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Analysis of the Current Situation of Drug Clinical Trial Institutions in Shaanxi Province

Yurong Zhang[1], Qi Zhang[2], Li Wang[1]*, Rui Xu[1], Lili Zhao[1], Enze Li[1], Xin Wang[3]

[1]Department of Clinical Trial Institution, the First Affiliated Hospital of Xi'an Medical College, Xi'an 710077, Shaanxi Province, China
[2]Department of Drug and Vaccine Inspection, Shaanxi Medical Products Administration, Xi'an 710065, Shaanxi Province, China
[3]Department of Clinical Coordination, Xi'an Evidence-Based Medicine Co., Ltd, Xi'an 710000, Shaanxi Province, China

Corresponding author: LiWang, 394004312@qq.com

Abstract: To understand the current situation of institutional registration in Shaanxi Province after the implementation ofregistration system management in drug clinical trial institutions. Relevant information was collected on the "Announcement on the Accreditation of Drug Clinical Trial Institutions" issued by the National Medical Products Administration from 2005 to August 2022, the record management information system of drug and medical device clinical trial institutions, and the drug clinical trial registration and information publicity platform. A retrospective analysis was carried out in terms of institutional development, regional distribution, registered majors, principal investigators, and the number of drug clinical trials. After the implementation of institution registration, the number of drug clinical trial institutions in Shaanxi Province increased by 47.4%, 884 principal investigators were registered, the number of registered majors expanded from 58 qualified to 117, and the professional scope increased by 50.4%. The policy of institution registration is conducive to promoting the rational use of medical resources and the development of drug clinical trial institutions and improving the healthy development of the pharmaceutical industry in Shaanxi Province.

Keywords: Drug clinical trial; Institution registration; Registered majors; Current situation analysis; Professional group; Shaanxi Province

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1. Introduction

In recent years, China's pharmaceutical-related industries have developed rapidly, and the research and development of new drugs have attracted much attention, with clinical trials serving as an important stage for the marketing of new drugs [1]. In 2017, China successfully became a member of the International Technical Coordination Committee for the Registration of Pharmaceutical Products for Human Use (ICH), which not only opened a new chapter for the pharmaceutical industry but also led to opportunities and great challenges of international standards [2]. To encourage the development of drug clinical trials, streamline the process, and ease market demand, the state has successively issued the Opinions on Deepening the Reform of the Review

and Approval System to Encourage the Innovation of Pharmaceutical Medical Devices (hereinafter referred to as the "Opinions") [3], the Drug Administration Law, the Quality Management of Drug Clinical Trials (2020 edition) [4,5] and other relevant documents to encourage and reform measures, and many mention the record management of drug clinical trial institutions. The management mode of lenient entry and strict exit not only requires higher capability of drug clinical trial institutions and professional departments but also stricter ethical review and supervision and management of the implementation process [6]. At present, there is a great disparity in the number of institutional records in China and the regional distribution is unbalanced, mainly distributed in first-tier or economically developed cities, such as Beijing, Shanghai, and Guangdong [7]. Through the comparison of the number of institutional records and drug clinical trial projects before and after the record-keeping system in Shaanxi Province, this study analyzes the current situation of drug clinical trial institutions in Shaanxi Province and discusses the existing problems, aiming to promote the high-quality and efficient operation of drug clinical trials in Shaanxi Province.

2. General information and methods

2.1. General information

The relevant data of the "Announcement on the Accreditation of Drug Clinical Trial Institutions" issued by the State Drug Administration from February 2005 to August 2022, the record management information system of drug and medical device clinical trial institutions, and the drug clinical trial registration and information publicity platform were collected.

2.2. Methods

(1) Query was carried out on the "Announcement on the Accreditation of Drug Clinical Trial Institutions" issued by the National Medical Products Administration (NMPA) to collect and analyze the qualified medical institutions and recognized specialties in Shaanxi Province.

(2) Query was done on drug and medical device clinical trials for the record management information system (https://beian.cfdi.org.cn/CTMDS/apps/pub/drugPublic.jsp). The level of the institution for the record of Shaanxi Province, regional distribution, registered majors, and principal investigators of the record in Shaanxi Province were collected.

