COMMENTARY

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TO THE EDITOR:

Practical strategies for creating diversity, equity, inclusion, and access in cancer clinical research: DRIVE

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Introduction

Cancer is a leading cause of mortality in the United States. In 2021, 1 898 160 new cases and 608 570 deaths were projected to occur in the United States. Cancer mortality rate increased in the United States until 1991 but decreased in 2018 by 31% from its peak, with a reduction in cancer deaths by 3.2 million in this period. However, these improvements are not equally applicable to all races, with significant differences in cancer mortality rates between Black and White patients.[1] The 5-year relative survival rates for all cancers diagnosed between 2010 and 2016 were 68% (White patients) and 63% (Black patients).[2]

Wealth inequality contributes to disparities in cancer mortality rates among patients of different races owing to differences in exposure to risk factors and barriers to cancer care.[3] It stems from hundreds of years of structural racism, including residential, educational, and occupational segregation and discriminatory policies in criminal justice and housing, which have altered the balance of prosperity, security, and health.[4]

Disparities in cancer treatment, a major contributor to unpromising outcomes in cancer mortality can be related to the underrepresentation of Black patients and other racial minorities in clinical trials. Race reporting is frequently omitted in clinical trials, resulting in regulatory approval, but is worse in studies falling outside the regulatory purview. Between 2008 and 2018, only 7.8% of 230 trials (recruiting 112 293 patients) documented the 4 major races in the United States, and 25.2% reported racial subgroup analyses. The actual representation of trial participants was (1) 76.3% White, (2) 18.3% Asian, (3) 3.1% Black, and (4) 6.1% Hispanic, largely underrepresenting the proportion of cancer incidence in the United States for Black and Hispanic patients (22% and 44%, respectively) compared with White and Asian patients (98% and 43.8%, respectively).[5] This gap in representation is worse for specific tumor types, particularly in prevalence-adjusted participation for cancers that are more common in African American patients.[6] Pooled data from 9 large cooperative group clinical trials of newly diagnosed multiple myeloma cases for more than 2 decades showed only 18% of participants were non-White,[7] shocking for a disease with incidence rates double for Black patients than those seen in White patients (15.9 vs 7.5 cases per 100 000); this trend also extends to mortality rates (5.6 vs 2.4 multiple myeloma deaths per 100 000) for African American patients compared with White patients.[8,9] In addition, in pivotal trials leading to regulatory approval of immune checkpoint inhibitors in the United States, Black patients constituted <4% of enrollees in lung cancer trials, with similar underrepresentation observed in renal cell carcinoma and other tumor types. This issue is particularly problematic because clinical responses to immunotherapeutic agents are dependent on unique, individual, frequently racially determined, genetically mediated host and tumor-biological interactions.[10] A study of 358 trials (85 pharmaceutical company-sponsored trials and 273 Southwest Oncology Group [SWOG] Cancer Research Network trials) comprising 93 825 patients (pharmaceutical

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company-sponsored trials, 46 313; SWOG trials, 47 512) for 15 cancer types between 2008 and 2018 also found a significant underrepresentation of Black patients in pharmaceutical company-sponsored trials compared with SWOG trials (2.9% vs 9.0%), which was consistent across individual cancer types.[11] This debunks the myth that underrepresentation of Black patients in clinical trials is due to the refusal of African American patients to participate in clinical research and argues for appropriate steps to be taken to promote racial diversity in research.

The absence of diversity in genomic trials designed to establish potential benefits in breast cancer therapy results in an underestimation of the risk of relapse in Black patients with breast cancer, further confirming the pervasiveness and clinical implications of the lack of minority representation in treatment and nontreatment cancer research.[12]

