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Current Status of Antidepressant Drug Research and Development in China: A Feature Analysis Based on Drug Clinical Trial Registration and Information Disclosure Platform

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Abstract: *Objective*: To systematically review the clinical trial data of registered antidepressant drugs in China, conducted an in-depth analysis of their current status and development trends, and provided reference for the research and development of antidepressants. *Methods*: Clinical trials of registered antidepressant drugs registered from April 16,2013, to December 31,2025, were searched. The development status of antidepressant drug clinical trials in China was analyzed from various aspects, including drug types, indications, trial classification, phase, and design types. *Results*: A total of 675 trials were included, comprising 667 domestic multicenter trials and 8 international multicenter trials. Among them, chemical drugs accounted for 96.0%, while biological products were absent. There were 500 bioequivalence studies (74.1%), with Phase II and III trials employing parallel group, randomized, and double-blind designs. 501 (74.2%) clinical trials provided trial injury insurance for participants, and research resources were concentrated in leading psychiatric specialty hospitals. *Conclusion*: Although the overall development of antidepressant drug clinical trials in China has shown a steady trend, the number of international multicenter trials remains significantly low, while bioequivalence studies and early exploratory trials are more prevalent. Future efforts should focus on strengthening international cooperation and exchange, as well as innovative drug development, to accelerate the fulfillment of clinical needs for patients with depression in China.

Keywords: Depression; Drug clinical trial; Registration and information disclosure platform; Feature analysis

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1. Introduction

Major Depressive Disorder (MDD) is a prevalent psychiatric and neurological condition that imposes significant personal and socioeconomic burdens, affecting hundreds of millions of people worldwide [1].

China faces a challenge in preventing and treating depression across the entire lifespan. Survey data indicates that the detection rate of depression risk among adults in China is 10.6%, affecting approximately 90 million individuals. Influenced by various life and social factors, the annual increase in the rate of depression-related medical consultations among young people aged 18 to 35 is 18% [2]. Particularly noteworthy is that adolescence is emerging as a high-risk group for depression. Studies show a significant upward trend in the detection rate of depressive symptoms among children and adolescents in China, with this issue becoming increasingly prominent due to the interplay of multiple factors, including the psychological characteristics of adolescence, academic pressure, and the digital social environment [3]. Major public events such as the COVID-19 pandemic have further exacerbated mental health risks across the population, highlighting the urgency of addressing this major public health challenge [4].

However, current clinical treatment options remain inadequate. Traditional drugs based primarily on the "monoamine hypothesis", such as selective serotonin reuptake inhibitors (SSRIs), generally suffer from limitations including delayed onset of action, insufficient treatment efficacy, frequent residual symptoms, and prominent adverse effects. For adolescent patients whose brains are still developing, concerns about the safety and applicability of existing drugs are even more pronounced. This results in a large number of patients experiencing poor treatment response and high relapse rates, with clinical needs across different age groups far from being met.

Therefore, the development of innovative drugs with new targets, rapid onset of action, and improved safety profiles has become a strategic imperative for enhancing national health. In line with this trend, the National Medical Products Administration (NMPA) has issued the "Technical Guidelines for Clinical Trials of Antidepressant Drugs" to encourage the standardized development of innovative antidepressants [5].

This study aims to conduct a cross-sectional analysis of relevant clinical trials based on official data from the "Drug Clinical Trial Registration and Information Disclosure Platform" of the Center for Drug Evaluation (CDE) under the NMPA. By comprehensively reviewing the current status of research and development of registered innovative antidepressants, this study seeks to deeply analyze the bottlenecks they face, with particular attention to the specific needs of drug development for adolescents, ultimately providing effective references for the advancement of clinical trials for innovative antidepressants in China.

2. Materials and methods

2.1. General information

The data for this study were sourced from the Drug Clinical Trial Registration and Information Platform of the National Medical Products Administration (http://www.chinadrugtrials.org.cn/clinicaltrials.searchlist.dhtml). This platform serves as China's official and authoritative clinical trial registry, encompassing comprehensive information and research status of all drug clinical trials conducted within China.

2.2. Research methods and content

2.2.1. Data retrieval

Using "depression" as the primary search term, all registered drug clinical trials with initial announcement dates

ranging from April 16, 2013, to December 31, 2025, were retrieved from the Drug Clinical Trial Registration and Information Platform of the National Medical Products Administration.