(3) Query was performed on the website of the Center for Drug Evaluation (CDE) of the National Medical Products Administration (http://www.cde.org.cn/) to collect and analyze the number of projects undertaken by drug clinical trial institutions in Shaanxi Province.

2.3. Statistical methods

The collected data were processed statistically using Excel.

3. Results

3.1. Review of the accreditation process of drug clinical trial institutions in Shaanxi Province

In 2004, after the release of the "Measures for the Accreditation of Drug Clinical Trial Institutions (Trial)" [8], the First Affiliated Hospital of the Fourth Military Medical University of the Chinese People's Liberation Army and the Tangdu Hospital of the Fourth Military Medical University of the Chinese People's Liberation Army were certified as drug clinical trial institutions in 2005. Until the end of 2016, Xi'an Mental Health Center (Xi'an

Tenth Hospital), Shaanxi Provincial Hospital of Traditional Chinese Medicine, Shaanxi Provincial Cancer Hospital, and 11 other hospitals have passed the qualification certification. On October 8, 2017, the "Opinions on Deepening the Reform of the Review and Approval System to Encourage Innovation of Pharmaceutical Medical Devices" was released, which promoted the development of drug clinical trial institutions. Based on **Figure 1**, the number of drug clinical trial institutions in Shaanxi Province increased steadily from 2017 to 2022. By the end of 2019, the total number of qualified drug clinical trial institutions in Shaanxi Province reached 20.

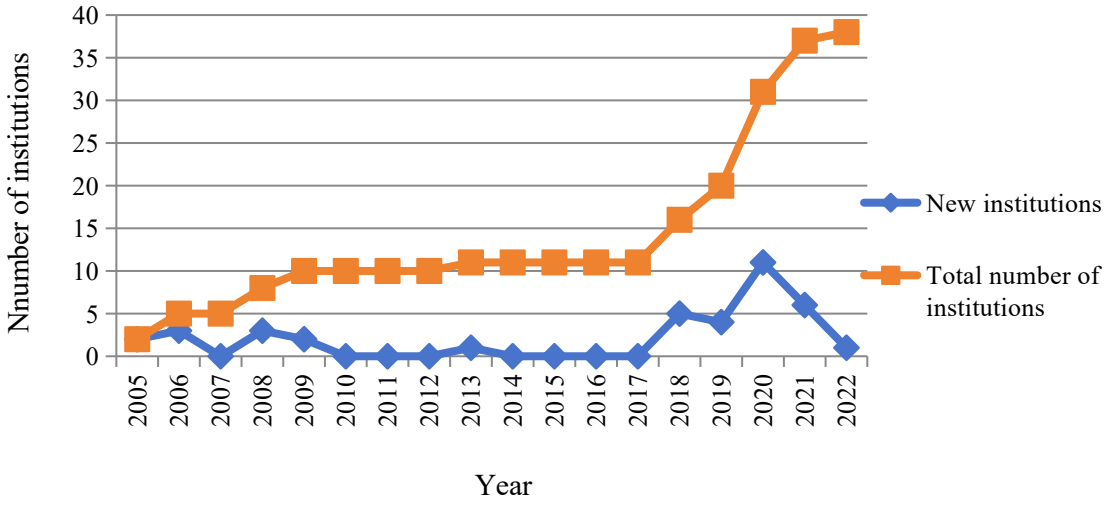

Figure 1. Number of new drug clinical trial institutions from 2005 to 2022

On November 29, 2019, the "Regulations on the Management of Drug Clinical Trial Institutions" clearly stated that "drug clinical trial institutions have changed from qualification recognition to record management." As of August 2022, the number of institutions in Shaanxi Province has jumped to 38, an increase of 47.4% compared with the number before the record-keeping system, indicating that medical institutions in our province are putting increasing emphasis on drug clinical trials. According to the National Bureau of Statistics annual data (https://data.stats.gov.cn/easyquery.htm?cn=C01), there are a total of 751 general hospitals in our province by the end of 2020, but only 38 hospitals are involved in drug clinical trials, constituting only 5.1%. This shows that our province still has significant room for development, with abundant clinical resources available.

3.2. Distribution of drug clinical trial institutions in Shaanxi Province

Among the 38 drug clinical trial institutions registered in Shaanxi Province, 18 are third-level A-level hospitals, accounting for 47.37%; 19 are third-level hospitals, accounting for 50%; and 1 is Shaanxi Provincial Center for Disease Control and Prevention, which did not specify the level of institutions. Based on the regional distribution of institutions in **Figure 2**, 28 drug clinical trial institutions in Shaanxi Province are located in Xi'an, accounting for 73.68% of the total number of institutions; the remaining 10 hospitals are located in Xianyang, Baoji, Yan'an, Ankang, and Hanzhong, and there are no drug clinical trial institutions in Weinan, Tongchuan, Yulin, Shangluo, and Yangling Demonstration Zone. Eleven of the institutions in Shaanxi Province are affiliated hospitals of colleges and universities, mainly concentrated in Xi'an, Xianyang, and Yan'an. It can be inferred that the development of drug clinical trial institutions is closely related to the distribution of educational resources, economic conditions, and health resources in various regions of our province.

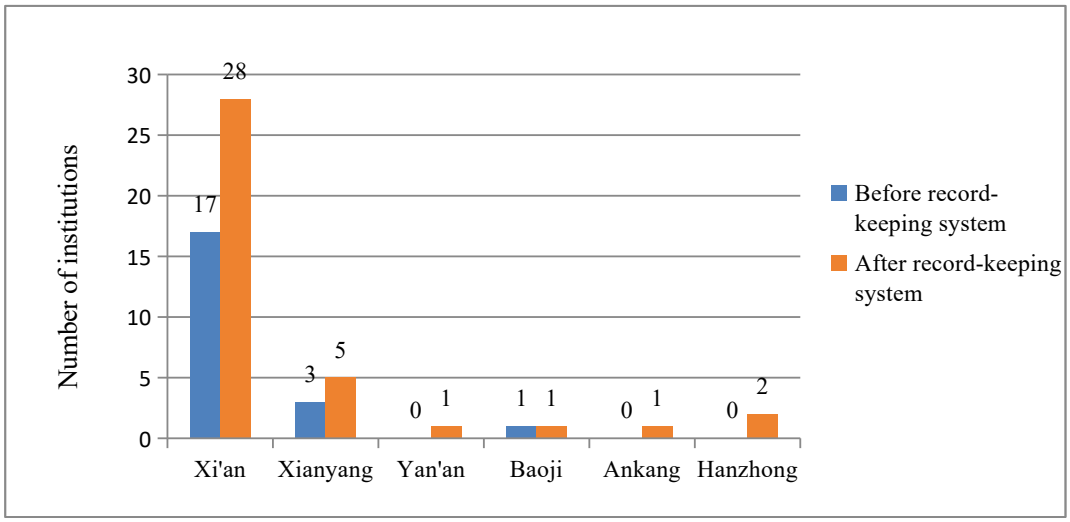

Figure 2. Distribution of drug clinical trial institutions before and after the implementation of record-keeping system in Shaanxi Province

3.3. Records of principal investigators

Principal investigator (PI) is crucial to the smooth conduct of drug clinical trials. In the Regulations on the Administration of Drug Clinical Trial Institutions, PI is required to have a senior title and participate in more than three drug clinical trials for registration purposes [9]. A total of 884 PIs were recorded in Shaanxi Province, of which 550 had senior titles, accounting for 62.2% of the total number of PIs, and 334 had associate senior titles, accounting for 37.8% of the total number of PIs. They were mainly concentrated in medical institutions with high levels of medical resources and strength, of which 122 were recorded in the First Affiliated Hospital of Xi'an Jiaotong University. In **Figure 3**, there are 15 hospitals with less than 10 PI records, 10 hospitals with 10–20 PI records, 9 hospitals with 21–50 PI records, and 4 hospitals with more than 50 PI records. Most of the top 10 medical institutions with higher number of PI records are hospitals with earlier drug clinical trials and higher medical level, and most of them are affiliated hospitals of colleges and universities.

