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Race and ethnicity representation in clinical trials: findings from a literature review of Phase I oncology trials

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Aim: To provide an assessment of published literature on the demographic representation in Phase I trials of biopharmaceutical oncology agents. Materials & methods: We conducted a rapid evidence assessment to identify demographic representation reported in Phase I clinical trials for biopharmaceutical oncology agents published in 2019. Results: Globally, the population was predominantly White/Caucasian (62.2%). In the USA, the distribution was heavily skewed toward White/Caucasian (84.2%), with minimal representation of Blacks/African–Americans (7.3%), Asians (3.4%), Hispanics/Latinos (2.8%) or other race/ethnicity groups. Conclusion: Our data highlight that Phase I oncology trials do not reflect the population at large, which may perpetuate health disparities. Further research is needed to understand and address barriers to participation, particularly among under-represented groups

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Keywords: clinical trial • disparities • ethnicity • oncology • Phase I • race

Clinical trials provide answers to scientific questions that enable global regulatory agencies (i.e., the US FDA and the EMA) to evaluate the safety and efficacy of novel therapeutics, inform medical professionals on the use of new therapeutic agents, and make approval decisions. Clinical trial participation provides benefits both for participants and for informing drug development to improve treatment options for patients. It is important that clinical trials provide evidence regarding pharmacokinetics/pharmacodynamics, safety and efficacy of investigational treatments across different demographic populations. An important consideration in drug development is addressing health disparities (defined by Healthy People 2020 as ‘a particular type of health difference that is closely linked with social, economic and/or environmental disadvantage’) [1] which exist among racial or ethnic minority groups. These disparities can include health outcomes influenced by unequal access to health insurance, as well as differences in the incidence [2] and survival rates [3] for people with cancer. For example, there is a disproportionately higher incidence of multiple myeloma, colorectal cancer, triple negative breast cancer and prostate cancer in African–Americans, gastric cancer in Asians and Pacific Islanders, and cervical cancer in Hispanic and American–Indian/Alaska Native women [2]. Hence, there is a compelling need for clinical trials including oncology trials, to have an equitable representation of diverse racial and ethnic groups rather than the current over-representation of non-Hispanic White individuals.

A study published in 2018 reported on the racial/ethnic composition of individuals participating in biobanks, genomic studies and clinical trials [4]. Of patient-provided oncological samples, data on the donor’s race/ethnicity
was not reported (NR) for 48.3% of samples, and remaining specimens were from White (37.5%), Asian (10.0%), African–American (3.8%) and Hispanic (0.4%) donors. Of particular note is that among 416 cancer-related genome-wide association studies including more than 6.3 million samples, 92% of the samples were obtained from people of European descent [4]. This trend calls into question whether the effectiveness and safety of investigational drugs are tested in a broader percentage of the population that will eventually use the approved drug.

The FDA Safety and Innovation Act of 2012 (FDASIA) [5] directs the FDA to investigate the demographic representation (sex, age, race and ethnicity) of applications for medical products for both inclusion in clinical trials and for subgroup-specific safety and effectiveness data. Section 907 of the Act focused 27 actionable items into three priorities, which aim to increase the completeness and quality of demographic subgroup data, improve the public availability of demographic subgroup data, identify barriers to subgroup enrollment in clinical trials, and employ strategies to encourage greater participation. Additionally, in June 2019, under Section 610(a)(3) of the FDA 26 Reauthorization Act of 2017 (FDARA) (21 U.S.C. 360bbb note) [6], the FDA issued draft guidance to broaden eligibility criteria in clinical trials for drugs intended to treat rare diseases or conditions so as to avoid unnecessary population exclusions from clinical trials, develop eligibility criteria and improve clinical trial recruitment [7]. The overall aim of these measures is for participants enrolled in clinical trials to better reflect the population most likely to use the drug, if approved, while maintaining safety and effectiveness standards.

