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Growing disparities: an analysis of equity in China's oncology clinical trials relative to disease burden (2014–2023)

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Background Oncology clinical trials have expanded rapidly in China over the past decade, but concerns remain about whether the distribution of these trials is proportionate to the national cancer disease burden. Previous studies have described oncology trial trends and noted imbalances for certain high-incidence cancers, yet lacked a systematic quantitative assessment of their equity. We aimed to quantify the alignment between oncology clinical trial activity and cancer-specific disease burden in China. We also examined temporal changes in this alignment and differences between industry-sponsored and investigator-initiated trials.

Methods We used disability-adjusted life years as the indicator of disease burden. By calculating the concentration index (CI) and horizontal inequality index (HII) of oncology drug clinical trials in China, we analysed the equity of oncology drug clinical trial development relative to the distribution of disease burden.

Results Between 2014 and 2023, a total of 18,429 oncology clinical trials were conducted in China, with investigator-initiated trials (IITs) constituting the majority (76.1%). Although research efforts were generally concentrated in cancers with a high disease burden (CI=0.51), the allocation of trials was disproportionately skewed towards lower-burden cancers (HII=−0.17). This misalignment worsened over time (β=−0.010/year, P=0.002). The inequity was more pronounced in industry-sponsored trials (ISTs) (HII=−0.22) compared to IITs (HII=−0.16).

Conclusions China's oncology drug clinical trials generally showed an upward trend from 2014 to 2023, with substantial variation in trial numbers across different tumour types. Research resource allocation was disproportionately biased towards low-burden tumours, a trend more pronounced in ISTs. These findings suggest that future research policies should incorporate disease-burden alignment into trial prioritisation and funding decisions, particularly by creating targeted public funding streams and regulatory incentives for high-burden but relatively under-studied cancers.

Keywords oncology; clinical trials; disease burden; equity

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Malignant tumours pose a severe threat to global health and are a leading cause of death worldwide. They impede progress in life expectancy and impose a substantial disease burden on public health and national economies [1]. Disability-adjusted life years (DALYs), which combine years of life lost due to premature mortality and years lived with disability, provide a comprehensive measure of population health loss. Compared with incidence or mortality alone, DALYs capture both fatal and non-fatal consequences of cancer and allow disease burden to be compared across different cancer types. To address the significant health challenges posed by malignancies, global research institutions and pharmaceutical enterprises have invested substantial resources in oncology research over the past few decades. The number of oncology clinical trials in China has grown rapidly since 2018, with China accounting for nearly one-third of global clinical

trial activities, a proportion that has been increasing in recent years. Additionally, the number of key clinical trials for innovative drugs in China surpassed those in Europe in 2020 and exceeded those in the USA by 2023 [2].

Health needs drive scientific and research innovation, which in turn serves as a critical support for health promotion [3]. The Global Forum for Health Research and the World Health Organization (WHO) highlighted the well-known '10/90 gap' in 1999 – where only 10% of global health investments were allocated to addressing the health needs of 90% of the global population – sparking discussions on the imbalance between scientific research distribution and health needs [4]. In the context of clinical research resource allocation, equity refers to the proportionality between research effort and disease burden, rather than numerical equality across cancer types. From this perspective, cancer types that impose a greater disease burden would be expected to attract proportionately greater research attention. Empirical evidence has documented such resource misalignment: A previous global study found that cancer drug development disproportionately favoured cancer types with lower unmet medical needs, indicating inequities in the allocation of clinical research activity [5]. It remains unclear whether this skewed pattern applies to China's fast-growing oncology trial landscape. In China, previous studies have examined the relationship between cancer research output and disease burden, or described trends in oncology drug innovation, but they have primarily focused on descriptive trends or correlations rather than employing formal equity assessment frameworks [6,7]. Therefore, a systematic, quantitative framework is needed to assess this alignment between oncology clinical trials and cancer disease burden. To address this gap, we applied the concentration index (CI) and horizontal inequality index (HII) to evaluate the equity of oncology clinical trial distribution in China. Specifically, we aimed to assess whether oncology clinical trials were proportionally aligned with cancer-specific disease burden as measured by DALYs; examine how this alignment changed from 2014 to 2023; and compare whether the degree of inequity differed between industry-sponsored trials (ISTs) and investigator-initiated trials (IITs).

