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Analysis of Reasons for Suspension of Drug Clinical Trials Between China and Other Countries

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Abstract: *Objective*: To analyze the various reasons for the suspension of drug clinical trials, provide suitable solutions to reduce the incidence of such suspensions, prevent wastage of resources, and enhance the completion rate of clinical trials. *Method*: Relevant information on drug clinical trials suspended in China and other countries was retrieved from "Drug Clinical Trial Registration and Information Disclosure Platform" and "ClinicalTrials.gov". Various factors were statistically summarized, comparing the reasons for clinical trial suspensions between China and other countries, and analyzing differences among groups in various classification variables, including indications, years, trial phases, and types of drugs. *Result*: A total of 323,248 drug clinical trials were conducted internationally, with a suspension rate of 0.48% (1,564/323,248). Within this dataset, China reported 377 suspended clinical trials, constituting 1.66% (377/22,703) of its total studies, while other countries conducted a total of 300,545 clinical trials, resulting in a suspension rate of 0.39% (1,187/300,545). The primary cause of suspension in various countries was attributed to issues related to sponsors and funding. Notably, there existed a statistically significant difference in the number of suspended trials between China and other countries ($p < 0.05$). *Conclusion*: During the research preparation phase, sponsors should meticulously assess the feasibility of clinical trials and exercise prudence in development decisions. The clinical trial protocol design must prioritize safety and scientific validity. Research teams should be equipped with emergency risk control measures, adhere to pertinent laws and regulations governing clinical trial, and ensure adequate management. Thus, drug clinical trials can only be conducted with high quality, thereby ensuring the progression of drug marketing.

Keywords: Drug clinical trial; Suspension; Reasons; China and other countries; Measures

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1. Introduction

Development of a new drug necessitates progressing through the phases of clinical trials. Clinical trials involve systematic research on drugs, aiming to assess their efficacy, adverse reactions, and dynamic changes within the human body. It aims to determine whether the investigational drug poses significant health risks or produces expected therapeutic outcomes [1–3]. Clinical trials are usually conducted in distinct phases, encompassing phase I to IV, bioequivalence (BE) and bioavailability studies (BA) [4–6].

The first proposed definition of Clinical Hold (CH) was introduced by the United States Food and Drug Administration (FDA). It represents a mandatory directive, requiring applicants to suspend or delay the clinical trial [7,8]. Once the Investigational New Drug (IND) is submitted, the clinical trial will be initiated and progress through various phases. Throughout this entire period, the trial may be suspended at any time.

During the various phases, unforeseen factors or overlooked aspects may lead to suspension, resulting in irreversible losses for all parties involved. Studies have shown that the development of an innovative drug typically spans from 7.3 to 10.5 years, with costs ranging from $0.8 billion to $2.3 billion, escalating at an annual rate of 8.5% [9–11]. Notably, approximately 60% to 70% of these costs are attributed to the clinical trial phase, yet an alarming 80% of trials fail to meet their designated timelines [12,13]. The halting of clinical trials not only wastes financial resources, time, and effort invested, but also poses risks to the rights and health of the participants.

Although the suspension of trials may result in losses for sponsors, investors, companies, researchers, and participants, there is still a lack of further research on this issue, with few studies have provided comprehensive analyses of the reasons for clinical trial suspension [14]. Therefore, this paper provides a comprehensive review of clinical trials halted in China and other countries, analyze the factors causing trial suspension and propose several constructive solutions. In the final section this study will consider possible plans to prevent the suspension of clinical trials, intend to tackle this one of the significant challenges in the current drug development process.

2. Data and methods

2.1. Data

Chinese data were sourced from the “Drug Clinical Trial Registration and Information Disclosure Platform” (http://www.chinadrugtrials.org.cn/index.html). The search criteria were defined as “suspended,” including “voluntary suspension”, “IEC/IRB suspension”, and “ordered by oversight agencies”, screening clinical trials registered from January 1, 2014, to December 31, 2023.

The data from other countries were sourced from “ClinicalTrials.gov” (https://clinicaltrials.gov/), with the search criteria were consistent with those for Chinese data.

