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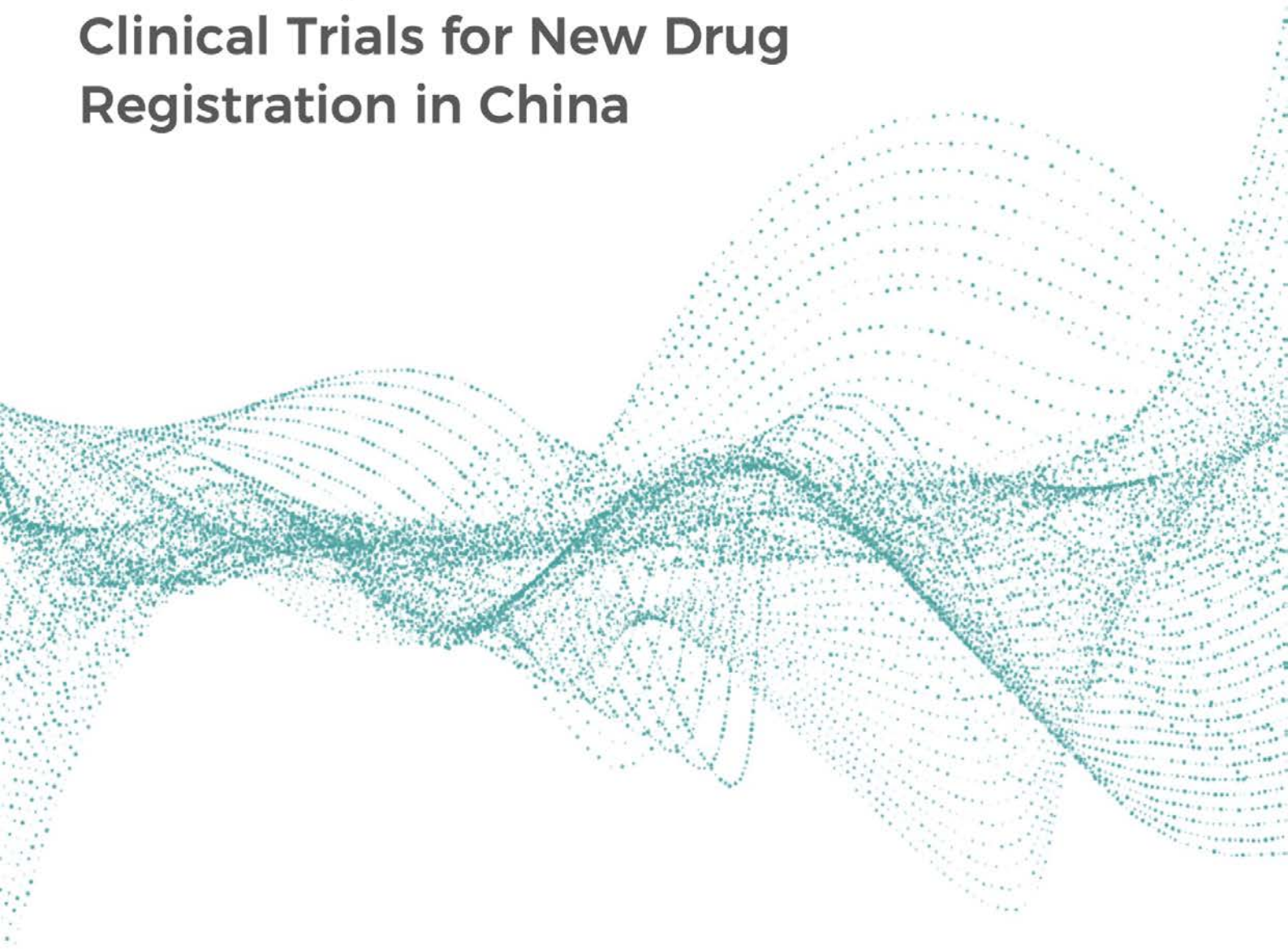
Annual Report on the Current Status of **Clinical Trials for New Drug Registration in China**



Center for Drug Evaluation,
National Medical Products Administration

Attachment: Annual Report on Clinical Trials for New Drug Registration in China (2022)

Center for Drug Evaluation, National Medical Products AdministrationSeptember 2023

Abstract

Objectives

To better understand the current status of clinical trials for new drug registrations in China, to disclose clinical trial progress information to the public, and to provide a reference for new drug research and development (R&D), resource allocation, drug review and approval, the Center for Drug Evaluation of the National Medical Products Administration (hereinafter referred to as "CDE") has produced a comprehensive summary and analysis of clinical trials in China in 2022 according to data from the Drug Clinical Trial Registration and Information Disclosure Platform, and analyzed the change trend characteristics in recent years to gradually improve the ability of supervision of drugs by using informatization technology.

Methods

The annual report mainly summarizes and analyzes the overall trend and main characteristics of clinical trials based on the information of drug clinical trials registered in 2022, from the perspective of the type of drugs, varieties, indications, type of sponsors, registration classification, trial classification, trial phases, trials in special populations, clinical trial institutions, time for first register of clinical trials, time for initiation, Data Monitoring Committee (DMC) and completion of trials. It also summarizes and analyzes the clinical trials of innovative drugs approved for marketing in 2022 and complies with the Annual Report on Clinical Trials for New Drug Registration in China (2022).

Key Findings

1. Number of Clinical Trials for New Drug Registration

The total number of clinical trials on the Drug Clinical Trial Registration and Information Disclosure Platform in 2022 reached more than 3,410, which was the highest ever. It slightly increased by 1.5% compared with the total registered number in 2021, in which the number of new drug clinical trials (registered with an acceptance number) was 1,974. The number of new drug clinical trials decreased slightly in 2022 compared to 2021 (2,033 vs. 1,974).

2. Drug Types and Varieties

According to the classification of chemical drugs, biological products and traditional Chinese medicines (TCMs), in recent years, the percentages of new drug clinical trials of both chemical drugs and biological products were relatively high, with that of chemical drugs being the highest, exceeding 50%, and that of biological products accounting for about 40%, and the percentage of TCMs still showed a downward trend year by year.

A total of 46 clinical trials of cellular and gene therapy products were registered in 2022, with the largest number of clinical trials of mesenchymal stem cells, 12 in total. A total of 11 clinical trials of drugs for medical imaging were registered, which was the largest in recent years..

3. Trial Classification and Sponsors

Drug clinical trials were classified into new drug clinical trials and bioequivalence trials (BE trials). In 2022, new drug clinical trials accounted for 57.9%, and BE trials accounted for 42.1%. Compared to 2021, the percentage of new drug clinical trials decreased slightly in 2022 (60.5% vs. 57.9%). Domestic sponsors still accounted for the majority, with 88.5% in 2022.

4. Target Indications and Clinical Trial Phases

The target indications of clinical trials of chemical drugs and biological products in 2022 were still mainly concentrated in the anti-tumor field. The indications of TCMs were mainly concentrated in respiratory, digestive, skin and ENT, and psychoneurological fields, with no significant changes in recent years.

The percentage of clinical trials in each phase in 2022 was essentially the same as in 2021, with phase I clinical trials still accounting for the highest percentage at 43.0%; there were no significant changes in clinical trials conducted in special populations, and compared to 2021, there was a slight increase in the number of clinical trials conducted in the pediatric population only (64 vs. 61). The number of clinical trials of rare disease drugs still showed an increasing trend (68 vs. 43), with no significant change in indications compared to 2021, still mainly concentrating in blood system diseases, nervous system diseases and respiratory system diseases.

5. Geographical Distribution of Clinical Trials

The leading and participating clinical trial institutions in 2022 were still mainly in Beijing, Shanghai, Jiangsu Province and Guangdong Province. The leading institutions of clinical trials in children were mainly in Beijing.

6. Implementing Efficiency of Clinical Trials

In 2022, the percentage of new drug clinical trials that could initiate subject recruitment within six months of approval increased further to 55.8% overall, while the percentage for chemical drugs and biological products were 56.7% and 59.1%, respectively, still significantly higher than that of TCM trials. The percentage of TCM trials that initiated subject recruitment within one year of approval (21.2%) was higher than that in 2021 (4.4%). The analysis of the location of clinical trial institutions suggested that in provinces, autonomous regions and municipalities directly under the Central Government with more leading clinical trial institutions, it still took longer to initiate clinical trials.

Compared to 2021, the time taken to initiate subject recruitment in the year following approval of clinical trials in 2022 further shortened, with an average of 3.3 months (compared to an average of 3.8 months in 2021), and the percentage of clinical trials that initiated subject recruitment within six months of approval also further increased, reaching 91.5% (compared to 85.7% in 2021).

7. New Drugs Marketed in the Year

A total of 21 innovative drugs (excluding TCM extracts and varieties for new indications) were approved in 2022, mainly with domestic marketing authorization holders, accounting for 76.2%. Chemical drugs accounted for a relatively high percentage (52.4%), with a total of 11 varieties. The anti-tumor drugs were the most in the innovative drugs, and one variety of TCM was approved for each of psychoneurology, gynecology, nephrology, and digestion fields.

Conclusion

The total number of clinical trials on the Drug Clinical Trial Registration and Information Disclosure Platform in 2022 reached 3,410, which slightly increased from 2021. The percentage of new drug clinical trials declined slightly (57.9% vs. 60.5%), with phase I clinical trials still accounting for the highest percentage, and the percentage of clinical trials initiated by domestic sponsors further increased.

Clinical trials of chemical drugs and biological products were still mainly for tumor indications, mainly phase I clinical trials. Clinical trials of cell and gene therapy products in biological products were also mainly for tumor indications, accounting for more than half of the total (54.4%), with phase I clinical trials accounting for more than 45.7% (21/46), and phase III clinical trials accounting for less than 5% (2/46). There were a total of 39 clinical trials of novel coronavirus vaccines, which still accounted for a relatively high percentage of clinical trials of preventive vaccines, reaching 41.1% (39/95). TCMs still underwent the smallest number of clinical trials, mainly concentrated in respiratory, digestive, skin and ENT, and psychoneurological indications.

The percentage of clinical trials carried out in the elderly and pediatric populations (except for preventive vaccines) was still relatively low, but the percentage of phase III clinical trials in the pediatric population was the highest in the current year, reaching 40.6%. The number of clinical trials of rare disease drugs showed a year-on-year growth trend, but few types of diseases were involved and there was little change. The number of clinical trials of drugs for medical imaging has been increasing every year.

Applicants took longer to complete their first trial registration, with the average time taken for acceptance number registration being significantly longer than that for BE filing registration (116 days vs. 67 days), and the percentage of registration completed and submitted within one month was significantly lower than that of BE filing registration (25.9% vs. 79.1%). The efficiency of clinical trial initiation was further improved in 2022, with 55.8% of clinical trials that initiated subject recruitment within six months overall. The percentage of approved clinical trials that initiated subject recruitment within six months in 2022 reached 91.5%. Among the innovative drugs approved for marketing in 2022, approximately 50% of varieties were marketed within 5 years.

To sum up, the number of new drug clinical trials in China has been constantly growing, and the efficiency and quality of clinical trial implementation has been gradually improved. With the active guidance of the policy of encouraging innovation in China and the joint efforts of the industry, the process of marketing for new drugs will be gradually accelerated to better meet the medication needs of Chinese patients, including the clinical medication needs of the pediatric population, rare diseases, and traditional medicine.

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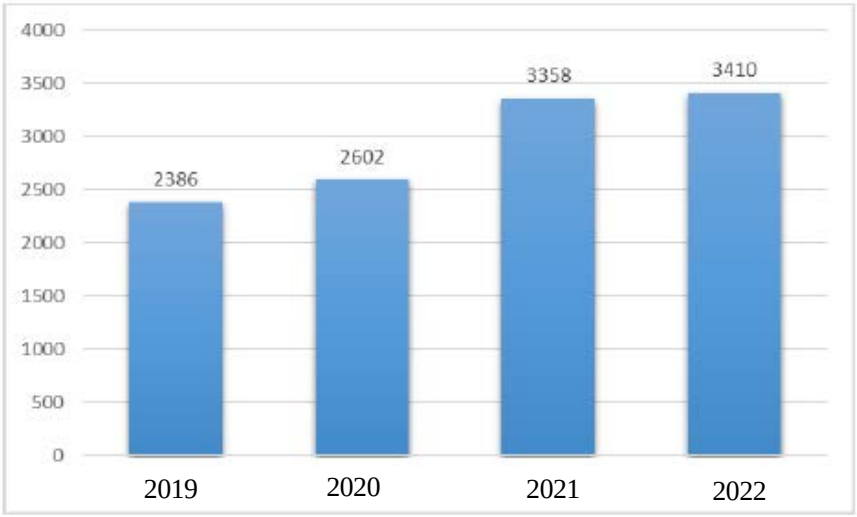
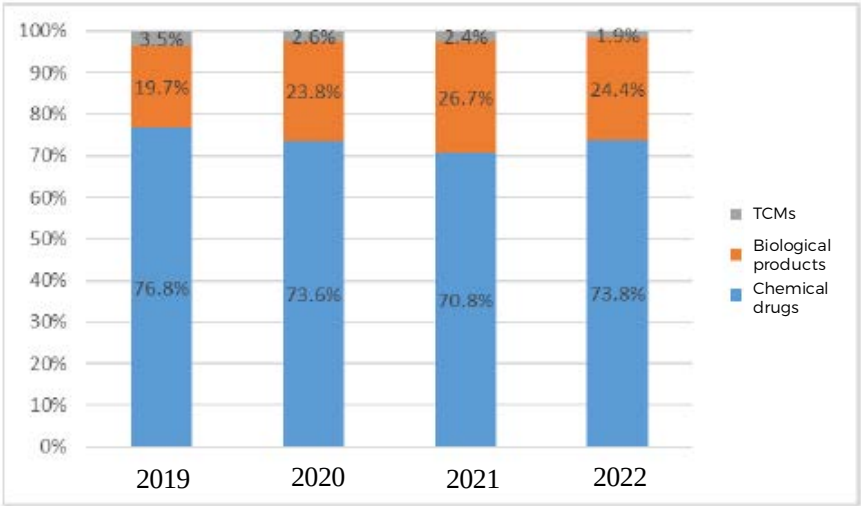
Chapter Ⅰ Overview of Drug Clinical Trial Registration

A total of 3410 drug clinical trials were registered in China in 2022 (based on CTR, the same below), which slightly increased from 2021 (1.5%) compared with 2021. Among them, 1,974 were registered with acceptance number and 1,436 with BE filing number.