Although guidance has been introduced to increase the inclusion of racial/ethnic minorities in clinical trials, participation in oncology trials by individuals with these demographics remains low. For example, in 2019, 3593 patients participated in clinical trials used to generate evidence for FDA submissions for oncology drugs, resulting in the approvals of 11 new oncology therapeutics. Of these, the majority of participants were male (62%) and White (73%), as compared with Asian (18%), Black or African–American (4%), and Hispanic (5%). Just over half of participants (59%) were ≥65 years and approximately one quarter (24%) of participants were from US-based enrollment sites [8].

Eligible participants in Phase I oncology trials generally have advanced disease, with limited or no evidence-based treatments available [9], and inclusion in such trials is of benefit to a wide patient demography. Better representation of the population at large in Phase I trials should allow assessment of drug candidates in populations that are likely to receive the drug when marketed.

Objective
This manuscript reports a summary from a rapid evidence assessment (REA) of recently published Phase I clinical trials in clinical oncology. The primary objective of the REA was to conduct a descriptive assessment of published literature on the demographic representation in Phase I clinical trials of biopharmaceutical oncology agents.

Materials & methods
Search strategy
This REA was guided according to the principles of the Interim Guidance from the Cochrane Rapid Reviews Methods Group [10] and guidance from the University of York Centre for Reviews and Dissemination [11]. The REA employed a standardized, systematic and transparent approach to identify, describe, report and interpret published evidence in adherence with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol guidelines and as described in an a priori study protocol (unpublished). The search strategy was designed to identify current literature (published between January and December 2019) that reported the demographic representation of individuals recruited for Phase I clinical trials for biopharmaceutical oncology agents. Searches were run on 18 December 2019 in the following literature databases, for publications in English: Embase®, via Ovid, MEDLINE® (including in-process citations, etc.) via Ovid and PubMed. The full search strategy and number of identified hits for each database are presented in Supplementary Appendix 1.

Selection criteria & screening
The population, intervention, comparator, outcomes and study types included in the REA are described in Table 1. Publications that met the criteria described in Supplementary Appendix 2 were excluded. These included non-English publications, congress abstracts, studies of benign hematologic disorders, and reviews or meta-analyses.

One reviewer (K Smoyer) screened the titles and abstracts (level 1) of the references identified in the database searches against study inclusion/exclusion criteria; a second reviewer (C Rolland) conducted a 20% cross-check to
validate the screening. The same process was applied for the full-text (level 2) screen of the papers identified in level 1, including a 20% validation by a separate reviewer (C Rolland). Disagreements were discussed until consensus, or a third reviewer (I Jacobs, LJ Lee or J McGinnis) was consulted to make the final inclusion/exclusion decision.

Data extraction & reporting
One reviewer (G Bowden) extracted the data from the included manuscripts into a prespecified data extraction form, and a second reviewer (K Smoyer) validated 100% of the extractions. Discrepancies were resolved by consulting the original manuscript. Missing data were coded as ‘not reported’. Data are reported as a whole for all trials and stratified by three main regions as follows: the USA only, mixed (USA + ≥ 1 other country) and USA-excluded (any country other than the USA). Due to a relatively homogeneous population (90% or more Asian ethnic groups, or classified as ‘homogenous’ according to the CIA Factbook) [12], all participants in trials from the following single countries were classified as Asian if not otherwise specified: China, Japan, South Korea, Taiwan and Vietnam. Details of the data extraction and classification into regions are provided in Supplementary Appendix 3.

Patient counts for each demographic group were summed across the included Phase I trials and for the three regions. Data were tabulated for all participants, patients only and healthy volunteers, and are reported at the clinical trial level as well as the population level. The results presented here, however, mainly focus on those from clinical trials conducted in patients in the USA, in order to assess demographic representation in accordance with FDA guidance [5].

Results
Clinical trial characteristics
Out of 1431 references identified from the literature searches and undergoing title/abstract screening, 381 were retained for full-text screening, and 1050 were excluded. After full-text screen of 381 papers, 374 papers were included with a combined total of 16,763 participants. A complete list of included papers is provided in Supplementary Appendix 4. A summary of results from the database searches and publication selection process is presented in Figure 1. Characteristics of the included trials are summarized below (Table 2).

The proportion of males and females across all trials was balanced (48.7 and 47.7%, respectively). Gender was NR or not available in 13 (3.5%) studies, comprising 613 participants. Race or ethnicity was identified in 220 (58.8%) of the 374 Phase I oncology clinical trials assessed in this review, encompassing a total of 9972 participants. Among the 220 clinical trials with demographic data, the population was predominantly White/Caucasian (62.2%) (Table 3). Asian participants (29.9%) were predominantly from studies conducted in Asian countries (all participants classified as Asian). Black participants (3.9%) and Hispanic/Latino participants (1.2%) were under-represented.

US-only trials
A total of 139 trials was conducted in the USA only; 137 of these were in patients and two trials were in healthy subjects. Of the subset of Phase I oncology trials conducted in US patients, 64.2% reported race/ethnicity, representing 3197 patients. The distribution of patients in US trials was heavily skewed toward Whites (84.2%), with minimal representation of Blacks/African–Americans (7.3%), Asians (3.4%), Hispanics/Latinos (2.8%) or other race/ethnicity groups among the trials that reported race or ethnicity data (Table 4). Blacks and Hispanics, who account for an estimated 13.4 and 18.3% of the total US population, respectively, were under-represented in the clinical trials identified in this study, even though age-adjusted cancer rates are comparable to Whites.
Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram of publication selection process.

Table 2. Characteristics of Phase I oncology trials.

<table>
<thead>
<tr>
<th>Trial characteristic</th>
<th>Studies (n = 374), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I studies</td>
<td>374 (100.0)</td>
</tr>
<tr>
<td>– Studies in patients</td>
<td>367 (98.1)</td>
</tr>
<tr>
<td>– Studies in healthy subjects</td>
<td>7 (1.9)</td>
</tr>
<tr>
<td>First in human studies</td>
<td>89 (23.8)</td>
</tr>
<tr>
<td>Demographic characteristics</td>
<td></td>
</tr>
<tr>
<td>– Race/ethnicity reported</td>
<td>220 (58.8)</td>
</tr>
<tr>
<td>– Gender reported</td>
<td>361 (96.5)</td>
</tr>
<tr>
<td>Geography of trials</td>
<td></td>
</tr>
<tr>
<td>– US population only</td>
<td>139 (37.2)</td>
</tr>
<tr>
<td>– Ex-US population only</td>
<td>150 (40.1)</td>
</tr>
<tr>
<td>– Mixed US and ex-US population</td>
<td>79 (21.1)</td>
</tr>
<tr>
<td>– Unable to determine</td>
<td>6 (1.6)</td>
</tr>
<tr>
<td>Cancer type</td>
<td></td>
</tr>
<tr>
<td>– Solid malignancies</td>
<td>297 (79.4)</td>
</tr>
<tr>
<td>– Hematological malignancies</td>
<td>58 (15.5)</td>
</tr>
<tr>
<td>– Solid + hematological malignancies</td>
<td>12 (3.2)</td>
</tr>
<tr>
<td>– Conducted in healthy subjects</td>
<td>7 (1.9)</td>
</tr>
</tbody>
</table>

Solid malignancies: e.g., breast, lung colorectal, prostate, gastric and so on. Hematological malignancies: e.g., multiple myeloma, lymphomas, leukemias and so on. Ex-US: the USA-excluded.
Table 3. Race/ethnicity of participants in Phase I clinical trials in oncology: all regions globally.

