Lung Cancer Enrollment of Demographic Subgroups in US Clinical Trial Sites

**Authors:** Caroline Der-Nigoghossian<sup>1</sup>, Kevin Blum<sup>1</sup>, Evon Okidi<sup>1</sup>, Keith Fleming<sup>1</sup>, Cameron McClure<sup>2</sup>, Kim Doggett<sup>2</sup>

**Affiliations:** <sup>1</sup>Medidata Solutions, a Dassault Systèmes company, New York City, NY, USA <sup>2</sup>BeiGene, USA, Inc.

## Background:

Most clinical trials globally are not representative of a diverse patient population and 78% of trial participants remain White. This may limit the generalizability of trial results to the broader population, create an insufficient understanding of drugs' safety and efficacy between different patient populations, and hinder equitable access to investigational drugs. We compare the racial and ethnic composition of US clinical trials sites for lung cancer to epidemiology data.

## Methods:

The de-identified data was sourced from Medidata's clinical trial database. The cohort included clinical trial participants enrolled in US sites in phase 1-3 interventional lung cancer studies conducted between 2016 and 2022. Lung cancer incidence estimates were taken from the National Cancer Institute's incidence data. Sites were classified as at/above or below expected demographic composition based on a relative ratio calculation, RR = proportion of trial patients/proportion of population with lung cancer. RR >=1 means site recruited at/above expected ratio for the demographic group and vice versa. A 10% tolerance was used to capture minor deviations. A Mann-Whitney U test was used to determine if the two site types have statistically different enrollment rates, with a p-value of 0.05 for significance.

The analysis cohort consisted of 6,988 lung cancer patients from 85 studies and 876 US sites. Most sites enrolled White non-Hispanic patients at/above the epidemiological threshold. Conversely, the majority of sites enrolled non-White patients below the threshold (Table 1). The overall enrollment performance of sites enrolling a representative cohort of Black, American Indian and White patients did not differ from their counterparts. However, sites enrolling at or above the epidemiological threshold of Asian non-Hispanic and Hispanic patients had a higher enrollment rate than sites underrepresenting these patient populations.

## **Conclusion:**

The majority of US clinical trial sites underrepresent demographic subgroups except White non-Hispanic patients. Sites enrolling a representative pool of racial and ethnic demographic subgroups did not have a lower overall enrollment performance.

## Table 1. Enrollment Rate of Sites Recruiting At/Above vs. Below EpidemiologicalThreshold

Race/Ethnicity Sub-group	Enrollment Rate (pts/site/month) Median (IQR)				P-value
	Sites Enrolling At or Above Epidemiological Threshold		Sites Enrolling Below Epidemiological Threshold		
	N (%) sites	Enrollment Rate	N (%) sites	Enrollment Rate	
Asian (non-Hispanic)	67 (13%)	0.11 (0.03 - 0.23)	439 (87%)	0.04 (0.02 - 0.08)	<0.0001
Black (non-Hispanic)	96 (15%)	0.04 (0.02 - 0.08)	553 (85%)	0.04 (0.02 - 0.09)	0.99
American Indian (non-Hispanic)	6 (4%)	0.08 (0.06 - 0.12)	137 (96%)	0.04 (0.01 - 0.07)	0.19
White (non-Hispanic)	461 (59%)	0.04 (0.01 - 0.09)	326 (41%)	0.04 (0.02 - 0.07)	0.64
Hispanic	76 (14%)	0.07 (0.03 - 0.14)	447 (86%)	0.04 (0.02 - 0.08)	0.002