METHODS

Data sources

We obtained annual cancer-specific DALY estimates for China from 2012 to 2021 from the Global Burden of Disease Study 2021 (GBD 2021), coordinated by the Institute for Health Metrics and Evaluation (IHME) at the University of Washington, USA. We screened clinical trial data from the PharmaCube™ database. The dataset includes clinical trials registered on two platforms: the Drug Clinical Trial Registration and Information Disclosure Platform [8] established and managed by the Center for Drug Evaluation of the National Medical Products Administration, and the Chinese Clinical Trial Registry [9] recognised by WHO. The most recent available GBD estimates used in this study covered cancer-specific DALYs in China from 2012 to 2021. Clinical trial data were available for the period from 2014 to 2023. To account for the time lag between disease burden and subsequent research activity, the main analysis applied a two-year lag assumption, matching DALYs from 2012–2021 with oncology clinical trials conducted from 2014–2023. Thus, DALY estimates for 2022 and 2023 were not imputed or extrapolated.

Data processing and cancer classification

If a clinical trial had two or more registration records, it was counted as a single unique trial. We assigned trials involving multiple cancer indications to each relevant cancer category in the main analysis. Therefore, the sum of cancer-specific trial counts could exceed the total number of unique clinical trials. Trials with broad or non-specific indications, such as 'solid tumours' or 'cancer', that could not be mapped to one of the 30 specific cancer categories were not included in the denominator for cancer-specific percentage calculations.

We classified cancers from GBD and PharmaCube™ using International Classification of Diseases, 10th revision codes. We mapped the GBD cancer categories and PharmaCube™ indication categories into 30 mutually exclusive cancer categories. We excluded the 'other neoplasms' category in GBD because it could not be assigned to a specific cancer type (Table S1 in the **Online Supplementary Document**).

Statistical methods

We used the CI to assess the distribution of clinical trials across tumour types with varying disease burdens. We employed CI, a widely used measure of inequality in healthcare resource allocation, to quantify the distribution of disease burdens and scientific research efforts across different tumours [10,11].

The formula for CI is

$$CI = \frac{1}{n}\sum_{i=1}^{n}\left[\frac{Y_i}{\overline{Y}} - \left(2E_i^X - 1\right)\right]$$

where Y_i represents disease burden (DALYs) or the number of clinical trials for tumour i; $\overline{Y}$ is the mean value of Y_i; and E_i^X denotes the fractional rank of tumours sorted by ascending DALYs. CI ranges from −1 to 1.

CI = 0: there is no net concentration of clinical trials by DALY rank.

CI > 0: trials are concentrated in high-DALY tumours (tumours with higher DALY rankings).

CI < 0: trials are concentrated in low-DALY tumours (tumours with lower DALY rankings).

When CI = −1, all trials are concentrated in the tumour type with the smallest disease burden (lowest DALY ranking); when CI = 1, all trials are concentrated in the tumour type with the largest disease burden (highest DALY ranking).

We plotted a concentration curve (CC) to depict this distribution. The relationship between CI and CC is:

$$CI = 1 - 2\int_0^1 C_c\,dx$$

The CI equals twice the signed area between the 45-degree line of equality and the concentration curve, with its sign indicating the direction of concentration.

To evaluate whether trial distribution aligns with disease burden needs, we calculated the HII, which reflects the degree to which trial distribution matches proportional disease burden requirements [11].

The formula for HII is:

$$HII = CI_{trials} - CI_{DALYs}$$

where CI_{trials} is the CI for clinical trials, and CI_{DALYs} is the CI for DALYs. HII ranges from −2 to 1:

HII = 0: trials are distributed proportionally to disease burden.

HII > 0: trials are disproportionately concentrated in high-DALY tumours relative to disease burden.

HII < 0: trials are disproportionately concentrated in low-DALY tumours relative to disease burden.

A larger |HII| indicates greater inequity.

The relationship between HII and the CC is:

$$HII = 2\left(\int_0^1 C_{c\ DALYs}\,dx - \int_0^1 C_{c\ trials}\,dx\right)$$

where Cc DALYs is the CC for DALYs, and Cc trials is the CC for trials. The absolute value of HII equals twice the area between the CC for DALYs and the CC for trials. If the CC for trials lies below the CC for DALYs, HII > 0; if above, HII < 0; if overlapping, HII = 0 (indicating equitable distribution, *i.e.* each tumour type received trials proportional to its disease burden).