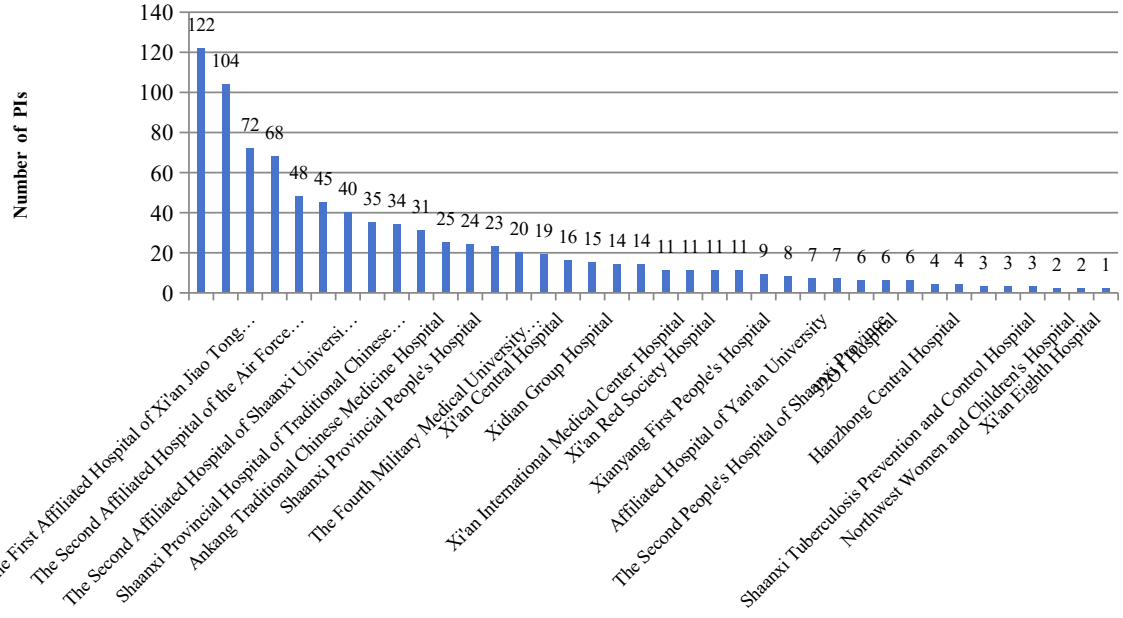

Figure 3. Number of registered PI in drug clinical trial institutions in Shaanxi Province

3.4. Records of registered majors

As presented in **Figure 4** and **Table 1**, there are 9 institutions with more than 15 majors on record, all of which are top three general hospitals. Except for Ankang Hospital of Traditional Chinese Medicine and the Second Affiliated Hospital of Shaanxi University of Chinese Medicine, the number of majors recognized by the record-keeping system is not less than 5, while the new institutions have 10–14 majors on record except Xi'an Daxing Hospital, Xidian Group Hospital, and Xi'an Central Hospital; the others have 1 to 9 registered majors. The number of majors recorded by specialized hospitals is relatively small [10]. For example, Stomatological Hospital of Xi'an Jiaotong University and Shaanxi Provincial Cancer Hospital both recorded one major, and Xi'an Children's Hospital and Xi'an Honghui Hospital both recorded three majors, with no difference before and after the record-keeping system. It indicates that there is a positive correlation between the number of registered majors and the service scope and medical level of hospitals [10].