Changes in the total number of clinical trial registrations in 2019-2022 (based on CTR)

According to the classification of chemical drugs, biological products and TCMs, in 2022, China's drug clinical trials were dominated by chemical drugs, accounting for 73.8%, followed by biological products, accounting for 24.4%, and then still TCMs, accounting for only 1.9%. Comparative analysis of the data in recent years showed that the percentages of clinical trials of various drugs were similar, but the percentages of chemical drugs and biological products fluctuated slightly, while the percentage of TCMs still showed a downward trend.

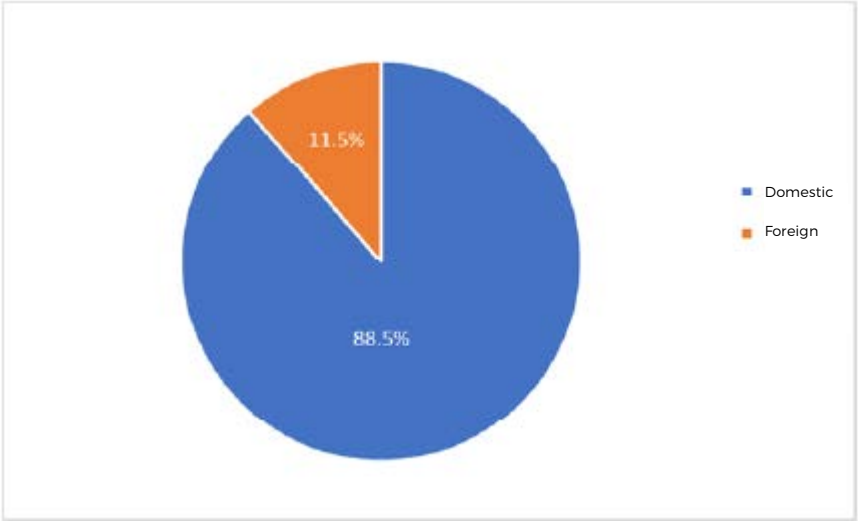


Changes in the overall percentages of various drugs (2019-2022)

Chapter Ⅱ Analysis of Basic Clinical Trial Characteristics

Ⅰ. Type of Sponsors

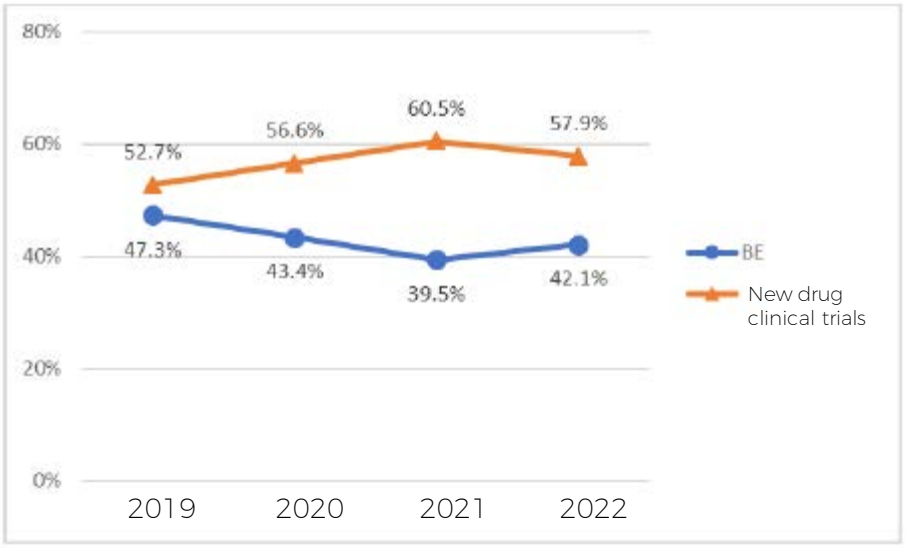
The types of sponsors were analyzed in accordance with the type of acceptance number, i.e., those with the initial letter J were counted as foreign sponsors, while the others were domestic sponsors. Clinical trials registered in 2022 were still mainly initiated by domestic sponsors, accounting for 88.5% (3,018 trials). Compared to 2021, the percentage of foreign sponsors has decreased by 10%.



Distribution of types of clinical trial sponsors in 2022

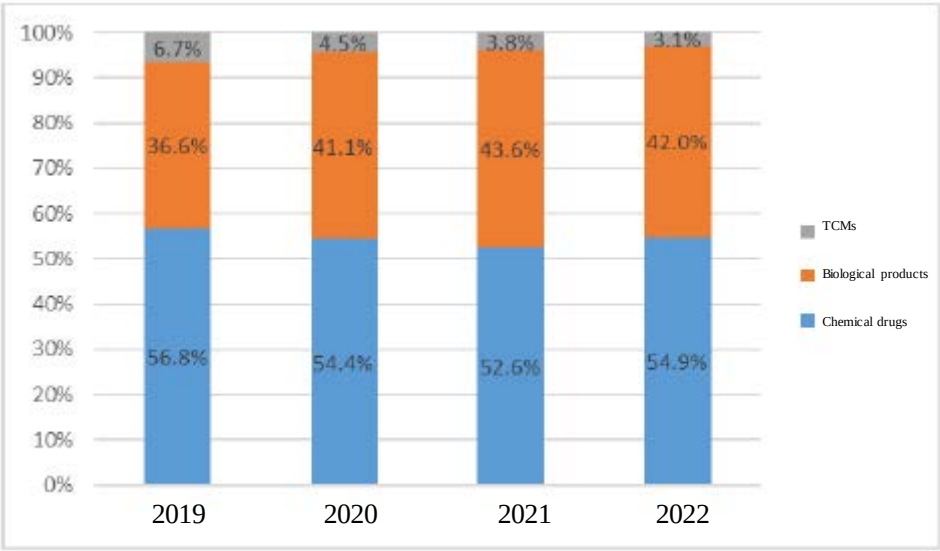
Ⅱ. Types of Clinical Trials

According to the new drug clinical trial statistics (registered by acceptance number) and bioequivalence trials (BE trials, registered by filing number), in 2022, 1,974 (57.9%) new drug clinical trials and 1,436 (42.1%) BE trials were registered. Compared to 2021, the percentage of new drug clinical trials decreased slightly.



Changes in the percentages of new drug clinical trials (2019-2022)

Among the new drug clinical trials registered by acceptance number in 2022, 1,083 (54.9%), 829 (42.0%) and 62 (3.1%) were registered for chemical drugs, biological products and TCMs, respectively. A comparison of the new drug clinical trial registration data in recent years showed that the percentages of various drugs remained the same, with chemical drugs registered the most (more than 50%), followed by biological products (about 40%), while the percentage of TCMs were declining year by year.



Changes in the percentages of new drug clinical trials for different types of drugs (2019-2022)

Ⅲ. Drug Types and Varieties

1. Types of New Drugs in Clinical Trials

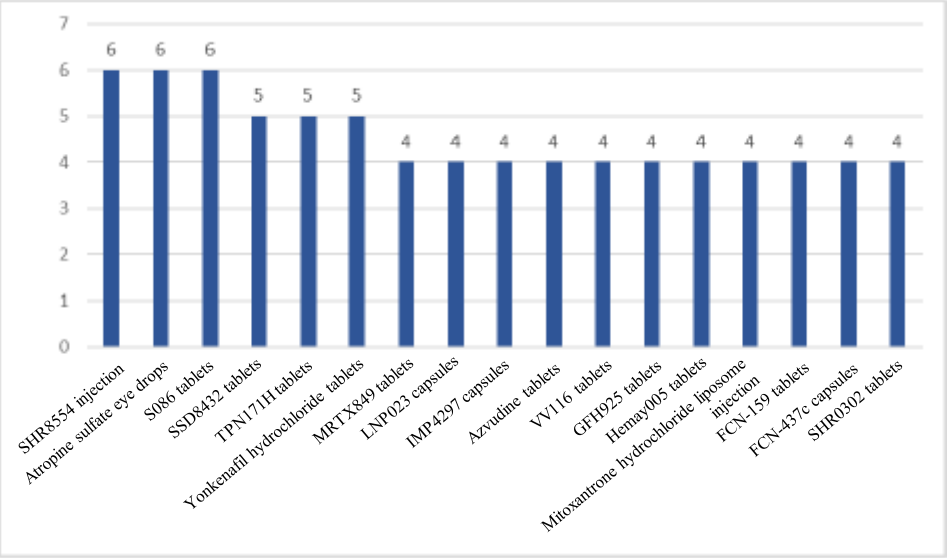
The number of drugs (drug names in accordance with the clinical trial approval documents) in the 1,974 new drug clinical trials in 2022 were counted by type.

TCMs: Only one clinical trial was performed for nearly 85% of all TCMs in 2022. Varieties that underwent more than two clinical trials included Qingfei Xiaoyan pills (3 trials), Xingqi Tannikaer capsules (2 trials), Compound Zanghuixiang Enteric Liquid Capsule (2 trials), and Hongqishe Babu Patch (2 trials). One trial each of Xiaoer Kechuan Granules and Jimu (Loropetalum chinense) Granules were actively suspended, and one trial of Shehuang Cream was actively terminated for non-safety-related reasons.

The overall trend of the data was basically the same in recent years, and only one trial was carried out in the same year for most varieties.

Chemical drugs: In 2022, a total of 77 trials were registered for the top 10 varieties of chemical drugs, accounting for 7.1% (77/1,083) of the overall number of chemical drugs. SHR8554 injection, atropine sulfate eye drops and S086 tablets underwent the largest number of clinical trials (all n=6). Indication analysis showed that there were a total of 21 anti-tumor drug trials among the trials of the top 10 varieties, involving six varieties. Notably, the three varieties with the largest number of trials conducted were all non-anti-tumor drugs.

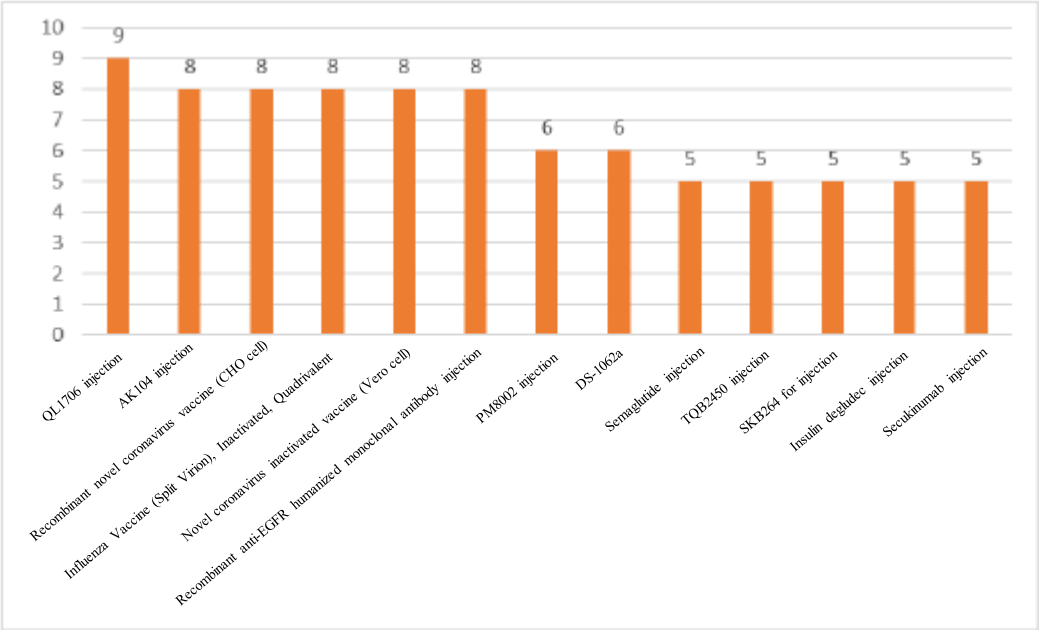
Compared with the data in 2021, the top 10 varieties all included mitoxantrone hydrochloride liposome injection, yonkenafil hydrochloride tablets, and SHR0302 tablets.



Top 10 varieties of chemical drugs in terms of number of clinical trials in 2022

Biological products: In 2022, a total of 86 clinical trials were registered for the top 10 varieties of biological products, accounting for 10.4% (86/829) of the overall number of biological products, mainly therapeutic biological products, involving a total of 62 trials (72.1%) for 10 varieties. Preventive biological products involved 24 trials (27.9%) for 3 varieties. There were 47 (54.7%, 47/86) anti-tumor drug trials, involving 7 varieties.

An analysis of the number of clinical trials of a single variety showed that QL1706 injection underwent the largest number of clinical trials (n=9).