Based on the above terms, this study organized relevant research data and reasons for suspension, conducted summarization, and performed statistical analysis.

2.2. Analysis methods

The information from suspended clinical trials was collected and analyzed. Variables included drug type, indication, trial phase, site and location, and reasons for suspension. These variables were then compared between China and other countries.

2.3. Statistical methods

Based on specific variables, classification and statistical analysis were performed using SPSS software. Additionally, this study conducted a comprehensive assessment of clinical trials, comparing between China and other countries. The Chi-square (χ^2) statistic was utilized to examine count variables. Differences were determined using a significance level of $p < 0.05$.

3. Results

3.1. Current situation of suspension in China and other countries

This study conducted statistical analyses to determine the annual total number of clinical trials and suspended trials in China and other countries from January 1, 2014 to December 31, 2023. The results (**Figure 1**, **Figure 2**) indicate that since 2016, there has been a consistent annual rise in the number of clinical trials in China, accompanied by the highest suspension rate (5.20%) observed in that year, which is the highest proportion over the past decade. Subsequently, the suspension rate has shown a decreasing trend each year. On the other hand, clinical trials have remained active in other countries over the past decade, showing a continuous upward trend, and the suspension rate has also declined annually since 2019. Comparing the two groups reveals that the suspension rate of clinical trials is significantly lower in other countries than in China.

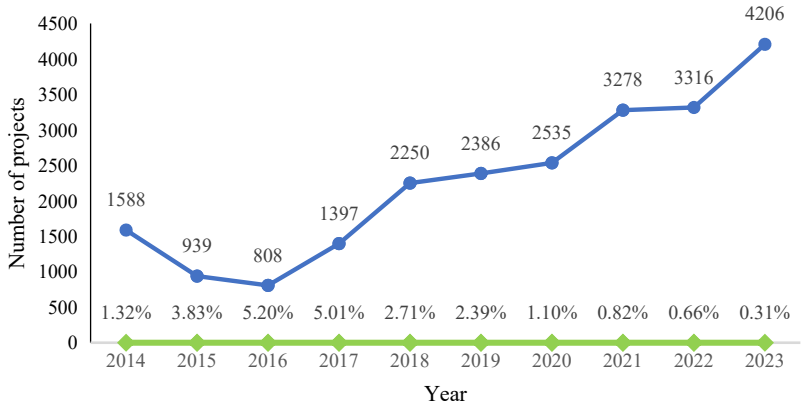

Figure 1. The quantity of drug clinical trials and the proportion of suspensions in China.

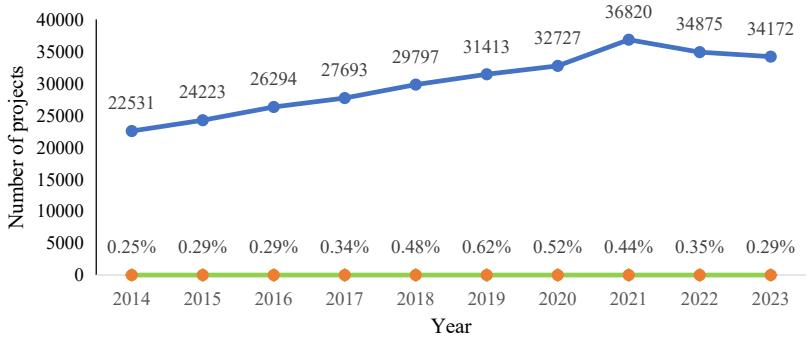

Figure 2. The quantity of drug clinical trials and the proportion of suspensions in other countries.

Over the past decade, China conducted a total of 22,703 drug clinical trials, with 377 trials suspended, accounting for 1.66% (377/22,703). In comparison, other countries conducted 300,545 drug clinical trials, with 1,187 trials suspended, accounting for 0.39% (1,187/300,545). Both countries conducted 323,248 clinical trials, with 1,564 trials suspended, the ratio is 0.48% (1,564/323,248).

These results indicate a higher proportion of suspended clinical trials in China compared to other countries. The chi-square test indicates a statistically significant difference between the two groups ($p < 0.05$) (**Table 1**).

