DOI: 10.7860/JCDR/2026/84646.23669

Research Protocol

Public Health Section

Equity in Clinical Trial Participation in India (2020-2024) across Oncology and Vaccination Trials: A Systematic Review and Meta-analysis Research Protocol

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ABSTRACT

Introduction: Clinical trials in India have historically struggled to reflect the lived realities of disadvantaged communities. The inclusion of individuals in research continues to be shaped by gender, geography, and social position. Evidence shows that women, rural residents, and tribal groups are often missing from trials; even in national priority areas such as cancer and vaccination, narrowing the evidence base and deepening structural gaps in participation.

Need of the study: While clinical trials are expanding in India, there is a lack of systematic evidence regarding the representation of marginalised groups. Assessing reporting gaps using a structured framework like the Equity Transparency Index (ETI) is essential to identify systemic biases and ensure that clinical evidence in oncology and vaccination is generalisable to India's diverse population.

Aim: To examine equity-relevant participation and reporting, specifically related to women, rural populations, and Scheduled Tribe inclusion, in oncology and vaccination clinical trials registered in India.

Materials and Methods: This systematic review Protocol complies with Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines, covering trials registered between 1st January 2020 and 31st December 2024. The primary source will be the Clinical Trials Registry–India (CTRI). The World Health Organisation (WHO) International Clinical Trials Registry Platform (ICTRP) will be consulted where registry entries are unclear. India-site oncology or vaccination trials registered 2020–2024 will be included. The following data will be extracted: trial identifiers, year, design, sponsor, sample size, recruitment setting, sex numerators, rural reach, tribal inclusion, and linked publication status. Transparency will be graded using a six-domain ETI adapted from the REP-EQUITY toolkit. Proportions will be meta-analysed under random effects (REML) with Hartung–Knapp confidence intervals; heterogeneity assessed by I^2. Planned subgroups include trial type, domain, and sponsor.

Keywords: Access to trials, Health equity, Healthcare research, Recruitment barriers, Vaccination studies

INTRODUCTION

Achieving equity in health research goes beyond by simply including diverse populations in clinical trials. It also requires fair distribution of both the benefits and burdens of research participation [1,2]. In the context of the Coronavirus Disease-2019 (COVID-19) pandemic, researchers have asserted that conducting research without a careful emphasis on equity risks perpetuating global health inequities [1]. This is most worrying when trials are outsourced to Low-and Middle-Income (LMIC) nations, where there may be insufficient safeguards for participant welfare and limited access to post-trial benefits [1]. Despite growing awareness, clinical research has repeatedly failed to include socioeconomically and demographically diverse participants, especially in LMIC such as India [3]. To address this gap, equitable research design must critically evaluate recruitment practices, the allocation of burdens among participants, and the accessibility of the innovation derived from the research to those who have taken the risk of participation [1].

Globally and in India, tribals, rural populations, and women are disproportionately underrepresented in clinical trials. According to the Census of India (2011a), 68.8% of the population resides in rural areas [4]. India's tribal communities, officially known as 'Scheduled Tribes' comprise 104 million individuals, or 8.6% of the population [5] and women, constitute almost half (48.6%) of India's population [4].

However, when it comes to the equitable inclusion of women in therapeutic cancer clinical trials, they are significantly underrepresented globally [6]. Similarly, in the Indian context, women's involvement in health research is largely confined to maternal and reproductive health studies [7]. Even when trials recruit participants of different sexes, very few actually conduct sex-specific subgroup analyses or evaluate outcomes by gender, leaving trial data vulnerable to bias and limiting their interpretability [8]. The situation is similar, if not more severe, for rural and tribal populations. Research funding, institutional infrastructure and clinical trials remain concentrated in urban centres and elite institutions, leaving rural contexts largely invisible in the evidence base [9-11]. Due to such marginalised representation of rural populations, it becomes difficult to translate findings into effective interventions within these communities. Moreover, India's tribal population experience a disproportionately high burden of disease and poorer health outcomes compared to non tribal populations [8]. They experience geographic marginalisation and socio-cultural exclusion, and their presence is often missing from national health data systems [12]. Although some gains have been made in tribal health outcomes in recent years, the research underpinning these changes is sparse and insufficiently tailored to their unique lived realities [9]. All together, such exclusions are a reason for grave concern for the generalisability of research as well as the potential for health inequities in health outcomes, access to healthcare, and public confidence in the research process [10,11].