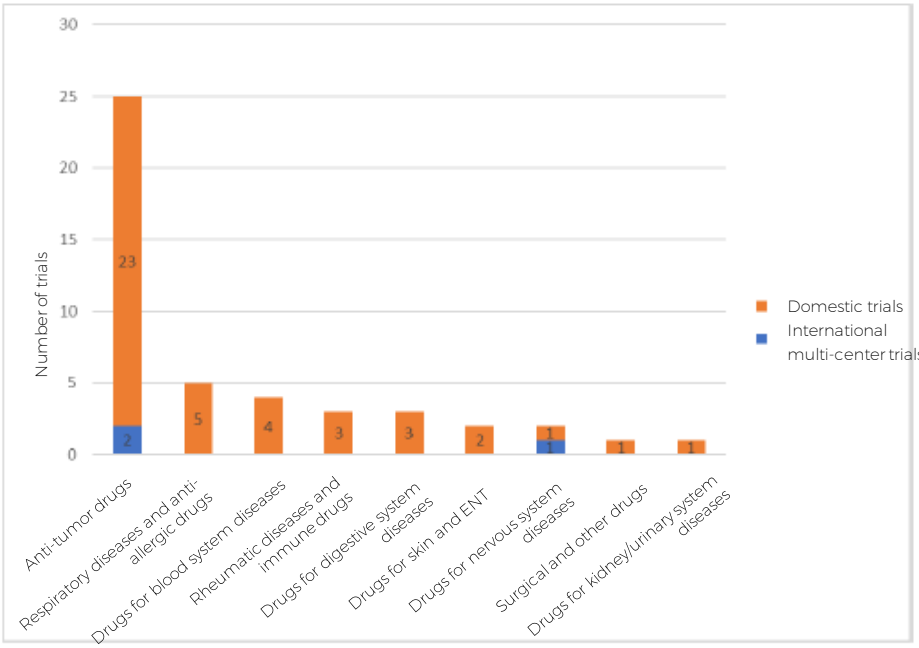


Top 10 varieties of biological products in terms of number of clinical trials in 2022

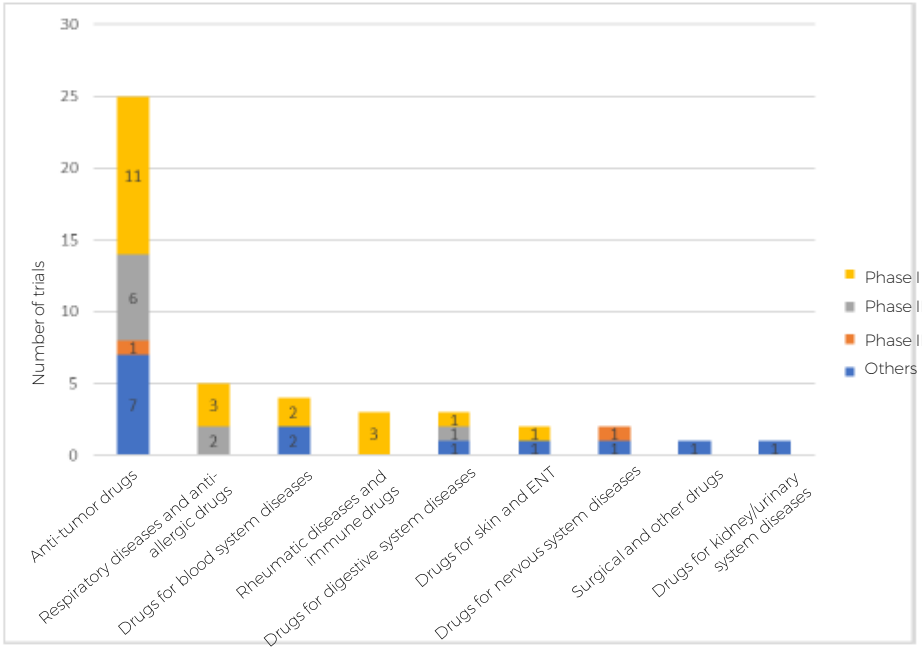
2. Cell and Gene Therapy Varieties

A total of 46 clinical trials of cell and gene therapy products (based on CTR) were registered in 2022, with the largest number of clinical trials of mesenchymal stem cells, 12 in total, followed by 9 clinical trials of autologous T-cells targeting CD19. There were 2 clinical trials of gene therapy.

The 46 trials mentioned above involved a total of 41 varieties (based on acceptance number), mainly domestic clinical trials (43, 93.5%). The indication was mainly concentrated in anti-tumor drugs (25, 54.4%). For trial phases, phase I clinical trials were still dominant (21, 45.7%), and phase III clinical trials accounted for only 4.4% (2/46).



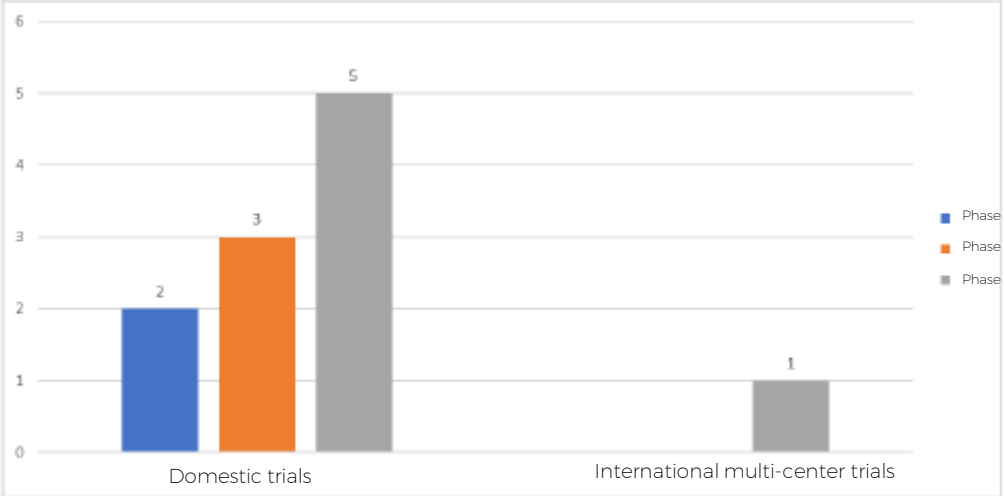
Indications of cell and gene therapy products and distribution of trials in 2022



Indications of cell and gene therapy products and trial phases in 2022

3. Medical Imaging Varieties

In 2022, a total of 11 clinical trials of drugs for medical imaging were registered by acceptance number, involving 10 varieties (based on drug name), mainly domestic clinical trials. Only one international multicenter clinical trial was involved. There were a relatively large number of phase III clinical trials, 6 in total.

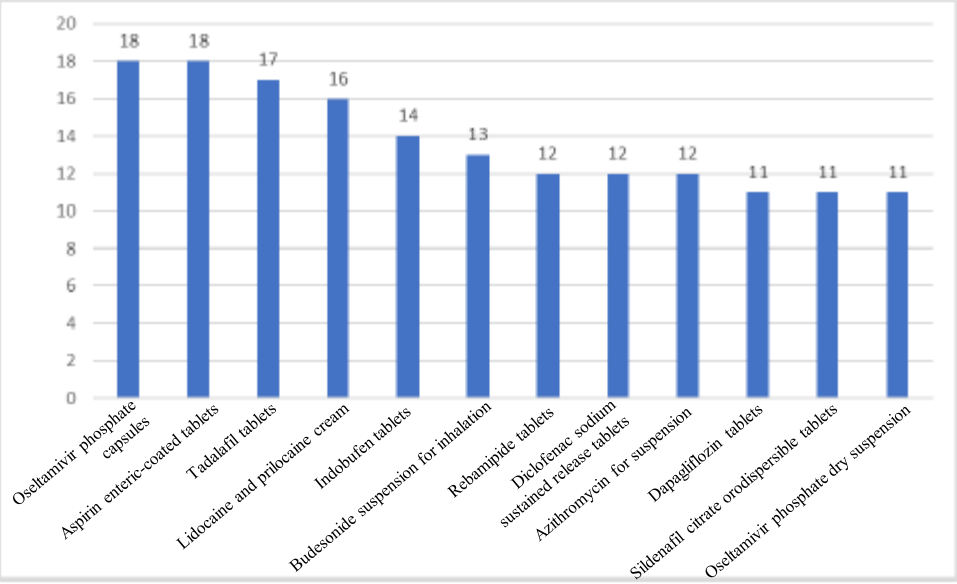


Distribution of clinical trials of drugs for medical imaging and trial phases in 2022

A comparison of the clinical trial registration data since 2019 showed that the number of clinical trials of drugs for medical imaging has been increasing year by year, but the overall number was still relatively small, with 0, 5 and 8 trials from 2019 to 2021, respectively.

4. Drugs Involved in Bioequivalence Trials

Among the top 10 varieties involved in BE trials in 2022, oseltamivir phosphate capsules and aspirin enteric-coated tablets registered the largest number of trials (n=18), as shown below.

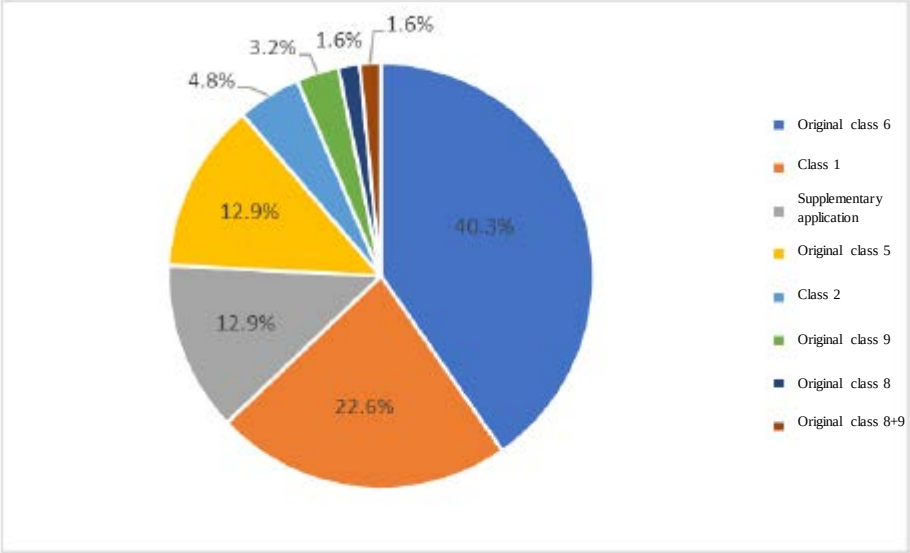


Top 10 varieties in terms of number of BE trials in 2022

Compared with 2021, three varieties remained in the top 10 varieties, namely oseltamivir phosphate capsules, tadalafil tablets and oseltamivir phosphate dry suspension, and both oseltamivir phosphate capsules and tadalafil tablets were two of the top three varieties in recent two years.

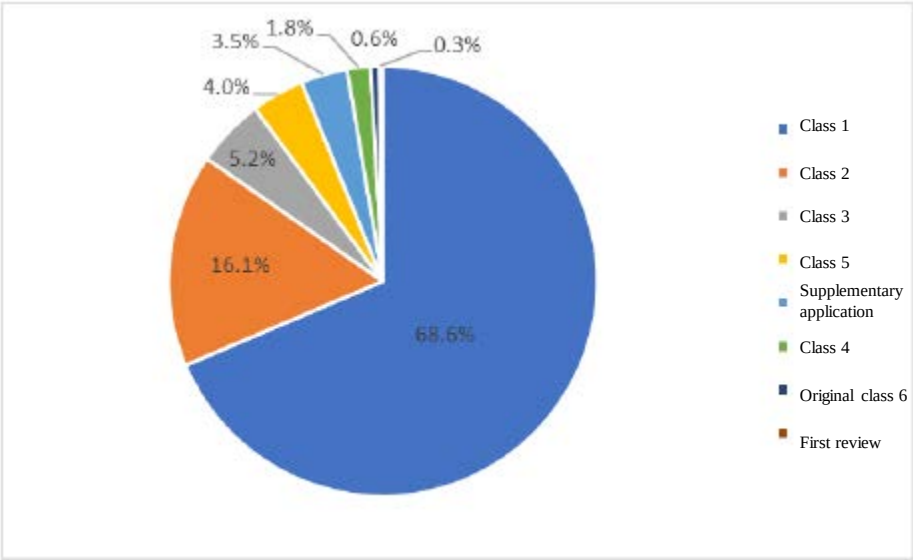
Ⅳ. Drug Types and Registration Classifications

TCMs: 62 clinical trials were registered in 2022, mainly in the original registration classification class 6, which accounted for 40.3%, followed by class 1, accounting for 22.6%.



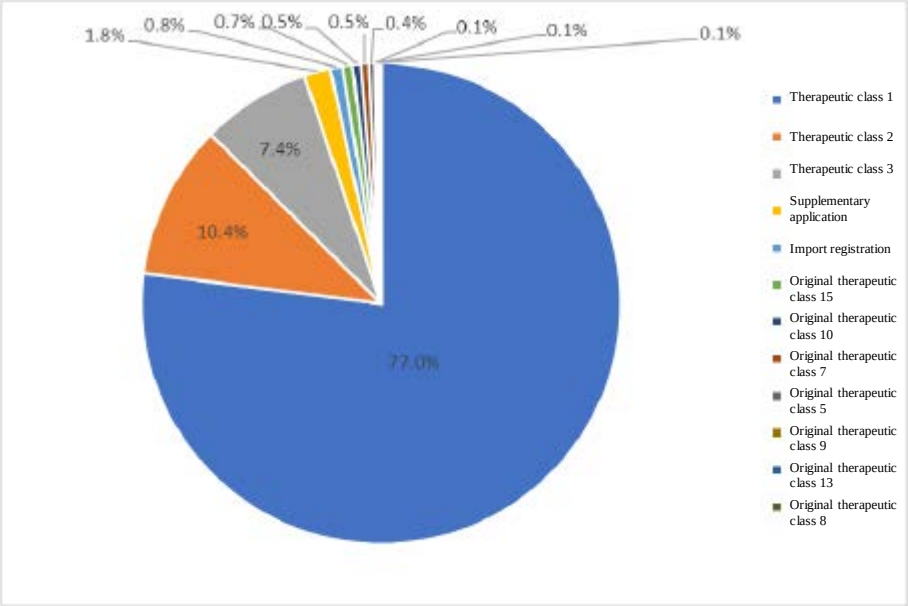
Registration classification of TCMs in 2022

Chemical drugs: For new drug clinical trials registered by acceptance number, the drugs in registration class 1 (including the original registration classification) accounted for the largest percentage, reaching 68.6%, followed by class 2 accounting for 16.1%.

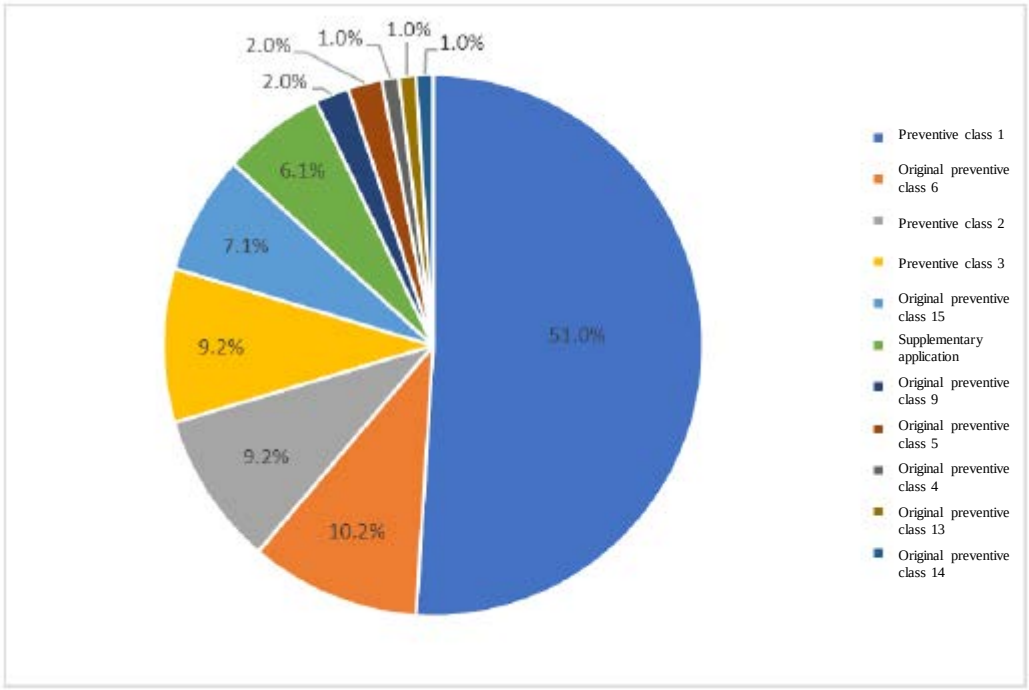


Registration classification of chemical drugs in 2022

Biological products: In2022, therapeutic biological products were mainly class 1 and class 2 (including the original registration classification), accounting for 77.0% and 10.4%, respectively; preventive biological products were mainly class 1 and original class 6, accounting for 51.0% and 10.2%, respectively.



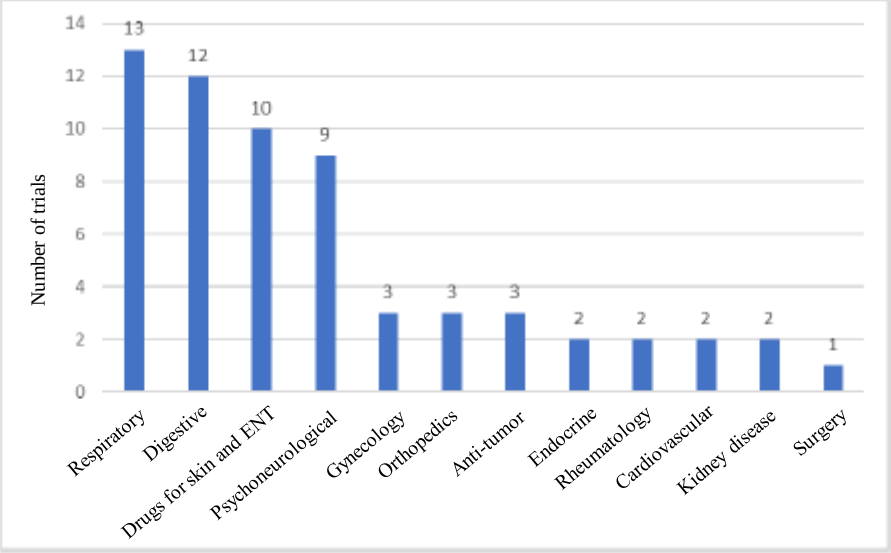
Registration classification of therapeutic biological products in 2022



Registration classification of preventive biological products in 2022

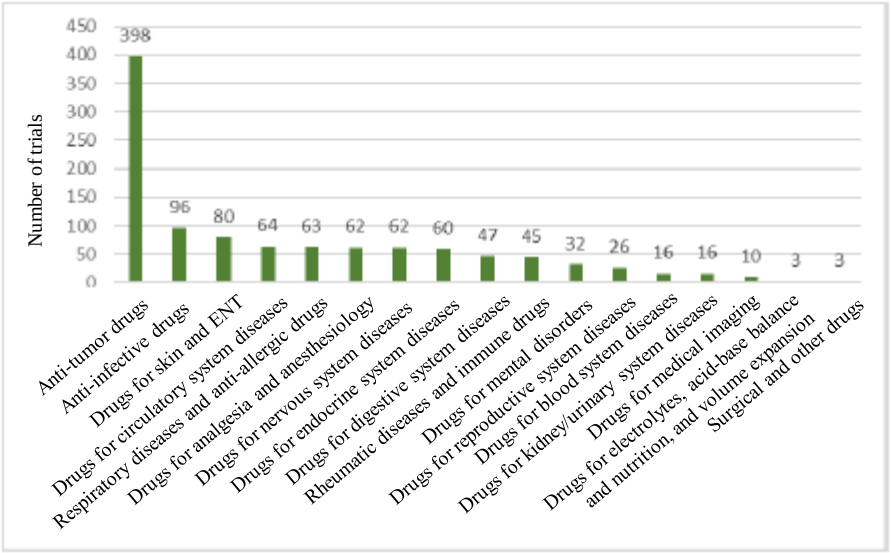
V. Target Indications

TCMs: In 2022, new drug clinical trials for TCMs mainly focused on five indications, i.e., respiratory, digestive, skin and ENT, psychoneurological and gynecology indications, accounting for approximately 75.8% of the overall clinical trials of TCMs. Among them, respiratory indications accounted for the highest percentage of 21.0%.



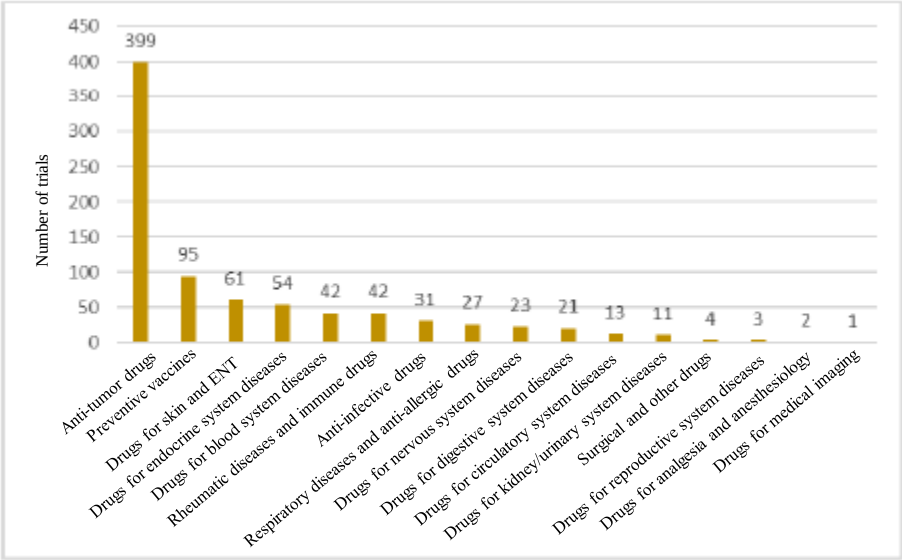
Indication Distribution of Clinical Trials for TCMs in 2022

Chemical drugs: In 2022, chemical drug indications were still mainly concentrated in anti-tumor drugs, accounting for 36.7% of all clinical trials of chemical drugs, followed by anti-infective drugs (8.9%), drugs for skin and ENT (7.4%), drugs for circulatory system diseases (5.9%), and respiratory diseases and anti-allergic drugs (5.8%).



Indication Distribution of Clinical Trials for Chemical drugs in 2022

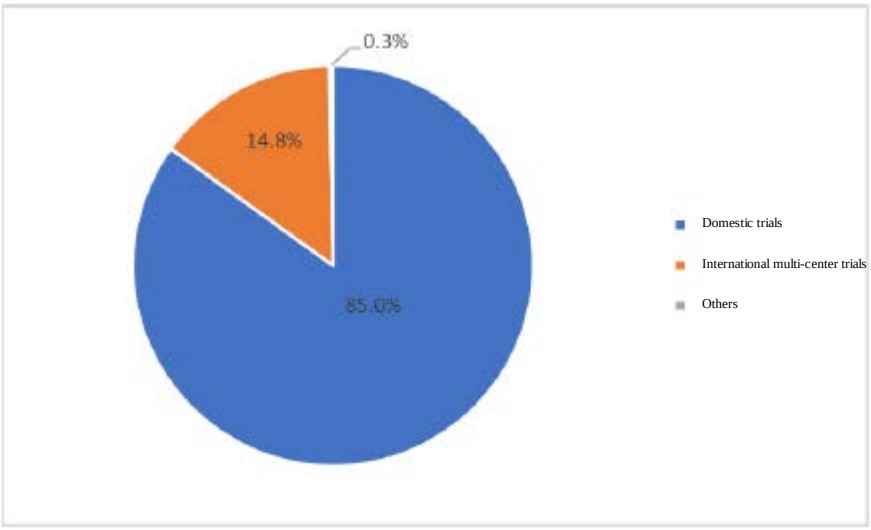
Biological products: In 2022, biological product indications were also mainly concentrated in anti-tumor drugs, accounting for 48.1% of the overall clinical trials of biological products, followed by preventive vaccines (11.5%), drugs for skin and ENT (7.4%), drugs for endocrine system (6.5%), drugs for blood system diseases and rheumatic diseases and immune drugs (5.1% each). There were a total of 39 clinical trials of novel coronavirus vaccines, accounting for 41.1% (39/95) of the clinical trials of preventive vaccines.



Indication distribution of clinical trials of biological products in 2022

VI. Domestic and Foreign Distribution of Clinical Trials

Overall, new drug clinical trials were still dominated by domestic clinical trials. Domestic drug clinical trials in 2022 accounted for 91.1% (n=3,105), and international multi-center trials accounted for 8.6% (n=292). Single-center clinical trials that did not recruit subjects in China or were only conducted abroad were counted under the classification of "others" and accounted for 0.4% (n=13). Among the new drug clinical trials registered by acceptance number in 2022, international multi-center trials of new drugs accounted for a relatively high percentage, reaching 14.8% (n=292), and domestic trials accounted for 85.0% (n=1,677).

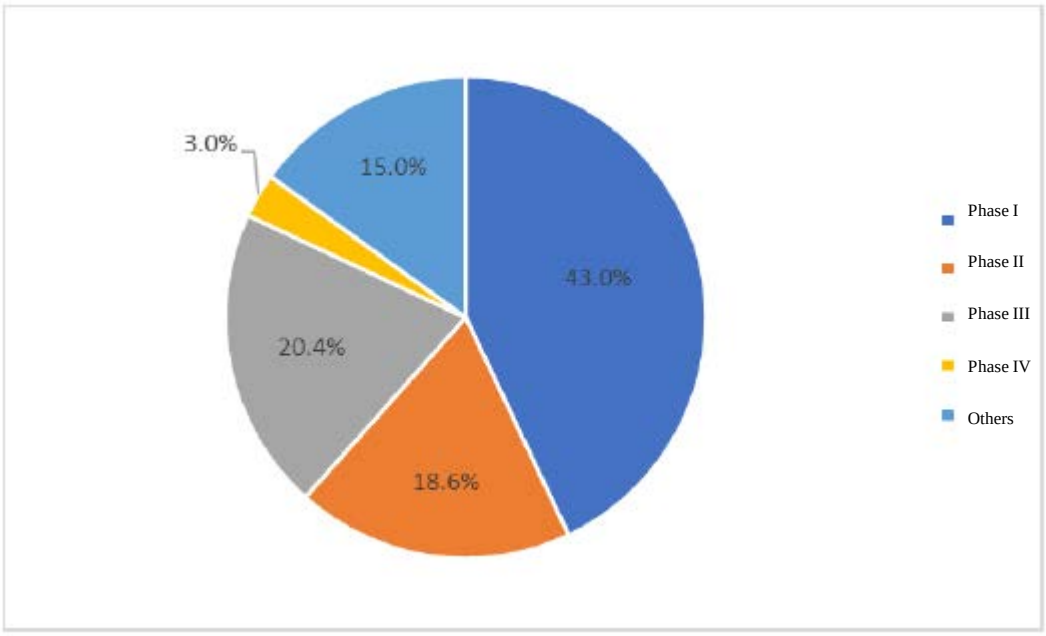


Distribution of new drug clinical trials in 2022

Ⅶ. Clinical Trial Phases

Among the new drug clinical trials registered by acceptance number in 2022, phase I accounted for 43.0% (n=848), and phase II and phase III accounted for 18.6% (n=368) and 20.4% (n=402), respectively. There were 59 phase IV clinical trials (mainly clinical trials explicitly required in the marketing approval). Trials that could not be completely divided into phases I-IV should be counted as "others", such as phase I/II.

Compared to 2021, the percentage of clinical trials was basically consistent for each phase. The percentage of phase I clinical trials was the highest, followed by phase III and phase II and then phase IV.



Percentage of different phases of new drug clinical trials in 2022

Ⅷ. Sample Size Distribution of Clinical Trials

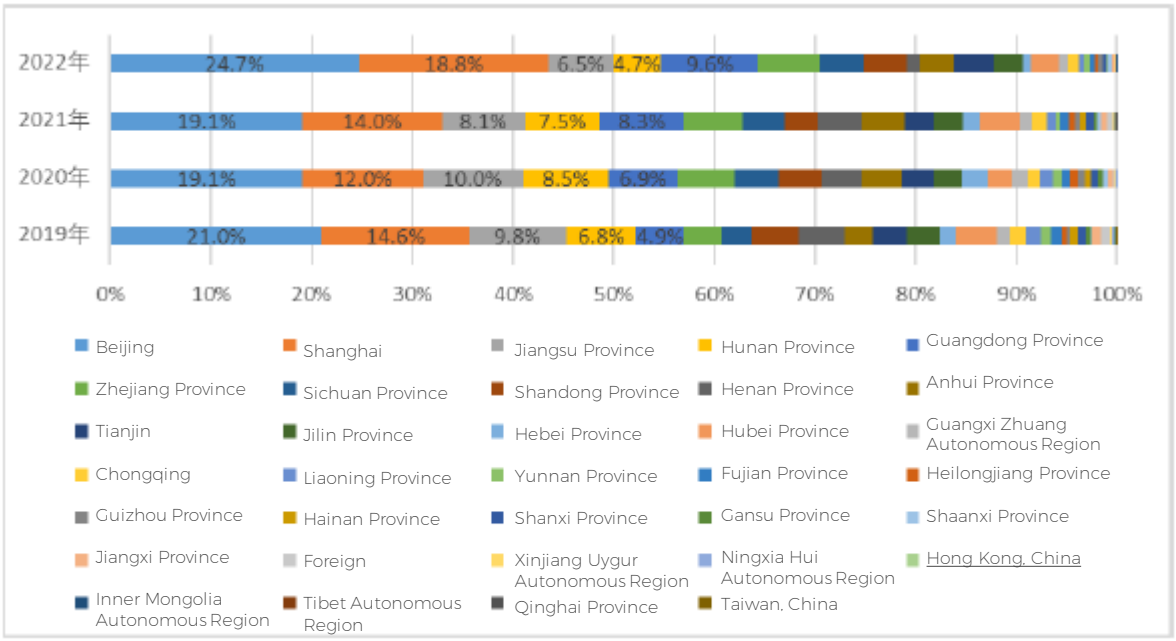
Among the new drug clinical trials registered by acceptance number in 2022, a total of 1,878 trials had domestic target enrollments registered, with the average target enrollments of 349.2. According to the drug types and trial phases, the sample size distribution is as follows:

Drug Type	Average Target Enrollment				
	Phase I	Phase II	Phase III	Phase IV	Others
TCMs	42.3	191.6	390.3	1700.0	252.0
Chemical drugs	49.6	112.7	272.5	3011.0	114.4
Biological products	75.5	151.3	805.2	7348.3	186.6

IX. Leading Clinical Trial Institutions

Among the drug clinical trials registered by acceptance number in 2022, clinical trial institutions in Beijing still participated as the leading institutions (if an institution participated in multiple trials as a leading institution at the same time, it was counted separately, the same below) the most frequently (621 times), exceeding 1/5 (24.7%) of the total.

