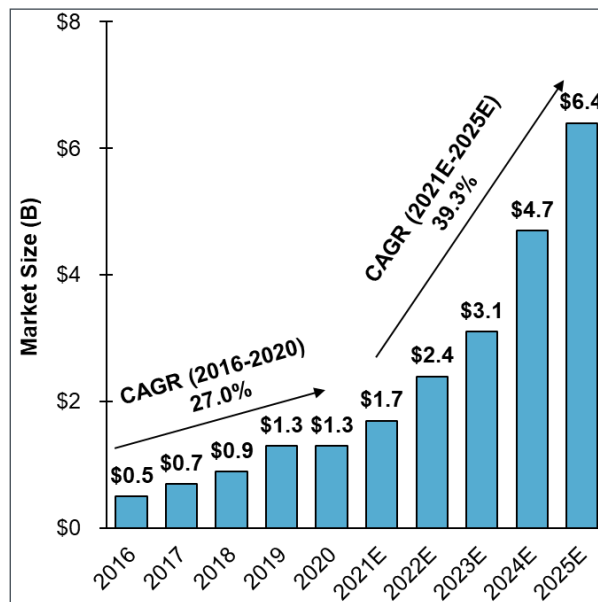


Figure 8: Rare Disease Drug Market in China¹¹

From 2019 to 2021, 26 drugs from foreign pharmaceutical companies have been approved to treat 18 rare diseases. Names, manufacturers, and rare disease indications of drugs from foreign pharmaceutical companies approved in China from 2019 to 2021 are listed in Figure 9 and Table 2.¹²

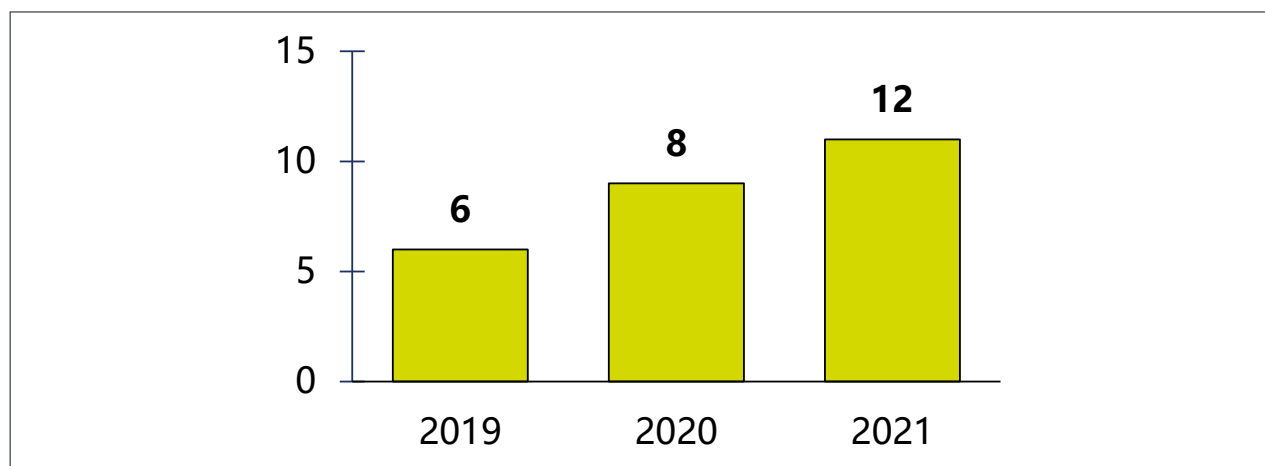


Figure 9: Rare Disease Drugs from Foreign Pharmaceutical Companies that Have Been Approved in China¹²

Table 2*: Rare Disease Drugs from Foreign Pharma Approved by NMPA from 2019 to 2021¹²

Drug Name	Manufacturer	Indications	Approval Date
nusinersen	Biogen	Spinal Muscular Atrophy	2019-02-22
elosulfase alfa	BioMarin	Mucopolysaccharidosis IV	2019-05-21
fingolimod	Novartis	Multiple Sclerosis	2019-07-12
edaravone	Mitsubishi Tanabe Pharma	Amyotrophic Lateral Sclerosis	2019-08-07
bosentan	J&J	Pediatric Pulmonary Hypertension	2019-09-05
agalsidase beta	Sanofi	Fabry's Disease	2019-12-18
tafamidis	Pfizer	Idiopathic Cardiomyopathy	2020-02-05
sildenafil	Pfizer	Idiopathic Pulmonary Arterial Hypertension	2020-02-05
siponimod	Novartis	Multiple Sclerosis	2020-05-07
deutetrabenazine	Teva	Huntington's Disease	2020-05-12
laronidase	Sanofi	Mucopolysaccharidosis I	2020-06-02
agalsidase alfa	Takeda	Fabry's Disease	2020-08-26
lanadelumab	Takeda	Hereditary Angioedema	2020-12-02
turoctocog alfa	Novo Nordisk	Hemophilia A	2020-12-29
burosumab	Kyowa Kirin	Hypophosphatemia Rickets	2021-01-05
icatibant	Takeda	Hereditary Angioedema	2021-04-07
dimethyl fumarate	Biogen	Multiple Sclerosis	2021-04-13
eftrenonacog alfa	Sanofi	Hemophilia B	2021-04-20
velaglucerase alfa	Takeda	Gaucher's Disease	2021-04-27

Drug Name	Manufacturer	Indications	Approval Date
satralizumab	Roche	Neuromyelitis Optica	2021-04-30
fampridine	Biogen	Multiple Sclerosis	2021-05-11
tetrabenazine	Bausch Health	Huntington's Disease	2021-06-16
risdiplam	Roche	Spinal Muscular Atrophy	2021-06-16
nitisinone	Sobi	Hereditary Tyrosinemia Type I	2021-06-16
siltuximab	EUSA Pharma	Castleman's Disease	2021-11-30
ofatumumab	Novartis	Multiple Sclerosis	2021-12-20

* Only drugs approved for indications classified as rare disease by China's First List of Rare Disease (121 rare diseases). tafamidis capsule (Vyndamax) and tafamidis soft capsule (Vyndaqel) are only counted once. Note that Table 2 includes drugs approved by NMPA from 2019 to 2021 for their first rare disease indication. For example, emicizumab is not included as it is approved by NMPA for hemophilia A (with FVIII inhibitors) in Nov 2018, and its indication extended to hemophilia A (without FVIII inhibitors) in May 2021. nintedanib is not included as it is approved by NMPA for idiopathic pulmonary fibrosis, and its indication extended to scleroderma in Jun 2020.

C. Overview of Registrational Trials in China**

On June 7, 2022, the Center for Drug Evaluation (CDE) released the *Annual Report on Clinical Trials for New Drug Registration in China (2021)* compiled with data from the Drug Clinical Trial Registration and Information Disclosure Platform, from January 1 to December 31, 2021.¹³ Detailing the current status and future development trends of new drug research and development in China, the report is a comprehensive summary and analysis of clinical drug trials in China, and can serve as reference for new drug R&D.

1. Overview of Drug Clinical Trials in China in 2021

Figure 10 provides a comprehensive summary of clinical trials approved by the CDE in 2021¹⁴. A total of 3,358 clinical trials were registered in 2021, an overall increase of 29.1 percent from 2020. Domestic clinical trials accounted for up to 90 percent and international multicenter trials accounted for about 10 percent; The number of clinical trial registrations was higher for novel drugs than for generic drugs, accounting for 60 percent (2,033) and 39.5 percent (1,325), respectively. Trials registered for innovative drugs were mainly initiated by domestic sponsors (accounting for 80 percent) while clinical trials for chemical drugs and biological products accounted for a higher proportion than those for traditional Chinese medicine. Phase I clinical trials accounted for the highest proportion (42.9 percent), followed by Phase III and Phase II. For drug clinical trials registered in 2021, the average domestic trial enrollment number was 943.5, with the average target enrollment number of chemical drugs and biological drugs Phase III being 285.7 and 639.1, respectively.

** The chart data in this section are all from the Annual Report on Clinical Trials for New Drug Registration in China (2021)

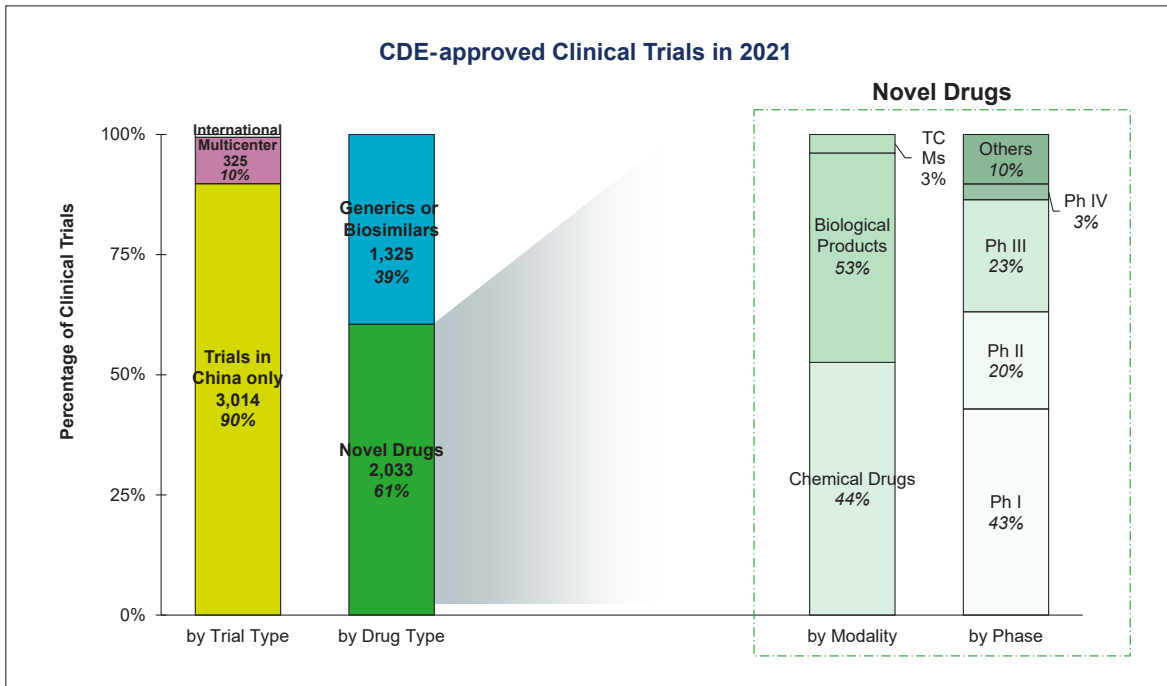


Figure 10: Clinical Trials Approved by CDE in 2021

Among the chemical drugs in clinical trials, top 10 by number of trials are mainly oncology drugs, including 4 non-oncology drugs (see Figure 11). Biological products whose number of trials ranked in the Top 10 are mainly therapeutic biological products (see Figure 12).

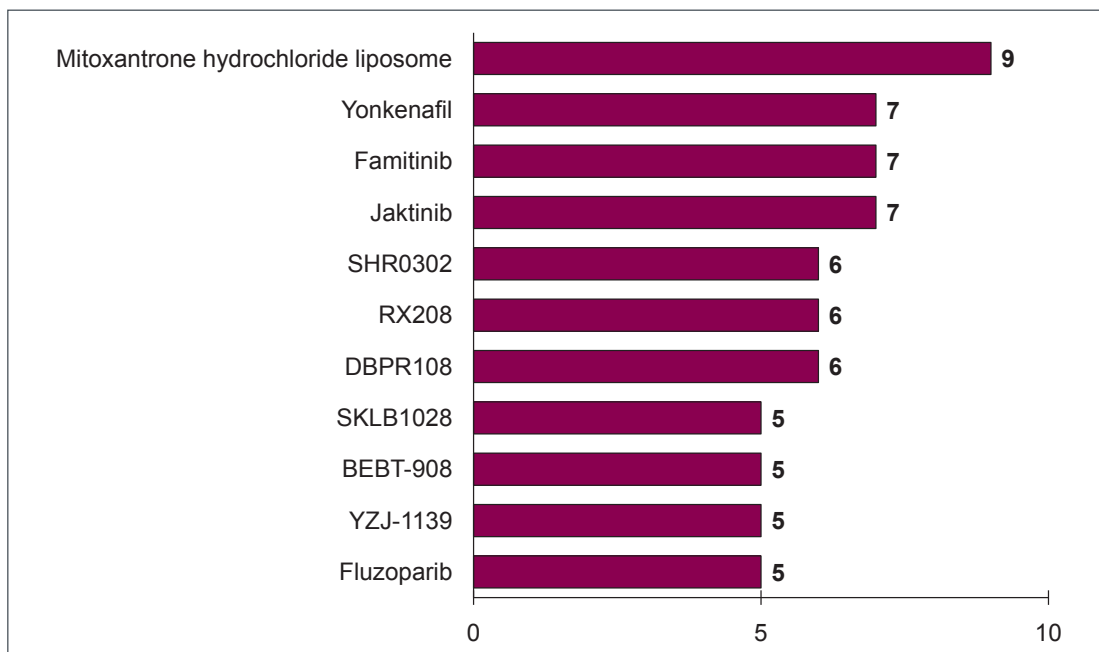


Figure 11: Chemical Drugs Involved in Non-BE/Consistency Evaluation Clinical Trials

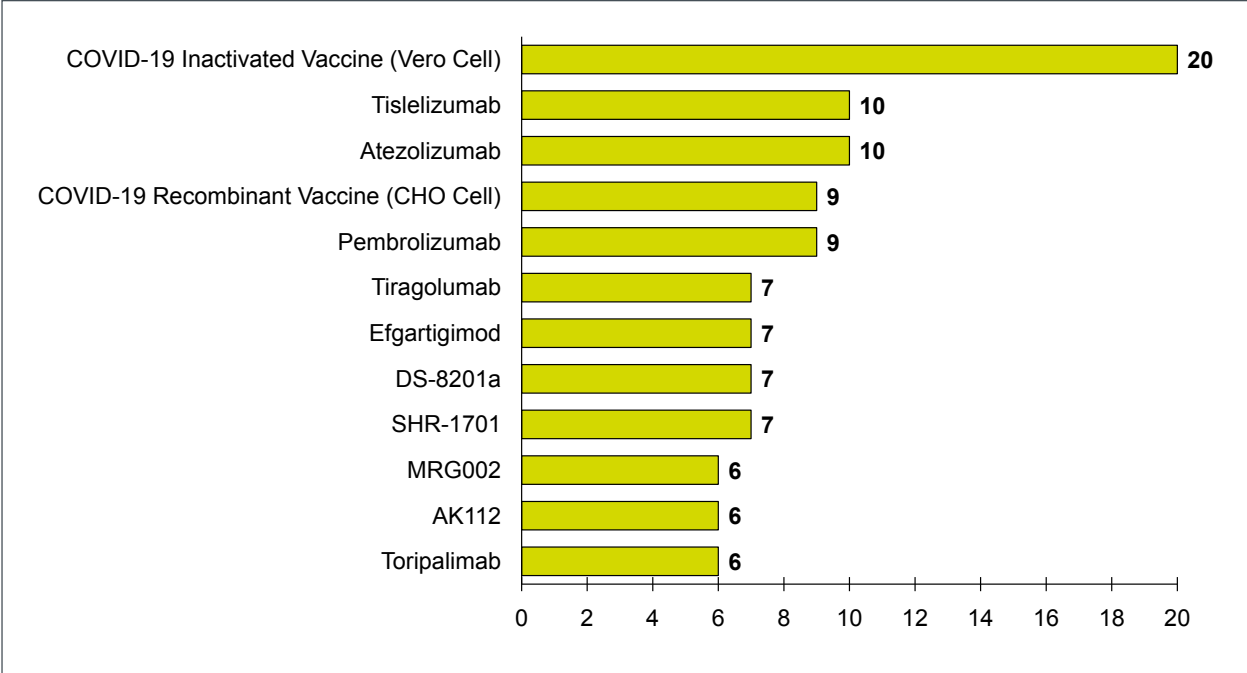


Figure 12: Biological Products Involved in Non-BE/Consistency Evaluation Clinical Trials

2. Indications and Targets of New Drug Trials

In terms of indications, chemical drug indications were mainly concentrated on oncology drugs, accounting for 39.5 percent of all trials. The indications of biological products are also mainly oncology drugs, accounting for 45.8 percent of all trials (see Figure 13). In addition, clinical trials of COVID-19 vaccines also occupied a notable share in 2021.

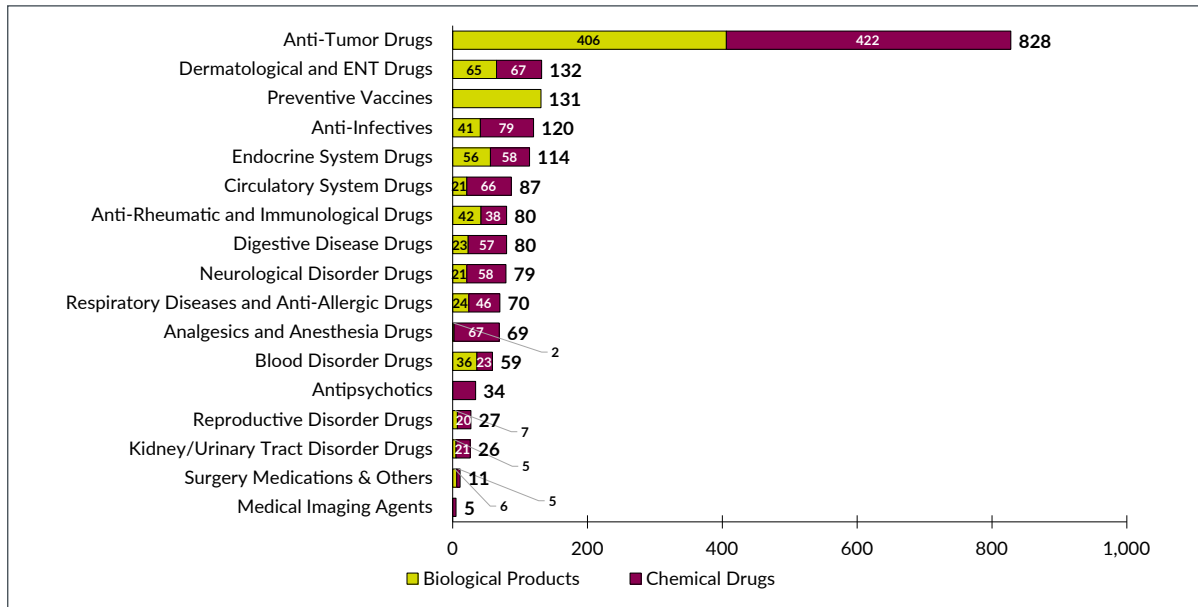


Figure 13: Clinical Trials of Chemical Drugs and Biological Products by Indication in 2021

The top 10 targets for clinical trial drugs registered in China are shown in figure 14; among these top 10 targets the largest number of clinical trials are concentrated on PD-1, PD-L1, etc.. In addition, phase I clinical trials accounted for more than 40 percent of the drug clinical trials of four targets. Phase II clinical trials account for between 8 percent and 37 percent of each target.

