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Analysis of Ophthalmology Drug Clinical Trial Institutions in China: Challenges and Opportunities Under the Registration System

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Abstract: *Objective:* To analyze the status of ophthalmology drug clinical trial institutions in China following the implementation of the registration system and provide a reference for their development. *Methods:* An analysis was conducted using data from the Drug Clinical Trial Institution Registration Management Information Platform and the Drug Clinical Trial Registration and Information Publicity Platform of the National Medical Products Administration. The search period was up to April 19, 2024. *Results:* As of April 19, 2024, 314 ophthalmology-specific institutions were registered nationwide, comprising 274 comprehensive medical institutions and 40 specialized ophthalmology institutions, representing a 245% increase compared to the qualification certification phase. There were 965 major researchers in ophthalmology, accounting for 6.3% of the total number of researchers across all registered ophthalmology institutions. These institutions were predominantly located in economically developed areas such as Guangdong, Zhejiang, and Jiangsu Provinces, with the top five provinces and cities comprising 39.8% of the total registered institutions. Beijing had the highest number of major researchers (126), with their distribution positively correlated with the geographic spread of registered institutions. Furthermore, as of April 19, 2024, there were 216 clinical drugs related to eye diseases, with the top three provinces conducting 77.8% of national clinical trial projects. The number of institutions was directly proportional to the volume of clinical trials conducted. *Conclusion:* The implementation of the registration system has facilitated the release of ophthalmic medical resources. However, regional disparities remain in the number of ophthalmology-specific institutions, the availability of major investigators, and the distribution of clinical trial projects.

Keywords: Ophthalmology; Drug clinical trial institutions; Research personnel; Registration system

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1. Introduction

The prevalence of visual impairment in China continues to rise due to lifestyle changes, altered eye use habits, and an aging population [1,2]. Currently, imported drugs dominate the Chinese ophthalmology market, while domestic drug development remains in its infancy, with few new ophthalmic drugs possessing independent intellectual property rights [3,4]. The research and development of new drugs offer hope to patients and represent the primary pathway for addressing this issue.

In recent years, the Chinese government has implemented policies aimed at reforming the drug review and approval system [5,6]. These reforms have transitioned the qualification certification process for drug clinical trial institutions from an accreditation system to a registration system. This change has effectively alleviated the shortage of drug clinical trial institutions, optimized the utilization of clinical trial resources, and provided robust support for drug research, development, and innovation in China [7,8].

While the filing system presents development opportunities, it also poses challenges for ophthalmology specialties. Although some discussions have emerged regarding the filing status of clinical professional institutions, no comprehensive statistical analysis has yet been conducted for ophthalmology drug clinical trial institutions in China. Based on data from the Drug Clinical Trial Institution Registration Management Information Platform, this study analyzes the filing status of ophthalmology specialty institutions at the current stage in China. The analysis aims to evaluate the current status and identify challenges associated with the filing system for ophthalmology drug clinical trial institutions, offering a reference for their improved development.

2. Materials and methods

2.1. Data sources

Data were obtained from the Drug Clinical Trial Institution Filing Management Information Platform (https://beian.cfdi.org.cn/CTMDS/apps/pub/drugPublic.jsp), including information such as institution filing numbers, institution names, levels, addresses, the number of professional groups filed at each institution, the number of ophthalmology professional group filings, and the number of ophthalmology principal investigators (PIs). Additional data on the number of projects undertaken by nationally filed ophthalmology specialty drug clinical trial institutions were collected from the website of the Center for Drug Evaluation (CDE) of the National Medical Products Administration (http://www.cde.org.cn/). Statistical analyses were performed on the filing status of ophthalmology professional groups, their geographical distribution, and their involvement in drug clinical trial projects. The retrieval period spanned from the establishment of the filing platform to April 19, 2024.

2.2. Statistical analysis

Microsoft Excel was used to collect and organize the data for statistical processing. SPSS version 23.0 software was employed to perform statistical analyses. The correlations between data points were evaluated using Pearson's correlation coefficient. A P-value of < 0.05 was considered statistically significant.

3. Results

3.1. Filing status of ophthalmology specialty institutions

Between 2003 and December 1, 2019, a total of 886 drug clinical trial medical institutions obtained qualification accreditation [9]. Of these, 91 were ophthalmology specialty drug clinical trial institutions, including six traditional Chinese medicine institutions. Among the 91 institutions, 81 were comprehensive medical institutions, and 10 were ophthalmology-specialist medical institutions. From December 2, 2019, to April 19, 2024, the total number of nationally filed institutions increased to 1,570, representing a 77.2% growth from the time of qualification accreditation [9]. This reflects a 1.8-fold increase compared to the earlier period.