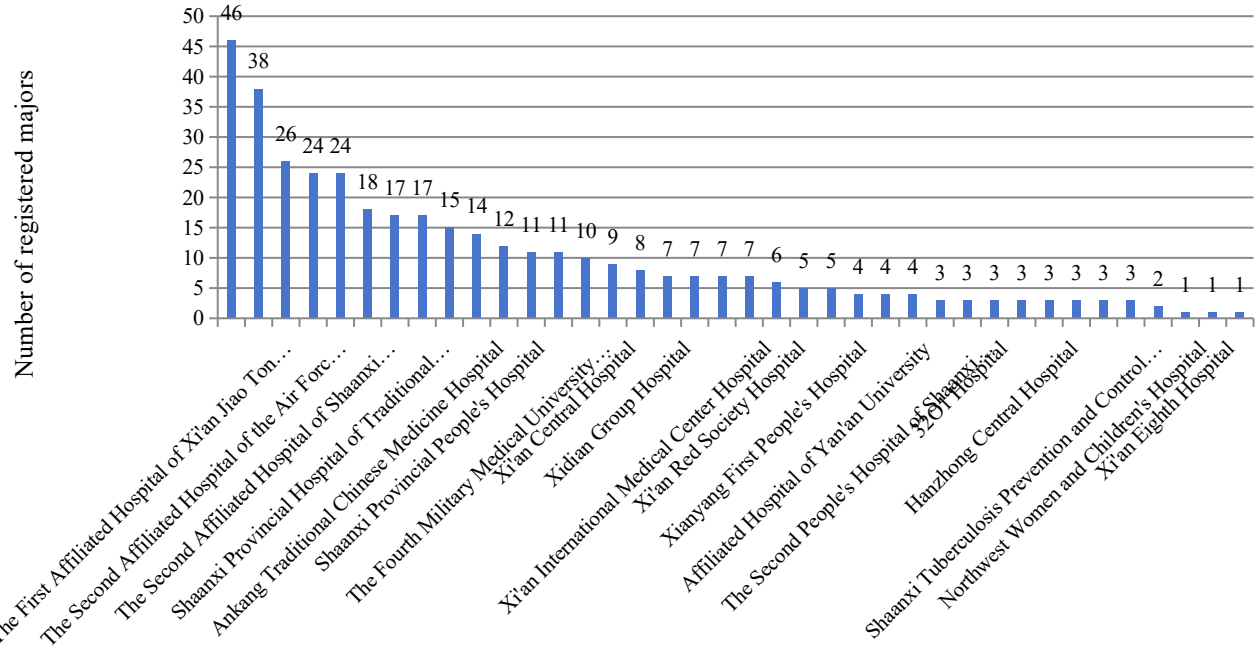

Figure 4. The number of majors registered by drug clinical trial institutions in Shaanxi Province after the record-keeping system

Table 1. The number of majors registered by drug clinical trial institutions in Shaanxi Province before the record-keeping system

Institutions	Number of registered majors
The First Affiliated Hospital of Xi'an Jiaotong University	28
The Second Affiliated Hospital of Xi'an Jiaotong University	23
The First Affiliated Hospital of the Fourth Military Medical University of the Chinese People's Liberation Army	20
Shaanxi Provincial Hospital of Traditional Chinese Medicine	12
Shaanxi Provincial People's Hospital	10
Tangdu Hospital, Fourth Military Medical University of the Chinese People's Liberation Army	9
Affiliated Hospital of Shaanxi University of Chinese Medicine	8

Table 1 (Continued)

Institutions	Number of registered majors
Xianyang Hospital of Yan'an University	7
Baoji Central Hospital	6
The First Affiliated Hospital of Xi'an Medical College	5
Xi'an High-tech Hospital	5
Xi'an Fourth Hospital	4
Xi'an Chest Hospital	4
Xi'an Red Society Hospital	3
Xi'an Children's Hospital	3
Xi'an Eighth Hospital	2
Stomatological Hospital of Xi'an Jiaotong University	1
The Fourth Military Medical University Stomatological Hospital	1
Shaanxi Provincial Cancer Hospital	1
Xi'an Mental Health Center	1

There were 117 registered majors in the province with 58 qualified majors, constituting an increase of 50.4%. The majors with the largest number of records are oncology, endocrinology, and neurology, which is attributed to the fact that these topics are popular fields for new drug research and development in recent years, with high incidence and large market demand for clinical trials [7,11]. The other hospitals with more than 10 records are all internal medicine majors, which is basically consistent with the majors' distribution of drug clinical trial institutions in China [10]. Although the number of registered majors in our province has increased, nearly half of the majors are recorded in only one hospital, concentrated in surgical kidney transplantation, vascular surgery, breast surgery, radiation therapy, pediatrics, and traditional Chinese medicine, as displayed in **Table 2**.

Table 2. Majors registered by drug clinical trial institutions

Registered majors	Recorded institution(s)
Oncology, endocrinology, neurology	18
Respiratory medicine, cardiovascular medicine	17
Gastroenterology department	16
Gynecology, nephropathy	12
Orthopedics, hematology	11
Ophthalmology	10
Anesthesiology department	9
Dermatology	8
Centers for Disease Control and Prevention, urology, general surgery	7
Phase I drug clinical trials, psychiatry, neurosurgery	5
Bioequivalence test, nose, ear, geriatrics, immunology, cardiovascular medicine, reproductive health and infertility, thoracic surgery, throat, intensive care medicine	4

Table 2 (Continued)

Registered majors	Recorded institution(s)
Obstetrics, TCM (Traditional Chinese Medicine) nephropathy, TCM digestion, TCM hepatology, emergency medicine, rehabilitation medicine	3
Ultrasonic diagnosis, otorhinolaryngology, maxillofacial head and neck surgery, hepatobiliary surgery, nuclear medicine, nail and breast surgery, encephalopathy of Traditional Chinese Medicine, endocrinology of Traditional Chinese Medicine, gastrointestinal surgery, obstetrics and gynecology, rheumatology and immunology, infectious diseases, stomatology, tumor surgery, burn surgery, pediatric neurology, pediatric endocrinology, pediatric hematology, periodontal disease, plastic surgery, medical cosmetology, tuberculosis, Chinese Medicine medical oncology, orthopedics and traumatology	2
CT diagnosis, X-ray diagnosis, ultrasound imaging, magnetic resonance imaging diagnosis, animal infectious diseases, TCM - ear, nose, and throat (ENT), TCM - gynecology, integrated Chinese and Western medicine - liver disease, hepatitis, TCM - proctology, respiratory infectious diseases, interventional radiology, oral surgery, oral maxillofacial surgery - oral surgery, cranio-maxillofacial trauma orthognathic surgery, oncology, oral prosthodontics, oral mucosal diseases, TCM - encephalopathy, TCM - spleen and stomach disease, TCM - rheumatism, TCM - respiratory, TCM - cerebrovascular, TCM - blood, ENT specialty, pediatrics (infection), Otorhinolaryngology Head and Neck Surgery Hospital, AIDS, radiation (diagnosis), radiotherapy, examination, structural heart disease, breast surgery, kidney transplantation, cardiovascular surgery, blood transfusion, blood surgery, medical imaging, medical imaging (diagnosis), blood infectious diseases, peripheral blood vessels, TCM - surgery, pediatric respiratory, pediatric digestive, pediatric nephropathy, pediatric immunization, cardiac vascular surgery, cardiac generalized vascular disease, sexually transmitted diseases, dental pulp disease, cosmetic and maxillofacial beauty, preventive oral medicine, integrated TCM, tumor radiotherapy, pain, pathology, TCM - skin	1

3.5. Status quo of drug clinical trials

By setting the advanced query of "clinical trial institutions" in the CDE webpage "Trial publicity and inquiry," the drug clinical trial institutions registered in Shaanxi Province were searched successively. The results show that our province has undertaken a total of 1723 drug clinical trials since 2013, of which the First Affiliated Hospital of Xi'an Jiaotong University undertook 607 drug clinical trials, far more than other institutions. The four other hospitals that carried out the top five clinical trial projects were the First Affiliated Hospital of the PLA Air Force Military Medical University (Xijing Hospital) (174 projects), the Second Affiliated Hospital of Xi'an Jiaotong University (160 projects), Shaanxi Provincial People's Hospital (106 projects), and Xianyang Hospital of Yan'an University (91 projects). This distribution is closely related to the number of principal investigators, the number of professional departments, the length of qualification recognition time, and the availability of medical resources.

4. Discussion

In recent years, after drug clinical trial institutions (referred to as institutions) implemented the record management system, drug clinical trials have been favored by more and more medical institutions. As of the end of August 2022, 1263 hospitals across the country have carried out institutional and professional group records. In the face of opportunities and challenges, the province has achieved certain development, and the number and scope of the record profession are also growing. In 2021, five institutions in our province, the First Affiliated Hospital of Xi'an Jiaotong University, the Tangdu Hospital of the Fourth Military Medical University of the People's Liberation Army, the Second Affiliated Hospital of Xi'an Jiaotong University, the First Affiliated Hospital of the Fourth Military Medical University of the People's Liberation Army, and the People's Hospital of Shaanxi Province, were listed in the overall list of the national "Test Value" [12], standing out among 300 institutions.