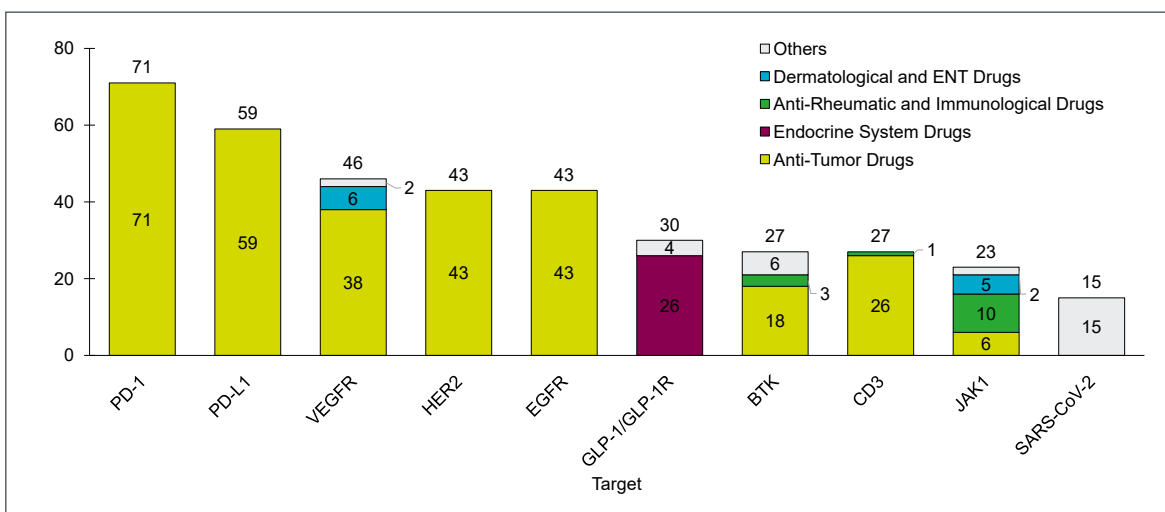


Figure 14: Top 10 Targets and Indications

The above data suggests a homogeneity of new drug clinical trials in China. The clinical trials registered in 2021 are mainly concentrated on oncology therapies.

3. Clinical Trials in Special Populations

Clinical trials involving geriatric population accounted for 74.5 percent of the total clinical trials of new drugs. With the increase of China's aging population, the potential demand of elderly older adult patients for drugs has been increasing, leading to more R&D efforts made by pharmaceutical companies for this population segment. However, currently, clinical trials specifically for geriatric older adult and pediatric populations only account for 0.1 percent, and 3.0 percent of total clinical trials of new drugs respectively (see Figure 15).

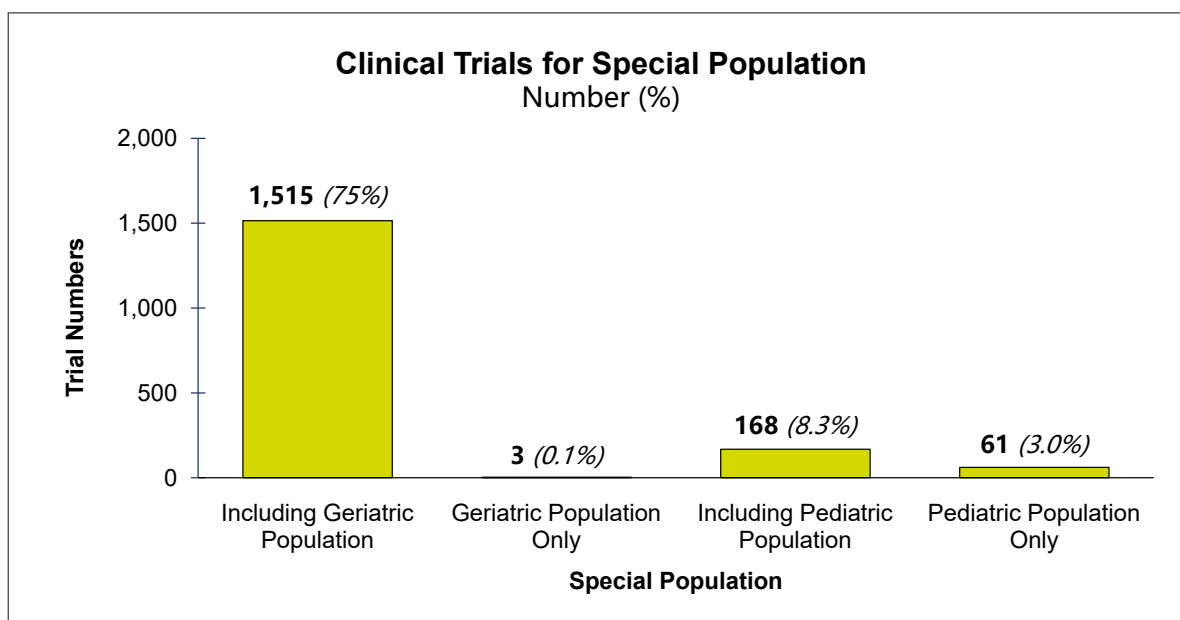


Figure 15: Number of Clinical Trials Conducted in Special Populations in 2021

For the pediatric-population-only trial, biological products accounted for 67 percent, mainly preventive vaccines. There were broader indications for chemical drugs, e.g., endocrinology, oncology, dermatology, ENT, etc. (see Figure 16).

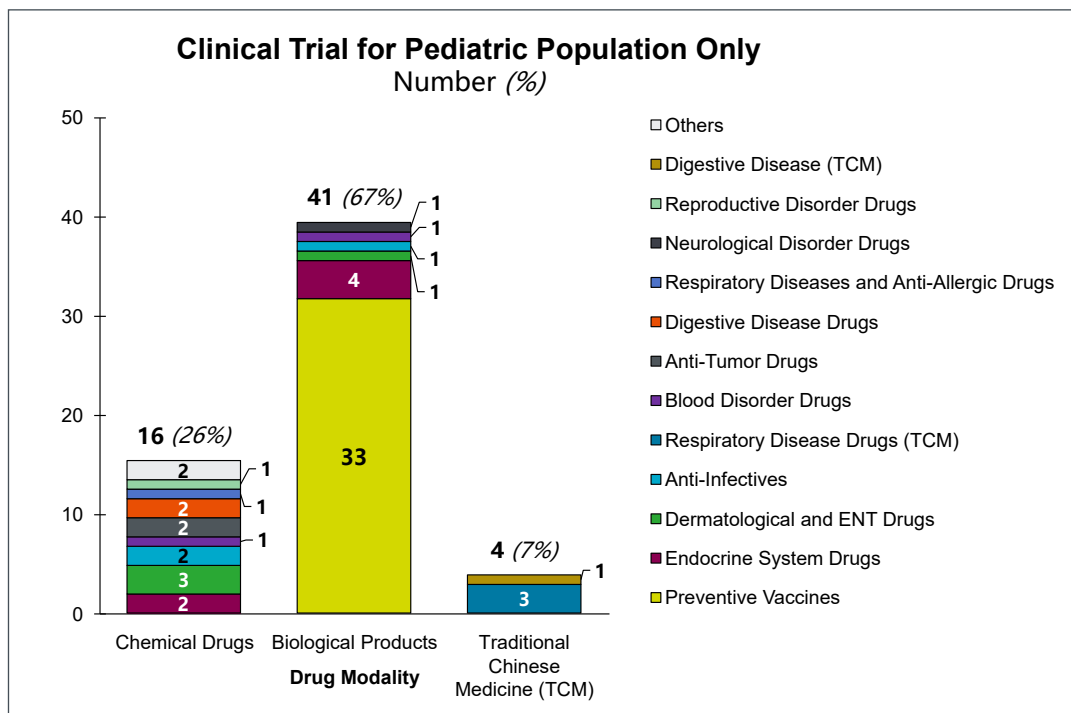


Figure 16: Pediatric Trials in 2021

4. Initiation Time and Completion Status

Among the 2,033 new drug clinical trials in China, 819 (40 percent) had registered the first Informed Consent Form (ICF) date (excluding those approved before 2021 but newly added in 2021). The time taken to initiate clinical trials was analyzed according to the ICF date and clinical trial approval date, and the results show that the elapsed time between clinical trial approval and clinical trial initiation ranged from 3 days to 91 months, with an average of 12.2 months (see Figure 17).