A total of 314 medical institutions with ophthalmology professional groups (including 41 traditional Chinese medicine ophthalmology medical institutions) were filed, accounting for 20% (314/1570). This represents a 245% growth compared to the prior period. Among these, 274 were comprehensive medical institutions, and 40 were ophthalmology-specialist medical institutions (see **Table 1**). The total number of professional groups filed by medical institutions with ophthalmology professional groups was 6,925, and the total number of ophthalmology specialty PIs was 965, accounting for 6.3%.

Of the 314 ophthalmology specialty institutions, comprehensive medical institutions accounted for 666 ophthalmology specialty PIs, while ophthalmology-specialist medical institutions accounted for 299. Detailed data are presented in **Table 2**.

Table 1. Status of ophthalmology specialty institutions

Personnel type	Number of people	Percentage (%)
Ophthalmology specialty PIs	965	-
All professional PIs in filed institutions	15,353	6.3
Ophthalmology specialty PIs in comprehensive institutions	666	69.1
PIs in ophthalmology-specialist institutions	299	43.0

Table 2. Filing status of ophthalmology specialty institutions

Institution type	Total filing institutions	Total filing ophthalmology specialty institutions	Percentage (%)
Medical institutions	1,570	314	20.0
Comprehensive medical institutions	-	274	87.3
Ophthalmology specialist institutions	-	40	12.7

3.2. Regional distribution

3.2.1. Distribution of ophthalmology-specialized institutions

Between 2003 and December 1, 2019, 91 ophthalmology-specialized institutions were distributed across 23 provinces. The top three provinces were Guangdong (11 institutions), Beijing (9 institutions), and Shanghai (8 institutions) (see **Figure 1**). From December 2, 2019, to April 19, 2024, the number of filed ophthalmology-specialized institutions increased to 314, spanning 30 provinces and municipalities. The top five provinces were Guangdong (33 institutions), Zhejiang (28), Jiangsu (24), Beijing (21), and Shanghai (19), collectively accounting for 39.8% of all filed institutions.

Ophthalmology-specialized medical institutions were located in 19 provinces. Guangdong and Shandong had the highest numbers, with five institutions each. Liaoning followed with four, while Hubei and Shanghai had three

each. Distribution data for traditional Chinese medicine ophthalmology institutions showed Beijing leading with five, followed by Guangdong (4) and Shandong (3) (see **Figure 2**). Regions with more developed economies had a higher concentration of ophthalmology-specialized group institutions, whether in comprehensive or specialist medical institutions.

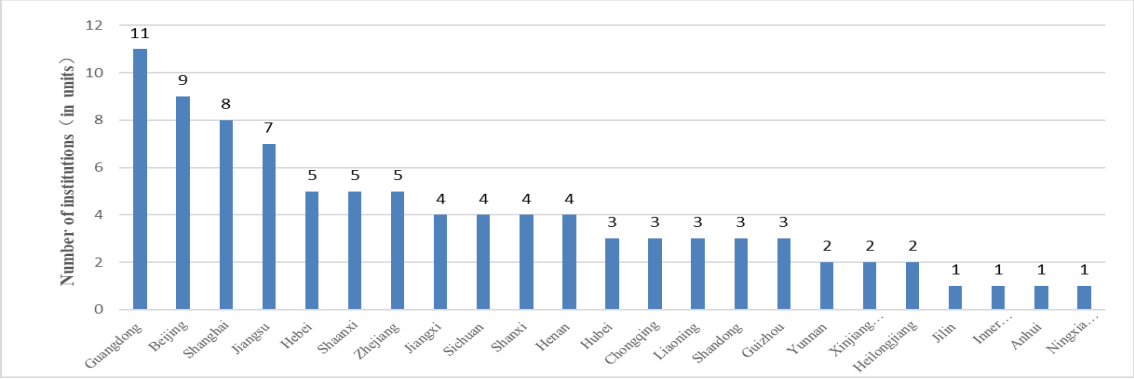

Figure 1. Regional distribution of qualified ophthalmology drug clinical trial institutions