REVIEW OF LITERATURE

Ensuring equitable representation has become especially important in key public health areas like oncology and vaccination [6,13].

Cancer continues to be one of the leading causes of death in India, with its incidence projected to rise from 529.40 per 100,000 individuals in 2022 to 549.17 by 2031 [14]. Vaccination, meanwhile, remains a central pillar of India's public health efforts. Flagship programmes like the Universal Immunisation Programme and Mission Indradhanush currently reach over 2.6 crore infants (0-1 year) and 2.9 crore pregnant women each year [15]. As of year 2023-24, full immunisation coverage has reached 93.5% [16]. These initiatives are aimed at reducing health disparities by extending protection to populations that have historically been underserved. However, in reality, Cancer trials have been concentrated in urban tertiary institutes, which may contribute to the under-representation of socioeconomically disadvantaged, rural and tribal populations [17]. During the COVID-19 public health emergency, many vaccination trials also lacked safeguards to promote diverse participant recruitment [13,18]. This long-standing exclusion has significant implications for equity, ethics, and scientific validity. In areas like oncology, where disease progression, immune responses, and treatment access vary so profoundly between groups, inclusive recruitment is not an option; it is a requirement [19]. Otherwise, clinical findings risk being misapplied or less effective for groups that were inadequately represented. Moreover, these patterns of exclusion undermine foundational ethical principles such as justice and respect for persons, as outlined in the Belmont Report [20].

In such a context, the role of CTRI is crucial. Even though National ethical guidance has emphasised equity and justice in participant selection and protections for vulnerable groups [21], poor reporting practices in CTRI continue to obscure who is actually being represented. Even when trials are registered, essential demographic details, such as gender breakdown and rural or tribal representation, are often incomplete or entirely missing. Since updates after trial completion are not mandatory in India, much of the available data remains outdated or insufficient. Efforts to obtain missing demographic details from linked publications often yield inconsistent results, and a substantial number of trials remain unpublished. As noted by researchers [22], the combination of low publication rates and retrospective trial registrations in Indian cancer research continues to limit transparency, underscoring the need for dependable, quantitative data on the inclusion of underrepresented groups.

Recent Indian Council of Medical Research (ICMR) reporting highlights targeted support aligned with national research priorities across multiple sites, emphasising comprehensive regional and demographic representation [23]. However, empirical evidence quantifying under-representation in Indian clinical trials remains scarce. The present study protocol describes a systematic review to estimate the pooled proportion of women, rural, and tribal populations in oncology and vaccine trials registered from January 1, 2020, to December 31, 2024. This was a period, marked by the COVID-19 pandemic, that led to notable changes in research emphasis and enrolment practices globally [24]. The timeframe also coincided with the period when there was greater focus on inclusive approaches to research and better trial reporting standards, as reflected in recent policy recommendations and institutional efforts [2,23,25]. It is hoped that findings will be used to support more equity-informed trial design and serve to build a health research ecosystem in India which is more inclusive of disadvantaged populations. Thus, the present review aims to systematically estimate the pooled proportion of women, rural and tribal populations in oncology and vaccine trials.

Objective:

1. To quantify planned enrolment in trials that include ≥1 rural/PHC/community/outreach recruitment site.
2. For measuring the number of planned enrolments in clinical trials that specifically mention the inclusion or recruitment of scheduled tribes and women.
3. To describe patterns in equity-relevant reporting across all five domains of the ETI, including gender, rural/urban reach, tribal inclusion, geographic coverage, and Socioeconomic Status (SES), by trial domain (oncology versus vaccination) and other characteristics.