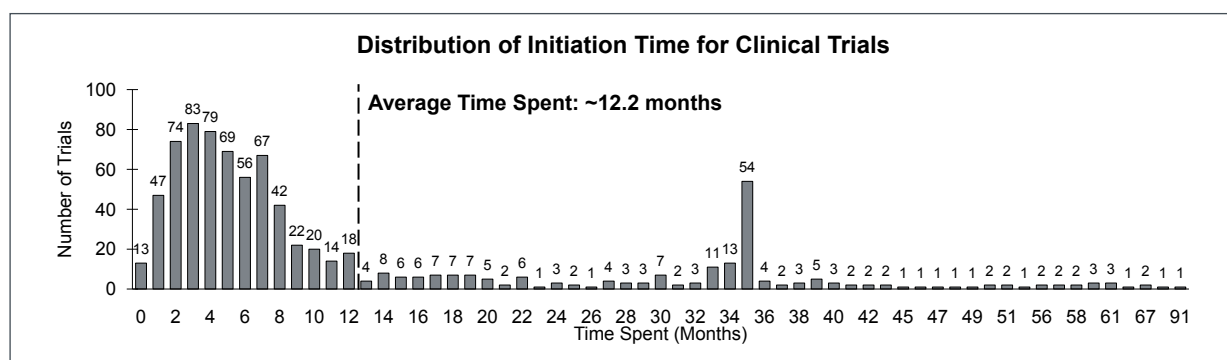


Figure 17: Distribution of Initiation Time for Clinical Trials in 2021

For clinical trials of novel chemical drugs/biological products, the percentage of clinical trials initiating subject recruitment within six months after IND approval was 51-58 percent, and 77-79 percent within one year after IND approval. If calculated on the basis of a three-year (< 36 months) approval validity period, approximately 93-96 percent of the clinical trials initiated subject recruitment within the validity period of the approval (see figure 18).

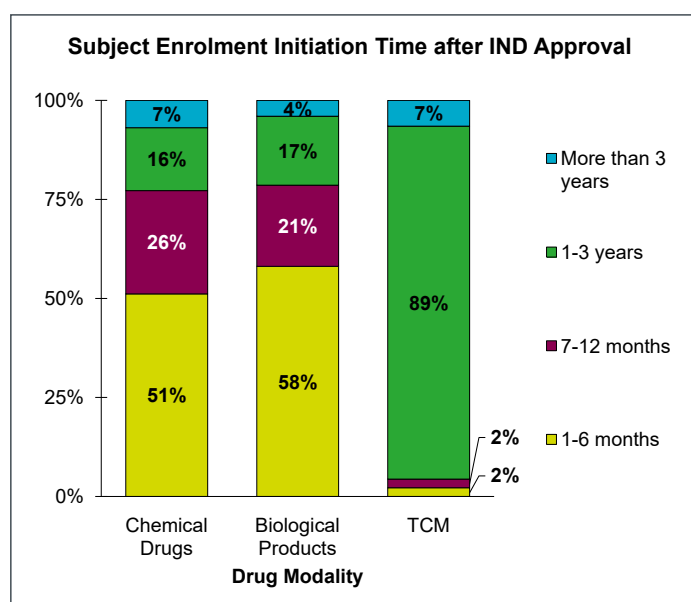


Figure 18: Subject Recruitment Initiation Time after IND Approval in 2021

In terms of trial completion, among the 2,033 clinical trials of new drugs, 108 were completed in 2021 (see Figure 19). By trial phases, the number of phase I clinical trials completed was 95 in total - which was the largest and accounted for 88 percent of total, followed, in descending order, by 3 phase II, 5 phase III trials. In terms of drug modality, 91 trials for chemical drugs were completed, which accounted for the largest share (84 percent) of total trial completion.

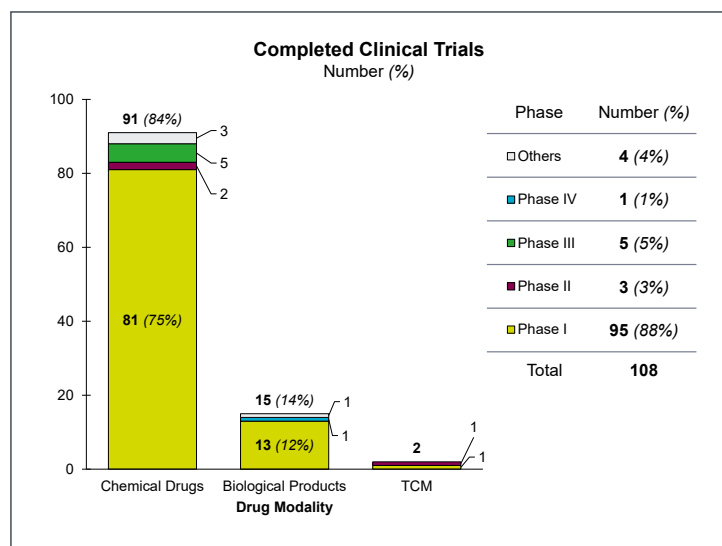


Figure 19: Clinical Trial Completion Status in 2021

In 2021, there were 6 voluntary suspensions and 18 voluntary terminations (Table 3). By drug modality, there were 15 voluntary suspensions/terminations of chemical drugs mainly due to adjustment of the R&D strategy. On the other hand, there were 8 voluntary suspensions/terminations for biologics due to a wider variety of reasons, e.g., safety, limited clinical benefit, adjustment of R&D strategy, etc.

Table 3: Analysis of Suspension/Termination of Clinical Trials in China

Drug Type	Voluntary Suspension	Voluntary Termination	Type of Reasons (number of clinical trials)
Traditional Chinese Medicine	1	-	- Adjustment of R&D Strategy and Protocol Design
Chemical Drugs	1	14	- Adjustment of R&D Strategy (10) - Safety problem (2) - Limited Clinical benefit (1) - Protocol design problem (1) - Suspension after meeting (1)
Biological Products	4	4	- Safety problem (2) - Limited clinical benefit (2) - Suspension/termination due to adjustment of R&D strategy (2) - Fail to fulfill enrollment target (1) - Termination due to end of global enrollment (1)
Total	6	18	

The above data shows that, on the whole, the implementation efficiency after IND approval is not high. Among the registered clinical trials in 2021, around 21-23% of all trials initiated subject recruitment for chemical drugs/biological products take more than one year after IND approval. This serves as a reminder to sponsors that when outsourcing a trial to a CRO company, it is critical to choose a partner with demonstrated recruitment efficiency, good quality of completion to help shorten the approval time and remain competitive, and to achieve significant commercial interests.

5. Distribution of Participating Sites

The clinical trial institutions in Beijing, Shanghai, Guangdong, Jiangsu and Hunan recorded the most participation in clinical trials as leading sites, accounting for approximately 57 percent of the total (see Figure 20). The data shows that the geographical distribution of clinical trials in China today is very uneven, with new drugs trials being concentrated in Beijing, Guangdong, Jiangsu, Shanghai and Zhejiang. This phenomenon is a result of the unbalanced economic and healthcare sector development in various provinces and cities in China. On the other hand, however, it also indicates the potential of other provinces and cities for future potential clinical trials.

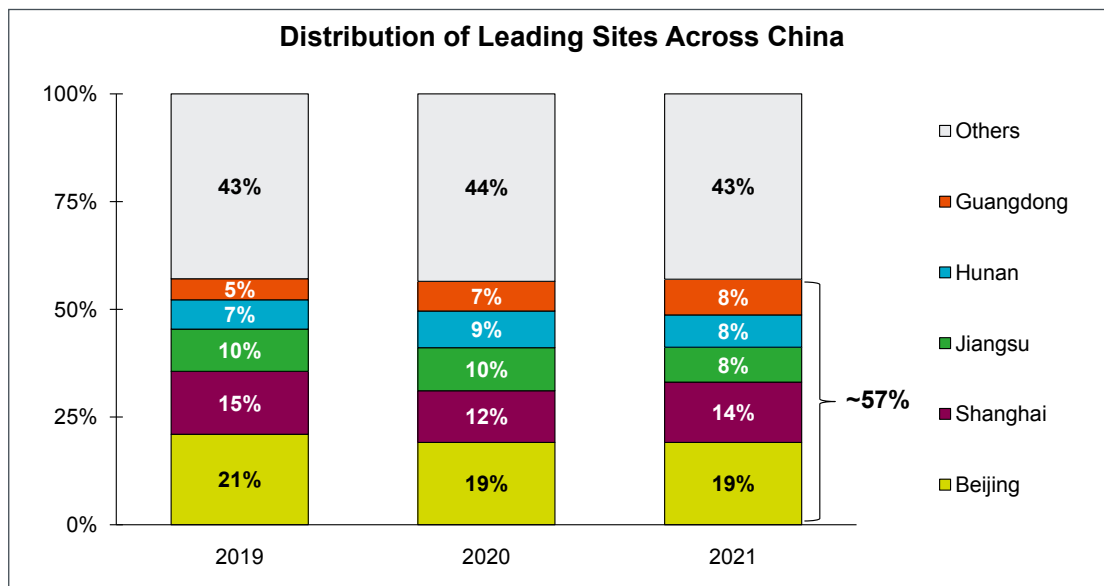


Figure 20: Distribution of Leading Sites Across China in 2021

Part III. China's Regulatory and Reimbursement Environment, and Drug Development Strategies

Prior to 2015, a number of difficulties were faced by China's pharmaceutical industry. These included a huge number of drug registration applications filed with regulators (the backlog of applications reached as high as 22,000 in September 2015), an overly long approval process for drug clinical trials and marketing applications, and a lack of innovation in drug development. All of these factors contributed to a lag in launch status for many urgently needed innovative drugs in China, behind those in Europe, the US, and Japan.