Recent worldwide social events have highlighted the need to remove structural barriers to diversity and equity in all spheres of life, leading to the publication of position papers from all major cancer societies and organizations[13] such as the American Society of Clinical Oncology (ASCO),[14] American Association for Cancer Research (AACR),[15] American Cancer Society,[16] American Society of Hematology (ASH),[17] the Food and Drug Administration (FDA),[18] and the pharmaceutical industry.[19] However, despite this, plenary and podium presentations at the 2020 and 2021 annual meetings of ASCO and ASH have continued to highlight studies with significant underrepresentation of racial minorities, particularly African Americans, Native Americans, and Hispanics, clearly indicating a lack of progress. An important example is the ZUMA-7 trial of chimeric antigen receptor (CAR) T-cell therapy in relapsed diffuse large cell lymphoma presented in the plenary session of the ASH 2021 conference and simultaneously published,[20] in which <1% of the enrolled patients were African American but which had a declaratory conclusion of a "new standard of care" notwithstanding human leukocyte antigen polymorphisms across racial groups that could affect results across races and potentially render these results invalid and thus preclude the broad conclusion reached. This study and similar studies not only fail in diversity, equity, inclusion, and accessibility (DEIA) but are scientifically invalid in their conclusions, which have major implications for the patients we all care for. Other consequences are an inability to evaluate treatment-related severe adverse effects (SAEs) that could differ between races and immunologically diverse ethnicities. Additional examples include studies of Bruton's tyrosine kinase inhibitors in hematologic malignancies, with hypertension being a major SAE but with a minimal representation of Black patients, who have a higher prevalence of hypertension or checkpoint inhibitors that are associated with diabetes, and a significant underrepresentation of Hispanic and Native American populations, who have a higher incidence of diabetes, thus underreporting the potential risks in these populations with significant human and economic consequences. Such deleterious effects are borne by both the excluded minorities and the broader population, who are ultimately saddled with the cost and economic burden engendered as a result. Coronavirus disease 2019 (COVID-19) has further exacerbated these disparities in the United States and globally, particularly in racial and ethnic minorities and socioeconomically disadvantaged groups who have borne a disproportionate burden of illness and death.[21] Recommendations for obtaining post-marketing data in minority groups may be considered by many as a "step in the right direction," but as a standalone solution, it creates a "separate but equal" outcome, an unacceptable doctrine prohibited by the US Supreme Court in *Brown v. Board of Education* in 1954.[22]

Methods

DRIVE: practical steps to promote DEIA in clinical cancer research

As a result of these poor outcomes with their resultant implications and the need for grassroots and community action, Indy Hematology Education Inc (IHE), a 501(c) non-profit organization incorporated to promote education and advocacy, has established a practical 5-step initiative to promote DEIA in cancer research.

The acronym DRIVE stands for diversity officer for clinical research studies; ranking of clinical studies for diversity; individual diversity, equity, inclusion, and access plan; verification of study diversity; and elevate and enhanced training of minority investigators and research team members.

D: diversity officer for clinical research studies

Currently, most clinical trials include an obligatory statement on diversity with targets that are frequently not reached. A major contributor to this is that these studies do not have an official tasked with ensuring that goals are prospectively established, monitored, and when necessary, modified, adjusted, or amended to reach the intended target. The safety of human participants is recognized as essential and paramount, resulting in the Greenberg Report of 1967, leading to the mandatory establishment of data and safety monitoring boards (DSMBs) that are required to provide independent oversight of major studies[23] with the achievement of the objectives of the report, except for ensuring that clinical data results apply to all mankind. Good clinical studies, as defined by the Greenberg Report, include the following: the problem to be studied is an important one that must be resolved (1) from a purely scientific point of view and/or (2) for the benefit of mankind through improved methods of prevention, diagnosis, and or therapy.[24]

Major corporations have chief diversity officers as strategists to promote their DEIA efforts, a concept that can be applied in clinical cancer research as well. We recommend that all clinical trials for cancer appoint a diversity officer with the responsibility of ensuring that diversity goals are reached.

Responsibilities of a diversity officer are (1) to prospectively develop an achievable, flexible and monitorable DEIA plan with accrual goals for diverse populations in cancer clinical research trials as required in the National Institutes of Health trials; (2) to establish an infrastructure to monitor and adjust recruitment efforts prospectively, including, when necessary, countries outside the United States to promote diversity goals, particularly in African countries where the infrastructure may not already exist; (3) to identify impediments to meeting accrual goals at the micro and macro levels with the proposed solutions, including removal of exclusion criteria that disproportionately affect minorities but may not affect clinical trial results; (4) to develop culturally appropriate study materials to promote minority accrual; (5) to identify potential scientific questions and study design solutions to answer for mankind and improve methods of prevention, diagnosis, and

therapy in keeping with the Greenberg principles; and (6) to advise the study sponsor(s), principal investigators (PIs) and the steering committee on potential challenges and solutions.

Qualifications of the diversity officer include (1) being trained in cancer research; (2) being trained in cultural awareness, sensitivity, appropriateness, and diversity; (3) having an understanding of the historical factors precluding potential enrollment in clinical trials including but not limited to the Tuskegee syphilis study[25] and the Nuremberg Code[26]; and (4) leadership.

Training of diversity officers. Training programs must be developed, established, and funded by study sponsors for diversity officers at the academic centers or organizations promoting the principles of DEIA in clinical research in the following core areas: (1) clinical study design and statistics; (2) historical issues relating to diversity: slavery, racism, sexism, gender, and sexuality, with particular attention paid to understanding the Tuskegee syphilis study and the Nuremberg human experiments; (3) regulatory law and practice; (4) cultural sensitivity and awareness training; (5) understanding the interplay between safety and diversity, and an understanding of the Greenberg Report; (6) understanding the economic impact and implications of clinical research diversity; (7) understanding the social construction including cultural factors and drivers in diverse communities; (8) understanding economic promoters and inhibitors of research participation in diverse communities; and (9) leadership.