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>All participants (n = 9972), n (%)</th>
<th>Patients (n = 9550), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total with race or ethnicity reported</td>
<td>9972 (100.0)</td>
<td>9550 (100.0)</td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>6198 (62.2)</td>
<td>6056 (63.4)</td>
</tr>
<tr>
<td>Black/African–American</td>
<td>388 (3.9)</td>
<td>371 (3.9)</td>
</tr>
<tr>
<td>Asian</td>
<td>2986 (29.9)</td>
<td>2734 (28.6)</td>
</tr>
<tr>
<td>Native Hawaiian/Pacific Islander</td>
<td>8 (0.1)</td>
<td>5 (0.1)</td>
</tr>
<tr>
<td>American–Indian/Native Alaskan</td>
<td>11 (0.1)</td>
<td>10 (0.1)</td>
</tr>
<tr>
<td>More than one race</td>
<td>11 (0.1)</td>
<td>4 (&lt;0.1)</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>321 (3.2)</td>
<td>321 (3.4)</td>
</tr>
<tr>
<td>Hispanic/Latino†</td>
<td>115 (1.2)</td>
<td>113 (1.2)</td>
</tr>
</tbody>
</table>

†Some studies reported Hispanic/Latino as a race category and some as an ethnicity; as a result the sum of participants by race/ethnicity category is greater than the total number of participants.

Table 4. Race/ethnicity of US patients in Phase I clinical trials in oncology compared with US demographics and cancer incidence.

<table>
<thead>
<tr>
<th>Race/ethnicity</th>
<th>US patients (%)</th>
<th>US Census† (%)</th>
<th>SEER data‡: 2013–2017 age-adjusted cancer incidence per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>White/Caucasian</td>
<td>84.2</td>
<td>76.5</td>
<td>452.1</td>
</tr>
<tr>
<td>Black/African–American</td>
<td>7.3</td>
<td>13.4</td>
<td>440.4</td>
</tr>
<tr>
<td>Asian</td>
<td>3.4</td>
<td>5.9</td>
<td>302.0</td>
</tr>
<tr>
<td>Native Hawaiian/Pacific Islander</td>
<td>0.1</td>
<td>0.2</td>
<td>NR§</td>
</tr>
<tr>
<td>American–Indian/Native Alaskan</td>
<td>0.1</td>
<td>1.3</td>
<td>310.1</td>
</tr>
<tr>
<td>More than one race</td>
<td>0.0</td>
<td>2.7</td>
<td>NR</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>3.7</td>
<td>–</td>
<td>NR</td>
</tr>
<tr>
<td>Hispanic/Latino†</td>
<td>2.8</td>
<td>18.3</td>
<td>348.4</td>
</tr>
</tbody>
</table>

‡Source: Surveillance, Epidemiology and End Results (SEER) Program. 5-Year age-adjusted incidence rates, 2013–2017 for all cancers (https://seer.cancer.gov/explorer/).
§Hawaiian/Pacific Islander included with Asian.
NR: Not reported; SEER: Surveillance, Epidemiology and End Result.

Participation of Native Hawaiian/Pacific Islander and American–Indian/Native Alaskan patients was extremely low.

Discussion

Our review of the literature published in 2019 found the demographic composition of the 220 Phase I oncology clinical trials (n = 9972), for which race or ethnicity was identifiable, to be predominantly White/Caucasian (62.2%), followed by Asian (29.9%). For clinical trials conducted in the USA only, and the main focus for this report, the distribution was heavily skewed toward Whites (84.2%), with minimal representation of Blacks/African–Americans (7.3%), Asians (3.4%), Hispanics/Latinos (2.8%) or other race/ethnicity groups among the trials that reported race or ethnicity data. Despite the introduction of FDA guidance to increase enrollment of under-represented groups in clinical trials, the results of this REA indicate that participation in recent Phase I oncology trials by individuals with these demographics remains low. Because patients in Phase I trials may potentially experience therapeutic benefits [13], inclusion of a broader patient population in Phase I trials can help ensure that diverse groups, regardless of race or ethnicity, benefit from new treatment options.

This review of Phase I trials published in 2019 further showed that the imbalance in racial representation in oncology trials observed at later phases continues to exist in earlier phase trials. This can lead to Phase I oncology trials that are not representative of the population most likely to benefit from new cancer treatments. The demographic findings of the current study are similar to a study by Ramamoorthy et al. of Phase I–III pivotal trials of drugs approved by the FDA between 2008 and 2013 for breast, colorectal, lung or prostate cancer [14]. In those trials, 79.7% of patients were White, 12.4% Asian and 3.8% Black/African–American; Hispanic/Latinos comprised 3.6% of patients in the included trials [14]. Our findings are also similar to those of a recent study by Loree et al. of clinical trials leading to FDA approvals for cancer drugs between 2008 and 2018, which reported
that 63% provided data on at least one racial group, with Whites representing 76.3%, Asians 18.3%, Blacks 3.1% and Hispanics 6.1% of clinical trial participants [19].

An analysis of 358 oncology trials comparing those sponsored by pharmaceutical companies versus the National Cancer Institute's National Clinical Trial's Network reported that the proportion of Black patients was 2.9% for pharmaceutical company-sponsored trials and 9.0% for National Clinical Trial's Network trials, significantly lower than their calculation that estimated 12.1% of the US cancer population are Black (the calculation was based on an adjusted analysis of Surveillance, Epidemiology and End Results data to reflect the US cancer population by weighting estimates based on national distributions of age, sex and race using US Census data). The findings were generally consistent across individual cancer types [16].

The lack of racial representation may perpetuate health disparities due to the disproportionately higher incidence of certain cancers among non-White, non-Hispanic populations. African–American males develop cancer 25% more frequently than White males and have a 43% higher mortality rate compared with White men for all cancers combined [17]. Furthermore, according to the CDC, African–American men “have more cancers of the lung, prostate, colon and rectum than do White men. Overall, African–American men have more malignant tumors and are less likely to survive cancer than the general population” [17], further highlighting the importance for higher inclusion of African–Americans and other demographic groups in Phase I oncology trials to better reflect the populations that are most likely to benefit from a drug. Our REA provides an initial broad look at demographic representation across recently published Phase I oncology trials within defined parameters. Future analyses could include additional considerations such as reporting on the number of studies that request biomarker or targeted mutation analyses for preselection, and if this varies by race for example.

Race/ethnicity was NR in over 40% of the Phase I oncology trial publications included in our analysis; without this information, it was not possible to assess demographic representation in those trials. A lack of reporting impedes efforts to increase diversity and serves to perpetuate the status quo. When collecting race/ethnicity data, the use of a standardized method should be encouraged, and ideally self-reported versus investigator assessed (also see Standards for maintaining, collecting, and presenting federal data on race and ethnicity) [18]. Publications should be more explicit and conscientious when reporting race and other useful demographic data. Equitable demographic representation is particularly important in clinical trials of cancers with racial/ethnicity differences in incidence and/or survival; however, sizable disparities in participation persist. All-cause cancer rates in the USA are high for African–Americans and are only slightly lower than for Whites [19]. A greater presence of African–Americans in oncology trials is needed to identify whether novel therapeutics show efficacy in this population, as well as to assess their safety profiles.

A lack of racial representation in oncology trials is an issue that has persisted for many years. In 2006 [20] a review of 163 Phase I participants from five major cancer centers in the USA reported that most participants were White (88%), had health insurance (96%) and many (66%) were financially secure (household income ≥$50,000). Only 3% were African–American and 4% were uninsured. The sociodemographic characteristics of the patients were similar to the characteristics of participants from other Phase I trials, but did not reflect those of the community. For example, at the time of the analysis, 12.3% of the US population was African–American according to the 2000 US Census [21]. Part of the reason underlying the disparities in representation, in addition to health insurance coverage/restrictions, could be due to barriers to participation in Phase I trials such as a lack of information due to the types of institutions where patients receive care, physicians not recommending participation or not spending enough time with patients, or patient mistrust. Also, Phase I trials, by definition, require more intensive visits, and thus access to a higher level of medical care. In a study using focus groups and interviews of US patients and community members in Louisiana, Davis et al. reported that although most were aware of clinical trials, they did not know about specific trials or where to find more information [22]. Recruitment of patients is often through an encounter with a participating physician or treatment center, which differs from healthy subject recruitment.