2.2.2. Information collection

Key information was extracted, including trial status, lay/professional titles, applicants, announcement dates, drug types, indications, trial classifications, phases, design types, trial scopes, principal research institutions, reasons for suspension, etc.

2.2.3. Data processing

Data entry and organization were performed using Excel software, with two researchers independently extracting and cross-verifying the data to ensure accuracy. The registration date for all trials was based on the initial announcement date on the platform.

2.3. Statistical methods

Categorical statistics and data integration were performed using Excel as needed.

3. Results

3.1. Overall clinical trial status

3.1.1. General trends

A total of 675 registered drug clinical trials for depression were retrieved, including 667 domestic trials and 8 international multicenter trials. Data analysis revealed that drug development activities for depression have remained consistently high. Despite annual fluctuations, the average number of registered trials per year has remained above 70 since 2020, with registration numbers in 2024 and 2025 remaining at a high level, as shown in **Figure 1**. This trend indicates that the field of depression, as a core area of psychiatric drug development, continues to receive significant attention from both industry and academia.

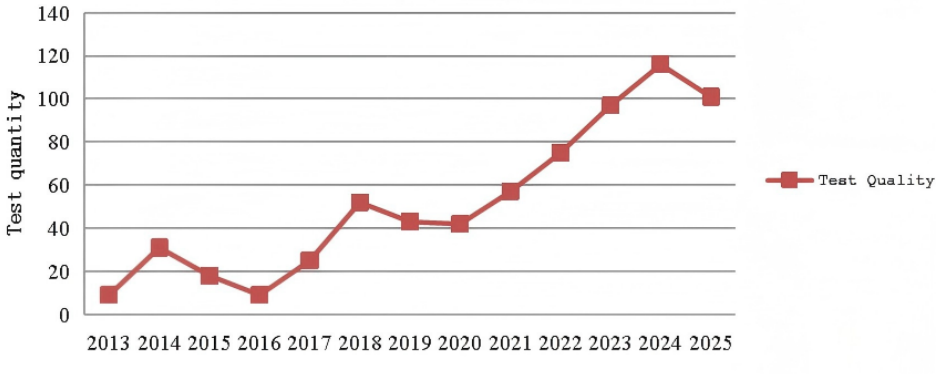

Figure 1. Annual distribution of drug clinical trials.

3.1.2. Trial status

Statistical data indicate that 500 projects have been completed, accounting for a high proportion of 74.1%. Meanwhile, 152 projects remain "in progress". Notably, the combined total of projects that have been

voluntarily suspended and voluntarily terminated is only 23, representing 3.4% of the total, which aligns with the objective laws of clinical research.

3.1.3. Drug types

According to the statistics, the distribution of drug types exhibits a highly uneven pattern. Chemical drugs (648 items) are the absolute research focus, which may be closely related to China's current pharmaceutical R&D industry landscape and policy orientation. Traditional Chinese medicine/natural drugs (27 items) maintain a certain level of vitality as a specialized field. The absence of biological product projects may reveal a gap and development potential in this specific area within the statistical period or scope.

3.1.4. Trial phases

Among the 675 registered drug clinical trials, bioequivalence drug clinical trials dominate (500 items, accounting for 74.1%), with 498 involving chemical drugs and only 2 involving traditional Chinese medicine/ natural drugs. Following this, the number of registered Phase I drug clinical trials is 97, accounting for 14.4%. A total of 75 drug clinical trials have entered Phase II and Phase III, representing 11.1% of the total. See **Table 1**.

Table 1. Distribution of trial phases for depression drug clinical trial projects from April 2013 to December 2025 (Items)

Drug type	Phase I	Phase II	Phase III	Phase IV	Other: Bioequivalence
Chemical drugs	93	30	25	2	498
Traditional Chinese medicine / Natural drugs	4	12	8	1	2
Total	**97**	**42**	**33**	**3**	**500**

3.1.5. Trial design

In bioequivalence drug clinical trials, 494 trials employed a crossover design, accounting for 98.8%; 499 trials were randomized, representing 99.8%; and 492 trials were open-label, making up 98.4%. Phase I projects primarily adopted a parallel-group, randomized, open-label trial design. Both Phase II and Phase III projects utilized a parallel-group, randomized, double-blind trial design. Phase IV projects mainly employed a single-arm, non-randomized, open-label trial design. See **Table 2**.