The provinces, autonomous regions and municipalities under the Central Government (including Hong Kong, Macao and Taiwan) with clinical institutions that participated in clinical trials most frequently as leading institutions in recent years have always been Beijing, Shanghai, Guangdong Province and Jiangsu Province, accounting for 24.7%, 18.8%, 9.6% and 6.5% in 2022, respectively. Beijing and Shanghai have both ranked as the top two over the years, and their percentages have both increased slightly compared to 2021.

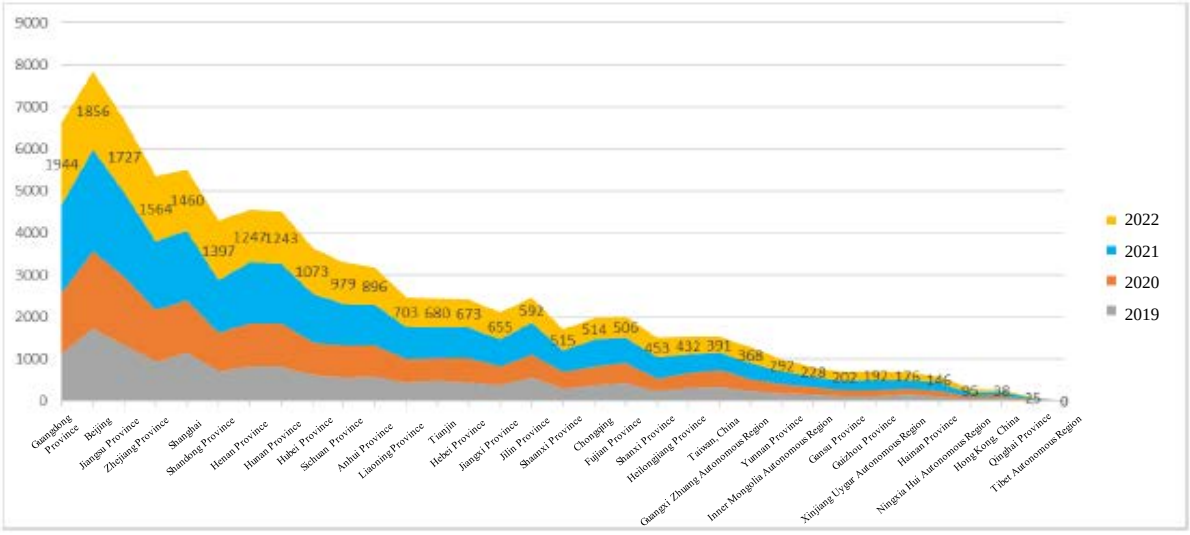


Changes in the percentage of leading clinical trial institutions in different provinces, autonomous regions and municipalities under the Central Government (2019-2022)

X. Participating Clinical Trial Institutions

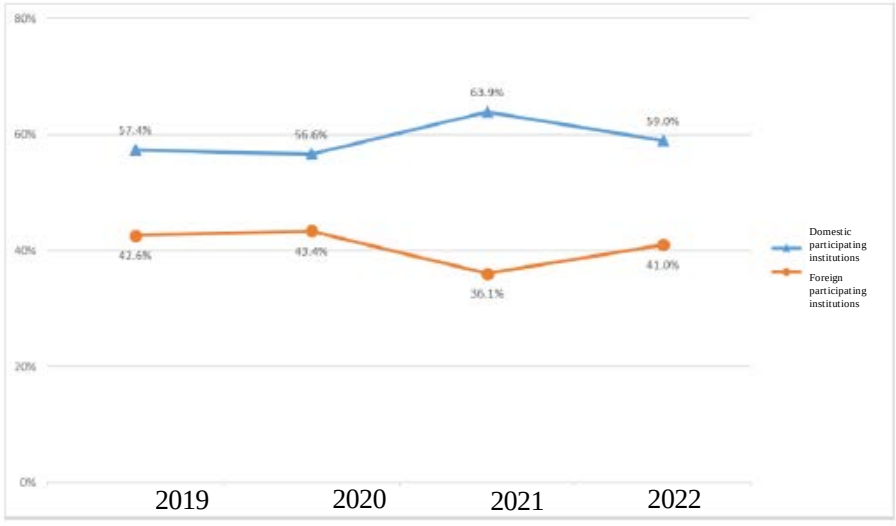
Clinical trial institutions participated in trials 39,427 times in China and abroad in all drug clinical trials registered in 2022 (if a clinical trial institution participated in multiple clinical trials at the same time, it was counted separately, the same below) and 23,262 times in China (including Hong Kong, Macao and Taiwan). Both showed a decline compared to 2021.

Four provinces, autonomous regions and municipalities under the Central Government with clinical institutions that participated in clinical trials more than 1,500 times in 2022 included Guangdong Province, Beijing, Jiangsu Province, and Zhejiang Province, with Guangdong Province being the region with the highest number of participating institutions.



Frequency of participation in clinical trials by provinces, autonomous regions and municipalities under the Central Government in China (2019-2022)

In 2022, the percentage of times of participation in domestic clinical trials for foreign institutions was 41.0%, a slight rebound from 2021 (36.1%) and basically the same as that in 2020 (43.4%).



Changes in the percentage of participating institutions at home and abroad (2019-2022)

Chapter III Other Characteristics of Clinical Trials

Ⅰ. Drug Clinical Trials in Special Populations

1、Drug Clinical Trials in Geriatric Populations

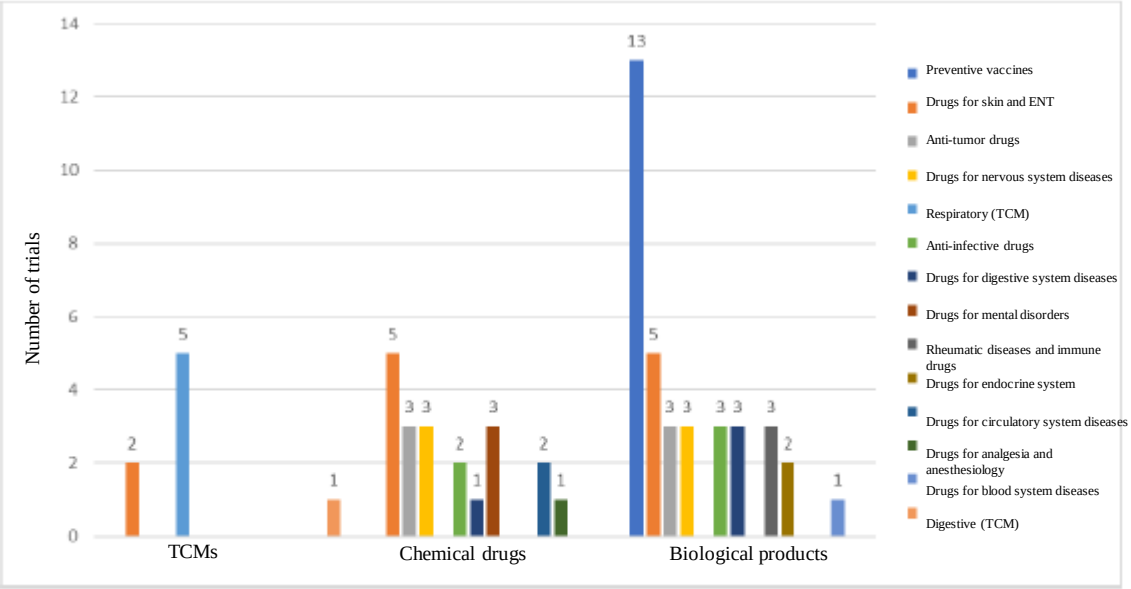
There were 1,427 trials involving geriatric subjects in drug clinical trials in 2022, accounting for 72.3% (1,427 vs. 1,974) of the new drug clinical trials registered by acceptance number. One trial was carried out only in the geriatric population, accounting for 0.05% only. The specific information is as follows.

Drug Type	Trial Phase	Indication	Total
		Treatment-naïve geriatric subjects with locally advanced squamous cell carcinoma of the head and neck (LA-HNSCC)	
Chemical drugs	Phase III	1	1

2、Drug Clinical Trials in Pediatric Populations

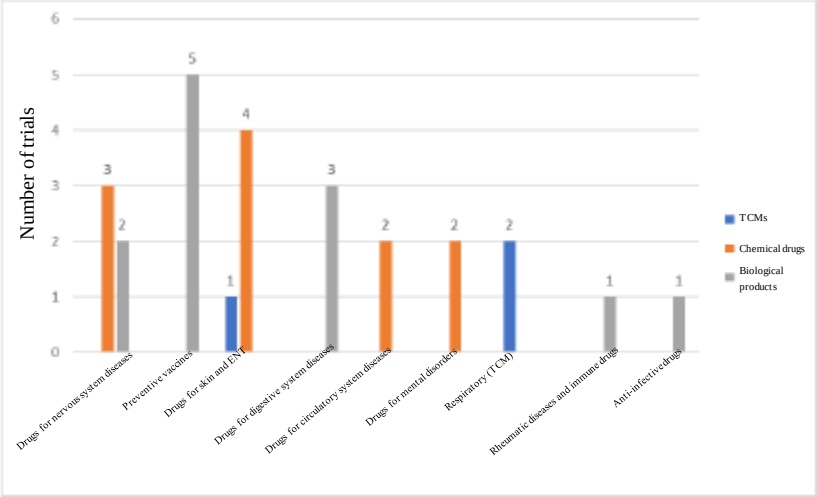
There were 164 trials involving pediatric subjects in 2022, which accounted for 8.3% (164 vs. 1,974) of the new drug clinical trials registered by acceptance number. According to an analysis by drug types, 114 trials were registered for biological products, the largest amount, followed by chemical drugs and TCMs; according to the analysis by indications, biological products were mainly preventive vaccines and blood system disease drugs; chemical drugs were mainly drugs for skin and ENT and anti-tumor drugs; TCMs were mainly respiratory drugs.

A total of 64 new drug clinical trials were registered only for the pediatric population, accounting for 3.2% (64 vs. 1,974) of all new trials. According to an analysis by trial scope, there were 13 international multi-center trials. According to an analysis by drug types, 36 trials for biological products were registered, the largest amount, followed by 20 chemical drug trials and 8 TCM trials. According to the analysis by indications, biological products were mainly preventive vaccines, accounting for 36.1% of overall biological products. Chemical drugs were mainly for skin and ENT indications. TCMs were mainly for respiratory indications.



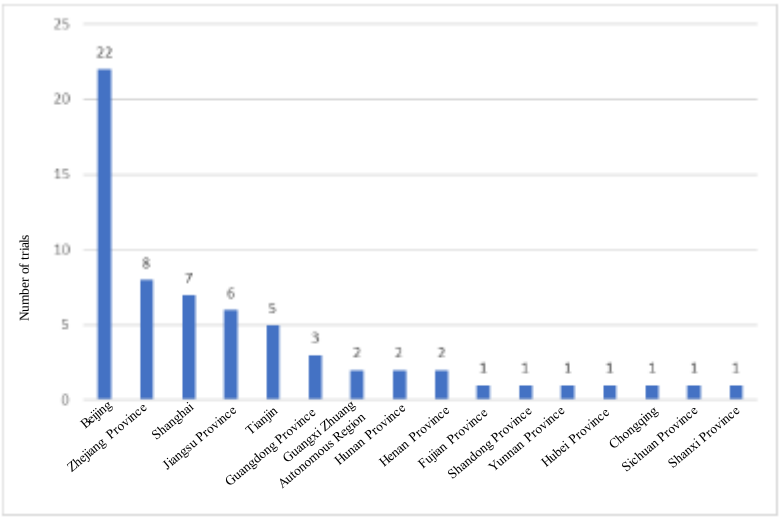
Number and indication distribution of clinical trials conducted only in the pediatric population in 2022

Based on the analysis of trial phases, phase III clinical trials accounted for the highest percentage of the 64 trials in pediatric population, reaching 40.6% (26 vs. 64). Among the 26 phase III clinical trials, the top three indications were those of drugs for nervous system diseases, preventive vaccines, and drugs for skin and ENT.



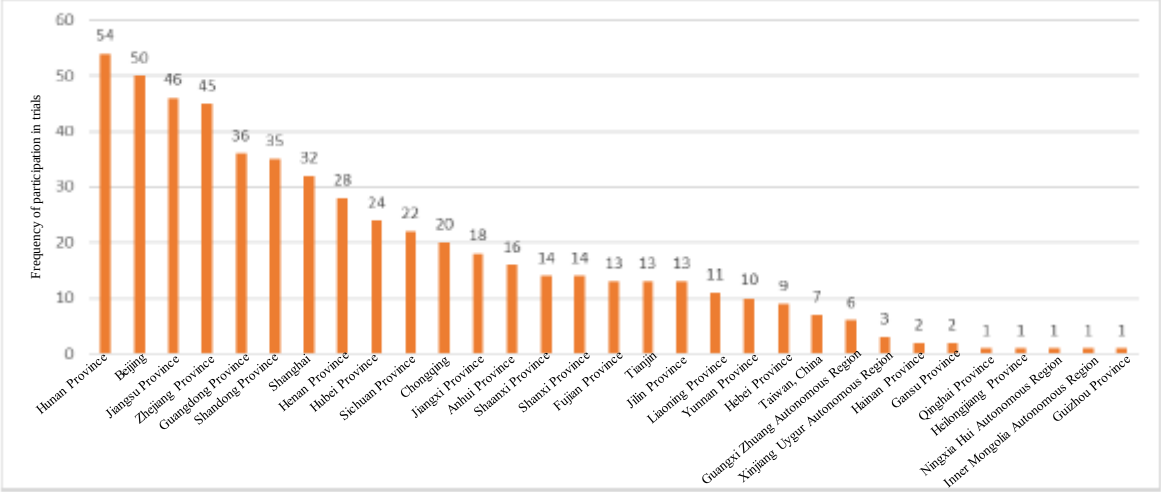
Number and indication distribution of phase Ⅲ clinical trials conducted only in the pediatric population in 2022

According to the analysis of the distribution of leading institutions of clinical trials conducted only in the pediatric population, the leading institutions of 64 clinical trials in pediatric population were in 16 provinces, autonomous regions and municipalities under the Central Government, of which trials of clinical trial institutions in Beijing as leading institutions were still the most, reaching 22, while those of other provinces were less than half of the number of trials conducted in Beijing, and there was only one clinical trial institution as a leading institution in seven provinces.