A qualitative study from the USA of patient visits to oncologists found that physicians spent less time with African–American than White patients and recommended that oncologists make an effort to discuss clinical trial participation, purpose and risks with patients, particularly African–Americans [23]. Another factor to consider is that Medicaid is not required by federal law to provide coverage for the routine care costs for patients participating in a clinical trial [24]. Since patients covered by Medicaid tend to be ethnic and racial minorities, women, children and rural populations, the lack of coverage for Medicaid enrollees in clinical trials may exacerbate under-representation of these groups in clinical trials.
In high-risk prostate cancer, multiple randomized clinical trials have shown that definitive therapy improves overall survival among patients. However, a recent publication reported that many patients do not receive definitive therapy because of sociodemographic and health-related factors [25]. In an analysis of factors associated with the receipt of nondefinitive therapy and survival among patients with high-risk prostate cancer, it was found that compared with White patients, Black and Hispanic patients were more likely to receive only systemic therapy, or not be treated at all. The most significant factors associated with receiving nondefinitive therapy were insurance status, race/ethnicity, median household income, and health- and disease-related factors, including tumor stage and medical comorbidity score [25]. In an analysis of the role of sociodemographic factors in treatment decisions for non-small-cell lung cancer, however, socioeconomic factors rather than race/ethnicity appeared to influence the refusal of cancer treatment in patients with stage IV non-small-cell lung cancer [26]. Various other reports have highlighted racial or ethnic disparities in cancer incidence, treatment and outcomes, across a broad range of cancer types [27–33].

Further research and dissemination of data highlighting the under-representation of ethnic minorities in Phase I clinical trials should help increase awareness. In this respect, the American Society of Clinical Oncology convened a working group, which resulted in a series of recommendations and position statement to increase participation in Phase I trials [13,34]. The key goals of these recommendations were: improve payers' coverage of routine patient costs in Phase I trials, improve patients’ and clinicians’ understanding of goals of Phase I trials, increase the number of patients who enroll in Phase I trials, increase researcher and trial sponsor compliance with best practices for Phase I trials and increase biopharmaceutical industry support of pediatric Phase I trials. Recommendation 2 suggested that the educational efforts of professional societies should target improving the ability of clinicians and researchers to explain the goals of Phase I cancer trials, including how to discuss the purposes and risk-benefit assessment to potential patient participants [13]. Recommendation 3 advised that professional societies should enhance educational materials for clinicians and researchers to help overcome challenges to Phase I trial enrollment, such as incomplete understanding of insurance coverage and attitudes that Phase I trials should be considered only after other treatment options fail [13]. There is also a need for more clinicians and researchers from under-represented groups, which may help build trust and confidence in trial participation. A recent report highlighted that although progress is being made in this respect, much work remains to be done in increasing the number of under-represented racial/ethnic groups in medical schools and faculty rosters [35].

This current review of Phase I trials that were published in 2019 reveals that the imbalance in racial representation seen in later phase oncology clinical trials is also present in earlier phase trials. This period was chosen given that it represented the most recent publications available at the time the REA was performed. Current barriers to participation may arise due to the types of institutions where patients receive care, physicians not recommending trials or not spending enough time with patients, health insurance coverage/restrictions, certain social determinants of health, or patient mistrust of clinical trials. As a result, many Phase I oncology trials are not representative of the general population, and this may perpetuate health disparities [36]. When taking the COVID-19 pandemic into account, which has disproportionately impacted communities of color and limited access to some trials, there is the potential for this imbalance to worsen. Conscious efforts are paramount to resolve these disparities in participation in Phase I oncology trials, which can provide access to novel therapeutics.