Table 2. Design of registered depression drug clinical trials in China from 2013 to 2025

Phase	Design type			Randomization		Blinding		
	Single-arm trial	Crossover design	Parallel group	Randomized	Non-randomized	Single-blind	Double-blind	Open-label
Phase I	11	34	52	81	16	2	45	49
Phase II	0	0	42	42	0	0	39	3
Phase III	1	0	32	32	1	0	32	1
Phase IV	2	0	1	1	2	0	1	2
Other: Bioequivalence	0	494	6	499	1	1	7	492

3.1.6. Safety protection measures for participants

From 2013 to 2025, the majority of registered drug clinical trials for depression did not establish a Data

Monitoring Committee (DMC). For 501 trials (74.2%), trial-related injury insurance was purchased for participants, while 174 trials (25.8%) did not purchase such insurance. The number of clinical trials that purchased trial-related injury insurance for participants significantly exceeded those that did not. See **Table 3**.

Table 3. Protection of participants in registered drug clinical trials for depression in China

Stage	With DMC	Without DMC	Purchased insurance	Did not purchase insurance
Stage I	4 (4.1%)	93 (95.6%)	71 (73.2%)	26 (26.8%)
Stage II	9 (21.4%)	33 (78.6%)	36 (85.7%)	6 (14.3%)
Stage III	6 (18.2%)	27 (81.8%)	27 (81.8%)	6 (18.2%)
Stage IV	0 (0%)	3 (100%)	2 (66.7%)	1 (33.3%)
Other: Bioequivalence	2 (0.4%)	498 (99.6%)	365 (73%)	135 (27%)

3.2. Distribution of sponsors

The top 10 participating institutions in terms of the number of clinical trials for depression drugs are presented.

The data reveal that domestic pharmaceutical companies hold an absolute dominant position, with significant differences in the R&D characteristics of leading institutions: Jiangsu Nhwa leads with 26 trials, establishing itself as a frontrunner in psychotropic drugs covering the entire development cycle; Zhejiang Huahai, Shandong Jingwei, and others focus on generic/specialty drugs, reflecting the industry's characteristic of "parallel development of generics and innovative drugs"; the industry-academia-research collaboration between the Academy of Military Medical Sciences and Shiyao Group, as well as Chengdu Kanghong's strategic positioning in biologics, underscore the diverse pathways of innovative R&D.

Meanwhile, the primary participation years of these institutions are concentrated between 2017 and 2025, aligning with the rapid growth trend in depression drug R&D in recent years and highlighting the core competitiveness of domestic enterprises in this field. See **Table 4**.

Table 4. Distribution of sponsors in registered drug clinical trials for depression in China

Rank	Sponsor name	Number of trials	Main participation years	Core features
1	Jiangsu Nhwa Pharmaceutical Co., Ltd.	26	2018–2025	Involved in Phase I-IV projects; generic drugs + innovative drugs
2	Zhejiang Huahai Pharmaceutical Co., Ltd.	18	2019–2024	Primarily bioequivalence studies
3	Shandong Jingwei Pharmaceutical Co., Ltd.	14	2020–2025	Primarily bioequivalence studies
4	Institute of Pharmacology and Toxicology, Academy of Military Medical Sciences, PLA / CSPC Pharmaceutical Group	11	2017–2023	Industry-academia-research collaboration
5	Jiangsu Hansoh Pharmaceutical Group Co., Ltd. / Shanghai Hansoh Biomedical	10	2019–2024	Innovative drug company; primarily Phase III trials
6	Hunan Dongting Pharmaceutical Co., Ltd.	9	2021–2025	Primarily bioequivalence studies
7	PKU HealthCare Corp., Ltd.	9	2020–2024	Primarily bioequivalence studies
8	Chengdu Kanghong Pharmaceutical Group Co., Ltd.	9	2018–2023	Dual focus: biological products + chemical drugs
9	Shandong Luye Pharmaceutical Co., Ltd.	8	2022–2025	Phase I-III projects; primarily Phase I projects
10	Hebei Longhai Pharmaceutical Co., Ltd.	8	2021–2024	Primarily bioequivalence studies

3.3. Distribution of principal research institutions

From 2013 to 2025, among the registered drug clinical trials for depression, 235 principal research institutions undertook a total of 675 projects. The results show that Beijing Anding Hospital affiliated with Capital Medical University led with 58 trials (accounting for 8.6%), which was 2.2 times that of the second-ranked Shanghai Mental Health Center (26 trials). The top five institutions collectively undertook 131 trials (19.4%). See **Figure 2**.

