

Geographic relationship between lung cancer clinical trial sites and patient prevalence and demographics in the Medicare Fee-for-service program



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ABSTRACT

Racial and ethnic minority groups have low rates of inclusion in cancer clinical trials (CCTs). For example, African American patients comprise 5% of patients enrolled in CCTs that support US Food and Drug Administration approval of new drugs but represent 13.3% of the general US population. Though cancer is the leading cause of death for Asian Americans, only 3% of CCTs is composed of Asian American participants. With the promise and rise of precision medicine, it is critical that study populations in clinical research reflect the changing US

OBJECTIVES

To what extent does the current US CCT site placement for non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC) reflect the reality of lung cancer patient prevalence and demographics in the US?

METHODS

We used the following two primary data sources and conducted an overlap analysis and geo maps.

- Medicare Fee-for-Service (FFS) patient-level claims data from 2016, including the following data elements: prevalence, co-morbidities, hospital encounters, and costs for patients with ICD-10 codes for NSCLC and SCLC, by demographic (age, gender, race, and ethnicity). Locations were designated as high (greater than 0.87%) or low (less than 0.87%) prevalence, based on national average prevalence.
- CCT placement data was sourced from 2018 Clinical Trials.gov to determine ongoing NSCLC and SCLC studies where there are US study sites.
- Data were mapped on the Lung Cancer Index™, a National Minority Quality Forum (NMQF) geographic information system (GIS) with an interactive data warehouse and data visualization system, including geo-mapping.

RESULTS

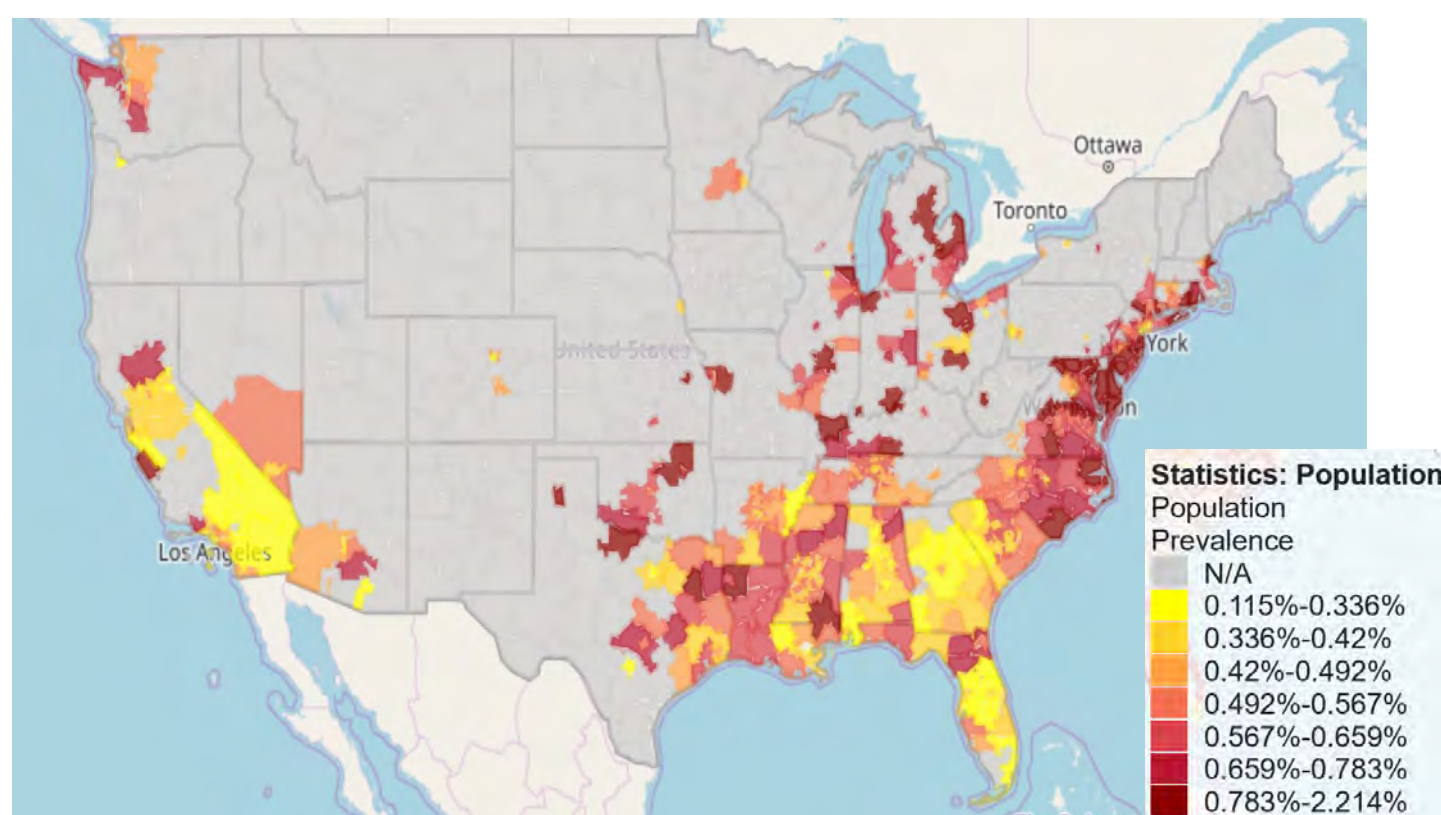
- Of the 2812 interventional CCTs, the study team mapped 495 therapeutic, interventional, currently enrolling CCTs (after excluding trials for behavioral interventions and palliative care).
- Of the 10,015 zip codes mapped, 58.8% of those were designated as zones of high prevalence (HP) of lung cancer. Of the 5,888 HP zip codes, only 10.5% had NSCLC trials and 5.6% percent had SCLC trials.
- When analyzed by counties, of the 59% of counties with high prevalence of African American patients, only 3% and 1% of counties had more than 10 NSCLC trials and 10 SCLC trials respectively.
- Similarly, of the 24% of counties with high prevalence of Asian American lung cancer patients, only 3% and 1% of counties had more than 10 NSCLC and 10 SCLC trials respectively.