Distribution of leading institutions of clinical trials in pediatric population in 2022

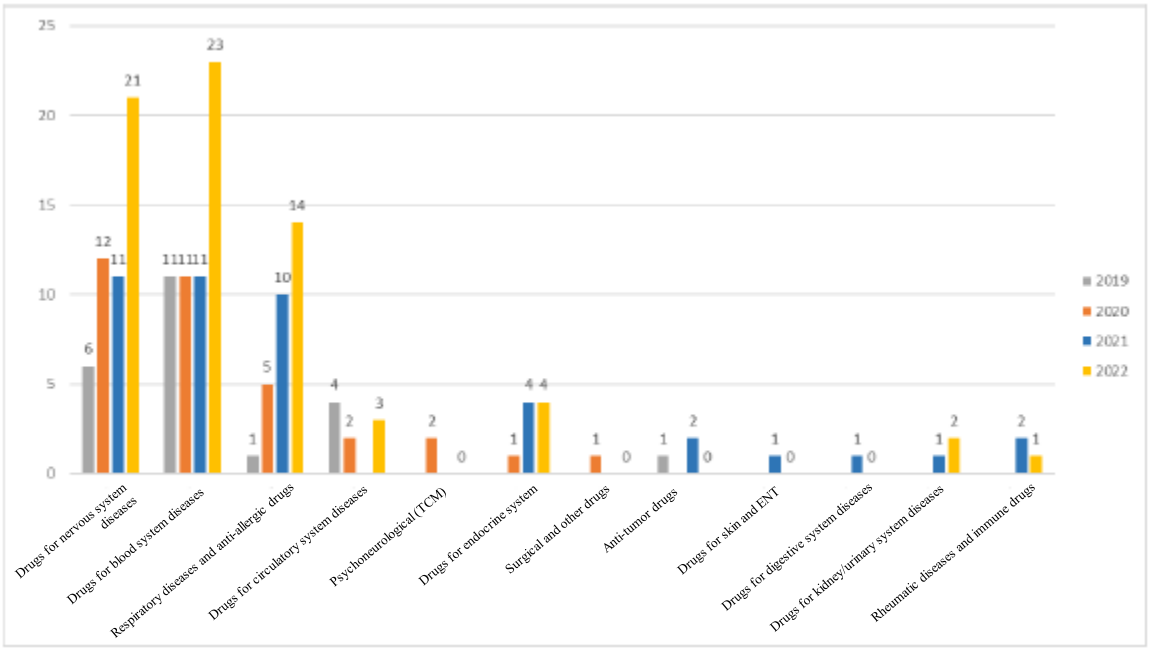
According to the analysis of participating institutions, the participating institutions of the 64 clinical trials in pediatric population were in 31 provinces, autonomous regions and municipalities under the Central Government, with a total of 548 times, among which the participating institutions in Hunan Province and Beijing participated most frequently, with both reaching more than 50 times.



Frequency of participation in clinical trials in pediatric population for participating institutions by provinces, autonomous regions and municipalities under the Central Government in China in 2022

3、Clinical Trials of Rare Disease Drugs

Using the Chinese term "rare diseases" as keywords, clinical trials of rare disease drugs were analyzed. The number of clinical trials showed year-on-year growth, with 68 trials being registered in 2022. According to an analysis by drug types, the drugs for the treatment of rare diseases were mainly chemical drugs and biological products, with 33 and 35 trials registered, respectively. According to the analysis by indications, trials were mainly for blood system diseases, nervous system diseases and respiratory system diseases.



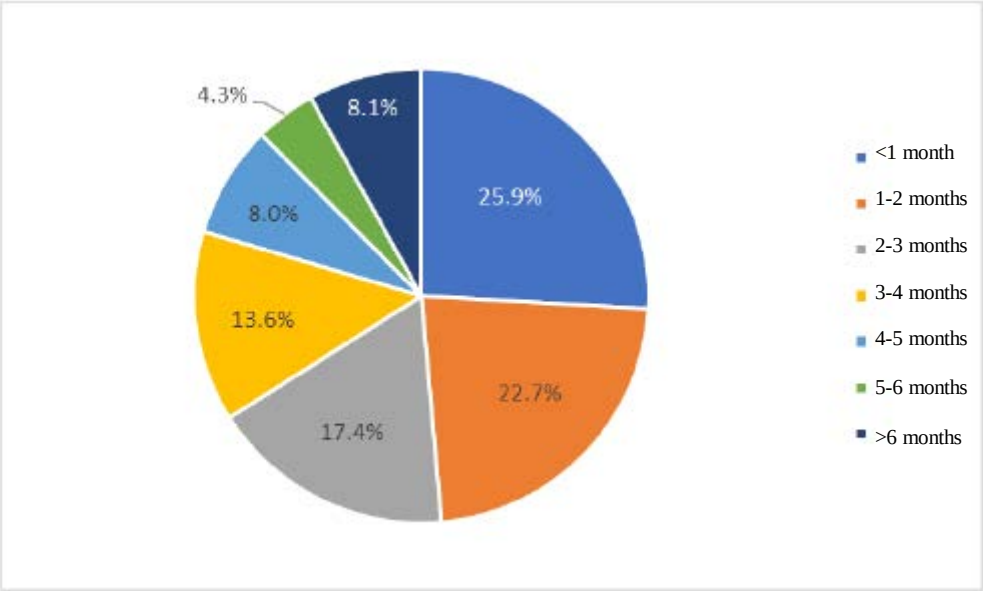
Changes in indication distribution of clinical trials of rare disease drugs (2019-2022)

Ⅱ. Time for First Clinical Trial Registration

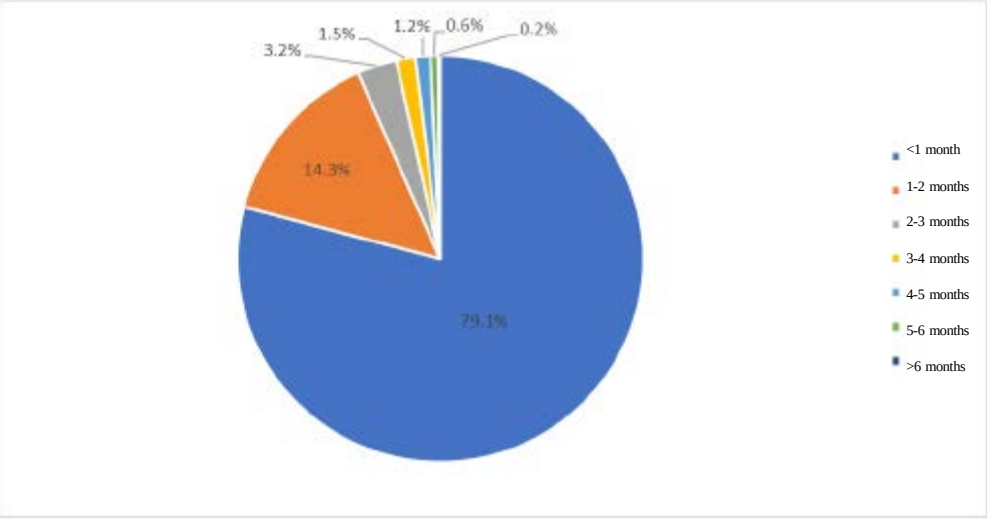
Time taken for trial registration was analyzed based on the implied date of license for the clinical trial (or BE filing date) and the date of the applicant's first submission for registration. There were a total of 2,114 trials registered with an implied license date (or BE filing date) within 2022, of which 788 (37.3%) were registered by acceptance number and 1,326 (62.7%) were registered by BE filing.

The average time taken for registration with an acceptance number was 116 days (1 to 328 days), with less than 50% of applicants being able to complete and submit their registration within two months, and only 25.9% completing and submitting their registration in less than one month.

The average time taken for registration of BE filings was 67 days (1 to 221 days), and about 93.4% of applicants could complete and submit their registration within two months, with 79.1% completing and submitting their registration in less than one month.



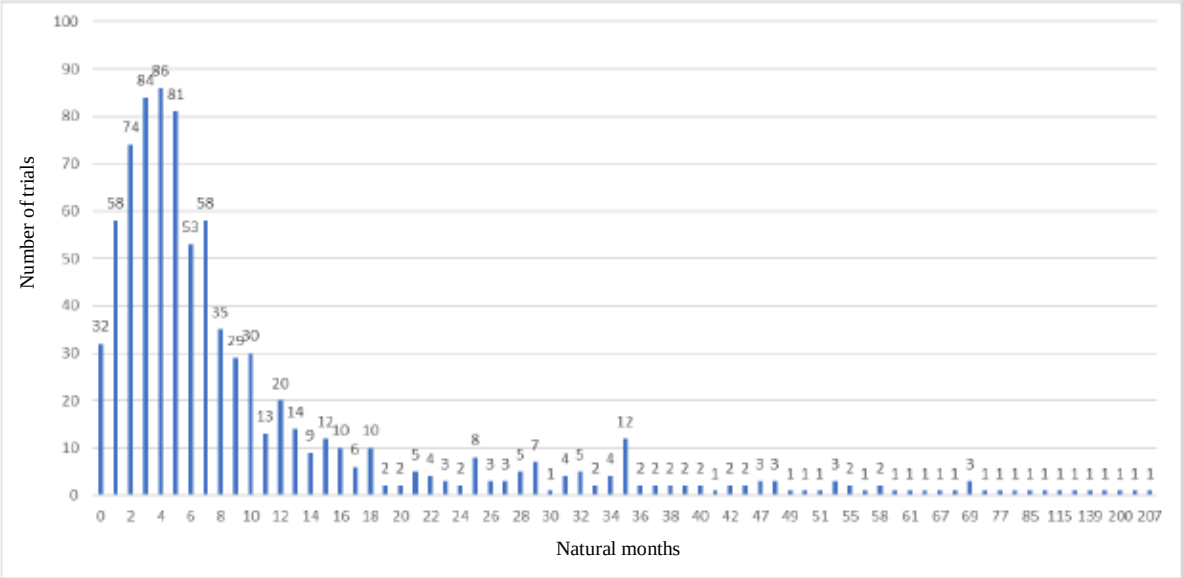
Distribution of percentages of time taken for trials registered with acceptance number in 2022



Distribution of percentages of time taken for trials registering BE filing in 2022

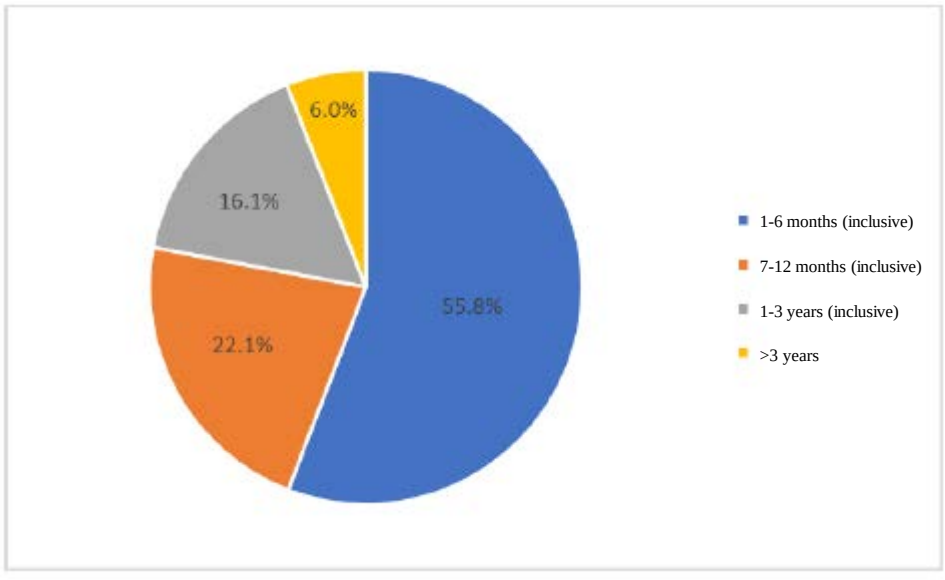
Ⅲ. Clinical Trial Startup Times

There were 846 trials registered in 2022 with the first valid subject's Informed Consent Form (ICF) date and no relevant registration number information (i.e., excluding trials approved before 2022 but newly added in 2022) in China. The elapsed time for clinical trial initiation (calculated by the ICF date and the clinical trial approval date) ranged from 1 day to 207 months, with an average of 48 months.

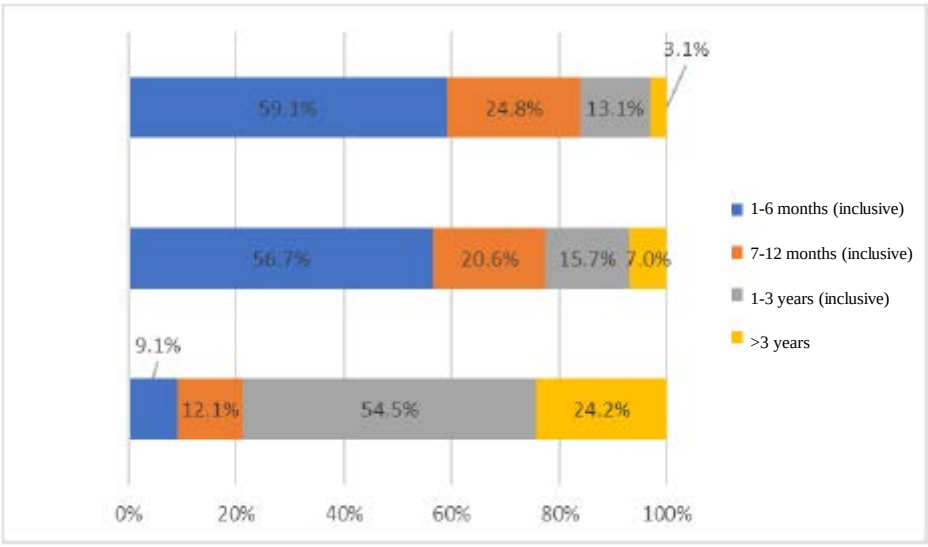


Distribution of startup times for new drug clinical trials in 2022

Overall, more than half of the trials (55.8%) were able to initiate subject recruitment within six months of approval, slightly higher than that in 2021 (51.4%). In terms of drug types, the percentages of chemical drug and biological product trials that initiated subject recruitment within six months (56.7% and 59.1%, respectively) were significantly higher than that of TCM trials, while the percentage (21.2%) of TCM trials that initiated subject recruitment within one year was significantly higher than that in 2021 (4.4%).

