Diversity in Phase I/II/III Lung Cancer Clinical Trials:
A Systematic Literature Review of Patient Racial Demographics

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BACKGROUND
Clinical research, in the United States, is undergoing a shift where the "one-size-fits-all" approach is being replaced with more personalized therapy. The makeup of oncology clinical trials in the United States does not reflect the diversity required to meet this goal.

Lung cancer is the second most prevalent cancer amongst both men and women. In 2016, 218,229 new cases were reported. Of those cases, approximately 40,650 were from minority backgrounds.

In order to help bridge the gap, the FDA, ASCO, and Individual states have taken specific measures aimed at increasing and maintaining minority enrollment.

RESULTS

SUMMARY OF BASELINE DEMOGRAPHICS FROM KEY LUNG CANCER TRIALS BETWEEN 2015 AND 2018

<table>
<thead>
<tr>
<th>Trial</th>
<th>Phase</th>
<th>Study Population</th>
<th>Men</th>
<th>Women</th>
<th>White</th>
<th>Black</th>
<th>Asian</th>
<th>Hispanic</th>
<th>Other</th>
<th>Caucasian</th>
<th>African-American</th>
<th>Native American</th>
<th>Other</th>
<th>Unknown</th>
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<td>A</td>
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<td>Phase 1</td>
<td>525</td>
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<tr>
<td>B</td>
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<td>18</td>
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<td>C</td>
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<td>D</td>
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<td>E</td>
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<td>5</td>
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<td>16</td>
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2016 CDC PERCENTAGES OF LUNG CANCER CASES BY RACE

<table>
<thead>
<tr>
<th>Race</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>83%</td>
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<tr>
<td>Black/African-American</td>
<td>11%</td>
</tr>
<tr>
<td>Native American/Alaska Native</td>
<td>1%</td>
</tr>
<tr>
<td>Asian</td>
<td>3%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>5%</td>
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</tbody>
</table>

OVERVIEW OF PATIENT’S RACIAL DEMOGRAPHICS BY TRIAL

- Of the 218,229 new cases of lung cancer reported by the CDC in 2016:
  - 83% were Caucasian
  - 11% were Black/African-American
  - 1% were Native American/Alaska Native
  - 3% were Asian
  - 5% were Hispanic

- For each respective trial reviewed, the percentage of minorities per study group is shown above and in the adjacent graph.

- With the exception of Asian minorities and Caucasians, representation in each clinical trial study group does not reflect real-world incidence data.

METHODS

Retrospectively identify completed clinical lung cancer trials conducted from 2015 to 2018 through PubMed search

- Protocol:	Conduct a systematic review of published clinical trials
- Inclusion Criteria:
  - Deaths
  - Bronchiolitis
  - Small cell or non-small cell lung cancer trials
  - Phase III trials
- Exclusion Criteria:
  - Protocol: Excluded trials with treatment regimens that are not targeted to specific racial or ethnic minorities

- Analyze racial demographic breakdown of total subject population from 12 trials compared to actual patient demographics

- Assess current barriers and potential strategies to increase patient diversity in clinical trials

- FDA - Food and Drug Administration
- NHI - National Institutes of Health
- ASCO - American Society of Clinical Oncology
- EHR - Electronic Health Record

LIMITATIONS AND STRATEGIES

Protocol Design Barrier
- The current study-centric model does not incorporate specific patient characteristics in study design which leads to significant recruitment barriers.

Investigator/Physician Network Barrier
- A majority of lung cancer clinical studies are conducted at large academic institutions.

Due to insurance barriers, minority groups are more likely to seek care at under-resourced hospitals.

Patient Awareness Barrier
- Less awareness of clinical studies is another reason for underrepresentation of minority groups in clinical studies.

- A root cause is language barriers and health literacy barriers.

CONCLUSION

- The 12 lung cancer clinical trials reviewed indicated a lack of diversity for enrolled patients.
  - 11 out of 12 (92%) trials fall below the 2016 patient demographics
  - 1 out of 12 (8%) trials came close to representing the 2016 patient demographics for Black/African American patients

- No representation was observed by Hispanic and Native American patients

- Potential strategies surrounding eliminating the existing barriers of protocol design, investigator/physician networks, and patient awareness

- Inclusion of diverse patient populations can be helpful to reflect the efficacy and safety of a therapeutic agent in specific racial groups, in order to maximize pharmacotherapy outcomes

AUTHOR CONTACT INFORMATION & DISCLOSURES
- The authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities.