Original Article

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Equity in Clinical Trial Participation in India with a Focus on Reporting Gaps and Recruitment Reach in Oncology and Vaccination from 2020 to 2024: A Systematic Review

Public Health Section

ARIJITA MANNA[1], S TEJESH[2], ROVENA YAZHINI[3], HOTHA SAI SRINIVAS KATRPURAM[4]

ABSTRACT

Introduction: To ensure the generalisability of research findings, equitable participation in research studies is very important. In India's context, women, rural populations, and tribal populations have been observed to be less represented in certain critical research areas like oncology and vaccination research.

Aim: To assess demographic discrepancies in recruitment for oncology and vaccination research conducted in India.

Materials and Methods: A Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) -guided review of Clinical Trials Registry-India (CTRI) records spanning January 1, 2020, to December 31, 2024, was undertaken (PROSPERO registration: CRD420251086878; ethics approval: IIPHH/TRCIEC/442/2025). The analysis focused on prespecified indicators: sex-disaggregated participant counts, rural representation (defined as inclusion of ≥1 rural/PHC/CHC/community/outreach site), and tribal participation. To evaluate reporting completeness, a study-specific Equity Transparency Index (ETI) was applied, encompassing five domains. Descriptive statistics were generated, and associations were tested using χ^2 and Fisher's exact tests, implemented in R software (version 4.5.1).

Results: A total of 113 trials (n=68 oncology, n=45 vaccination) were analysed, with a planned enrolment of 192,330 participants. Sex-disaggregated data were available for only 31,940 (17.8%) oncology participants and 841 (6.4%) vaccination participants, primarily from women-only trials. Rural recruitment was reported in 55 (80.9%) oncology studies and 44 (97.8%) vaccination studies, with an overall rural enrolment of 76.0%. Reporting for Scheduled Tribes (ST) was very low, 3 (4.4%) oncology; n=0 vaccination, with these three studies inflating the oncology participant count significantly. No trials reported socio-economic indicators, leading to low-to-moderate transparency scores across funding sources.

Conclusion: Although rural recruitment is improving, significant gaps in reporting {sex, tribal status, and Socio-economic Status (SES)} hinder meaningful equity assessments. It is crucial to mandate equity-focused reporting and plans to improve trial approval processes.

Keywords: Research subjects, Patient selection, Vulnerable populations

INTRODUCTION

Equity in health research is not only about participation in studies but also about how fairly the benefits and risks are shared [1,2]. In public health, experts warn that research without an equity focus can worsen existing inequalities, especially in low- and middle-income countries, where protections may be weak and post-trial access uncertain [1]. In India, concerns have often been raised about the poor representation of diverse social and demographic groups in clinical trials and the limited visibility of marginalised groups in reporting [3]. Equity is therefore linked to what is measured, recorded, and reported clearly. This is especially important in India, where 68% of people live in rural areas [4], 104 million belong to STs (8.61% of the population) [5], and women make up nearly half the population [4]. Yet important equity-related data, such as sex-disaggregated enrolment, rural or tribal participation, and socio-economic details, are often missing or inconsistently reported. When such fields are left blank or marked "not applicable," the evidence reflects convenience rather than necessity. Even when both sexes are enrolled, results are not always analysed or presented in ways that allow proper interpretation [6].

For rural and tribal communities, the problem is compounded by the fact that most research infrastructure and trial activity are concentrated in urban tertiary centres, leaving rural and tribal settings underrepresented in published studies [3,7,8]. These gaps raise serious questions about representativeness, the use of evidence in practice, trust in research, and the fair spread of innovations [9,10]. The CTRI is the main registry for trials in India and is widely used to check participant reporting and enrolment. However, analysis of CTRI data is limited by missing demographic details, irregular post-trial updates, and difficulties in linking registry entries to publications. In this context, the equity issue becomes a reporting issue: without accessible equity-related data, it is hard to assess or improve practices. To address this, the present systematic review aimed to evaluate equity-related participant characteristics reported in oncology and vaccination trials registered in CTRI between 2020 and 2024. The review used the ETI framework to assess equity indicators. It aimed to analyse where equity reporting is strong, where it is missing, and what this means for the credibility and usefulness of India's clinical trial evidence base.