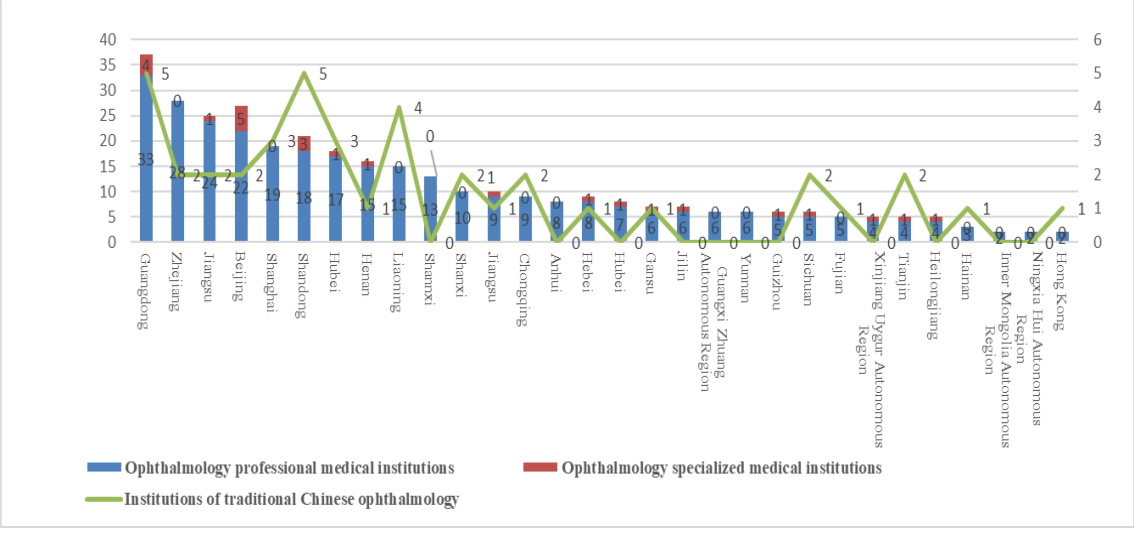

Figure 2. Regional distribution of ophthalmology specialty drug clinical trial institutions

3.2.2. Distribution of PIs of filed ophthalmology specialized groups

A total of 965 ophthalmology-specialized group PIs were filed. Beijing had the highest number (126), followed by Zhejiang (100), Guangdong (86), Shanghai (79), and Jiangsu (63), which collectively accounted for 47.0% of the total. Among the 299 PIs in ophthalmology-specialist institutions, Guangdong led with 44 PIs, followed by Zhejiang (40), Shandong (38), Shanxi (30), and Tianjin (29), accounting for 60.5% of the total (see **Figure 3**).

A correlation analysis revealed a positive relationship between the number of ophthalmology-specialized PIs and the number of filed ophthalmology-specialized institutions ($r = 0.890$, $P < 0.001$).

3.3. Distribution of medical institutions where PIs are located

Statistics showed that the institutions with the most filed PIs were Zhongshan Ophthalmic Center of Sun Yat-sen University and Shanxi Eye Hospital, each with 28 PIs. These were followed by Beijing Tongren Hospital

(27), the Eye Hospital of Wenzhou Medical University (26), and Peking University Third Hospital (22). The top 15 institutions with 10 or more PIs accounted for 29.4% (284/965) of the total, while the top eight institutions accounted for 74.6% (223/299) of the ophthalmology-specialized PIs. PIs were concentrated in a small number of institutions, highlighting disparities in distribution (see **Figure 4**).

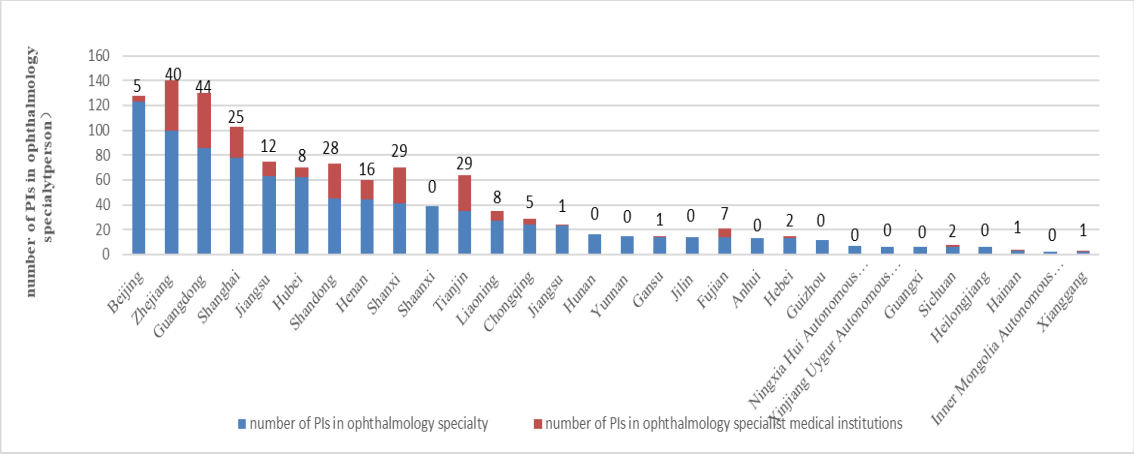

Figure 3. Regional distribution of ophthalmology-specialized PIs

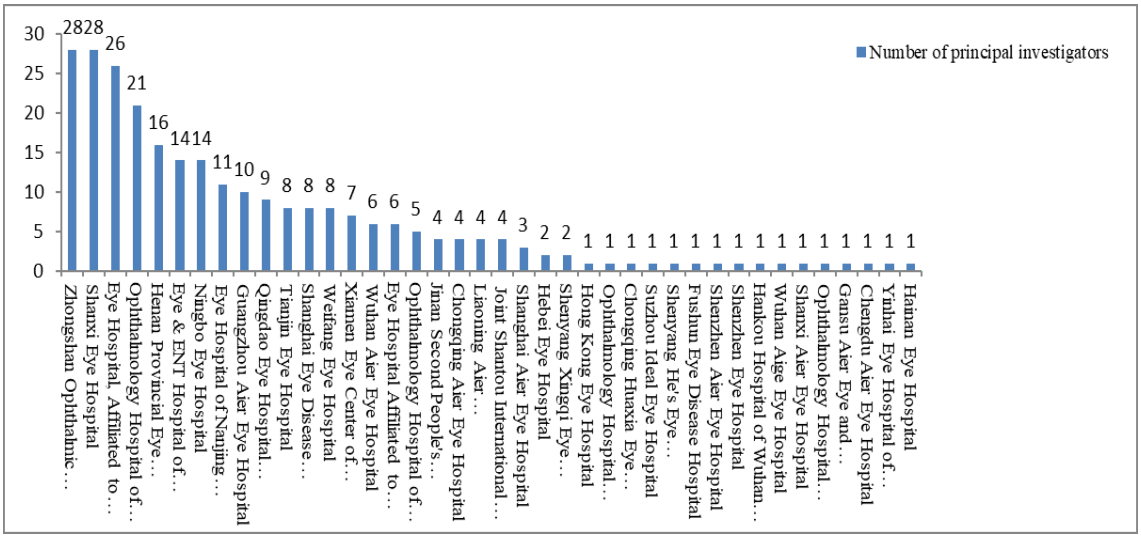

Figure 4. Distribution of medical institutions with ophthalmology-specialized PIs

3.4. Statistics by region and institution

3.4.1. Regional statistics

A query of the drug clinical trial registration and information publicity platform of the Center for Drug Evaluation (CDE) of the National Medical Products Administration reveals that, as of April 19, 2024, there are 38 ophthalmology specialties with filings for drug clinical trials, distributed across 15 provinces and cities, undertaking a total of 216 clinical trials. Based on statistics of leading institutions by region, Beijing leads with 8 institutions, followed by Zhejiang Province, Guangdong Province, and Shanghai City, each with 4 institutions, and Henan and Hubei Provinces, each with 3 institutions. Together, these regions account for 168 drug clinical trials or 77.8% of the total (168/216).

Statistics on the volume of clinical trials by region indicate that Beijing has the highest number, with 82 trials,

followed by Zhejiang Province with 37 and Shandong Province with 21. The cumulative total for the top three regions is 121 trials, representing 56% of the total (121/216). See **Figure 5**.

A correlation analysis between the number of leading institutions and the volume of clinical trials they undertake indicates a positive correlation ($r = 0.904$, $P < 0.001$). By clinical trial phase, phase I/BE, phase II, and phase III trials are concentrated in first-tier developed cities such as Beijing, Zhejiang Province, Shandong Province, Shanghai City, Guangdong Province, and Tianjin City. These cities collectively account for 156 trials, or 72.2% of the total (156/216). See **Figure 6**. This trend suggests that first-tier developed cities are leaders in clinical trial capacity, largely due to their abundant medical resources, strong research capabilities, and sponsor preferences.