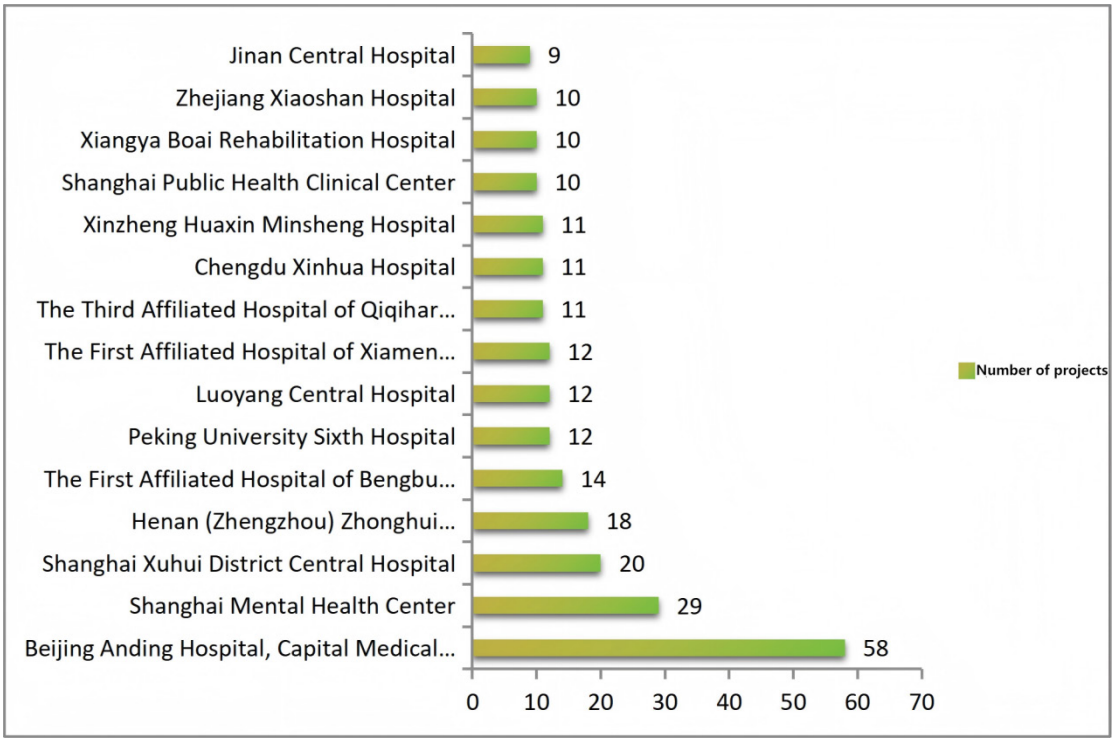

Figure 2. Distribution of principal research institutions in registered drug clinical trials for depression in China.

4. Discussion

This study included 675 drug clinical trials for depression registered between 2013 and 2025. The annual number of trial registrations has remained stable above 70 since 2020, with sustained high levels in 2024–2025, and a trial completion rate as high as 74.1%. Only 3.4% of projects were voluntarily suspended or terminated, reflecting not only the urgent clinical demand but also the stability and continuity of China's antidepressant research field. This trend is directly related to the substantial disease burden of depression in China and corresponds to the policy orientation of the National Medical Products Administration in recent years, which has successively introduced measures to encourage drug innovation and optimize the review and approval process [6,7]. Currently, chemical drugs remain the mainstream in depression drug R&D in China, with a notable absence of biological products. This may be due to the relative maturity of chemical drugs in R&D, production, and application, as well as their proven efficacy and stability. Although biological products account for a relatively low proportion in antidepressant clinical trials, their potential in depression treatment cannot be overlooked. This phenomenon may indicate that biological products are in the early stages of exploration and development for depression treatment, with the potential to offer new therapeutic breakthroughs in the future.

Data on the R&D stages show that bioequivalence trials account for a high proportion (74.1%),

significantly exceeding the proportions of early-stage innovative drug exploration (Phase I, 14.4%) and confirmatory research (Phase II/III, 11.1%). This reflects that the current domestic antidepressant drug R&D is primarily driven by the market launch of generic drugs and the improvement of dosage forms of existing drugs, highlighting the urgent need to strengthen R&D capabilities for innovative drugs targeting new targets. The clinical R&D pipeline for innovative drugs is relatively weak, with gaps compared to international breakthroughs in areas such as rapidly acting antidepressants (e.g., NMDA receptor antagonists) [8,9].