Elements of the diversity plan in cancer research as established in the AACR recommendations for myeloma clinical research, should include concrete epidemiologically based accrual targets, with well-designed postapproval studies in which data gaps exist, with modeling to reach scientifically valid conclusions.

R: ranking of clinical studies for diversity (DRIVE rank and composite rank)

The world is not governed by force but by moral persuasion, with information being the currency. Ranking is the informational tool for measuring and comparing groups in most endeavors of humankind but is also used to encourage positive change for the desired goal. Global performance indicators (GPIs) that rate and rank states relative to 1 another help in shaping decisions. This power has been used by the World Bank (WB), which has marshaled the ease of doing business (EDB) index to influence global regulatory policies, a domain over which it has no explicit mandate and there is ideological contestation too. GPI rankings have been used by the WB to effectuate positive changes among nation-states and international institutions. Creators of GPI also aim to set standards of appropriate behavior, change policy outputs, and ultimately, outcomes. Therefore, the WB's EDB index motivates reforms, even above and beyond what is expected from consulting with or borrowing alone has demonstrated.[27]

A single rank is easily understood and creates pressure for reform. As in sports, once you start keeping score, everyone wants to win.[28]

The ranking of clinical studies for diversity (DRIVE rank**),** based on the achievement of representation of minority participants relative to the epidemiology of the disease, is an informational tool to evaluate DEIA efforts and provide a readily accessible measurement of the applicability of clinical data to all patient subgroups with the potential to force positive changes to promote DEIA and the health of mankind. We propose a standardized ranking of 0 to 5 for diversity, as shown in Table 1.

Table 1. Rank score for clinical trials

Drive rank score	Racial or nationality enrollment of the sum of all minority groups relative to the epidemiology of the disease in studies*
0	≤20% of the sum of all minority groups relative to the epidemiology of the disease.
1	21%-40%, the sum total of all minority groups relative to the epidemiology of the disease, and at least 1 minority group† reaching 50% relative to the epidemiology of the disease.
2	21%-40%, the sum of all minority groups relative to the epidemiology of the disease, and at least 2 minority group† reaching 50% relative to the epidemiology of the disease.
3	41%-60%, the sum of all minority groups relative to the epidemiology of the disease, and at least 2 minority groups reaching 60% relative to the epidemiology of the disease.
4	61%-80%, the sum of all minority groups relative to the epidemiology of the disease, and at least 3 minority groups reaching 60% relative to the epidemiology of the disease.
5	80%, the sum of all minority groups relative to the epidemiology of the disease, and at least 3 minority groups reaching 80% relative to the epidemiology of the disease.

*Studies will be ranked at the next lower rank if not all criteria for next higher rank are reached.

†Minority groups in the United States are self-defined by the participants and are listed as follows: African American or Black, Native American, Asian, Hispanic, and others. In other countries, minorities should be defined as appropriate, based on societal norms and internationally medically acceptable groups/nationalities.

Utility and reporting of rankings

1. Rankings should be reported by authors and be required for all abstracts presented at major medical meetings and required for publication in peer-reviewed journals and favorably included in each journal impact factor assessment[29] when these proposed rankings of clinical studies are used as a factor in the review of manuscripts for possible publication.
2. Establish a reportable corporate ranking system (DRIVE score) for pharmaceutical companies based on the diversity of clinical data from the totality of studies from each company, which can inform the choice of ethical investors.

I: individual strategy for promoting DEIA in clinical cancer research

The modern Hippocratic oath begins with "I," and similarly diversity can only be achieved with each team member embracing DEIA efforts. An individual's diversity plan is central to this altruistic and self-preserving desire. Achieving diversity in medical research is beneficial for minority and majority populations, both for individual, economic, and scientific reasons. The individual diversity plan should include the following: (1) understand and address unconscious bias and develop strategies to overcome these issues in the immediate environment, community, and in practice; (2) implement

a cultural competency plan and remove communication barriers. (cultural competency is defined as the healthcare providers' ability to function effectively in the context of cultural differences[30,31]); (3) self-education on the historical, structural, and systemic effects of racism, redlining, and economic factors precluding or preventing enrollment in clinical trials with their applicability to the community; and (4) develop a diverse workforce and research teams and enhance your organizational DEIA plans.

V: verification of diversity in clinical research studies

Diversity reporting should be based on self-reporting by the clinical research team; however, robust strategies for auditing data should be in place, as it would be used by internal organizations, institutional review boards (IRBs), DSMBs, and regulatory agencies to review safety with robust sanctions for malfeasance.[32]

Studies with a verified minimal threshold (DRIVE score ≥ 3) are a requirement for podium presentations at major medical meetings and publications in journals with a high impact factor.

E: elevate and enhanced training of a diverse research and clinical team

Medical and research team diversity has been shown to improve the likelihood of achieving diversity goals in clinical research.[33] Clinical team diversity improves outcomes and compliance, as a result, the Liaison Committee on Medical Education (LCME) of the US Department of Education, which accredits the United States and Canadian allopathic medical schools, has diversity accreditation standards that mandate students from diverse backgrounds and programs to broaden diversity among qualified applicants.[34] In contrast, accreditation of clinical research sites does not require diversity of investigators, research coordinators, navigators, and team members; thus, most study sites do not meet the lofty goals of the LCME.

Scholarships, grants, and funding mechanisms should be established to train minority/diverse investigators and non-minority investigators practicing in minority communities. Training should include physicians, advanced providers, nurses, social workers, pharmacists, navigators, medical assistants, students, and other members of the clinical and research team, with enhanced funding and training of potential investigators in historically Black colleges and medical schools ensuring that various cultures and voices are included at the point of recruitment.

The funding sources for training could be the establishment of a research diversity fund by the pharmaceutical industry, philanthropy, and government agencies. Examples of these are emerging as collaborations between the pharmaceutical industry and major medical societies.[35]

Study leadership should be diverse for the race, gender, cultural, and economic status, using the same principles as elucidated by the LCME[36] and in determining membership of study steering committees, DSMBs, PIs, IRBs, authorships, medical journal peer reviewers, editorial board members, and editors-in-chief.

Finally, the requirement of diversity from regulatory agencies, journal editors-in-chief, major medical societies studying PIs, and study teams will further promote this goal. In the United States, FDA regulatory enhancements will certainly promote research diversity and the current guidance[37] is a step in the right direction, but more is required to achieve these goals.

Discussion

Global issues associated with DEIA have long been identified across healthcare; however, research studies have shown little quantitative progress. Impactful change lies in deliberate actions, as suggested by the DRIVE initiative. Each practical step has been outlined to illustrate and emphasize problems within the current system, while simultaneously offering directives to achieve the long-established but not yet reached DEIA goals of the medical field.

Continuing to discuss and analyze these issues rather than actively working to solve them produces dangers that are evident in the adverse outcomes experienced by minority groups excluded from therapy studies. However, actions directed at the improvement of DEIA across clinical research are important for the improvement of all people. The DRIVE initiative offers a comprehensive approach to lead the field of cancer research to more significant and widely applicable solutions. The emphasis on cancer research allows providers serving this population to be trailblazers and serve as examples to other specialties, concretely demonstrating the positive outcomes associated with making the changes outlined in DRIVE. The action items outlined in the initiative value creating long-term permanent shifts in behavior, and enacting DRIVE will have a ripple effect on medical research, education, and treatment. Informed, care providers will practice with a greater intention to provide their patients with superior, more individualized treatment.

DRIVE is an initiative based on data and evidence obtained from other successful groups/agencies. The infrastructure necessary for this type of structurally remodeling cancer research exists already, but in part; therefore, structural change cannot be fully enacted without the implementation of each part together. Although the individual action items in DRIVE are valuable on their own, when executed concurrently, they have the power to elevate DEIA in clinical cancer research. Similarly, the DRIVE initiative can be impactful on a small scale, but the magnitude of change it is intended to bring is not possible without the direct commitment from the major cancer societies and FDA. The implementation of DRIVE to an appropriate scale requires significant, consistent funding, which is possible with tangible collaboration efforts along with financial and intellectual investments.

IHE, the corporation responsible for the DRIVE initiative, now requires that all data presented at its annual hematology review[38] to include rankings. IHE also hosted a summit of stakeholders in September 2022 to formally adopt the initiative's steps and inaugurate "The Indianapolis Black Paper" based on these principles to establish scale and promote DEIA in cancer research, with measurable goals and ultimately eradicate inequalities of cancer care in keeping with the Greenberg principles.

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Squibb & Sons, L.L.C., AstraZeneca Pharmaceuticals LP, Sanofi, Diachi Sancho, MorphoSys, Regeneron, Glaxo Oncology, Seagen, CTI, and Blue Medicines, and the advisory boards of Array Biopharma Inc., Lilly Oncology, Janssen Scientific Affairs, LLC, Epizyme, TG Therapeutics, Regeneron, Janssen, AbbVie, Takeda, and Sanofi. M.N.B. declares no competing financial interest.

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