A. Reform of China's Drug Review and Approval System

In August 2015, the State Council released the Opinions of the State Council on Reforming the Drug and Medical Device Evaluation and Approval System, which signifies the beginning of the reform of the drug review and approval system. In October 2017, the General Office of the State Council published the Opinions on Deepening the Reform of Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices, another programmatic document, in addition to the previous one issued in 2015, for the reform of the drug review and approval system, and which serves as a cornerstone for the innovative development of China's pharmaceutical industry. Overall, the reform was focused on three aspects: 1. addressing the backlog of drug registration applications by increasing the efficiency of the review process; 2. encouraging drug innovation and improving the quality of drugs; 3. improving regulations and promoting drug regulatory legislation.

1. Addressing the Backlog of Applications by Improving Review Efficiency

In order to provide conditions that are necessary for advancing reform in subsequent stages, China's drug regulatory authorities are dedicated to building an efficient drug review, approval, and regulatory procedure. On July 22, 2015, the former CFDA (China Food and Drug Administration, now NMPA) instituted a requirement for self-inspection and examination of clinical trial data involved in drug registration applications. This was not only to ensure the authenticity and integrity of data, but also to reduce the workload for the former CFDA so that the huge backlog of applications, including CTAs and MAAs, could be cleared by the end of 2016. Additionally, the former CFDA also raised application fees and expanded the review team to avoid a further pile-up of applications and to improve review efficiency. The backlog issue was resolved by the middle of 2017 and the number of pending applications was reduced from its peak of 22,000 in 2015 to 6,000¹⁵.

In July 2018, the Announcement on Adjusting the Review and Approval Procedures of Drug Clinical Trials was released. **This shortened the review time limit of drug clinical trial applications to 60 working days, leaving behind the era when it took about 9 to 18 months to complete the review and approval of clinical trials.** According to the "2020 Drug Review Report" and "2021 Drug Review Report" released by the Center for Drug Review and Evaluation, the overall annual review rate of clinical trial applications within 60 working days in 2020 and 2021 were 99.87% and 99.86%, respectively.

2. Encouraging Drug Innovation and Improving Drug Quality

Under the pre-reform legal framework, the broad definition of new drugs has hindered true innovation in drug development. To address this, on November 4, 2015, the National People's Congress issued a decision to authorize the State Council to launch a three-year Pilot Program of a market authorization holder (MAH) system for drugs in ten provinces/municipalities and to reform the drug registration system. According to the Pilot Program, drug manufacturing license holders can differ from market authorization holders, and research and development organizations and Chinese scientific research personnel with limited manufacturing capacity are permitted to submit IND or new drug applications. On March 4, 2016, the former CFDA issued Work Plan for Reforming Chemical Drugs Registration Classification System, officially releasing the new classification system for chemical drugs, and redefining new drugs as those developed (i.e., not approved) in any part of the world, rather than merely those developed/not approved in China.

On October 8, 2017, the General Office of the State Council issued the Opinions on Deepening the Reform of Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices. According to this document, despite rapid development and continuous advancement of reforms, China's pharmaceuticals & medical device industry still lacked sufficient support for technological innovation, resulting in a significant gap between the products within the China market and those of the more-advanced international level. The document offered several suggestions to promote industrial restructuring and technical innovation and satisfy the unmet clinical needs of the public, among which the highlights include the following opinions related to encouraging drug innovations and improving drug quality:

- ▶ Pharmaceutical clinical trial organizations shall be subject to filing administration, supporting the clinical trial organizations and personnel to conduct clinical trials ; the Institutional Review Board Mechanism should be improved to increase the efficiency of ethical reviews, and the clinical trial data obtained from overseas multi-center clinical trials, which meet relevant requirements for pharmaceuticals and medical device registration in China, can be used for registration applications in China.

- › To encourage drug innovation and improve drug quality, the following suggestions are offered: establish a Catalog of Approved Drug Products which shall include newly approved drugs, or generic drugs that have passed the quality and efficacy consistency evaluation and carry out a pilot program of the compensation system for pharmaceutical patent terms for some new drugs. This program will grant appropriate patent term compensation for the delay of the drug launch due to the clinical trial or marketing approval process, improve and implement the drug trial data protection system, encourage pharmaceutical and medical device manufacturers to increase investments in R&D, strengthen research and development of new drug products and continue research for products already on the market, and continue to improve manufacturing processes, support clinical application of new drugs, improve the dynamic adjustment mechanism for the NRDL, include new drugs in the reimbursement scope of basic medical insurance in a timely manner according to regulations, and support new drug research and development.

3. Further Improving Legal Framework, Promoting Drug Regulatory Legislation

To support the smooth implementation of the policies mentioned above, the Chinese government has amended corresponding laws and regulations to facilitate reform at the legislative level.

The amended version of the *Drug Administration Law of the People's Republic of China* was approved at the 12th meeting of the Standing Committee of the 13th National People's Congress on August 26, 2019 and took effect on December 1, 2019. The revision incorporated clinical value-oriented innovative drug research and development, clinical trial ethics review, accelerated review and approval, communication and exchange mechanism, and the drug marketing authorization holder system into the Law, providing a legal basis to support the innovative development of China's pharmaceutical industry.

On January 22, 2020, the State Administration for Market Regulation approved and published the amended version of the *Provisions for Drug Registration* (hereafter referred to as the *Regulations*) which took effect on July 1, 2020. The new version of the *Regulations* was formulated based on the *Drug Administration Law*, the *Vaccine Administration Law*, and other relevant Chinese laws and administrative regulations. It incorporated the results of the reform of the drug review and approval system and specified basic requirements for new drug registration by defining the basic system and procedures for new drug registration and the main responsibilities and obligations of stakeholders. These measures not only highlighted and consolidated the outcomes of reform for pharmaceuticals, but also gave impetus to the further deepening of the reform in other areas. In terms of encouraging R&D of innovative drugs, the document also provided more-specific content to encourage innovations in a bid to increase drug accessibility.

- › Based on the status quo of China's pharmaceutical industry and actual needs for clinical treatment, as well as the experiences of international practices, a new chapter regarding procedures for accelerating drug registration was written into the *Regulations*. In addition to the original Special Approval Procedure, another three expedited procedures were added, which include **Breakthrough Therapy**, **Conditional Approval**, and **Priority Review and Approval**, along with the eligibility criteria, procedures, and supporting policies for each of them.

- › Urgently needed drugs in clinical practice, pediatric drugs, rare disease drugs, drugs for urgent public health needs, vaccines urgently needed for epidemic prevention and control, and innovative vaccines specified in the Drug Administration Law, the Vaccine Administration Law, and other documents issued by the State Council, were explicitly included in the scope of accelerated approval.

In addition, the new version of the *Regulations* accounts for the specific technical requirements in drug registration management which will be continuously adjusted and improved in combination with technological development. Therefore, if it is not appropriate to specify provisions in the *Regulations*, Chinese regulators will publish them in the form of supporting documents and technical guidelines in order to conform to a more scientific approach to drug development. The official website of the CDE has specially set up a column with guiding principles for this purpose, such as guiding principles for the *Regulations*, guidelines for development of oncology drugs, as well as guidelines for individual medicines, which will help improve efficiency of the review process and shorten time to market by providing applicants with reference and guidance for the drug development and registration process.

B. An Overview of Reimbursement Policies in China

Incorporating pharmaceutical products into the NRDL upon approval in China is a step towards higher sales performance. Additionally, price negotiation for NRDL inclusion is also an important means for innovative drugs to increase sale volumes.

Founded in 2018, the National Healthcare Security Administration (NHSA) is responsible for upgrading the *China's National Essential Drug List and the Directory of Drugs for National Basic Medical Insurance*, which will be adjusted on an annual basis through a dynamic adjustment mechanism. With the acceleration of the development and approval of innovative (generic) drugs, and more companies pursuing the same target, competition among top pharmaceutical companies and biotech firms is fierce. Obtaining NRDL inclusion for their products is critical for many pharmaceutical companies, key to a significant competitive advantage in the marketplace.

