#2114: Racial and Ethnic Disparities in Enrollment to Breast Cancer Clinical Trials from 2000 to 2025

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Abstract

Background: Breast cancer (BC) remains the most common malignancy among women worldwide and is the leading cause of cancer-related mortality. Despite significant advances in treatment and an increase in clinical trial (CT) activity over the past two decades, equitable access to trials has not kept pace. Racial and ethnic disparities in trial enrollment persist, limiting the generalizability of findings and perpetuating outcome gaps. Non-Hispanic Black women, in particular, face higher BC mortality despite similar or lower incidence compared to non-Hispanic White women. Understanding trends in CT representation is essential to addressing these inequities. This study aimed to evaluate global enrollment patterns by race and ethnicity (R/E) in completed BC CTs.

Methods: We conducted a retrospective analysis of completed BC CTs registered on clinicaltrials.gov between 1/1/2000 and 6/1/2025. A total of 283 phase III-IV interventional studies were included. Trials were reviewed for reporting of R/E. The key outcome was to evaluate enrollment by R/E, in 5-year intervals to assess temporal trends. For each trial, the proportion of participants (pts) by R/E was extracted, and aggregate enrollment ratios were calculated across all reporting trials. Descriptive statistics were used for data analysis.

Results: Of the 283 eligible trials, 120 (42%) reported race and 63 (22%) reported ethnicity. Most studies were conducted in North America and Europe. Among trials reporting race, White pts were the most represented, while Native Hawaiian and Pacific Islander pts were the least represented. Temporal trends demonstrated a decrease in White race enrollment from 88.9% (2000-2005) to 66.7% (2015-2021), alongside an increase in Asian enrollment from 4.5% to 21.5% over the same period. Among the 63 trials reporting ethnicity, 62 included non-Hispanic and 56 included Hispanic pts. Non-Hispanic individuals accounted for 81.4% of total enrollment across these trials. Overall, 75% of all pts identified as White, while Black pts accounted for only 3.4. Notably, 15 trials reported only a single race, often reflecting geographic enrollment patterns.

Conclusions: Over the past 25 years, Black and Hispanic patients remained underrepresented in BC CTs. While modest improvements have occurred over time, particularly in Hispanic and Asian enrollment, persistent disparities limit the generalizability of trial findings and hinder progress toward equitable cancer care. This analysis is limited by the lack of standardization in how R/E are defined and reported, absence of geographic or population-adjusted benchmarks, and reliance on registry-reported data may underestimate disparities or mask regional variation. Greater transparency and standardization in demographic reporting, along with proactive efforts to diversify CT participation, are essential to ensure all patient populations are equitably represented in BC research.

Introduction

- Breast cancer (BC) remains the most common malignancy among women worldwide and is the leading cause of cancer-related mortality.
- Despite significant advances in treatment and an increase in clinical trial (CT) activity over the past two decades, equitable access to trials has not kept pace.
- Racial and ethnic disparities in trial enrollment persist, limiting the generalizability of findings and perpetuating outcome gaps.
- Non-Hispanic Black women, in particular, face higher BC mortality despite similar or lower incidence compared to non-Hispanic White women.
- Understanding trends in CT representation is essential to addressing these inequities.
- This study aimed to evaluate global enrollment patterns by race and ethnicity (R/E) in completed BC CTs.

Methods and Materials

- **Study design:**
  Retrospective analysis of completed BC CTs.
- **Data source:** ClinicalTrials.gov.
- **Study period:**
  Trials registered between **January 1, 2000 – June 1, 2025.**
- **Eligibility criteria:**
  Phase III–IV interventional studies (n=283)
- **Data extraction:**
  Trials were reviewed for reporting of race and ethnicity (R/E).
  For each trial, the proportion of participants by R/E was extracted.
- **Outcome measure:**
  Primary outcome: Enrollment distribution by **R/E**.
  Temporal trends evaluated in 5-year intervals (2000–2005, 2006–2010, 2011–2015, 2016–2020, 2021–2025).
- **Statistical analysis:**
  Aggregate enrollment ratios calculated across all reporting trials.
  Descriptive statistics used for data analysis.

Table 1. Demographic Representation and Enrollment Ratios in Breast Cancer Clinical Trials (1/1/2000 to 06/01/2025)

Racial Groups Represented, n(%)	Trials (n=120)		Participants (n=85,756)	
White	106	88.3	64,314	75
Asian	99	82.5	13,215	15.4
Black/African American	97	80.8	2,935	3.4
American Indian or Alaska Native	53	44.2	765	0.9
Native Hawaiian or Pacific Islander	33	27.5	91	0.1
Unknown	69	57.5	2,681	3.1
More Than One Race or Other(s)	55	45.8	1,755	2.1
Ethnicity Categories Represented, n(%)	**Trials (n=63)**		**Participants (n=29,830)**	
Non-Hispanic	62	98.4	24,290	81.4
Hispanic	56	88.9	3,290	11.1
Ethnicity Unknown	41	65.1	2,250	7.5

Future Directions

- Enhance transparency and standardization in demographic reporting.
- Develop population-adjusted benchmarks to contextualize enrollment trends.
- Implement targeted outreach and inclusive recruitment strategies to increase trial diversity.
- Ensure equitable representation of all patient populations in future BC clinical research.

Results

- **Total eligible trials:** 283
  Reported race: 120 (42%)
  Reported ethnicity: 60 (22%)
- **Geographic distribution:**
  Most studies were conducted in **North America** and **Europe**.
- **Race representation:**
  White pts were the most represented, while **Native Hawaiian and Pacific Islander pts** were the least represented.
- Temporal trends (2000–2021):
  White enrollment decreased from **88.9% → 66.7%**
  Asian enrollment increased from **4.5% → 21.5%**
- **Ethnicity** reporting (n=63):
  62 trials included **non-Hispanic** pts
  56 trials included **Hispanic** pts.
  Non-Hispanic individuals accounted for 81.4% of total enrollment across these trials.
  Overall, **75% of all pts identified as White**, while **Black pts** accounted for only **3.4.** Notably, **15 trials reported only a single race**, often reflecting geographic enrollment patterns.

Conclusions

- Black and Hispanic patients remained underrepresented in BC clinical trials over the past 25 years.
- Modest improvements observed in Hispanic and Asian enrollment over time.
- Persistent disparities continue to limit generalizability of trial results and hinder progress toward equitable cancer care.

- **Study limitations:**
  - Lack of standardized definitions for R/E.
  - Absence of geographic or population-adjusted benchmarks.
  - Reliance on registry-reported data, which may underestimate disparities or mask regional variation.

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References

1. Lipsyc-Sharf M, Ballman KV, Campbell JD, et al. Age, Body Mass Index, Tumor Subtype, and Racial and Ethnic Disparities in Breast Cancer Survival. JAMA Netw Open. 2023;6(10):e2339584. doi:10.1001/jamanetworkopen.2023.39584
2. Yedjou CG, Sims JN, Miele L, et al. Health and Racial Disparity in Breast Cancer. *Adv Exp Med Biol*. 2019;1152:31-49. doi:10.1007/978-3-030-20301-6_3

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