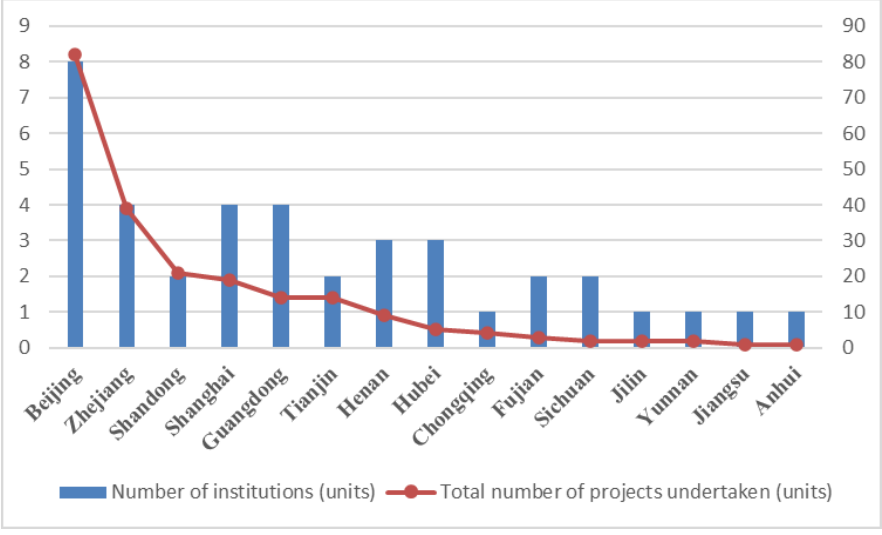

Figure 5. The group leader of ophthalmology professional institutions and the geographical distribution of clinical trials

Figure 6. Geographical distribution of each phase of clinical trials

3.4.2. Institution statistics

Nationwide, 38 ophthalmology medical institutions serve as leading institutions for drug clinical trials, of which 12 are ophthalmology specialist medical institutions, accounting for 31.6% (12/38). These specialist institutions account for 105 clinical trials or 48.6% of the total (105/216). Among the top five leading medical institutions, all except Beijing Tongren Hospital, affiliated with Capital Medical University, are ophthalmology specialist medical institutions.

By clinical trial phase, there are 47 phase I/BE trials, including 24 conducted by comprehensive ophthalmology-specialized medical institutions and 23 by ophthalmology specialist medical institutions. Phase II trials number 67, with 33 conducted by comprehensive institutions and 34 by specialist institutions. Phase III trials number 83, with 47 undertaken by comprehensive institutions and 36 by specialist institutions. A total of 194

phase I/BE, phase II, and phase III trials account for 16.7% (36/216) of the total.

Ophthalmology specialist medical institutions are capable of conducting drug clinical trials across all phases, but the number of trials they undertake remains limited. See **Table 3** for detailed statistics.

Table 3. Development of drug clinical trial projects in ophthalmology-specialized medical institutions

Institution name	Total number of drug clinical trial projects	Phase I/BE	Phase II	Phase III	Phase IV
Eye Hospital of Wenzhou Medical University	32	10	4	14	2
Eye Hospital of Shandong First Medical University	20	7	6	6	1
Eye & ENT Hospital of Fudan University	15	0	3	9	1
Tianjin Medical University Eye Hospital	13	2	8	2	1
Zhongshan Ophthalmic Center, Sun Yat-sen University	11	0	4	4	1
Henan Provincial Eye Hospital	7	4	3	0	0
Xiamen Eye Center of Xiamen University	2	0	2	0	0
Joint Shantou International Eye Center of Shantou University and the Chinese University of Hong Kong	1	0	1	0	0
Tianjin Eye Hospital	1	0	1	0	0
Shandong Provincial Key Laboratory of Ophthalmology	1	0	0	1	0
Yinhai Eye Hospital affiliated to Chengdu University of Traditional Chinese Medicine	1	0	1	0	0
Eye Hospital Nanjing Medical University	1	0	1	0	0

4. Discussion

Given the significant number of patients with moderate to severe visual impairment and blindness in China, public attention to eye health and the demand for effective diagnosis and treatment continue to grow [1]. Consequently, there is a need for innovative and highly effective ophthalmic drugs. However, most ophthalmic drug clinical trials in China are concentrated in first-tier developed cities, resulting in an uneven development of new drug research and development across regions and medical institutions. The implementation of the filing system seeks to address this imbalance by optimizing clinical resources and promoting the expansion of ophthalmic drug trials to more regions, thereby benefiting a broader range of patients.