Objectives:

- To evaluate the reported proportion of female participants in recent oncology and vaccination clinical trials in India, among trials providing sex-disaggregated data.
- To evaluate the proportion of participants enrolled in trials with a rural component in recent oncology and vaccination clinical trials in India.
- To evaluate the proportion of recent oncology and vaccination clinical trials in India, and report on the inclusion of tribal (ST) populations.

MATERIALS AND METHODS

The protocol for this systematic review was developed in accordance with the PRISMA-P guidelines [11]. It was prospectively registered with PROSPERO (CRD420251086878). The study received ethics approval from the Institutional Ethics Committee of the Indian Institute of Public Health-Hyderabad (IIPH-H; approval no. IIPHH/TRCIEC/442/2025.

Eligibility criteria:

- (P) Participants: patients with cancer; healthy volunteers only for vaccine/cancer prevention trials;
- (I) intervention as oncology care (treatment/management/survivorship), vaccine (including immunisation/COVID-19 vaccines);
- (Co) country as India (India only trials, multi-country trials with Indian sites); and
- (S) study type as interventional/observational trials, registration between 1st January 2020 and 31st December 2024. This period was chosen because it reflects the impact of the COVID-19 pandemic on research priorities and recruitment practices, as well as heightened policy and institutional attention to equity in trial reporting.

Exclusion criteria: Trials involving healthy volunteers were excluded if they were designed solely for pharmacokinetic, biosimilarity, or drug safety testing, such as single-dose bioequivalence studies in healthy males, since these do not involve patient recruitment or reflect actual access to cancer trials.

Additional exclusions were made where trials lacked human participants, were unrelated to cancer or vaccination, or did not report key demographic data, such as gender, tribal status, or rural/urban background, even after supplementary searching. These feasibility-based exclusions were informed by the pilot search experience, which highlighted frequent gaps in CTRI reporting, especially in demographic fields [12,13].

For data availability, trials had to become eligible with registry data showing at least one equity metric (sex-disaggregated counts, rural/urban, or inclusion of ST); trials with unavailability of extractable equity data were excluded after additional searches.

Sex vs gender: The CTRI labels a variable as "Gender" with binary categories (male/female). In this review, these were reported as sex-disaggregated counts, referring to the availability of separate male and female numerators. Single-sex trials (e.g., breast or cervical cancer) were included in the review but were not classified as sex-disaggregated for comparative analysis. This approach was adopted to permit statistical differentiation and quantitative assessment of representation. The term gender was reserved for social constructs, policy dimensions, or when the original wording from sources was retained.

Rural reach: The sample-size-weighted share of participants enrolled via rural-inclusive trials was reported. "Rural-inclusive" was operationally defined a priori as trials with ≥1 recruitment site in public primary-care or outreach settings (e.g., PHC/CHC/community/outreach), consistent with Indian Public Health Standards (IPHS) definitions [14].

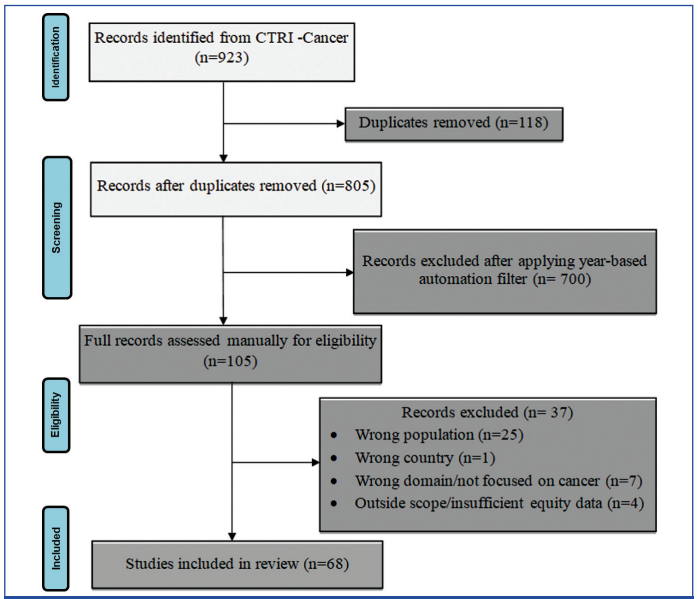
Tribal inclusion: Explicit ST mention or recruitment from Scheduled Areas/ST-focused programs. If absent/unclear, coded as not reported.