Table 1. Chi square test of suspended drug clinical trials

	Whether drug clinical trials are suspended?		χ^2	p
	Yes	No		
China	377	22326	702.22	0.00
Other countries	1187	299358		

3.2. Characteristics and categorization of suspended clinical trials in China

The information regarding the suspended clinical trials was summarized into drug type, indication, trial phase, site and location, and registration year of the trial. **Table 2** shows that, in terms of drug type, chemical drugs constituted the largest proportion of suspension, at 77.94% (275/377), surpassing half of all trials suspended in China; biopharmaceutical products accounted for 20.69% (78/377), ranking second; and traditional Chinese medicine/natural drugs had the lowest proportion, at 6.37% (24/377). Regarding trial phase, the proportions of suspended clinical trials for Phase I, II, III, IV, BE, and other phases were 17.51% (66/377), 14.06% (53/377), 19.36% (73/377), 1.06% (4/377), 9.28% (35/377), and 38.73% (146/377) respectively. Although the proportion of other phases was the highest, encompassing a variety of trial phases, they were insufficient to pinpoint specific issues.

Therefore, they were excluded when comparing the two sets of data in the subsequent section. The second-highest proportion of suspended trials consisted of Phase III and Phase I clinical trials, while Phase IV clinical trials had the lowest proportion of suspensions. In terms of site and location, the highest proportion of suspended study centers was local, at 85.41% (322/377), while international multicenter trials accounted for a smaller proportion, at 14.59% (55/377). Regarding indications, oncology clinical trials had the largest proportion of suspensions among all types, at 24.40% (92/377), and it was the only type with a suspension proportion exceeding 20% among other indications.

Only cardiovascular and hematologic system, immune system or anti-infective agent, nervous system, and endocrine and metabolic system clinical trials had suspension proportions exceeding 10%. Concerning years, the highest proportion of suspended clinical trials occurred in 2017, at 18.57% (70/377), while the proportions for 2018 and 2019 were around 15% (61/377, 57/377). And for 2016, it was 11.14% (42/377). The proportions of suspension in other years did not exceed 10%. (**Table 2**).

Table 2. Information and categorical variables of suspended clinical trials in China

Information	Categorical variables	Number of suspended clinical trials	Suspension proportion
Drug type	Chemical drugs	275	72.94%
	Biological products	78	20.69%
	Traditional Chinese medicine/natural drugs	24	6.37%
Trial phase	Phase I	66	17.51%
	Phase II	53	14.06%
	Phase III	73	19.36%
	Phase IV	4	1.06%
	BE	35	9.28%
	Other phases	146	38.73%
Site and location	Local study centers	322	85.41%
	International multicenter trials	55	14.59%
Indications	Tumors	92	24.40%
	Cardiovascular and hematologic system	61	16.18%
	Respiratory system	16	4.24%
	Immune system or anti-infective agent	54	14.32%
	Endocrine and metabolic system	46	12.20%
	Digestive system	33	8.75%
	Nervous system	47	12.47%
	Urinary reproductive system	12	3.18%
	Musculoskeletal system	6	1.59%
	Other system	10	2.65%
Year	2014	21	5.57%
	2015	36	9.55%
	2016	42	11.14%
	2017	70	18.57%
	2018	61	16.18%
	2019	57	15.12%
	2020	28	7.43%
	2021	27	7.16%
	2022	22	5.84%
	2023	13	3.45%

3.3. Classification of reasons for suspended clinical trials in China and other countries

Due to the significant number of trials that have been suspended, the reasons for these suspensions vary. To facilitate analysis and statistics, we categorized the reasons for suspension in both countries into ten major categories, as outlined below [14–16]:

(1) Sponsor-related suspension

This includes decisions made by sponsors to suspend trials, insufficient funding for clinical trials, adjustments to research and development strategies, restarting trials in compliance with existing regulations and requirements, pessimistic market prospects for investigational drugs, voluntary suspension following sponsor inspections, failure to comply with government regulations or commercial decisions, etc.;