There are some limitations to our analyses: for example, by observing data from trials published over just 1 year, we were unable to track any longitudinal effects on disparities, although several other studies already discussed corroborate our findings. The unavailability of precise information on race/ethnicity in trials conducted in Asian countries is another limitation of this analysis and may over-represent the percentage of trials reporting race and the percentage of Asian subjects in clinical trials globally in this region. However, this did not affect the dataset from the USA.

**Conclusion**

Recruitment and retention of under-represented groups in Phase I oncology clinical trials is essential to ensure the demographics of participants reflect the wider population at large. A targeted strategy to recruit representative populations is needed, and further research is required in order to understand, and thus reduce, the barriers to participation, particularly among under-represented groups.
**Future perspective**

It is clear that an imbalance in racial or ethnic representation in Phase I oncology trials has been an issue for many years, and still persists today. Further research and publication of data highlighting this under-representation would help increase awareness. The recommendations and guidance from bodies such as American Society of Clinical Oncology, the FDA and other organizations, along with educational materials for clinicians and researchers should help overcome challenges to Phase I trial enrollment. Patients may also become more aware of available options through greater interaction with clinicians and researchers from under-represented groups, which may help build trust and confidence in trial participation.

**Summary points**

- Clinical trials provide answers on the safety and efficacy of novel therapeutics, inform medical professionals on the use of new therapeutic agents, and enable global regulatory agencies to make approval decisions.
- Clinical trials should enroll patients that are representative of the demographics of the population to be treated. However, the literature reports disparities in trial participation, particularly in the inclusion of racial and ethnic minorities.
- This study investigated demographic representation in Phase I oncology clinical trials of biopharmaceutical oncology agents published during 2019, with a particular focus on US-based trials.
- We employed a standardized approach to identify, describe, report and interpret published evidence in adherence with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol guidelines.
- Globally, race or ethnicity was identified in 220 (58.8%) of 374 Phase I oncology clinical trials assessed in this review, with a total of 9972 participants.
- Among the 220 clinical trials with demographic data, the population was predominantly White/Caucasian (62.2%), followed by Asian (29.9%), Black (3.9%) and Hispanic/Latino participants (1.2%) were under-represented.
- The distribution of patients in US trials was heavily skewed toward White/Caucasian (84.2%), with minimal representation of Blacks/African-Americans (7.3%), Asians (3.4%) and Hispanics/Latinos (2.8%).
- Many current barriers to participation may contribute to this disparity, such as the types of institutions where patients receive care, health insurance coverage/restrictions and certain social determinants of health. As a result, Phase I oncology trials are not always representative of the general population, and this may perpetuate health disparities.
- Recruitment and retention of under-represented groups in Phase I oncology clinical trials is essential to ensure the demographics of participants reflect the wider population at large. Focused strategies to recruit representative populations are needed, and further research is required in order to understand any barriers to participation.

**Supplementary data**

To view the supplementary data that accompany this paper please visit the journal website at: www.futuremedicine.com/doi/suppl/10.2217/fon-2020-1262

**Author contributions**

I Jacobs, LJ Lee, J McGinnis and KE Smoyer contributed to the design, planning and conception of the study, as well as data interpretation and manuscript development. DR Camidge, H Park, Z Askerova and Y Zakharia contributed to data interpretation and manuscript development. All authors reviewed manuscript drafts and have reviewed and approved the final version for submission.

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- Summary of race reporting and representation in clinical trials leading to drug approvals from 2008 to 2018, with data similar to our current analyses of 2019 publications.


- Highlights racial disparities in cancer care and mortality in the USA.


- Provides a summary of the demographic composition of participants in trials for new therapeutic oncology products approved by the FDA between 2008 and 2017, showing similar data to our current analyses of 2019 publications.


- Highlights racial disparities in cancer care and mortality in the USA.


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