To calculate CI, we ranked cancer types in ascending order according to their DALYs. Because both DALYs and clinical trial counts are ratio-scale variables with meaningful zero values, they were treated as non-negative health and research activity measures in the concentration index estimation. We estimated standard errors and *P*-values to assess whether each CI differed statistically from zero [10]. We calculated HII as the difference between the CI for clinical trials and the CI for DALYs.

To formally assess the temporal trend in inequity, we conducted a *post hoc* linear trend analysis using the annual HII estimates from 2014 to 2023.

To assess whether the main findings were driven by outlying high-burden cancer types, we conducted sensitivity analyses by recalculating the CI and HII after excluding tracheal, bronchus, and lung cancer, which had the highest DALYs, and after excluding the three cancer types with the highest DALYs, namely tracheal, bronchus, and lung cancer, stomach cancer, and oesophageal cancer. We compared the direction and magnitude of the recalculated HII estimates with those from the main analysis.

To assess the potential influence of repeated cancer-type assignment in trials involving multiple indications, we conducted an additional sensitivity analysis using inverse-weighted trial counts. In this analysis, each unique trial contributed a total weight of one. If a trial was mapped to 'k' GBD cancer categories, each matched category was assigned a weight of 1/k. We then aggregated weighted trial counts by cancer type and used them to recalculate the CI and HII, which we compared with the main estimates.

We conducted all descriptive and statistical analyses using Microsoft Excel 2024 (Microsoft Corp., Redmond, Washington, USA) and Stata, version 17 (StataCorp LLC, College Station, TX, USA).

RESULTS

Sample overview

Between 2012 and 2021, China's total cancer burden, measured in DALYs, increased from 61.53 million to 71.22 million person-years. Substantial disparities in DALYs existed across different cancer types. Five cancer types-tracheal, bronchus, and lung cancer; stomach cancer; oesophageal cancer; colorectal cancer; and liver cancer-accounted for 67.59% of total cancer DALYs. By contrast, 15 types of cancer, including eye cancer, testicular cancer, Hodgkin lymphoma, and mesothelioma, collectively accounted for only 7.64%, with each cancer contributing less than 1% (**Figure 1**). From 2012 to 2021, tracheal, bronchus, and lung cancer consistently had the highest DALYs, whereas eye cancer had the lowest. The relative rankings of most cancer types remained stable, with only 7 types showing minor changes over the study period (Figure S1 in the **Online Supplementary Document**).

From 2014 to 2023, a total of 18,429 oncology clinical trials were conducted in China. Of these, 14,023 (76.1%) were IITs, compared with 4,406 (23.9%) ISTs.

After a stable start of 417 trials in 2014 and 413 in 2015, the number of trials increased rapidly, reaching a peak of 3,326 in 2021. The number of trials declined in 2022, with the annual total falling to 2,890, and remained relatively stable at 2,883 in 2023.

Clinical trials for tracheal, bronchus, and lung cancer were the most numerous (2,731 trials, accounting for 16.84%), followed by breast cancer (1,651 trials, 10.18%), colorectal cancer (1,524 trials, 9.40%), and liver cancer (1,489 trials, 9.18%). In contrast, testicular cancer (7 trials, 0.04%), non-melanoma skin cancer (11 trials, 0.07%), mesothelioma (13 trials, 0.08%), and eye cancer (19 trials, 0.12%) had the fewest clinical trials. Overall, there were significant disparities in the number of clinical trials across different tumour types (**Figure 2**). These percentages were based on the total number of clinical trial assignments across the 30 mapped cancer types, not on the total number of unique oncology clinical trials.