(2) Suspension related to participant recruitment

This encompasses difficulties in recruiting patients, a lack of eligible trial populations, and failure to meet expected recruitment targets, etc.;

(3) Suspension related to study results

This category involves non-significant study results, unsatisfactory outcomes, poor medical efficacy observed in the trial, lack of significant efficacy in interim analyses, and failure to achieve primary study outcomes, etc.;

(4) Safety concerns

This category pertains to the presence of safety hazards, occurrences of toxicities in patients after medication administration, and occurrence of serious adverse events (SAEs) or suspected unexpected serious adverse reactions (SUSARs) related to severe safety issues, etc.;

(5) Suspension related to protocol amendments

This includes modification to certain protocol contents, inadequacies in initial protocol design requiring amendments, and adjustments of control groups, etc.;

(6) Issues related to the investigational drugs

This category includes the requirement to adjust the drug manufacturing process, discovery of carcinogens in drugs, changes in production sites, inadequate drug supply, high variability in drugs, non-compliance of manufactured drugs, use of expired drugs during clinical trials, inability to provide new drugs before the expiration date of the last batch approaches, and replacement of drugs used in the trial, etc.;

(7) Related to clinical research units

This involves turnover of key investigators, investigators unwilling to participate in the research, researchers withdrawing from the study due to personal reasons, relocation of research sites, incomplete equipment at units, outdated equipment, etc.;

(8) Impact of the COVID-19 pandemic

This category relates to the outbreak of the pandemic resulting in stagnation of trials, etc.;

(9) Reasons that are unclearly specified;

(10) Other reasons

This includes issues with electronic data capture (EDC) systems, exemptions according to existing regulations and requirements, issues with collaborators, inability to perform laboratory tests or obstacles encountered during laboratory tests on patient samples, and expiration of clinical trial approvals, etc.

3.3.1. Reasons for suspension of drug clinical trials in China

In China, the primary reasons for suspending drug clinical trials are related to sponsors, including their decisions to suspend trials, insufficient funding to complete research, and adjustments to research and development strategies. This factor accounts for 32.63% (123/377) of clinical trial suspensions in China. Secondary reasons for suspension are issues related to trial results, such as non-significant outcomes, lack of efficacy, and failure to achieve expected study outcomes, accounting for 22.28% (84/377) of suspensions. Protocol amendments and issues related to investigational drugs also contribute to suspensions in China, representing 12.20% (46/377) and 10.61% (40/377) respectively. These findings suggest a close association between trial suspension in China and these factors. The proportions of other reasons for suspension are detailed in **Table 3**.

Table 3. Comparison of reasons for suspension of drug clinical trials in China and other countries

Reasons classification	China		Other countries	
	Number of suspended clinical trials	Suspension proportion	Number of suspended clinical trials	Suspension proportion
1. Sponsors	123	32.63%	205	17.27%
2. Participant recruitment and enrollment	21	5.57%	94	7.92%
3. Study results	84	22.28%	93	7.83%
4. Safety concerns	12	3.18%	25	2.11%
5.Protocol amendments	46	12.20%	45	3.79%
6. Investigational drugs	40	10.61%	58	4.89%
7. Clinical research units	23	6.10%	91	7.67%
8. Impact of the COVID-19 pandemic	7	1.86%	200	16.85%
9. Reasons that are unclearly specified	1	0.27%	275	23.17%
10. Other reasons	20	5.31%	101	8.51%
Total	377	100.00%	1187	100.00%

3.3.2. Reasons for suspension of drug clinical trials in other countries

In other countries, the highest proportion of drug clinical trials suspended is attributed to reasons not clearly specified, accounting for 23.17% (275/1187). These suspended trials did not specify exact reasons for the suspension, thus cannot serve as accurate grounds for assessing the reasons of trial suspension. In addition to this factor, another significant cause of suspension in other countries, similar to China, is suspension caused by sponsors, which account for 17.27% (205/1187). Furthermore, the impact of the COVID-19 pandemic on clinical trials has been substantial in other countries, with a suspension proportion reaching 16.85% (200/1187). Other reasons did not exceed 10% in proportion. Refer to **Table 3** for more details.

