Evaluating CLL/SLL Clinical Trials:
A Participation-to-Prevalence Analysis Using Institutional and SEER Data from 2012-2024

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INTRODUCTION

- Chronic lymphocytic leukemia (CLL) is the most common adult leukemia. Clinical trials in the past decade have significantly improved treatment options.
- Underrepresented racial/ethnic populations have historically encountered barriers to trial enrollment.

OBJECTIVES

- Evaluate the demographic characteristics of CLL clinical trial participants at a National Cancer Institute (NCI)-designated Cancer Center in Northern California from 2012-2024
- Compare these characteristics to CLL prevalence in national and regional populations using NCI's Surveillance, Epidemiology, and End Results (SEER) data

METHODS

- **Study design.** Retrospective analysis of interventional trials involving adult participants with CLL at a single cancer center from 2012 to 2024.
- **Outcome.** Participation-to-prevalence ratios (PPR) calculated to assess demographic representation of trial participants compared to CLL prevalence data from the SEER 21 database.
- **Predictor.** Demographic data extracted from medical records: age, sex, race/ethnicity, preferred language, insurance, ZIP code.
- **Analysis.** Trials were cross-referenced with ClinicalTrials.gov and categorized by phase, therapy category, and primary endpoints.
  - PPR calculated at national and regional levels (nine-county Bay Area). PPR of 1.0 indicates proportional representation; <1.0 indicates underrepresentation, >1.0 indicates overrepresentation; 0.8-1.2 is interpreted as proportionate enrollment
  - Descriptive statistics summarized patient and trial characteristics.

The **underrepresentation of racial and ethnic groups** in CLL trials **highlights ongoing challenges in ensuring equal access** and **threatens generalizability of results** to broader patient populations.

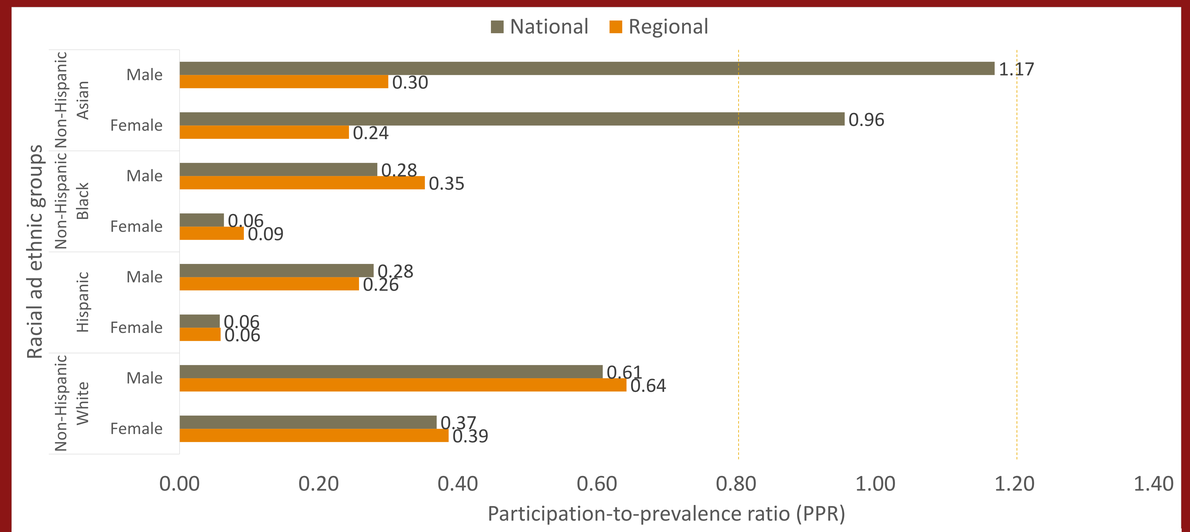

Figure 2. Participation-to-prevalence ratios by sex and race/ethnicity for clinical trials conducted at one institution compared to regional and national data

RESULTS

- **Demographics**. 212 unique patients participated in 30 clinical trials; 32 patients (15%) enrolled in multiple trials (total participations = 280) (**Table**).

Clinical Trial Participants	n=212 (%)
Male (%)	136 (64)
Median age, years [range]	66.6 [21.5-87.9]
Race	
Non-Hispanic Asian	11 (5)
Non-Hispanic Black	5 (2)
Hispanic	5 (2)
Non-Hispanic Other/Multi-racial	14 (7)
Non-Hispanic White	174 (82)
English as primary language	207 (98)
Median driving distance to academic center, km [range]	80.5 [3.2-4,829.7]

- **Trial characteristics**. 30 trials represented range of therapeutic strategies from 2012-2024 (**Figure 1**).

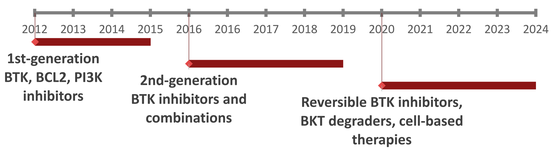

Figure 1. Evolution of clinical trials from 2012-2024

- **Enrollment Gaps.** Nationally, the largest gaps were in non-Hispanic Black and Hispanic females (PPR=0.06); non-Hispanic White females were also underrepresented (31% vs. 83%, PPR =0.37). Non-Hispanic Asian males (PPR=1.17) and Asian females (PPR=0.96) marginally surpassed or approached proportional representation (**Figure 2**).
  - Regionally, underrepresentation was seen across all groups, particularly Hispanic females (PPR=0.06), non-Hispanic Black females (PPR=0.09), non-Hispanic Asian females (PPR=0.24), and Hispanic males (PPR=0.26).

IMPLICATIONS

- Underrepresentation may limit the applicability of trial results across diverse patient groups and obscure differences in treatment responses among these subgroups.
- Racial and ethnic categorizations used in this study are based on NIH definitions and may not capture the ethnic diversity within ethnic subgroups. More detailed data collection would ensure clinical trails are representative and inclusive of all racial and ethnic groups.
- One-third of participants enrolled in multiple trials, indicating a limited pool of engaged individuals, highlighting systemic barriers to broader access and awareness.
- Enhancing equity and access will require intentional outreach, reduced logistical burdens, and structural support.

DISCLOSURES

None of the authors declare any relevant financial disclosures.

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