Socio-economic Status (SES) indicators: Any report of income, education, or social class at the participant level.

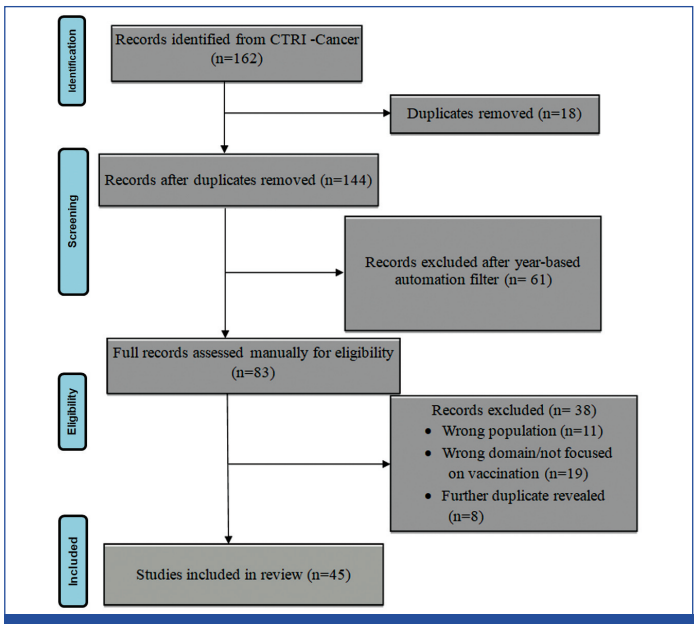
Equity-Transparency Index (ETI): Five-domain index of equity-reporting completeness (sex, rural/urban, tribal, geographic coverage, SES).

The primary database for this review was the CTRI, which tracks clinical trials in India. When demographic data such as sex distribution, tribal identity, or rural recruitment status were lacking in CTRI, a search was conducted using the WHO's International Clinical Trials Registry Platform (ICTRP). To find linked publications, additional searches using the CTRI registration number, title, and principal investigator's name were carried out on PubMed, Google, and ProQuest. A publication was considered "linked" only if the CTRI registration ID was mentioned in the full text; otherwise, the trial was marked as having no retrievable linked publication.

The CTRI search interface has some specific functional limitations. For example, only one keyword can be entered at a time per query, and there is no option for Boolean operators, truncation, or multi-term strings. In order to overcome these shortcomings and achieve comprehensive retrieval, an inclusive search strategy using high-level umbrella terms was employed. For the oncology domain, a preliminary pilot search was conducted in July 2025 to evaluate keyword feasibility. This initial search, which yielded 923 records, indicated that specific subtypes (e.g., "carcinoma") or intervention terms (e.g., "chemotherapy") yielded subsets of records that were also effectively captured under the broader term "cancer." Therefore, the retrieval set was based on the single keyword "cancer" entered under health condition/problem studied, yielding the most robust dataset for manual screening [Table/Fig-1a]. For the domain of vaccination, the search outputs were varied by search criterion, and hence the keyword "vaccination" was run in both Health Condition/Problem Studied and Intervention/Comparator Agent [Table/Fig-1b].



[Table/Fig-1a]: Identification of cancer studies via clinical trial registry-India.



[Table/Fig-1b]: Identification of vaccination studies via clinical trial registry-India.

The results of these two searches were combined and de-duplicated using the CTRI registration number as the primary identifier, forming a common dataset for screening. It should be noted here that CTRI includes not only India-affiliated studies but also those from countries without their own Primary Registry [15].

During the screening process, several inconsistencies were identified related to CTRI indexing. The keyword-based search occasionally yielded records outside this review's primary focus area (for example, studies exclusively addressing maternal health rather than oncology or vaccination). Such records were manually excluded as being in the 'wrong domain.' Additionally, certain records exhibited internal inconsistencies in location-related fields; for instance, listing a neighbouring country as the sole recruitment site with zero participants from India, despite being registered in the CTRI. These were excluded as 'wrong country/not India-based' following manual verification.