MATERIALS AND METHODS

This systematic review protocol complies with PRISMA-P guidelines [26].

Because post-trial updates on actual recruitment are not mandatory in the CTRI, this review systematically extracts demographic data based on the planned enrolment at the time of initial registration. Consequently, all eligible trials registered between 1 January 2020 and 31 December 2024 will be included in the analysis, regardless of their current ongoing or completed status. This protocol has received IEC approval (IIPHH/TRCIEC/442/2025) from IIPH-Hyderabad and is registered with PROSPERO (CRD420251086878). The primary source for registry data will be the CTRI, which is the designated national platform for registering clinical studies involving human participants. CTRI permits only a single keyword per query under a selected search criterion and does not support Boolean operators, truncation, special characters, or multi-term search strings. Therefore, separate single-keyword searches will be run under relevant CTRI criteria (primarily health condition/problem studied/ intervention).

Exact CTRI keywords (list format): Oncology keywords (each run as a separate CTRI query): cancer; oncology; tumour; carcinoma; chemotherapy; radiotherapy; neoplasm.

Vaccination keywords (each run as a separate CTRI query): vaccine; vaccination; immunisation.

Eligibility criteria:

(P)= Participants as human 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 1 January 2020 and 31 December 2024.

Exclusion criteria: Trials involving healthy volunteers will be excluded if they are designed solely for pharmacokinetic, biosimilarity, or drug safety testing, such as single-dose bioequivalence studies in healthy males. While scientifically valid, such trials are strictly regulatory in purpose; they do not involve true patient recruitment and do not contribute to questions of equity or trial accessibility. Additional exclusions will be made where trials lacked human participants, are unrelated to cancer or vaccination. These feasibility-based exclusions were informed by the pilot search experience, which highlighted frequent gaps in CTRI reporting, especially in demographic fields [22,27].

Given the inherent limitations of the CTRI interface, specifically the lack of bulk export functionality, records will be manually copied into Google Sheets. To ensure dataset accuracy and mitigate human error, the extracted data will be cross-verified by a second independent reviewer. De-duplication will be conducted using a rigorous two-step process to counter registry anomalies. First, programmatic de-duplication will be performed using Google Sheets' built-in data cleanup features, utilising the unique CTRI registration numbers as the primary identifier. Second, a manual screening of trial titles and secondary identifiers will be conducted to identify and remove any persistent duplicates. Consequently, when demographic fields (such as rural reach or tribal inclusion) are empty in the registry, these cells will not be left blank in our dataset. Instead, they will be explicitly coded as "Not specified."

A pilot CTRI search was performed in July 2025 to test feasibility (keyword: 'cancer'). Because CTRI lacks bulk export capabilities, all retrieved entries were manually tabulated into a Google Sheet. The dataset was subsequently de-duplicated and filtered by registration date (1 January 2020–31 December 2024). Full-text eligibility was then assessed, with exclusions made for non relevant records (e.g., wrong population, wrong country, or outside the equity scope). It was observed that several CTRI demographic fields were blank or outdated. Cross-verification with the WHO-ICTRP yielded minimal incremental data. Consequently, to identify missing demographic details (e.g., gender, tribal identity, rural recruitment), the extraction strategy will involve tracing exact CTRI registration numbers, trial titles, and investigator names across proprietary databases (PubMed/MEDLINE, Google Scholar, ProQuest). A publication was considered linked only if the CTRI ID is explicitly cited. When no publication was found, the trial was flagged as 'no linked publication retrievable.' These pilot observations directly informed the feasibility limits and extraction approach for the full systematic search.