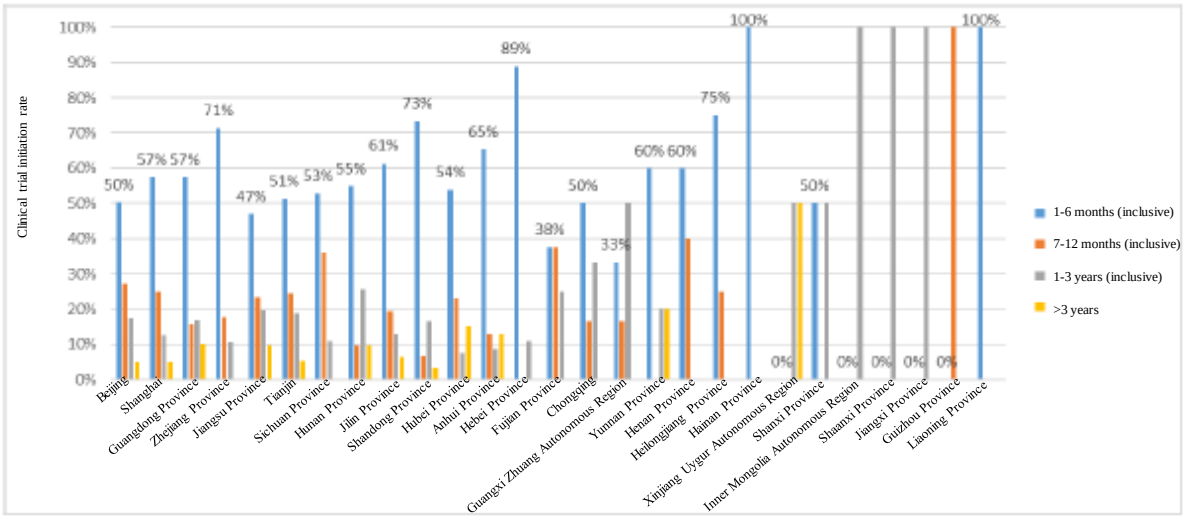


Distribution of percentage of overall startup time of new drug clinical trials in 2022



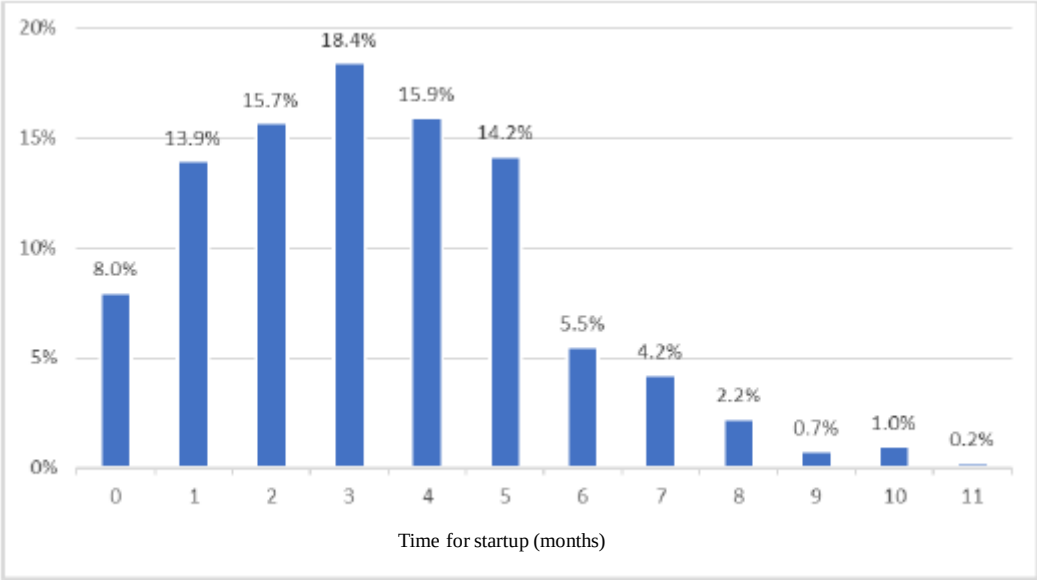
Percentage of overall initiation time of new drug clinical trials for different drug types in 2022

Further analysis based on the location of clinical trial institutions suggested that in provinces, autonomous regions and municipalities directly under the Central Government with more leading clinical trial institutions, it still took longer to initiate clinical trials. In the top five provinces, autonomous regions and municipalities directly under the Central Government in 2022, only trials that initiated subject recruitment within six months of approval in Zhejiang Province were all over 70%. In addition, more than 70% of trials in Shandong, Hebei and Heilongjiang Provinces initiated subject recruitment within six months after approval, and 100% of trials in Hainan and Liaoning Provinces were initiated within six months after approval.



New drug clinical trial initiation rate by provinces, autonomous regions and municipalities directly under the Central Government in 2022

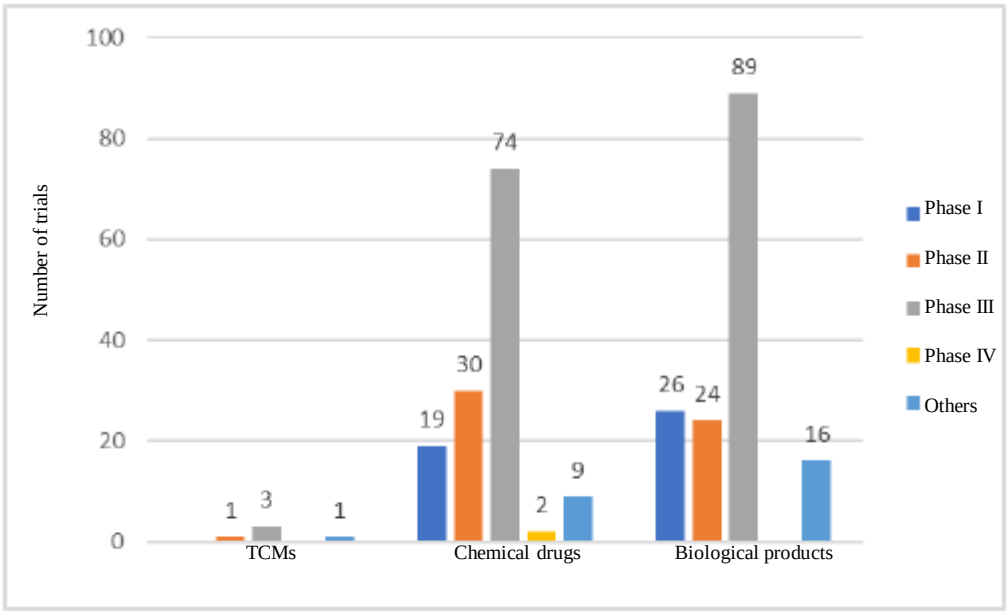
Analyzing only the recruitment of subjects initiated after the trial approval (if there were multiple relevant acceptance numbers in the current year, the earliest approval date would be calculated), there were 402 trials in 2022 with startup times ranging from 1 day to 11 months, with an average of 3.3 months. 91.5% of them initiated subject recruitment within six months of approval. Compared to 2021, there was a further reduction in the time for initiation (compared to an average of 3.8 months in 2021) and a further increase in the percentage of recruitment initiated within six months (compared to 85.7% in 2021).



Distribution of percentage of initiation times for new drug clinical trials in 2022

Ⅳ. Establishment of the Data Monitoring Committee (DMC)

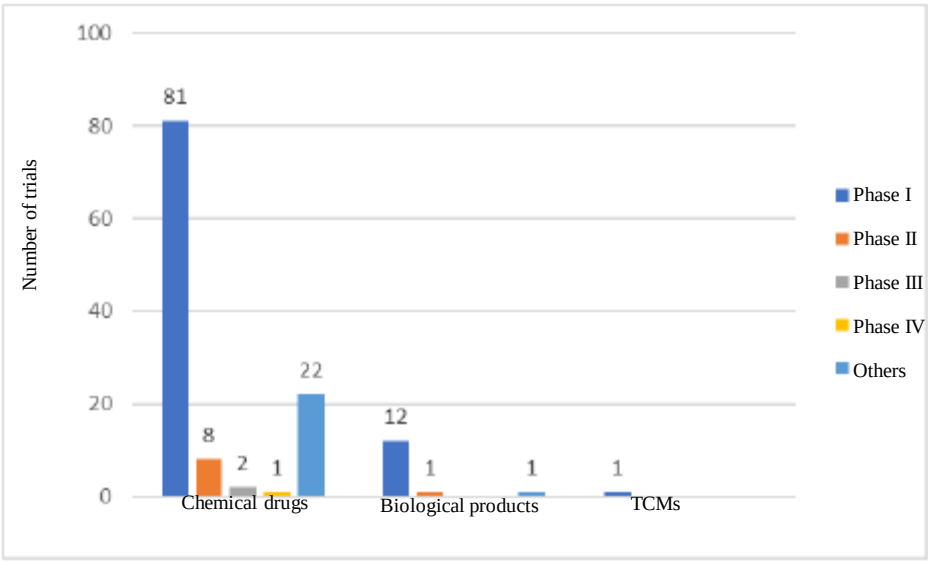
Of the 1,974 new drug clinical trials registered by acceptance number in 2022, the data monitoring committee (DMC) was established in a total of 294 trials (14.9%). From the analysis of the classification of drugs, the percentage of biological products trials with DMCs was the highest of 52.7% (155/294), followed by chemical drugs at 45.6% (134/294). From the analysis of the trial phases, the percentage of phase III clinical trials with DMCs was the highest, reaching 56.5%; that of phase IV clinical trials was the lowest, only at 0.7%; the percentages of phase I and phase II clinical trials with DMCs were basically consistent, at 15.3% and 18.7%, respectively.



Establishment of DMCs for new drug clinical trials in 2022

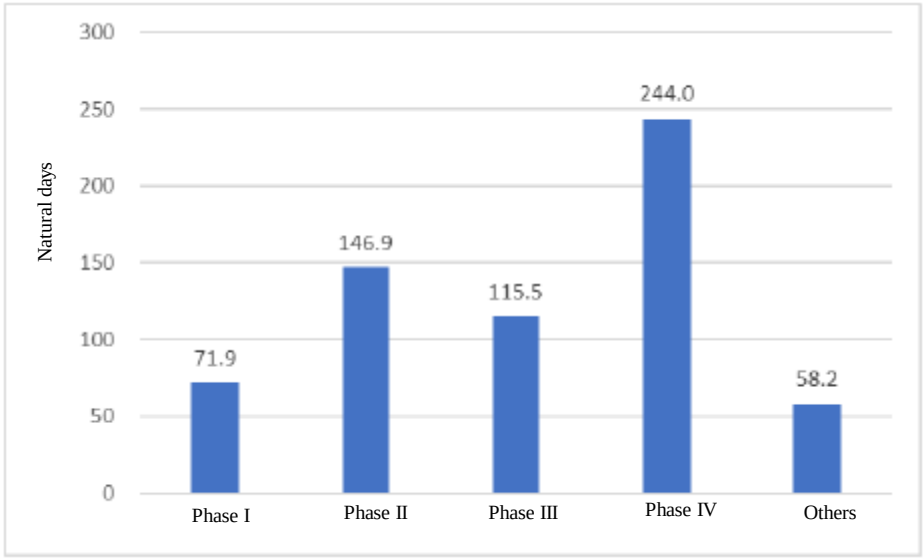
V. Completion of Clinical Trials

Among the 1,974 new drug clinical trials registered by acceptance number in 2022, 129 were completed in the same year (the trial status was "completed", and the first ICF date and trial completion date were both in 2022), which were all domestic, mainly phase I clinical trials (n=94, 72.9%). According to an analysis by drug types, the number of chemical drug trials completed was the largest (n=114, 88.4%), including two phase III clinical trials; 14 biological product trials were completed.



Completion and trial phases of new drug clinical trials in 2022

According to the analysis by the domestic trial completion date and first ICF date, trial completion time ranged from 11 to 258 days (natural days), with an average of 76.7 days. According to the analysis by the trial phases, the average completion time of phase I clinical trials was the shortest at 71.9 days, and the average completion time of phase IV clinical trials was the longest at 244 days.



Completion time of new drug clinical trials by phase in 2022

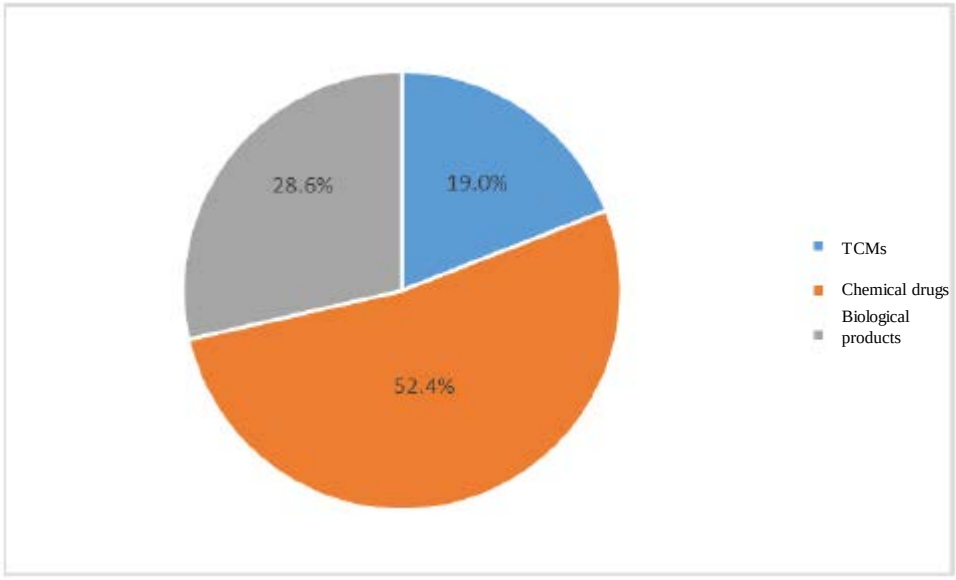
In 2022, 9 trials were voluntarily suspended (3 for chemical drugs, 4 for biological products, and 2 for TCMs), 16 trials were voluntarily terminated (10 for chemical drugs, 5 for biological products, and 1 for TCMs), and 1 biological product trial was ordered to be suspended. The reasons for the suspension and termination are as follows:

Type of Drugs	Voluntary Suspension	Voluntary Termination	Ordered Suspension	Reasons (Number of Clinical Trials)
TCMs	2	1	-	1) Suspension due to trial drug production issues (1); 2) Suspension due to trial funding issues (1); 3) Termination due to trial quality issues (1).
Chemical drugs	3	10	-	1) Suspension due to preparation quality standard issues (1); 2) Suspension due to protocol design issues (1); 3) Suspension due to adjustment of R&D strategy (1); 4) Termination due to limited clinical benefits (2); 5) Termination due to adjustment of R&D strategy (7); 6) Termination due to avoidance of novel coronavirus cross infection (1).
Biological products	4	5	1	1) Suspension due to limited clinical benefits (2); 2) Suspension due to adjustment of R&D strategy (1); 3) Suspension due to production process adjustment (1); 4) Termination due to adjustment of R&D strategy (3); 5) Termination due to limited clinical benefits (2); 6) Ordered suspension due to safety risks (1).
Total	9	16	1	

Chapter Ⅳ Clinical Trials of Marketed Innovative Drugs in the Year

Ⅰ. Overall Situation

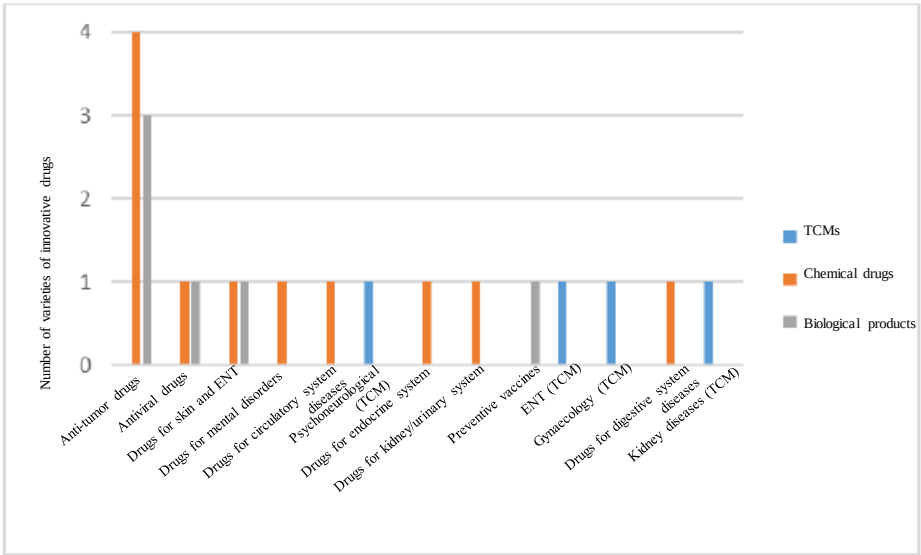
According to the date of the approval conclusion of the Center for Drug Evaluation, a total of 21 innovative drugs (excluding TCM extracts and varieties for new indications) were approved in 2022 by drug name, of which the largest number was chemical drugs, with a total of 11 varieties, accounting for 52.4%; while 6 and 4 varieties of biological products and TCMs were approved, respectively. According to the nature of marketing authorization holders, domestic holders predominated, accounting for 76.2%.



Percentage of innovative drugs approved for marketing by drug type in 2022

Ⅱ. Distribution of Indications

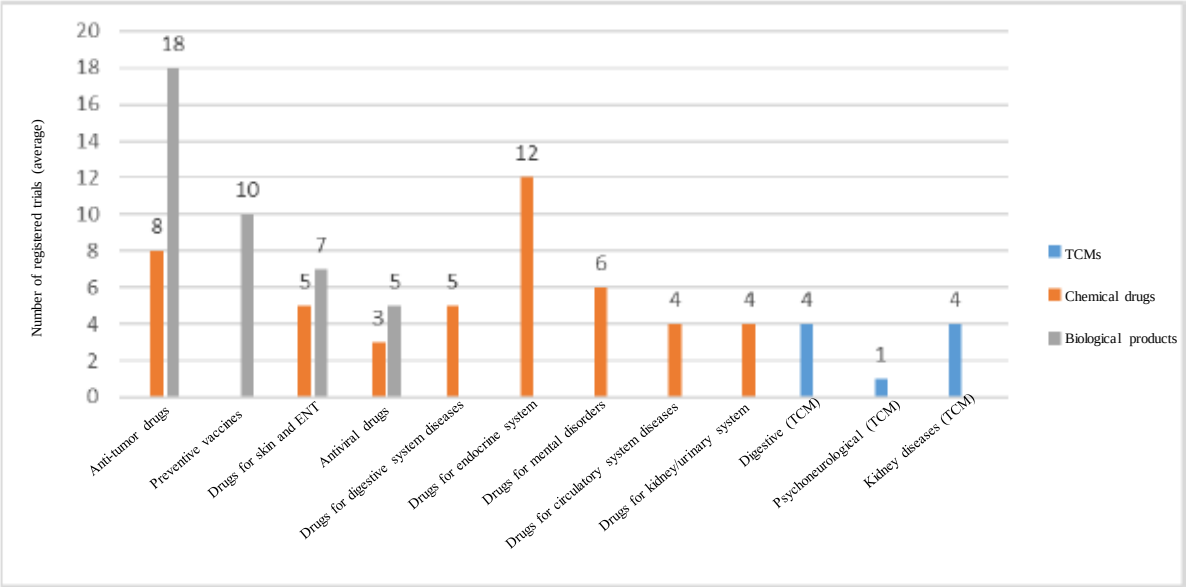
Overall, among the innovative drugs approved in 2022, anti-tumor drugs were the most, with 7 varieties (33.3%), among which chemical drugs were the most, with 4 varieties, followed by antiviral drugs and drugs for skin and ENT, with 2 varieties each. In addition, each one variety of TCM was approved for psychoneurology, gynecology, nephrology and digestion.



Number of varieties of innovative drugs approved for marketing by indication in 2022

Ⅲ. Status of Registered Trials

The number of clinical trials registered for innovative drugs approved for marketing in 2022 ranged from 1 to 21, with an average of 7.3, according to clinical trial registration number (CTR). According to the analysis by drug types, clinical trials registered for biological products were the most, with an average of 11.6, followed by chemical drug trials with 6.5 and TCM trials with the lowest number of 3. According to the analysis by indications, the indication fields in which the average number of registered clinical trials exceeded 10 were, in descending order, anti-tumor drugs, drugs for endocrine system and preventive vaccines.



Number of registered trials of innovative drugs approved for marketing in 2022

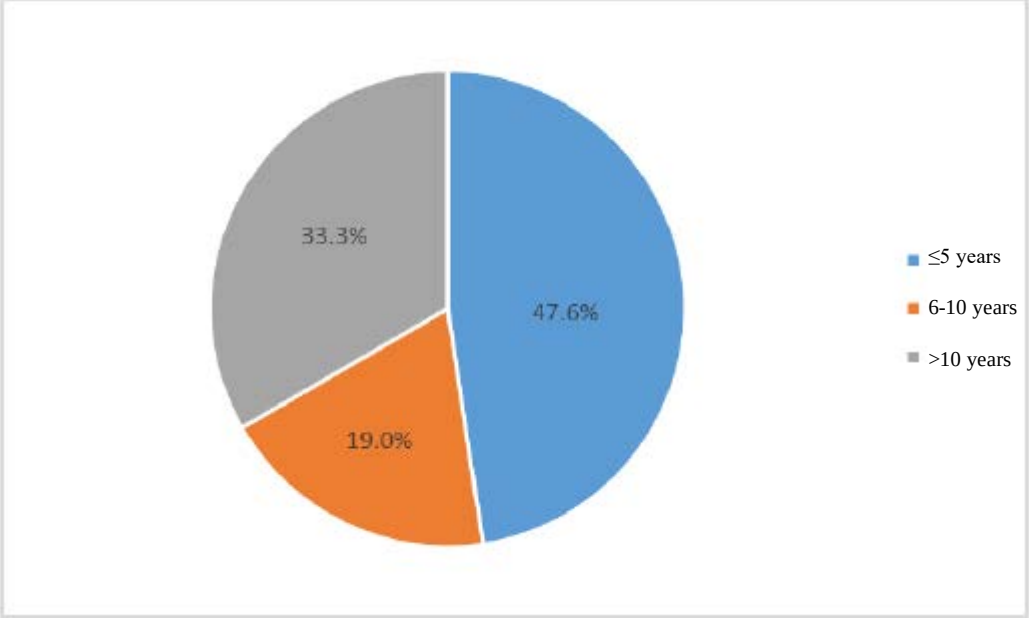
Note: 1. The trials registered for individual varieties include not only those conducted in support of marketing, but also clinical trials for other indications not yet approved for marketing. 2. Clinical trials completed before the registration platform was launched (end of 2012) for individual varieties are not included.

Ⅳ. Time to Market

Based on the date of the first approved clinical trial in China and the date of the approval conclusion of the marketing application, the time from the approval of the clinical trial to the approval of the marketing of the innovative drugs in the current year was analyzed (excluding varieties for new indications and extracts approved in 2022).

The average time taken for the innovative drugs approved for marketing in 2022 was 7.6 years. According to the analysis by drug types, biological products took the shortest time to be approved for marketing, with an average of 4.6 years, followed by chemical drugs, with an average of 6.9 years, and TCMs, which took the longest time, with an average of 15 years.

Among the innovative drugs approved for marketing in 2022, 10 varieties (47.6% of the total) were marketed within 5 years, of which 4 (19.0%) were anti-tumor drugs.



Time to market for approved innovative drugs in 2022

Appendix: Instructions for Compilation

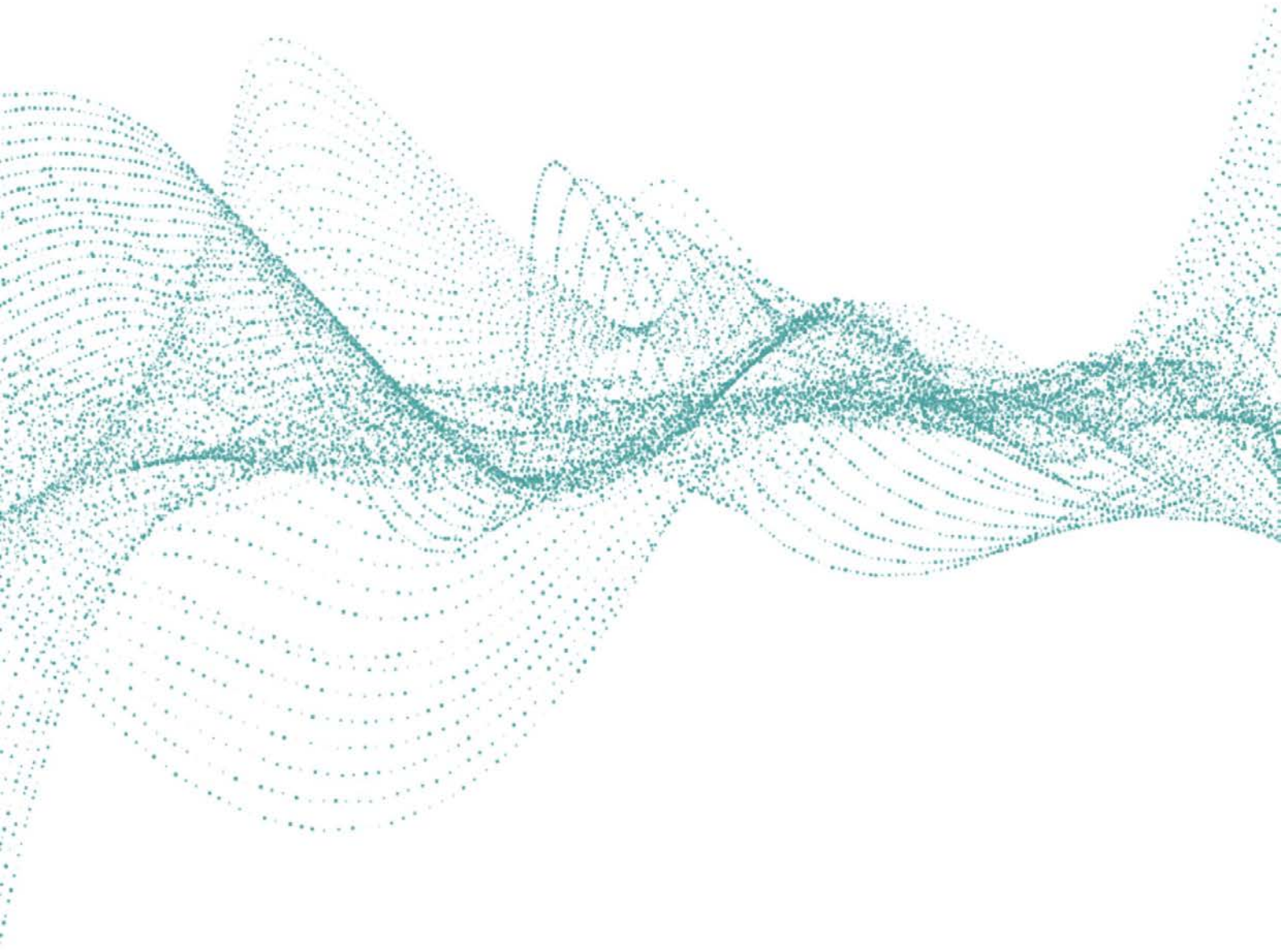
1. This report is statistically described and analyzed with the clinical trial registration (CTR) number by searching the clinical trial registration information first published from January 1, 2022 to December 31, 2022 in the Drug Clinical Trial Registration and Information Disclosure Platform database (hereinafter referred to as the "registration platform"), as well as by referring to the public database retrieval information in the industry. As there may be cases such as applicants deleting duplicated registration information, the number of clinical trials published in the report may be slightly different from the real-time data published on the Center for Drug Evaluation's website.

2. This report mainly focuses on the summary analysis of the registration information of new drug clinical trials (exploratory and confirmatory clinical trials registered by acceptance number). The registration information of bioequivalence trials (including the consistency evaluation of quality and efficacy of generic drugs) is only a general analysis and description.

3. In this report, the clinical trial registration information is classified and analyzed mainly by drug classification (TCMs [including natural drugs], chemical drugs and biological products), registration classification (including the original registration classification information), indications, clinical trial phases, trial progress, trials in special populations and trial initiation efficiency. The classification of indications is consistent with the Center for Drug Evaluation's annual review report.

4. The pediatric population is defined as subjects aged < 18, and the geriatric population is defined as subjects aged ≥ 65.

5. For rare diseases, refer to the Catalog of First Batch of Rare Diseases jointly formulated and released by five departments including the National Health Commission on May 11, 2018.



Center for Drug Evaluation,
National Medical Products Administration