All extracted trial-level information was organised into a structured spreadsheet (Google Sheet) template. The structured spreadsheet captured the following variables for each included trial: CTRI ID, year of registration, study domain (oncology or vaccination), study type (interventional or observational), funding source (governmental, institutional, pharmaceutical/industry, self-funded, NGO/philanthropic, mixed), recruitment scope (single-centre vs. multicentre), total sample size, number of female participants (where available), geographic recruitment location(s), rural/urban representation (if specified), tribal inclusion (if reported), publication link (if available or not), the link (pubmed, proquest, google scholar, or other source), and notes or comments (e.g., data gaps, clarifications from supplementary searches). Extraction was performed primarily by the lead author and verified by additional team members.

This review focuses on the transparency of equity-relevant reporting in registry entries, not the internal validity or clinical outcomes of the trials. Therefore, standard risk-of-bias tools were not used. Instead, a custom instrument, the ETI, was developed to appraise the completeness of reporting across five key equity domains.

The ETI framework was developed through iterative expert review to establish content validity and alignment with existing equity-reporting frameworks, such as the REP-EQUITY Toolkit [2], and WHO-ICTRP fields, which define minimum standards for trial registration transparency [16]. Each domain and scoring criterion was independently verified by two reviewers, with discrepancies resolved through discussion to increase reliability.

Each domain was assigned a score from 0 to 2 (2 if the domain was complete or present with quantitative information, one if partial or unclear qualitative reporting, and 0 if not reported or absent). The maximum score was 10. To maintain consistency and minimise bias, the ETI tool was pilot-tested on a random sample of 10 trials (k>0.80). Two independent reviewers, AM and ST, used the final criteria on the entire dataset. Discrepancies were resolved by consensus discussion. The overall level of transparency for each trial was assessed as High (8-10), Moderate (5-7), or Low (0-4). This index reflects reporting transparency only, not methodological quality.

STATISTICAL ANALYSIS

Statistical analyses were conducted in R 4.5.1. Reporting patterns and participant representation were summarised using descriptive statistics (frequencies, percentages). Sex-disaggregated counts, rural reach (participant-weighted share in trials with ≥1 rural/PHC/CHC/community/outreach site), and tribal inclusion were tabulated; owing to near-total non reporting, tribal inclusion was described narratively. Between-group differences (oncology vs vaccination; by funder) were tested using Pearson's χ^2 or Fisher's exact test was used when expected cell counts were fewer than five, as appropriate.

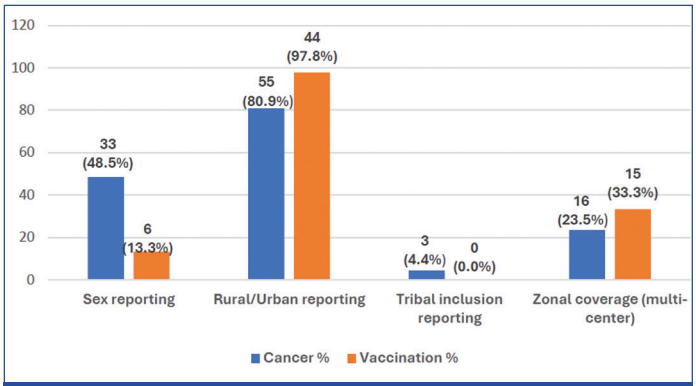
RESULTS

To accurately assess the equity landscape, findings are presented at the trial level (n=113 trials) and participant level (N=192,330). The median trial size was 200 (range: 15-100,000), with cancer trials dominating at 68 trials (60.2%) and 179,141 planned participants (93.1%). Most trials were funded by institutional sources (37 trials, 32.7%) but were generally smaller. Only five trials (4.4%) received NGO/philanthropic funding, yet they accounted for a significant portion of participants (N=113,500; 59.0%). Although most trials were single-centre (82 trials, 72.6%), multicentre trials (n=31; 27.4%) contributed the majority of participants (N=130,605; 67.9%) [Table/Fig-2].