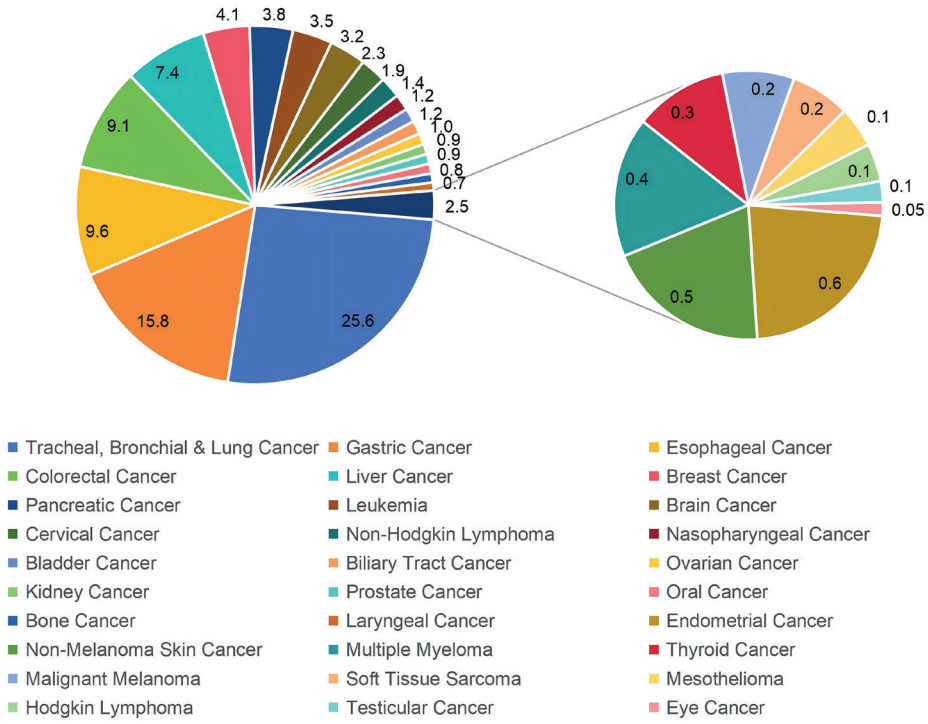


Figure 1. Proportions of DALYs by cancer type in China, 2012–2021.

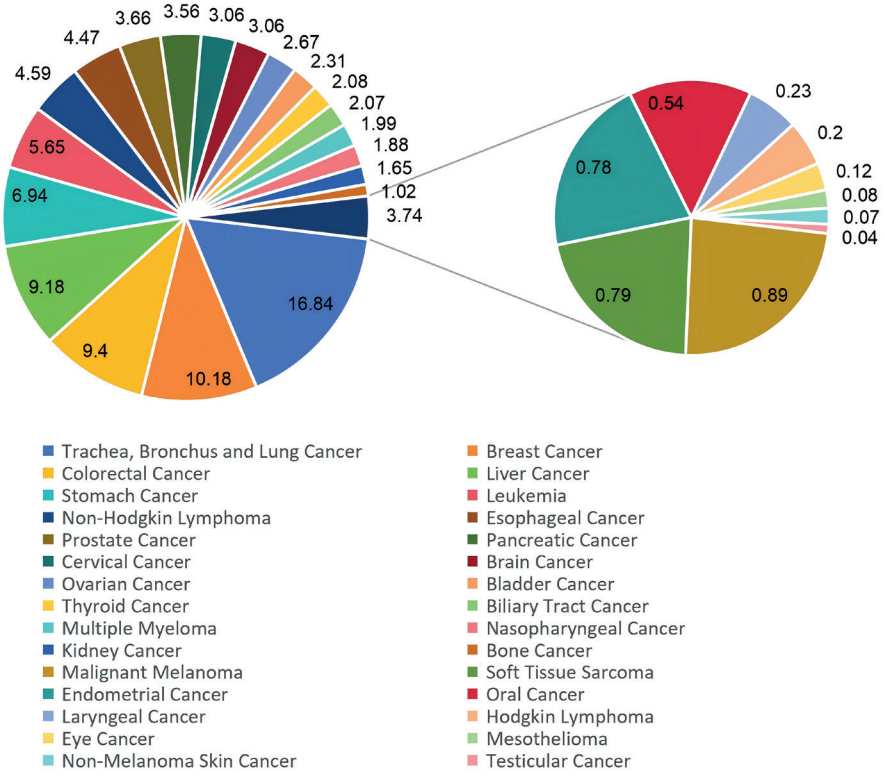


Figure 2. Proportions of clinical trials by cancer type in China, 2014-2023.