4.1. Encouraging medical institutions to carry out drug clinical trials

The smooth development of drug clinical trials requires the active communication and cooperation of institutions, ethics, research teams, sponsors, and other parties [6]. Institutions are a crucial subject, acting as the managers and supervisors of drug clinical trials. At present, there are 38 institutions in Shaanxi Province that can carry out drug clinical trials, which is a significant increase from before the implementation of the record-keeping system. However, compared with developed areas, the number of institutions in our province is relatively small. The earliest province to undertake drug clinical trials is Guangdong Province, there are 114 hospitals in Guangdong Province for institutional records as of August 31, 2022, which is three times that of our province. According to relevant statistics, the number of projects undertaken by our province in 2021 ranks 19th among 33 provinces (autonomous regions and municipalities directly under the Central Government), ranking in the middle and lower levels. The total number of projects in Guangdong Province in 2021 is 2031, nearly four times that of our province [13]. There are more general hospitals in Shaanxi Province, but the number of institutions only accounts for 5.1%, indicating that there are still a lot of available clinical resources, thus hospitals should be strongly supported and encouraged to actively carry out drug clinical trials and meet the requirements of professional groups for registration. In order to fully improve the core competitiveness of drug clinical trials in our province, we must mobilize the enthusiasm and strength of various institutions.

4.2. Promoting the development of drug clinical trial institutions

In order to promote the development of institutions and drug clinical trials, in 2022, our province established the "Clinical Trial and Research Professional Committee" and "Clinical Research and Medical Ethics Professional Committee." The establishment of the special committee has promoted cooperation and exchange between various institutions in the province, discussed various issues encountered in the process of drug clinical trials, and jointly promoted and improved the development of clinical research in our province. Additionally, the state is also increasing its support for clinical research. It is clearly mentioned in the Opinions that medical institutions, medical research institutions, and medical universities are supported to carry out clinical trials, and the evaluation of clinical trial conditions and capacity is included in the grade evaluation of medical institutions [3].

4.3. Balancing clinical resources and strengthening institutional management

The institutions, professional departments, and PI registered in Shaanxi Province are mainly concentrated in areas with rich medical resources, relatively developed economy, and more affiliated hospitals of colleges and universities. In addition to the Center for Disease Control and Prevention in our province, all of them are tertiary hospitals, most of which are public hospitals. In the Opinions, it is proposed to encourage social forces to invest in the establishment of clinical trial institutions, and to form a diversified drug clinical trial system [3]. The number of projects carried out is also mainly concentrated in the medical institutions with earlier registration and records, which have mature and optimal systems and SOP (standard operating procedure), experienced research teams and advanced medical facilities and equipment. Furthermore, the researchers have strong GCP (Good Clinical Practice) awareness and rich experience. The establishment of information systems and smooth procedures in all aspects can improve work efficiency and the quality of clinical trials, thus attracting sponsors to invest in these medical institutions. The new record institution should improve the full-time talent team, strengthen high-quality training of personnel, learn from well-developed institutions in an all-round way, and promote efficient and high-quality management of institutions.

4.4. Continuously improving the quality of drug clinical trials

With the implementation of the record-keeping system, the supervision of the whole process of drug clinical

trial is stricter, hence the quality of drug clinical trial must be emphasized. The institutions shall establish a long-term quality management system, and the research team shall clarify the responsibilities of all parties, strengthen the project supervision, quality control and audit, and fully implement quality control throughout the project. The drug clinical trial work of the new institution began late, and the experience and quality require improvement. The new institution should improve the implementation of the quality control system, and carry out fine management of the whole process by improving professional ability and risk control, strengthening personnel training, and establishing information management [14], so as to continuously improve the management level of the institution and the quality of the project, and provide a scientific, true, accurate, and reliable basis for the registration and listing of new drugs [6].

The development and listing of new drugs are a complex system with long cycle and huge cost. Clinical trials are the stage in which pharmaceutical companies invest the most money and time. It is expected that in 2022, the investment in China's clinical trial service market will reach nearly 8.5 billion yuan [15], and the number of drug clinical trials will also increase. The selection of institutions is crucial to the development of drug clinical trials. Sponsors will conduct comprehensive evaluation of institutions through various aspects. With the increasing number of new institutions, institutions must keep pace with the times, strengthen communication, and improve core competitiveness in order to withstand the severe challenge of clinical trial market.

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Disclosure statement

The authors declare no conflict of interest.

Author contributions

Conceptualization: Yurong Zhang
Data curation: Qi Zhang, Rui Xu, and Xin Wang
Formal analysis: Lili Zhao and Enze Li
Writing – Original draft: Yurong Zhang
Writing – Review & Editing: Li Wang

References

[1] Fan H, Hu J, Zhao T, et al., 2023, Focus Analysis of On-Site Verification of Drug Clinical Trials Based on Efficacy Index. China Pharmaceutical Affairs, 37(08): 864–869.

[2] Xiang Y, Huang Z, Yang G, 2021, Subject-Oriented Promoting Clinical Research Platform Construction. China Health Human Resources, 2021(10): 22–25.

[3] Xinhua News Agency, 2017, General Office of the CPC Central Committee and General Office of the State

Council Issued the "Opinions on Deepening the Reform of Review and Approval System to Encourage Innovation of Pharmaceutical Medical Devices," viewed November 9, 2020. http://www.gov.cn/zhengce/2017-10/08/content_5230105.htm

[4] Standing Committee of the 13th National People's Congress, 2019, Drug Administration Law of the People's Republic of China, viewed February 2, 2020. http://english.nmpa.gov.cn/2019-09/26/c_773012.htm

[5] National Health Commission, State Drug Administration, 2019, Announcement on the Release of Administrative Regulations on Drug Clinical Trial Institutions (No. 101 of 2019), viewed January 23, 2022. https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20191129174401214.html

[6] Cao L, Guo W, Xie L, et al., 2019, Practice and Thinking on Quality Control of Clinical Trial Projects in Drug Clinical Trial Institutions. China Pharmaceutical Affairs, 23(4): 713–715.

[7] Fang H, Fan Q, Wang X, et al., 2019, Analysis of Archival Status of Drug Clinical Trial Institutions in China. Chinese Journal of Clinical Pharmacology, 37(4): 458–460, 483.

[8] State Food and Drug Administration, Ministry of Health, 2004, Measures for Qualification Identification of Drug Clinical Trial Institutions (Trial), viewed February 18, 2021. https://www.nmpa.gov.cn/xxgk/fgwj/qita/20040219110801929.html

[9] Ning J, Wu H, Gao R, 2021, Analysis of Filing Requirements and Common Problems in Drug Clinical Trial Institutions. Chinese Journal of Clinical Pharmacology, 37(1): 3–7.

[10] You Y, Gao F, Xu X, et al., 2023, Analysis on the Status Quo of Drug Clinical Trial Institutions in China After Recording System. Chinese Journal of Advanced Medicine and Clinical Medicine, 42(03): 170–174.

[11] Huo L, Shi Z, Zhou Y, et al., 2023, Analysis of the Current Situation of Newly Registered Drug Clinical Trial Institutions in China. Chinese Journal of New Drugs and Clinical Medicine, 10: 645–650.

[12] China Clinical Research Capacity Improvement and Subject Protection Summit Forum (CCHRPP), 2022, National GCP Institutions Drug Clinical Trial Volume Ranking Grand Release, viewed January 23, 2022. https://www.cn-healthcare.com/articlewm/20220128/content-1310620.html

[13] Chinese Hospital Association, 2022, Annual Report of Chinese Hospital Drug Clinical Trials (2021), viewed January 23, 2023, https://www.cha.org.cn/site/content/d69d38f9825d176475bf6042b4f2d8df.html

[14] Wei Y, Wang X, 2020, Thinking on the Construction of Drug Clinical Trial Information System: A Case Study of Public Hospitals. Administrative Business Assets and Finance, 2020(5): 29–30.

[15] China Report Hall, 2022, Clinical Trial Industry Outlook: The Number of Clinical Trials Will Further Increase in 2022, viewed June 22, 2022. http://www.chinabgao.com/freereport/85757.html