Characteristic	Oncology trials (n=68; N=179,141) n (%)	Vaccination trials (n=45; N=13,189) n (%)	Total trials (n=113) n (%)	Total participants (N=192,330) N (%)
Funding source				
Governmental	13 (19.1)	10 (22.2)	23 (20.4)	24,841 (12.9)
Institutional	25 (36.8)	12 (26.7)	37 (32.7)	27,048 (14.1)
Pharmaceutical/ industry	12 (17.6)	13 (28.9)	25 (22.1)	21,679 (11.3)
NGO/Philanthropic	3 (4.4)	2 (4.4)	5 (4.4)	113,500 (59.0)
Self-funded	12 (17.6)	5 (11.1)	17 (15.0)	4,142 (2.2)
Mixed	3 (4.4)	3 (6.7)	6 (5.3)	1,120 (0.6)
Study type				
Interventional	36 (52.9)	35 (77.8)	71 (62.8)	144,466 (75.1)
Observational	32 (47.1)	10 (22.2)	42 (37.2)	47,864 (24.9)
Recruitment scope				
Single-centre	52 (76.5)	30 (66.7)	82 (72.6)	61,725 (32.1)
Multicentre	16 (23.5)	15 (33.3)	31 (27.4)	130,605 (67.9)

[Table/Fig-2]: Descriptive characteristics of included clinical trials (n=113).
n: Trial number; N: Participant number

The reporting of a trial's rural or urban setting was notable, with 80.9% of oncology trials (55 out of 68) and 97.8% of vaccination trials (44 out of 45) providing this information. In contrast, sex demographics were reported in only 33 (48.5%) of oncology trials and 13.3% of vaccination trials, primarily due to female-only studies. Genuine sex-disaggregated reporting was rare in both areas. Tribal representation was reported in just 4.4% of oncology trials and not at all in vaccination trials. Additionally, SES was not reported in any of the 113 trials reviewed [Table/Fig-3].



[Table/Fig-3]: Equity-relevant reporting and trial scope by study domain.
Note: Percentages shown in Table/Fig-3 are trial-level percentages (denominator =number of trials) and do not represent participant-level proportions

Only 34.5% of trials reported sex-disaggregated data, with female participation at 17.8% for oncology and 6.4% for vaccination, a gap of 11.4 percentage points [Table/Fig-4]. While 48.5% of oncology trials and 13.3% of vaccination trials provided sex data, these numbers are misleading due to the presence of women-only cancer trials. In mixed-sex trials, only one oncology and one vaccination trial reported actual male and female counts.

Study domain	Total participants (N)	Female participants reported (N, %)
Oncology	179,141	31,940 (17.8%)
Vaccination	13,189	841 (6.4%)
Total	192,330	32,781 (17.0%)

[Table/Fig-4]: Reporting coverage for participant sex, by study domain.
*Denominator: Planned participants per domain; Numerator: Female participants reported (i.e., sex-disaggregated female counts available). Percentages reflect availability of female numerators and are not the true female proportion across all trials; Coverage is skewed by women-only oncology studies

Out of 113 trials, 99 (87.6%) trials specified a recruitment setting. When weighted by sample size,76.0% (N=139,438) of participants were enrolled through rural-inclusive trials. Rural-inclusive recruitment was significantly higher in oncology trials (78.9%) than in vaccination trials (37.6%) (Chi-square test, p-value <0.001) [Table/Fig-5].

Study domain	Total participants (N)	Participants in rural-inclusive trials (N, %)	Participants in urban-only trials (N, %)
Oncology	170,579	134,621 (78.9%)	35,958 (21.1%)
Vaccination	12,812	4,817 (37.6%)	7,995 (62.4%)
Total	183,391	139,438 (76.0%)	43,953 (24.0%)

[Table/Fig-5]: Distribution of participants by recruitment setting and study domain*.
*Note: This analysis includes the 99 trials that specified a recruitment setting

The ST participation was rarely reported in trials, with only three of 68 oncology trials (4.4%) providing such information, accounting for 106,180 participants or 59.3% of total oncology enrolment. In contrast, none of the 45 vaccination trials reported any tribal inclusion (0.0%). This indicates that outreach to tribal communities is limited, primarily seen in a few large oncology trials, with no effort in vaccination research [Table/Fig-6].

Study domain	Total participants (N)	Participants in tribal-inclusive trials (N, %)	Participants in trials not reporting tribal inclusion (N, %)
Oncology	179,141	106,180 (59.3%)	72,961 (40.7%)
Vaccination	13,189	0	13,189 (100.0%)
Total	192,330	106,180 (55.2%)	86,150 (44.8%)

[Table/Fig-6]: Distribution of participants by tribal inclusion status and study domain.