3.3.3. Comparative analysis of reasons for suspension of drug clinical trials in China and other countries

This study compared the reasons for suspension of drug clinical trials in China and other countries (**Table 3**), and the results indicated differences in the reasons leading to suspensions between two groups. In China, the primary reason for suspensions was sponsor-related, while in other countries, the leading cause remained unspecified. However, in China, only 0.27% (1/377) of suspensions were due to unspecified reasons,

substantially lower compared to other countries. The difference in trial suspensions due to safety reasons between the two groups is similar. Additionally, the second-largest reason for suspension in China was related to trial outcomes, whereas in this aspect, the suspension rate in other countries was much lower than in China (7.83% vs 22.28%).

4. Discussion

Sponsors play a pivotal role throughout the entirety of clinical trials, undertaking tasks such as initiating and organizing the trials. Additionally, they provide funding, contribute to the design of the trials, ensure the preparation of all required experimental materials, and manage various other responsibilities. Essentially, sponsors play a central role in ensuring the quality of drug development and expediting the market entry of new drugs [17,18]. Therefore, as a crucial aspect, an error or omission in any of these steps has the potential to disrupt the smooth progress of the clinical trial, resulting in its suspension. Based on the China Good Clinical Practice (GCP) guidelines and relevant guidance from the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) , along with insights from this paper and related research [4,19,20]. The following recommendations are proposed to minimize trial suspensions attributed to sponsors.

(1) Sponsors should ensure that their personnel possess sufficient knowledge and basic skills, and undergo systematic management training, to ensure effective task fulfillment by the entire team;
(2) Prior to designing the trial, sponsors should ensure they are up-to-date with the principles and requirements governing drug market entry, and fully comply with relevant laws and regulations to minimize the risk of suspension;
(3) Sponsors should create appropriate risk management policies specific to the clinical trial, to proactively mitigate potential risks and respond promptly to emergencies;
(4) Sponsors should enhance monitoring and management throughout the trial implementation to promptly detect any issues and take preventive measures, identify suspicious risks, reduce the likelihood of errors, and increase the rate of completing the clinical trial.

Amendments to the clinical trial protocol may impact the progress and potentially result in delays or suspensions [21,22]. Given the professionalism and feasibility of each trial step, strict adherence to the official guidelines of protocol design is essential before protocol development. By integrating multiple articles, the following suggestions emerge [23,24].

(1) Engaging experienced medical writers with a robust knowledge base is vital for drafting the trial protocol. These writers should be well-versed in the process of clinical trials, ensuring precision and coherence in writing.
(2) Considering the intricate nature of protocol design spanning multiple domains, it is crucial to seek input from professionals across various fields. Collaborative engagement and discussion among multiple investigators are essential to bolster the robustness and feasibility of the protocol. This collaborative effort facilitates the seamless execution of the clinical trial protocol and helps minimize the need for protocol modifications during the trial, thereby preventing resource wastage.
(3) Medical writers of clinical trial protocols should thoroughly and accurately review relevant regulations to ensure compliance with government requirements and guidelines, thus avoiding the revisions of protocol due to non-compliance.

The COVID-19 pandemic underscored the critical need for clinical trials to be resilient to unexpected disruptions, prompting recommendations such as cultivating crisis awareness through regular training, improving dynamic emergency plans and crisis management systems, enhancing inter-departmental coordination to resolve issues systematically, leveraging electronic systems for remote trial management, and continuously summarizing past experiences to develop multiple contingency plans for future risks [25].

By systematically analyzing potential causes of suspensions during the clinical trial, and implementing appropriate interventions, the quality of clinical trial execution can be improved. This helps mitigate the impact of various risks during the research, thus minimizing the occurrence of clinical trial suspension and reducing research investment losses.

5. Conclusion

In conclusion, a meticulous and responsible approach to the clinical trial preparation phase is fundamental. By prioritizing safety, scientific validity, and regulatory compliance, and by ensuring robust emergency measures are in place, sponsors can guarantee the high-quality execution of trials. This disciplined process is essential for the successful and safe progression of drugs toward market approval.

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