To promote balanced development in ophthalmic drug research and development, the filing system for drug clinical trials in China encourages broader regional participation. This system expands the geographical reach of clinical trials and increases patient access to new drug innovations. Incentive policies in various provinces have further stimulated researcher participation, leading to a notable growth in available clinical trial resources. The number of filing institutions has seen significant increases.

A 2022 study [10] reported that the number of ophthalmology specialty filing institutions and total filing PIs in China ranked 15th and 12th, respectively, nationwide. By April 19, 2024, the total number of national filing institutions had reached 1,570, reflecting a 77.2% increase compared to the qualification accreditation period [9]. Ophthalmology specialty medical institutions numbered 314, marking a growth rate of 245%. Among national filings, ophthalmology specialty PIs accounted for 6.3%. While the share of ophthalmology specialty institutions

and PI resources remains moderate, the simplified filing process and application methods under the filing system have significantly boosted the number of participating institutions, advancing ophthalmic drug research and development.

From a geographical perspective, the 91 qualified ophthalmology specialty institutions are spread across 23 provinces, with Guangdong Province, Beijing City, and Shanghai City leading in numbers. Post-filing system implementation, ophthalmology specialty institutions now span 30 provinces and municipalities, totaling 314. Guangdong Province, Zhejiang Province, Jiangsu Province, Beijing City, and Shanghai City top the list. Additionally, 40 ophthalmology specialist medical institutions, distributed across 19 provinces and municipalities, have filed, with Guangdong Province leading, followed by Liaoning and Shandong Provinces in second place and Hubei Province in third.

Traditional Chinese medicine (TCM) ophthalmology institutions have also seen notable growth [11]. Following the filing system's implementation, TCM ophthalmology institutions are distributed across 16 administrative regions, with Beijing City, Guangdong Province, and Shandong Province leading the list. These institutions increased from six before the filing system to 41, primarily concentrated in the eastern region. However, disparities in the number of institutions among provinces remain significant. Ophthalmology clinical trial resources are heavily concentrated in economically advanced eastern regions with superior medical infrastructure, while western regions, constrained by limited economic development and medical resources, lag in clinical trial activity.

The distribution of ophthalmology specialty PIs also reflects this regional disparity. Economically developed regions, including Beijing City, Zhejiang Province, Guangdong Province, and Shanghai City, account for 47.0% of all filed ophthalmology specialty PIs. As a representative of the central region, Shanxi Province ranks second, but the majority of PIs are concentrated in developed areas. Institutions in top regions like Beijing City and Zhejiang Province handle the largest volume of trials, with Beijing undertaking over twice as many as the second-ranked region. In the top three provinces, clinical trial volumes account for 56% of the total, underscoring the regional imbalance. This concentration is likely due to the advanced technology, experienced researchers, diverse patient populations, and robust infrastructure of first-tier cities, which attract more sponsors [12].

Ophthalmic drug clinical trials in China show a positive development trend, with a high completion rate, particularly in trials targeting fundus diseases [13]. Both comprehensive and ophthalmology specialist medical institutions actively conduct trials across all phases. Of the 216 total trials, 194 are in phases I/BE, II, and III, accounting for 16.7% (36/216), reflecting rapid progress in innovation, safety, and efficacy in ophthalmology drug research. These findings align with the study by Liao *et al.* [14].

In central and western China, including Sichuan, Henan, and Shaanxi Provinces, where dense populations coincide with underdeveloped economies, the need for innovative drugs is pressing. While the number of newly filed institutions in these areas has surpassed the national average [7], the volume of trials undertaken remains limited. Addressing this gap requires leveraging population advantages, expanding patient recruitment through collaboration with primary and branch hospitals, and forming regional institutional alliances. A "strong leading weak" strategy—emphasizing collaboration in medical technology, personnel training, and project recommendations—could narrow disparities in project numbers and institutional development levels [15].

In conclusion, the implementation of the filing system has created a broader platform for ophthalmic drug clinical trials. It optimizes resource allocation, fosters balanced development in ophthalmic drug research, and better meets the growing public demand for eye health solutions.

Disclosure statement

The authors declare no conflict of interest.

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