Trial distribution in India is heavily concentrated in the South, West and North zones, which account for 64.6% of trials (73 out of 113) and 59.2% of participants (113,876 of 192,330) in single-zone studies. Meanwhile, the East, Central, and North-East zones were significantly underrepresented. However, cross-regional recruitment was also prevalent, with 26 trials (23.0%) spanning multiple zones and involving 74,247 participants (38.6%), highlighting that while many trials reach a broad audience, single-zone studies were limited to a few established research areas [Table/Fig-7].

Zone	Number of trials (n, %)	Total participants (N, %)
South zone	26 (23.0%)	27,858 (14.5%)
West zone	24 (21.2%)	51,757 (26.9%)
North zone	23 (20.4%)	34,261 (17.8%)
East zone	10 (8.8%)	2,759 (1.4%)
Central zone	3 (2.7%)	1,268 (0.7%)
North-East zone	1 (0.9%)	180 (0.1%)
Multi-Zone/Other*	26 (23.0%)	74,247 (38.6%)
Total	113 (100.0%)	192,330 (100.0%)

[Table/Fig-7]: Distribution of trials and participants by geographic zone.
*Note: The 'Multi-Zone/Other' category combines trials originally classified as Multi-Zone (n=25) and Not Specified (n=1)

Statistical tests showed no significant link between funding sources and the reporting of sex-disaggregated data (Fisher's exact test, p-value=0.55) or the inclusion of rural populations (Chi-square test, p-value=0.51). This indicates that data transparency and recruitment issues are systemic across all funders.

DISCUSSION

To accurately assess the equity landscape, findings are presented at the trial level (n=113 trials) and participant level (N=192,330). This dual approach prevents ecological fallacy, as participant-level data may appear equitable due to a few large government-funded screening programs. In contrast, trial-level data reveals that most clinical trials fail to report or recruit marginalised groups. This systematic review reveals a complex and often contradictory landscape of equity in Indian clinical trials. While the present study analysis indicates a shift toward greater recruitment from rural areas in oncology, this progress is undermined by a pervasive lack of transparency regarding sex, tribal status, and socio-economic indicators. Unlike previous assessments that characterised Indian research as almost exclusively urban-centric [7,9], the present findings suggest that large-scale screening trials are effectively reaching rural populations. However, this reach appears fragile, driven primarily by a small number of philanthropic initiatives rather than a systemic shift in the research culture sponsored by industry or government.

The "invisibility" of female participants in mixed-sex trials remains a critical concern. Consistent with Pillamarapu M et al., earlier analysis of the CTRI registry, it was found that sex-disaggregated reporting remains the exception rather than the norm [12]. Although the overall female representation appears high, this is a reporting artefact driven by women-only cancer trials (e.g., breast and cervical). In mixed-sex trials, the failure to report separate male and female counts makes it impossible to detect gender disparities, a trend that mirrors global deficits in trial reporting noted by previous researchers [17]. Without mandatory sex-disaggregated data fields, the CTRI cannot function as a tool for monitoring gender equity [18].

Furthermore, the representation of ST and low-socio-economic groups remains a systemic blind spot. While valid concerns exist regarding the logistical challenges of recruiting in remote tribal areas [19,20], this review found that tribal inclusion was concentrated in only three large-scale trials, with zero reporting in the vaccination domain. This extreme centralisation suggests that tribal health research is currently treated as a "special interest" niche rather than an integral component of national health research, perpetuating the historical neglect identified by previous research [19,20]. The complete absence of socio-economic data further prevents any assessment of whether trials are reaching the economically vulnerable or merely the urban elite [21].

Beyond these specific demographic gaps, the review process highlighted profound structural limitations within the registry itself. CTRI demographic fields (gender, rural/urban, tribal) were frequently incomplete, duplicate records appeared occasionally, and post-trial updates were inconsistent. Crucially, the extreme scarcity of linked publications; severely constrained our efforts to independently verify missing data, underscoring the limited global visibility of India-based research.