Since the National Healthcare Security Administration (NHSA) was founded, NRDL price negotiations have become an important part of the NRDL adjustment process, and is compulsory for any drugs to be included in the list. Pharmaceutical companies participate in negotiations with the NHSA to forego a certain amount of their profit margin in order to get the opportunity to be included on the list. From observing the results of previous rounds of negotiations, innovative drugs can rapidly achieve significant growth in sales revenues through a Lower-Price-for-Larger-Volume strategy after being incorporated into the NRDL. In 2020, the voluntary application mechanism was adopted for pharmaceutical companies to apply for inclusion in the NRDL. Innovative drugs have reaped the greatest benefits from this mechanism as the time frame for innovative drugs to receive marketing approval for NRDL inclusion has been shortened from around five years to less than two years. Novartis, for example, was one of the big beneficiaries in 2020 when its new drug approval coincided with NRDL adjustment. In 2020, Novartis' sales revenue in China was USD 2.573 billion, accounting for 5 percent of the company's total; the growth rate in China was 16 percent, greater than that in Japan (5.6 percent). Additionally, eight new products and indications were included in the 2020 NRDL through the negotiations, and four products' contracts were renewed¹⁶.

C. Development Strategies for Imported Drugs in China

In recent years, the Chinese government has set up a relatively complete pharmaceutical innovation ecosystem by promoting the reform of the drug review and approval system. The strategies which multinational pharmaceutical companies adopt for drug development have grown more diverse. This can be attributed to the virtuous interactions of state policies with capital, diversification of market participants, and extensive cooperation and communication between domestic and multinational pharmaceutical companies, biotech firms, investors, academia, and regulators to improve the ecosystem.

1. Registration Strategies for Drugs Approved in Overseas Markets

- › For drugs that have been launched in overseas markets to register in China, applicants can directly submit the inspection findings and conclusions from overseas national regulatory agencies that have adopted management standards based on international norms, and CDE will use them as a reference for quality assessment of clinical trial data.
- › A drug can be exempted from clinical trials and get directly authorized for marketing in China once it has been assessed to be safe and effective and has been shown by evidence to have no ethnic difference.
- › If the drug is safe and effective but lacks ethnic sensitivity data, relevant bridging trials need to be performed.
- › If global data cannot support the evaluation of safety and efficacy, and there is a continued wish to register and market the drug in China, necessary exploratory and confirmatory clinical trials should be carried out according to the requirements for new drug approval.

2. Registration Strategies for Drugs Not Yet Approved in Overseas Markets

At present, the regular procedure for new drug registration in China is characterized by a “Two-Applications and Two-Approvals” process, which refers to one application and approval for clinical trials, and another application and approval for marketing.

After completing a drug’s chemical, manufacturing and control (CMC) and non-clinical studies, pharmaceutical companies can submit an IND application to CDE. Currently, a tacit approval mechanism is adopted for such applications, which means applicants are permitted to conduct clinical trials if their applications are not denied or questioned within 60 days from the date of receipt of the application. Overseas pharmaceutical companies may consider including China in multi-regional clinical trials (MRCTs) or conduct a separate bridging study to synchronize their drug development and launch.

During the process of clinical trials or NDA, pharmaceutical companies can also apply for expedited programs (Breakthrough Therapy, Conditional Approval, Priority Review & Approval, and Special Approval) according to the characteristics of their drugs and indications, such as drugs for life-threatening diseases or diseases which significantly reduce the patient’s quality of life, urgent clinical needs, or for treating rare diseases. It is worth noting that the CDE allows eligible applicants to apply via multiple pathways for accelerated approval, instead of merely one to shorten the review and approval time.

3. Drugs Already Approved in Other Markets (Including Hong Kong and Macau) are Permitted to be Utilized in Specific Chinese Regions without Registration Approval

In November 2020, the NMPA Research Base for Regulation of Pharmaceutical Products and Medical Devices was established in the Boao Lecheng International Medical Tourism Pilot Zone, in Hainan Province. Its mission is to promote the role of Real-World Evidence (RWE) in regulatory decision-making and approval of pharmaceutical products and medical devices. Companies are encouraged to introduce imported drugs which have yet to be approved in China to the pilot zone, and utilize the data generated from the use to support subsequent NDA in China. High-quality, innovative drugs can then reach more Chinese patients faster. During the same approximate time period, under the approval of the State Council, eight ministries including the State Administration for Market Regulation and NMPA, jointly issued *the Work Plan for Regulatory Innovation and Development of Pharmaceutical and Medical Device in Guangdong-Hong Kong-Macao Greater Bay Area (GBA)*. According to this document, Guangdong Provincial Food and Drug Administration will review and approve drugs that are urgently needed in clinical settings which have already been launched in Hong Kong or Macao, and clinically advanced medical devices that are urgently needed in clinical settings which have been used by public hospitals in Hong Kong and Macao. After approval, they can be utilized by designated medical institutions in the nine inland cities of GBA.

Foreign sponsors are now permitted to have their drugs prescribed in the above-mentioned regions upon filing with regulators. This policy brings two direct benefits: patients in these two areas with no effective therapies for their diseases can have earlier access to new therapies and, the real-world data generated from these drugs can be used to support subsequent registration applications in China. Additionally, Chinese regulatory authorities are also actively researching and solving new problems and new technical difficulties encountered in the implementation of RWE pilot programs. The introduction of this new pathway can provide a good opportunity for regulators to summarize the practical experience, strengthen communication with sponsors, and continuously improve the contents of the guiding principles to enable them to guide the practice of adopting RWE effectively.

Part IV. Current Status of Innovation Adoption in the Pharmaceutical Industry in China

A. Patient Centricity

The fundamental goal of new drug development is to address the unmet needs of patients, and it has become a general consensus that drug development should focus on patients' needs and be guided by clinical value. A patient-centric trial is designed to increase patient awareness and engagement in clinical trials by addressing the barriers to participation, and to generate clinical data that can reflect the real demands of patients, rather than the demands perceived by physicians and pharmaceutical companies, an approach that can increase recruitment speed and the likelihood of success for a drug launch. According to *The Innovation Imperative: The Future of Drug Development*, a report commissioned by Parexel and conducted by the Economist Intelligence Unit, a patient-centric clinical trial strategy can reduce patient recruitment timeline by 40 percent, significantly reduce overall registration timeline, and increase drug launch success rates by 19 percent¹⁷.

1. Patient Centricity Viewed by Chinese Regulators as a Catalyst for Change

Although Chinese regulators have yet to publish special guidelines for patient-centric clinical trials, the concept of patient-centricity has been incorporated into relevant guidelines issued in recent years.

- On July 14, 2020, the CDE released the *Guidance on the Management of Clinical Trials During the COVID-19 Pandemic (Trial)*. The document states that ongoing or pending clinical trials may be hindered by various challenges due to the Covid-19 pandemic, so it is necessary to take special care of trial subjects by making the greatest possible effort to protect their safety. Additionally, it also stresses that “it is critically important, in whatever circumstances, to updated patients on changes which may affect their research or monitoring plans”, and to guarantee the quality of trial data in order to minimize the impact of the pandemic on the integrity of clinical trials.

- › On November 19, 2021, CDE released the *Guidelines of Clinical Value-Oriented Clinical Development for Oncology Drugs*, another example of the regulator’s commitment to patient centricity. The document states that China is embracing rapid progress in developing oncology drugs. New drug development should prioritize bringing the best treatment options to patients as the highest goal. The concept of patient-focused drug development should be reflected not only in the collection of patients’ needs and feedback but in every stage, from the determination of drug development instructions to the execution of clinical trials. Only in this way can we deliver the fundamental value of drug development, which is to address the unmet clinical needs and maximize the benefits for patients.
- › On August 9, 2022, CDE released the following three drafts for comments:
 - Technical Guidelines for Patient-Centered Clinical Trial Design (Draft for Comments)
 - Technical Guidelines for The Implementation of Patient-Centered Clinical Trials (Draft for Comments)
 - Technical Guidelines for Benefit-Risk Assessment of Patient-Centered Clinical Trials (Draft for Comments)

2. Parexel’s Practice in Patient-Centric Approach

In 2018, Parexel established the Patient Innovation Center (PIC). Keeping in mind the concept of patient centricity, the PIC’s professional team is dedicated to alleviating the burdens of clinical trials on patients and simplifying their journey to new treatments. Parexel seeks to enhance patient engagement and satisfaction by proactively collecting their input in every aspect, from trial design and subject recruitment, to execution of clinical trials, in order to work out a development plan which can bring better treatments to patients and build a better value story for market access. Since 2019, Parexel has started establishing patient advisory councils (PAC) in various locations around the world to build long-term partnerships with patients across different therapeutic areas and to collect their insights for improving the trial participation experience. To date, Parexel has held more than 15 PAC meetings worldwide, two of which took place in China.

B. Decentralized Clinical Trials

Decentralized Clinical Trials (DCTs) are defined as those executed through telemedicine and mobile/local healthcare providers, using procedures that vary from the traditional clinical trial model. DCTs allow subjects to participate in clinical trials at home or in the location of their choice where available. This model provides a patient-centric approach to address various patient demands that traditional trial designs are unable to meet. From the patient’s perspective, the increasing use of telemedicine has raised their expectations for the experience of clinical trials. Many pharmaceutical companies have embraced DCT as a strategy for clinical drug research and development. Against the backdrop of the Covid-19 pandemic, which has accelerated changes across the biopharmaceutical industry, DCT studies will continue to evolve and remain a critical path for studies in the future.