CONCLUSIONS

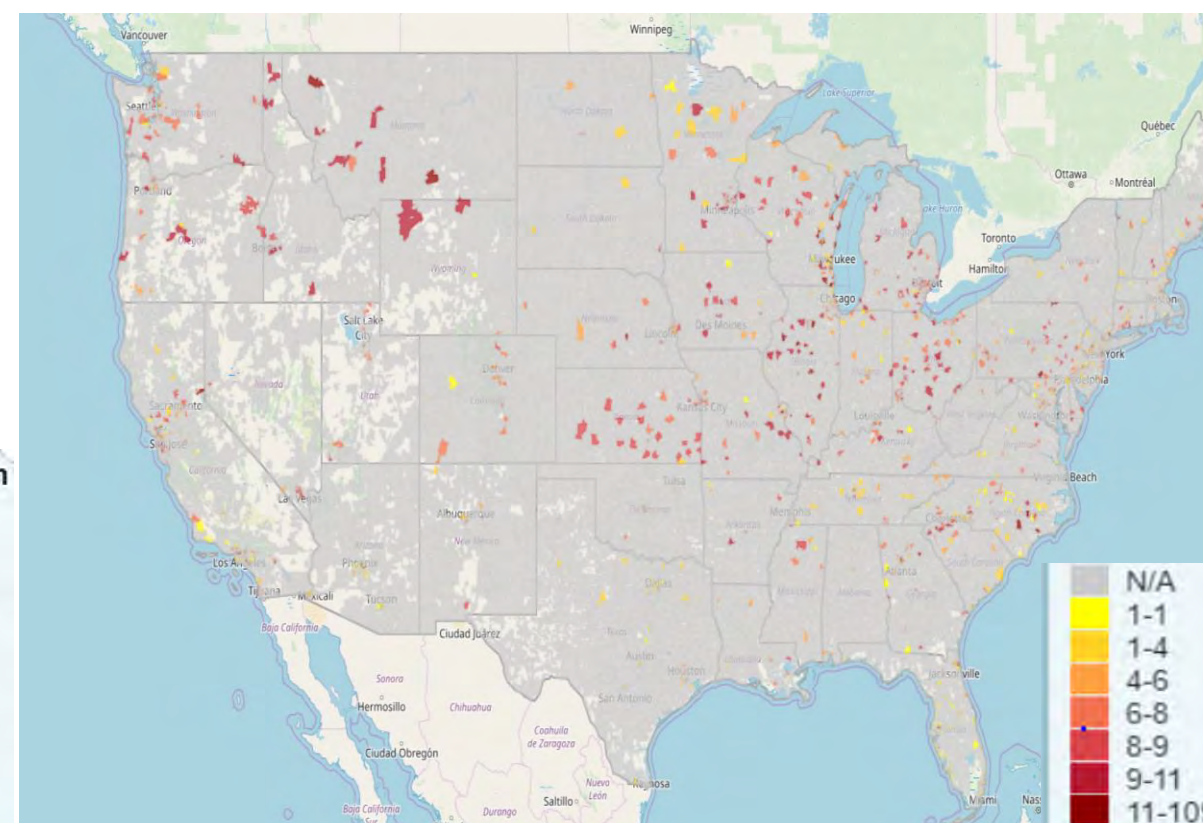
While additional analyses are ongoing, preliminary findings suggest that there is a major disconnect between US lung CCT placement and where patients with lung cancer, especially racial minorities live. The advent of precision medicine creates urgency to improve CCT enrollment of racial and ethnic minority groups, both for equitable benefit of resulting innovation and access to optimal treatment. Lung cancer prevalence, including by population demographics, at the zip code and county level can be a critical guide to CCT site placement.

REFERENCES

NMQF 2016 Lung Cancer Index, Medicare FSS {Database}



2016 Prevalence Lung CA in African Americans and Asian Americans 3 dig zip



2018 NSCLC, Trial Count by Zip (map shows actual zip outline)