Furthermore, the registry's search interface dictated our methodological approach. Initial attempts to use a multi-keyword pooling strategy (e.g., combining oncology, radiotherapy, carcinoma) were abandoned due to two primary issues: 1) High Redundancy, where specific keywords generated outputs that were mostly subsets of the broader "cancer" search; and 2) False Positives, where terms like "chemotherapy" retrieved non oncology trials (e.g., rheumatology), introducing considerable noise. Given the lack of bulk export functionality in CTRI, merging these highly redundant and noisy datasets posed a threat to data integrity, necessitating our optimised, single-keyword umbrella approach.

Deviations from Protocol

While the study was conducted according to the preregistered protocol in PROSPERO, several modifications were necessary based on the nature of the retrieved data:

The search strategy was consolidated from the multi-keyword approach in the protocol to single-umbrella terms ("cancer" and "vaccination") to eliminate high redundancy and false positives encountered during the pilot study.

Modification of the Equity-Transparency Index (ETI): This systematic review identified "Linked Publication" as the sixth domain; however, this component was excluded from the ETI calculation to ensure a strict focus on demographic representativeness. Publication availability will be reported separately.

Transition to qualitative synthesis: Although a random-effects meta-analysis was initially planned, it was deemed unfeasible due to high heterogeneity in study designs (interventional vs. observational) and a lack of comparable quantitative outcomes across trials.

Consolidation of subgroup analyses: The review included plans for analyses by sponsor type, but this could not be executed due to insufficient statistical power stemming from the fragmentation of the dataset into small subgroups; for example, there were only five trials sponsored by NGOs. The high incidence of zero-cell counts (where no trial in a specific sponsor category reported a particular equity metric) rendered Chi-square testing statistically invalid for sponsor comparisons. As a result, the analysis was consolidated to compare the Oncology (n=68) and Vaccination (n=45) domains, where the sample sizes were adequate to support robust statistical inference.

Limitation(s)

This review had several limitations due to the structural constraints of the CTRI database. First, since data were self-reported by investigators, missing demographic information (like rural or tribal inclusion) makes it unclear whether this indicated poor recruitment or inadequate reporting. Second, independent verification of the entries was often impossible due to a lack of linked publications, limiting our ability to cross-reference planned enrollment with outcomes. As a result, "Linked Publication" was excluded from our preregistered ETI, focusing solely on available demographic data. Third, the high heterogeneity in study designs made quantitative meta-analysis unfeasible, and planned subgroup analyses were abandoned due to insufficient statistical power. Lastly, the present study assessed planned sample sizes at the time of registration, which may differ from the actual enrollment achieved in the trials.

CONCLUSION(S)

Equity in recent Indian clinical trials presents a range of contrasts. There are indications of significant rural outreach in the oncology sector; however, this progress is not uniform and is often complicated by systemic issues in demographic reporting. Key challenges include the routine underreporting of sex-disaggregated data, limited reporting on tribal inclusion, and a lack of socio-economic data, which hinder the generation of generalised and equitable clinical evidence. To enhance the representativeness of trial evidence for India's diverse population, it is essential for regulators, funders, and researchers to prioritise and enforce transparent, comprehensive, and equitable reporting standards moving forward.

Authors' contribution: AM conceptualised the study, designed the review framework, led data extraction, conducted the analysis, and drafted the manuscript. ST contributed to data extraction, data verification, and manuscript review. RY contributed to data validation, interpretation of findings, and critical review of the manuscript. HSSK contributed to data verification, manuscript review, and overall project support. All authors reviewed and approved the final version of the manuscript.

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PARTICULARS OF CONTRIBUTORS:
1. Research Assistant, Department of Public Health Research, Public Health Foundation of India (PHFI), Indian Institute of Public Health (IIPH), Hyderabad, Telangana, India.
2. Research Assistant, Department of Public Health Research, Public Health Foundation of India (PHFI), Indian Institute of Public Health (IIPH), Hyderabad, Telangana, India.
3. Research Associate, Department of Public Health Research, Public Health Foundation of India (PHFI), Indian Institute of Public Health (IIPH), Hyderabad, Telangana, India.
4. Research Assistant, Department of Public Health Research, Public Health Foundation of India (PHFI), Indian Institute of Public Health (IIPH), Hyderabad, Telangana, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Arijita Manna,
Provident Kenworth, Tower 2, Flat 121, Pillar No: 294, PV Narasimha Rao Expy, Bhavani Colony, Hyderabad, Telangana, India.
E-mail: mannaarijita@yahoo.com

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