Abstract 8095: Lung cancer enrollment of demographic subgroups in US clinical trial sites

Evon Okidi[1], Caroline Der-Nigoghossian[1], Kevin Blum[1], Keith Fleming[1], Cameron McClure[2], Kim Doggett[2]
[1]Medidata Solutions, a Dassault Systèmes company, New York City, NY, USA; [2]BeOne Medicines, San Carlos, CA

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.

- **While majority of US clinical trial sites underrepresented 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.**
- **Results show that sites recruiting at or above epidemiologic threshold had similar or higher enrollment performance in general and therefore recruiting a representative set of patients does not reduce operational performance of a study but also makes results more generalizable.**

Methods

- We compare the racial and ethnic composition of US clinical trials sites for lung cancer to epidemiology data.
- De-identified data sourced from Medidata's clinical trial database.
- 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 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.
- 10% tolerance used to capture minor deviations. We used a Mann-Whitney U test with a p-value of 0.05 for significance.

Results

Race/Ethnicity Sub-group	Sites Enrolling At or Above Epidemiological Threshold		Sites Enrolling Below Epidemiological Threshold		
	# of Sites	Enrollment Rate	# of Sites	Enrollment Rate	P-value
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

- Data presented as median (IQR) or n (%); enrollment rate in pts/site/month
- Table shows proportion of sites that recruited at/above expected ratio for the demographic group (RR ≥1) and vice versa.

Future Directions

- Future research should evaluate barriers to proportional demographic representation in clinical trials and better understand differences in behavior across sites within the same geographic area and disease area specialists. These analyses would enable clinical trial participation that more accurately represents disease burden, and inform more effective recruitment efforts.

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Contact Information

Evon.Okidi@3ds.com