Equity in the distribution of clinical trials

By calculating the CI (**Table 1**), we found that oncology clinical trials were more concentrated in tumours with higher disease burdens (CI = 0.51, $P < 0.01$; the concentration curve of clinical trials lay below the 45° reference line). However, clinical trials also exhibited inequity favouring tumours

Table 1. CI and HII for DALYs and oncology clinical trials

	CI (SE)	*P*-value	HII*
Clinical trials	0.5131 (0.0764)	<0.01	−0.1732
DALYs	0.6863 (0.1277)	<0.01	

CI – concentration index, DALYs – disability-adjusted life years, HII – horizontal inequality index, SE – standard error
*HII was calculated as the CI for clinical trials minus the CI for DALYs and is therefore shown once for the comparison between the two distributions.

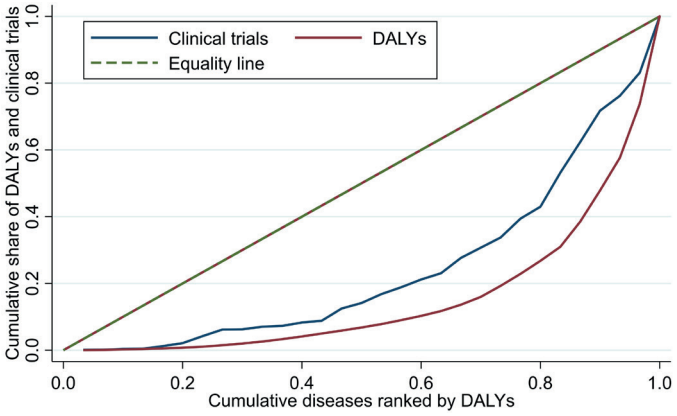


Figure 3. Concentration curves for DALYs and oncology clinical trials. DALYs – disability-adjusted life years.

with lower disease burdens (HII = −0.17); the concentration curve of clinical trials lay above the DALY concentration curve, meaning the number of clinical trials for low-disease-burden tumours exceeded the number expected based on their proportional disease burden (**Figure 3**). Although clinical trials were more concentrated in high-disease-burden tumours, the number of trials remained insufficient relative to their disease burden.

To further identify cancer-specific mismatches underlying the negative HII, we compared each cancer type's share of clinical trials with its share of DALYs (Table S2 in the **Online Supplementary Document**). A positive trial–DALY gap indicated relative overrepresentation in clinical trial activity, whereas a negative gap indicated relative underrepresentation. Breast cancer showed the largest positive gap, accounting for 10.18% of clinical trials but only 4.19% of DALYs. Other relatively overrepresented cancers included prostate cancer, non-Hodgkin lymphoma, leukaemia, and thyroid cancer. By contrast, tracheal, bronchus, and lung cancer showed the largest negative gap, accounting for 25.60% of DALYs but only 16.84% of clinical trials, followed by stomach cancer and oesophageal cancer. These results indicate that several high-burden cancers received a substantially smaller share of clinical trials than would be expected based on their disease burden.

Sensitivity analyses showed that the negative HII was not solely driven by outlying high-burden cancer types. After excluding tracheal, bronchus, and lung cancer, the HII remained nearly unchanged (HII = −0.17). After excluding the three cancer types with the highest DALYs – tracheal, bronchus, and lung cancer, stomach cancer and oesophageal cancer – the HII was attenuated but remained negative (HII = −0.09) (Table S3 in the **Online Supplementary Document**). These results suggest that the observed misalignment between oncology clinical trial distribution and disease burden was not solely attributable to high-burden outliers, although these cancers contributed to the magnitude of the inequality.

The inverse-weighted sensitivity analysis accounting for multiple-indication trials yielded similar results. After assigning inverse weights to trials mapped to multiple cancer categories, the HII remained negative and was highly consistent with the main estimate (weighted HII = −0.18 *vs.* main HII = −0.17). This suggests that multiple-indication assignment did not materially affect the main findings.