1. Regulatory Responses Towards DCT


As is the case with the concept of patient centricity, the CDE has yet to publish specific guidelines for DCTs. Still, sponsors are encouraged to conduct DCTs under the guidance of the Good Clinical Practice (GCP) and to communicate with CDE to discuss DCT designs.

- › On July 14, 2020, the CDE published the *Guidance on the Management of Clinical Trials During the COVID-19 Pandemic (Trial)*. The document explicitly states that challenges may hinder traditional clinical trials due to the Covid-19 pandemic, so adoption of DCT methods is encouraged for patient-centric trials via intelligent clinical trial management platforms and telecommunication technologies.
- › CDE held a themed seminar on March 23, 2021 to improve clinical trial efficiency, explore the application of digital & innovative technologies in clinical trials, and enhance supervision of safety for DCTs. The event was attended by industry experts and the staffs at the Department of Drug Registration, the CDE, and the Center for Food and Drug Inspection of NMPA as well as Tao Wang, deputy head of the CDE. During the conference, representatives of industry experts gave briefings on their practical experiences with DCTs, and in-depth exchanges were conducted regarding subject recruitment, tele-visit, e-sources, remote monitoring, and safety information management. The conference also explored scientific strategies for the safety regulation of DCTs. As a next step, the CDE will consider the work plan for subsequent stages, and on the basis of a scientific approach to regulation, it will continue to improve safety regulations of patient-centric DCTs¹⁸.
- › On November, 2021, the CDE issued the *Guidelines of Clinical Value-Oriented Clinical Development for Oncology Drugs*. The document explicitly suggests that sponsors can include elements of DCT in trial designs.

2. Technical Maturity and Market Environment for DCT

The outbreak of the Covid-19 pandemic has brought a sense of urgency to the pharmaceutical industry, providing an opportunity for the fast adoption of innovative technologies in clinical trials. Additionally, the development and maturity of digital healthcare technologies in China greatly encourages sponsors to conduct DCTs.

- › **Home Nursing:** During the trial, the home nurses may perform visits at the patient's home. Home nurses can also coordinate comprehensive support services such as support for patient travels, assistance with patient drug administration, collection and transport of specimens, and assistance with physical examinations. In 2019, China initiated the "Internet + Nursing Service" pilot project which by 2021 had been replicated across the country, with corresponding relevant rules and local guidelines published in support of this mode¹⁹. This has catalyzed the rise of commercial home care services, laying the foundation for future home care in clinical trials. Currently, major public home care platforms in China include Goldnurse, Homeincare, Nurseathome, Sharednurse, Unurse, Nurse+, as well as WeChat public accounts of various hospitals. These platforms adopt an online + offline mode, and their services are billed according to work complexities, the experience level of nurses, as well as the degree of service. Given the technical maturity level in China, an industrial chain formed in the internet healthcare sector; with the guidance of state policies, and together with continuous explorations by industry players, sponsors are better supported to conduct DCTs in China.



› **Direct to Patient Drug Delivery:** Direct shipment (to the patient) of drugs can overcome the travel restrictions imposed on patients during the Covid-19 pandemic. It also offers the possibility of transforming traditional clinical trials. During the pandemic, most hospitals provided direct shipment services for patients to avoid the disruption of drug supplies and to reduce the risk of infections during on-site visits. China's logistics service has matured and many primary care pharmacies have opened operations on "take-out" home delivery platforms, such as Meituan or Ele.me, as a convenience for patients to purchase drugs themselves with one-hour delivery service directly to patients' home. In addition, mobile applications such as Dingdong Drug Delivery and KF Drug Delivery, which provide round-the-clock drug delivery services, E-commerce platforms, such as Ali Health and JD Health, have also launched online pharmacy services, and drugs can be delivered to patients within two days after a purchase is made. In short, China's basic logistics services can successfully meet the demands for direct-to-patient shipment of drugs required for the future development of DCTs.

› **Wearable Devices and Sensors:** Wearable devices and sensors can enable near real-time monitoring of a patient's vital signs and quality of life. Investigators can determine the trial participants' results without site visits by patients, and can arrange additional visits as needed based on the data directly collected from the patient. Sponsors can also design the digital endpoints based on the almost real-time continuous patient data.

With the rapid development of wearable technologies at home and abroad, the standardization of the industry has been included as a priority in Chinese state policies. Meanwhile, the implementation of the "Internet + Healthcare" strategy is also expediting the development of the wearable devices industry. According to the Research Report on China's Wearable Industry 2021 by the CN-HEALTHCARE Institute²⁰, in 2020 the compound annual growth rate of the market for medical-grade wearable devices in China was 30 percent, with the market size expected to reach RMB 46.26 billion in 2025. In addition, in 2020 the volume of wearable devices shipped in China was estimated to be 107 million, accounting for around 25 percent of the world's total. Smart watches, as an example, reached a volume of 41.52 million shipments in China in 2019, expected to reach 56.23 million in 2022. Medical-grade wearable devices (such as smart wristbands and smart watches) can measure physical parameters of patients like ECG, heart rate, blood oxygen, and blood pressure, and can easily be connected to mobile phones, allowing data uploads to cloud databases and help provide important support for the development of DCTs.

- › **Televisit:** In 2018, the State Council published the *Opinions on Promoting the Development of “Internet Plus Healthcare”* (Doc. No. 26 issued by the General Office of State Council [2018])²¹ in an effort to seize the advantages and development opportunities brought by the rapid development of the internet. Subsequently, the National Health Commission issued the *Administrative Measures for Internet Diagnosis and Treatment (Interim)* and the *Management Measures and Standards for Internet Hospitals (Interim)*, as well as the *Management Specifications for Telemedicine Services* (Doc. No. 25 issued by NHC [2018])²², among others, as a way to help expedite the development of the *Internet Plus Healthcare* sector. According to the Market Research Report on Internet Hospitals in China 2021 by the CN-HEALTHCARE Institute²³, as of December 31, 2020, there were 1004 internet hospitals in China. A significant number of these - 689 - were established in 2020 alone, a year during which the approval process for internet hospitals was accelerated, stemming from the market access policies for *Internet Plus Healthcare* enacted in 2018, and from the impact of the Covid-19 pandemic. Today, internet hospitals are more common across the country and the service scope is extended throughout the entire patient journey (from registration reservation, to consultation, to post-consultation treatment), allowing patients to have tele-visits with doctors via video or audio links through mobile phones or PCs. This also opens up possibilities for the application of remote visits in future clinical trials.
- › **Remote Digital Monitoring:** Remote monitoring can be conducted during virtual conferences between CRA and clinical sites. Some major clinical trial centers in China, such as the Beijing Cancer Hospital and the Fudan University Shanghai Cancer Center, have launched their own remote monitoring platforms to allow sponsors and CROs to conduct remote monitoring in clinical trials^{24,25}.
- › **eConsent and eCOA:** Mobile applications that focus on collecting patients’ data, such as eConsent and eCOA, have begun to be used in clinical trials. These technologies can make it faster and easier for patients to understand study-related information and complete relevant trial procedures, while facilitating the collection of patient report outcomes and diaries from patients at home. As of June 2021, the number of internet users in China had surpassed 1 billion, and internet penetration had reached 71.6 percent, six percent higher than the world’s average level (65.6 percent). Among them, mobile internet users account for 99.6 percent, meaning mobile applications used in clinical trials are more likely to be accepted by patients.
- › **eSource System:** The eSource integration is intended for site staff and study team to obtain trial data and reduce the need for source data verification (SDV). Big data companies in the healthcare field, such as LinkDoc and YiduCloud, have emerged, and through the clinical data integration system, these companies can help hospitals and clinical departments establish a structured patient history database to improve the efficiency of diagnosis, clinical visits, and scientific research. At the same time, they can also increase efficiency of DCT operations by assisting doctors with clinical studies and decision-making via a structured electronic medical record (EMR)^{26,27}.
- › **Electronic Medical Records (EMRs):** EMRs can significantly improve the efficiency of clinical trials and reduce the demands for site visits, while at the same time, proper systems and controls can be adopted to protect the privacy of patients and ensure EMR data security.

3. Parexel's Experience with DCTs

Parexel has been involved with DCTs since 2011, giving it a wealth of experience to draw upon. Parexel has been dedicated to helping clients streamline clinical trial procedures while assisting them to navigate through the various market, regulatory, and patient accessibility challenges. In addition, Parexel's Patient Innovation Center staff and the APAC DCT Taskforce have been making local connections and establishing strategic partnerships with different suppliers to ensure that patients have the opportunity to participate remotely, just as in other parts of the world.

As a pioneer of DCT trial design and delivery, Parexel's technical team is able to create integrated technical platforms for clients, and design mobile applications, wearable devices, and sensors for patients, while also leveraging the resources of local clinical trial centers and patients to help support and facilitate the implementation of development projects.