Data Extraction

Data will be extracted directly from CTRI into a simple Excel template, which will retain the key information on the assessed variable related to the trial. The variables are: trial ID and title, year of registration, study type (interventional or observational), study phase (if applicable), study domain (oncology or vaccination), sponsoring institution and funding agency, geographic location of recruitment sites (if specified), target sample size, participant-level demographic information (gender distribution, rural/urban recruitment status, tribal identity or inclusion, and linked publication. Specifically for rural recruitment, sites will be classified based on Indian Public Health Standards (IPHS) definitions [28], and missing demographic data will be recorded as 'Not Specified'.

Quality Appraisal

As this study emphasises equity and demographic representativeness and not methodological quality or clinical outcomes, conventional risk of bias tools are not applicable. Instead, a study-specific Equity Transparency Index (ETI) derived from the REP-EQUITY Toolkit [2] will be used to measure transparency of reporting.

Completeness of reporting will be evaluated by ETI across five domains [Table/Fig-1]. To ensure reliability and standardise the assessment across reviewers, a pilot study on a random sample of 10 trials was conducted. Two reviewers independently scored these trials. An inter-rater reliability of Cohen's kappa k>0.80) was achieved, confirming the robustness of the criteria before proceeding with the full data extraction. Each domain will be given a score of 0 to 2 (2=Complete/Present with quantitative data; 1=Partial/Unclear; 0=Not Reported/Absent). This will give a total transparency score out of a possible 10. The studies will be classified into three groups according to their total scores: high transparency (8 to 10), moderate transparency (5 to 7), and low transparency (0 to 4).

Domain	Criteria	Scoring options	Trial score (to be filled)
Gender reporting	Does the trial report the number or percentage of male and female participants?	Complete/ Partial/ Absent	
Rural/urban representation	Does the trial specify rural vs urban recruitment settings?	Complete/ Partial/ Absent	
Tribal inclusion	Does the trial mention inclusion or exclusion of tribal populations?	Present/Not Present/ Unclear	
Geographic coverage	Are recruitment sites from multiple regions or just metro institutions?	Multi-regional / Single-region / Not stated	
Participant socio-economic indicators	Does the trial mention SES indicators (education, income, occupation)?	Present / Not Present	
Overall equity transparency score (optional)	Based on the above, how transparent is the trial in equity-related reporting?	High/Moderate/ Low	

[Table/Fig-1]: Quality appraisal criteria for assessing equity-relevant reporting in clinical trials.
Note: Adapted from equity domains described in Retzer A et al., (2023) [2], this checklist assesses the transparency of demographic and geographic representation in Indian oncology and vaccination trials

STATISTICAL ANALYSIS

Data will be analysed using R version 4.5.1. Extracted demographic proportions will be synthesised using random-effects meta-analysis with REML estimation of between-study variance (τ^2) and Hartung-Knapp adjustment for confidence intervals. Forest plots will be generated to present pooled estimates visually, and heterogeneity will be assessed using the I^2 statistic. If substantial heterogeneity is observed (e.g., $I^2 > 75\%$), potential sources will be explored using pre-specified subgroup analyses. If quantitative pooling is deemed inappropriate due to high clinical or statistical heterogeneity, the findings will be narratively synthesised rather than pooled.

Acknowledgement

We thank our institution, the Indian Institute of Public Health - Hyderabad (PHFI), for providing a supportive research environment.

We thank Dr. Nirupama A Y (MD, Community Medicine), Assistant Professor, Public Health Foundation of India - Indian Institute of Public Health, Hyderabad, for supervisory guidance and subject-matter inputs (life-course epidemiology, and health equity).

We also thank Dr. Varun Agiwal (PhD, Statistics), Assistant Professor, Public Health Foundation of India - Indian Institute of Public Health, Hyderabad, for methodological and statistical guidance.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Oct 03, 2025
- Manual Googling: Apr 10, 2026
- iThenticate Software: Apr 13, 2026 (1%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? NA
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Sep 30, 2025**
Date of Peer Review: **Jan 17, 2026**
Date of Acceptance: **Apr 16, 2026**
Date of Publishing: **Jun 01, 2026**