Table 2. CI and HII for DALYs and oncology clinical trials

Year	Clinical trials	DALYs	HII
	CI (SE)	CI (SE)	
2014	0.5973 (0.1000)	0.6871 (0.1268)	−0.0898
2015	0.5674 (0.0811)	0.6867 (0.1269)	−0.1193
2016	0.5694 (0.0970)	0.6860 (0.1264)	−0.1166
2017	0.5024 (0.0762)	0.6860 (0.1268)	−0.1836
2018	0.5296 (0.0796)	0.6861 (0.1274)	−0.1565
2019	0.5278 (0.0849)	0.6855 (0.1273)	−0.1576
2020	0.5020 (0.0698)	0.6856 (0.1275)	−0.1835
2021	0.5021 (0.0772)	0.6859 (0.1283)	−0.1838
2022	0.4918 (0.0769)	0.6869 (0.1299)	−0.1952
2023	0.5111 (0.0767)	0.6877 (0.1311)	−0.1766

CI – concentration index, DALYs – disability-adjusted life years, HII – horizontal inequality index, SE – standard error

Equity over time

Additionally, we observed an upward trend in the absolute value of the HII for clinical trials from 2014 to 2023 (**Table 2**). A *post hoc* linear trend analysis further confirmed the temporal pattern of HII. Using annual HII estimates as the dependent variable and year as an ordinal predictor, HII showed a significant decreasing trend from 2014 to 2023

Table 3. CI and HII for IST and IIT clinical trials

Clinical trials	CI (SE)	HII
IST	0.47 (0.09)	−0.22
IIT	0.53 (0.07)	−0.16

CI – concentration index, DALYs – disability-adjusted life years, HII – horizontal inequality index, IIT – investigator-initiated trials, IST – industry-sponsored trials, SE – standard error

(β=−0.010 per year, 95% CI=−0.015, −0.005, P=0.002; R^2=0.715). Because negative HII values indicate inequity favouring lower-burden cancers, these findings suggest that inequity in oncology clinical trial distribution became more pronounced over the study period.

When stratified by sponsor type, both ISTs and IITs showed negative HII values, indicating inequity favouring cancers with lower disease burden. The HII was more negative for ISTs than for IITs (−0.22 *vs.* −0.16), suggesting that this inequity was more pronounced among industry-sponsored trials (**Table 3**).

DISCUSSION

Oncology drug clinical trials in China exhibited an overall upward trend from 2014 to 2023. The number of oncology clinical trials in China has grown rapidly since 2018, accounting for nearly one-third of global oncology clinical trials by 2023 [2]. Several regulatory reforms may have facilitated this growth. China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use in 2017, signalling its commitment to global pharmaceutical development and regulatory standards [12]. This was followed by the introduction of the 60-working-day implied approval mechanism for clinical trial applications, under which applications proceed automatically unless objections are raised by regulators within the review period [13].

However, the rapid expansion of oncology trials did not translate into better alignment with disease burden. The annual CI for DALYs remained highly stable during the study period, indicating that the distribution of cancer disease burden across tumour types changed little. In contrast, the CI for clinical trials declined over time, and the HII became increasingly negative. This suggests that the worsening inequity was mainly driven by changes in the allocation of clinical trials, rather than by substantial changes in disease burden.

This temporal mismatch may reflect both self-reinforcing dynamics and differences in organisational foundations across cancer fields. Once a cancer type has established research networks, experienced investigators, mature clinical pathways, biomarker-defined populations, and accumulated prior evidence, additional trials may become easier to initiate and complete. Such advantages can reinforce subsequent trial concentration, even when the cancer type does not account for the largest share of national disease burden. By contrast, some high-burden cancers may face greater challenges in trial design, patient recruitment, endpoint selection, or therapeutic innovation, limiting the extent to which trial activity expands in proportion to population health needs.

The comparison between ISTs and IITs further highlights the role of commercial incentives. IITs, which focus on academic research and require less extensive regulatory procedures, accounted for the majority of oncology trials in China [14] . ISTs, by contrast, are conducted primarily for drug approval and commercialisation and are subject to more rigorous regulatory oversight.

Although both ISTs and IITs showed negative HII values, the inequity was more pronounced among ISTs (HII=−0.22 *vs.* −0.16). Pharmaceutical companies may prioritise indications with clearer biomarkers, more mature drug-development pathways, stronger market potential, or faster routes to regulatory approval, factors that can also confer higher clinical development success rates [15]. Industry-sponsored trial allocation is thus shaped not only by disease burden but also by expected commercial returns and development feasibility. In contrast, investigator-initiated trials can complement industry-sponsored research by supporting the investigation of new drugs and treatment strategies [16].

The cancer-specific gap analysis helps explain why high-burden cancers can still appear underrepresented despite having large absolute trial numbers. Tracheal, bronchus, and lung cancer, for instance, had the most clinical trials of any cancer type, yet their trial share (16.84%) remained lower than their DALY share (25.60%). This indicates that absolute trial volume alone is insufficient for judging equity; what matters is whether the trial share is proportionate to disease burden.

Digestive system cancers deserve particular attention in the Chinese context. Stomach cancer and oesophageal cancer accounted for a substantial share of national cancer burden, yet their clinical trial shares were clearly lower than their DALY shares. This pattern may be related to China's distinctive cancer burden structure, in which several digestive system cancers impose a heavier burden than in many high-income countries. Because global oncology drug development is often influenced by international market size, biomarker maturity, and multinational development strategies, cancers with particularly high burden in China may not receive trial attention proportionate to their domestic public health importance. This suggests that China may need more targeted clinical research support for high-burden digestive system cancers, rather than relying solely on global development priorities.

Overall, these findings are consistent with domestic and international evidence. A domestic bibliometric study showed that Chinese cancer research output was related to disease burden but varied substantially across cancer sites [6]. Internationally, Barrenho *et al.* found pro-low-need inequity in global cancer drug development, with clinical trial activity disproportionately favouring lower-need cancers [5].

Limitations

First, we measured clinical trial activity by trial counts, with all trials treated equally; therefore, differences in trial phase, sample size, duration, and resource intensity were not captured. The findings should thus be interpreted as reflecting the equity of trial distribution rather than actual research investment. Second, although a two-year lag was applied between DALYs and clinical trials, the true response time from disease burden to trial initiation may vary across cancer types. In addition, trials involving multiple cancer indications and the harmonisation between GBD and trial indication categories may have introduced minor classification uncertainty, although sensitivity analyses yielded similar results. Third, we used DALYs as the primary measure of disease burden, but they do not fully capture unmet therapeutic need, existing treatment availability, technical complexity, market incentives, patient recruitment feasibility, or the role of non-drug therapies. Finally, although PharmaCube™ compiles information from major Chinese trial registries, its completeness relative to all eligible oncology trials could not be independently verified. We also based our equity evaluation on the principle that proportionality to disease burden represents equity; other ethical perspectives on justice and research allocation could be considered.

CONCLUSIONS

China's oncology drug clinical trials showed an overall upward trend from 2014 to 2023, with substantial disparities in the number of trials across different cancer types. Despite a surge in oncology clinical trials in China, there was a significant and worsening misalignment with the national cancer burden. The allocation of research resources was disproportionately skewed towards lower-burden cancer types, a trend more prominent in trials sponsored by industry. These findings suggest that future research policies should incorporate disease-burden alignment into trial prioritisation and funding decisions, particularly by creating targeted public funding streams and regulatory incentives for high-burden but relatively under-studied cancers.

Ethics statement: We used published literature and de-identified databases; no human or animal subjects are involved, so ethics approval is not required.

Data availability: The DALY data used in this study are publicly available from the Global Burden of Disease (GBD) study by the Institute for Health Metrics and Evaluation (IHME). We obtained clinical trial data from the PharmaCube™ database, which compiles data from publicly accessible registries, including the Drug Clinical Trial Registration and Information Disclosure Platform and the Chinese Clinical Trial Registry. Due to licensing restrictions of the PharmaCube™ database, the raw clinical trial dataset is not publicly available. However, aggregated data and analytical results supporting the findings of this study are available from the corresponding author upon reasonable request.

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Authorship contributions: HJ contributed to the study conception and design, data analysis and interpretation, and manuscript drafting. LW contributed to methodological design, data validation, interpretation of results, and critical manuscript revision. LX contributed to data collection, data curation, visualisation, and manuscript revision. SL contributed to study supervision, interpretation of findings, and critical revision of the manuscript for important intellectual content. CJ secured funding, conceived and supervised the study, interpreted the findings, and critically revised and finalised the manuscript. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work.

Disclosure of interest: The authors completed the ICMJE Disclosure of Interest Form (available upon request from the corresponding author) and disclose no relevant interests.

Additional material
Online Supplementary Document

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