In the last five years, Parexel's experience includes more than 250+ Decentralized Clinical Trials (inclusive of home nursing visits) and experience in excess of 200 remote patient engagement strategies incorporated into trials (e.g., patient recruitment and retention platforms, e-visits/video dosing regimens and patient insight projects)²⁸.

C. RWD/RWE

Real-World Data (RWD) refers to data collected in conventional medical processes (instead of clinical trials). RWD is usually heterogeneous data from different sources. It may be challenging to consolidate and govern this data to make it applicable for clinical trials, but the rewards are substantial. As a supplement to conventional RCTs, RWD, if appropriately used, can reduce costs for clients and improve trial efficiency.

1. Regulatory Support for RWD/RWE in China

In recent years, Real World Study (RWS) has made good progress in China. A series of guidelines for RWD/RWE have provided clear guidance for the application of RWS and, at the same time, offer a basis for the practical use of RWS in drug development.

On January 7, 2020, the NMPA issued the *Announcement on the Guidelines for Real-World Evidence to Support Drug Development and Review (Interim)*. On August 27, 2020, the NMPA issued the *Technical Guidance for Using Real-World Evidence (RWE) to Support R&D and Regulatory Review of Pediatric Drugs (Interim)*. In April, 2021, the NMPA issued the *Guidelines for Using Real-World Data for Generating Real World Evidence (Interim)*.

In July, 2022, the NMPA issued the *Guidelines for Design and Protocol Frameworks for Real-World Studies of Drugs (Exposure Draft)*

In August, 2022, the NMPA issued the *Guidelines for Communication of Real-World Evidence to Support Drug Registration Applications (Exposure Draft)*

To support the development of real-world studies (RWS) in China, the CDE, together with the Drug Registration Department of NMPA, Hainan Provincial Drug Administration and Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration Bureau, jointly held a symposium on October 23, 2020, for the RWD pilot programs for imported drugs to be used in the Pilot Zone. Participants at the event discussed related implementation issues and assessed the RWS protocols for six drugs that have already been approved in the overseas market²⁹. In November of the same year, the NMPA Research Base for Regulation of Pharmaceuticals and Medical Devices was established in the Lecheng Pilot Zone, with the purpose of accelerating the building of a real-world data platform through base construction, establishing and improving the standards for RWD, expanding the role of RWS in the registration and marketing approval process for imported drugs and medical devices, and finally, attracting more drug and medical device developers and manufacturers to participate in subsequent pilot programs.

The Hainan Real-World Data Institute was established in December, 2020 to promote the creation of RWS standards, and research on the collection, analysis, and application of RWD by forming closer cooperation with related industries

2. Support of Chinese High-Tech Enterprises for RWD/RWE

In an effort to advance innovation of big data in healthcare, the General Office of the State Council published the *Guiding Opinions on Promoting and Regulating the Application of Big Data in Healthcare Sector (Circular No. 47 [2016])*³⁰ in June 2016. The document states that big data in healthcare is an important and fundamental national strategic resource and that the development and application of big data in healthcare can bring about profound changes to the country's healthcare model by stimulating momentum and dynamics for deeper reform of the healthcare system, improving efficiency and quality of healthcare service, and expanding supplies of healthcare resources. These initiatives will all help satisfy the multi-layered, diverse needs of the public for healthcare service.

To facilitate the implementation of the national strategy of establishing national healthcare big data centers, the National Healthcare Commission (NHC) has authorized the establishment of three major group enterprises for Big Data in Healthcare: China Healthcare Big Data Industrial Development Co. Ltd, China Healthcare Big Data Technology Development Co. Ltd, and China Healthcare Big Data Shareholding Co. Ltd. These three enterprises enjoy exclusive rights to directly access and process government-owned cloud healthcare data, such as lab data, data collected from clinical trials, and data collected by hospitals and pharmaceutical enterprises. Jin Xiaotao, former deputy director of the NHC, said that the establishment of the three enterprises, which are mostly funded by state capital, has explicit goals:

- › To promote allocation of high-quality medical resources to primary care through applications of big data in healthcare.
- › To utilize big data to advance the reform of the healthcare security system, the healthcare service system, and the drug distribution system, while facilitating tiered diagnosis and treatment, inter-city settlement, and remote service.
- › To further expand the application scope of big data, innovate the healthcare service ecosystem, develop new healthcare technologies, and facilitate the development of a full healthcare industrial chain that covers the primary, secondary and tertiary industries^{3***}.

The purpose of real-world study is to leverage RWE generated through proper RWD to empower innovative drug development. This process involves multiple key steps (such as data collection, data governance, universal data modeling, and data analysis) and the application of multiple innovative technologies (such as EDC, AI/NLP).

Many big data enterprises in China have developed innovative technologies and amassed a large amount of valuable data through RWS. Some are specialized in nationwide big data studies on single diseases, such as LinkDoc, which has made impressive accomplishments in the field of lung cancer^{3****}. Others may focus on developing innovative data technologies that are suited for the Chinese healthcare market, such as EPRO developed by the Jsure Health³³.

3. Parexel's Experience in RWD/RWE

Parexel has been at the forefront of RWE innovation and with more than 17 years experience in designing, implementing, and analyzing real-world studies across the globe. In China, Parexel has maintained a focus on RWD application at various stages of drug development. The company offers a full range of services to clients, including supporting feasibility analysis, offering guidance for trial design, assisting with patient recruitment, conducting pharmaco-economic research, and executing innovative trials.

››› Conclusion

Given the continuously rising demand for pharmaceutical products and the support from increasingly favorable policies, pharmaceutical companies, CROs and sites can work together to develop more innovative drugs faster and more efficiently to benefit patients with unmet needs in China and overseas.

Reference

1. The economist datatool
2. <https://www.mckinsey.com.cn/中国可能改变全球生物制药行业转变的8种方式/>
3. Health Advances analysis, company filings, Frost & Sullivan
4. Health Advances analysis, PharmaProjects (accessed in Jan 2022)
5. Health Advances analysis, Globocan
6. Health Advances analysis, company filings, Frost & Sullivan
7. Health Advances analysis, GBI Source, 国家医保局
8. Health Advances analysis, GBI Source, 国家医保局2017~2021公开数据
9. Health Advances analysis, company filings, Frost & Sullivan, FDA, NHFPC
10. 邵文斌,李杨阳,王菲,朱逸婧,肖磊,黄如方.(2019)中国罕见病药品可及性现状及解决建议.中国食品药品监管
11. Health Advances analysis, company filings, Frost & Sullivan
12. Health Advances analysis, PharmSnap, ICF Frost and Sullivan, GBI Source, NMPA
13. <https://www.cde.org.cn/main/news/viewInfoCommon/1839a2c931e1ed43eb4cc7049e189cb0>
14. Health Advances analysis, CDE
15. https://www.sohu.com/a/151220278_467781
16. https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2020.pdf
17. <http://www.pharmexec.com/patient-centric-trials-china-opportunity-innovate>
18. <https://www.cde.org.cn/main/newspic/view/b2720a35305ca89de7283fc3f960708a>
19. <http://www.nhc.gov.cn/zyygj/s7653pd/202012/abdde45b8f1d4343ae41452d738dbf73.shtml>
20. <http://zk.cn-healthcare.com/doc-show-53537.html>
21. http://www.gov.cn/zhengce/content/2018-04/28/content_5286645.htm
22. <http://www.nhc.gov.cn/zyygj/s3594q/201809/c6c9dab0b00c4902a5e0561bbf0581f1.shtml>
23. <https://zk.cn-healthcare.com/doc-show-53644.html>
24. https://www.sohu.com/a/373776545_100202861
25. https://www.sohu.com/a/389556104_120467603
26. <https://www.linkdoc.com/product/data>
27. <https://www.yiducoud.com.cn/solution.html>
28. <https://www.parexel.com/solutions/clinical-development-services/decentralized-clinical-trials>
29. <https://www.cde.org.cn/main/news/viewInfoCommon/e2e9e224946b341118990e194e03e280>
30. http://www.gov.cn/zhengce/content/2016-06/24/content_5085091.htm
31. <https://www.cn-healthcare.com/article/20170621/content-493381.html>
32. <https://www.cn-healthcare.com/article/20170809/content-494690.html>
33. <http://www.jsure.com/5071/>



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Health Advances, a Parexel company

Eric Woo specializes in commercial due diligence projects across biopharma and medtech in APAC and international markets. Prior to Health Advances, he worked as Analyst at Ginward (Venture Capital) in Singapore, and Product Specialist at Astellas Pharma in Hong Kong. Eric received his MS in Industrial Chemistry from the National University of Singapore – Technical University of Munich and BS with first-class honors in Chemistry from The University of Hong Kong. Eric is a CFA® charterholder.

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Chao Wang

Scientific Data Strategy Leader, Parexel

Chao Wang, a former Sr. data scientist at Cisco and visiting scholar at Duke Medical School, has over 10 years of experience in data science and project management. She has accumulated great expertise in RWD/RWE, SAS, Database, AI/NLP, among others; being certified as 6 Sigma black belt, she is familiar with project management and laws and regulations in RWD/RWE in China. She received her MS in Advanced Analytics from North Carolina State University and her BS in Electronic Engineering from Tsinghua University.

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