In terms of trial design, trials at each stage generally adhere to corresponding scientific design principles, with Phase II/III trials commonly adopting the "gold standard" design of randomized, double-blind, parallel-controlled trials. The Data Monitoring Committee (DMC) is crucial for independently assessing safety and efficacy data, trial progress, and protecting the rights and interests of participants during trials [10]. Among the trial phases, the design rate of DMCs is relatively high in Phase II and III trials. The 2006 DMC guidelines state that early-stage exploratory Phase I trials typically do not establish a DMC, whereas Phase III trials should more frequently incorporate a DMC [11]. As the number of participants increases from Phase I to Phase III, the complexity and risks of trials also rise. Phase I trials primarily focus on preliminary safety and efficacy assessments in small sample populations, while Phase III trials further evaluate drug efficacy and safety over longer periods, with larger sample sizes and higher failure risks. Therefore, establishing a DMC is more conducive to promptly identifying potential risks and better ensuring participant safety and trial progress.

Clinical trials are inherently accompanied by risks, and despite implementing a series of risk control measures, unexpected adverse events or other unforeseen circumstances may still occur. In the event of serious adverse events, sponsors and clinical research institutions may face substantial financial compensation [12]. Therefore, it is particularly important for sponsors to purchase trial injury insurance for participants. In China's depression drug clinical trials, 74.2% of trials involve the purchase of insurance, indicating that most sponsors comply with national regulations and purchase clinical trial injury insurance for participants. This not only effectively protects the rights and interests of participants but also transfers potential risks faced by sponsors during clinical trials. However, if the purchased insurance does not cover the compensation required for trial-related damages, sponsors remain fully responsible for the damages suffered by participants due to trial participation. Purchasing clinical trial insurance does not exempt sponsors from their legal obligations in the event of damages or disputes during trials; sponsors must continue to ensure timely and effective fulfillment of their protective and compensatory responsibilities towards participants [13].

The 675-antidepressant drug clinical trials included in this study were primarily applied for by domestic pharmaceutical companies. Among the top ten sponsors, companies such as Jiangsu Nhwa, Zhejiang Huahai, and Shandong Jingwei primarily focus on bioequivalence trials, reflecting that the current domestic antidepressant drug R&D is still primarily driven by the market launch of generic drugs and the improvement of dosage forms of existing drugs. This phenomenon is closely related to China's long-standing industrial foundation and policy environment centered on chemical generics [14]. However, it is noteworthy that some companies have shown a positive trend towards transitioning to innovative R&D. For example, Jiangsu Hansoh Pharmaceutical and Chengdu Kanghong Pharmaceutical not only focus on innovative chemical drugs but also explore new drug types such as biological products. The layout of "combining generics with innovation and exploring multiple avenues" reflects that domestic companies are gradually transitioning from "generic-dominated" to "balanced generics and innovation". However, overall, the clinical pipeline for original innovative drugs (especially biological products) with entirely new mechanisms of action remains weak, with

significant gaps compared to international frontiers [8,9].

Analysis of the distribution of principal research institutions shows that clinical trial resources are highly concentrated in top domestic psychiatric specialty hospitals. The top five institutions, including Beijing Anding Hospital affiliated with Capital Medical University and Shanghai Mental Health Center, undertake nearly 20% of trial projects. Sponsors typically prefer to select medical institutions with significant influence in the disease field as research units. These institutions not only possess solid professional expertise but also have researchers with high academic backgrounds and professional authority. Additionally, these institutions usually have abundant patient resources, facilitating the recruitment of eligible participants in a shorter time, thereby improving the efficiency and quality of clinical trial progress [15].

5. Conclusion

In summary, the number of clinical trials for antidepressant drugs in China has steadily increased, and the system operates generally stably. However, structural characteristics and challenges persist, including a low proportion of innovative drug R&D, a near-absence in the biological products field, concentrated distribution of R&D resources, a lack of international cooperation, and insufficient attention to key populations such as adolescents. There is significant room for exploration in this R&D field. It is hoped that pharmaceutical companies and R&D institutions will further enhance their sustained attention to depression drug research, increase R&D investment, promote innovative drug R&D, and diversify existing drug types, thereby providing more safe and effective treatment options for patients with depression.

Research Limitations: This study is a cross-sectional descriptive analysis based on a registration platform. While it can reflect the macroscopic characteristics and trends of registered trials, it cannot obtain specific efficacy and safety result data from the trials. Additionally, the completeness and timeliness of information updates on the platform may impact the analysis.

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Disclosure statement

The authors declare no conflict of interest.

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