Enhancing Clinical Decision Making in Cancer Treatment Through DRIVE Scores

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Summary

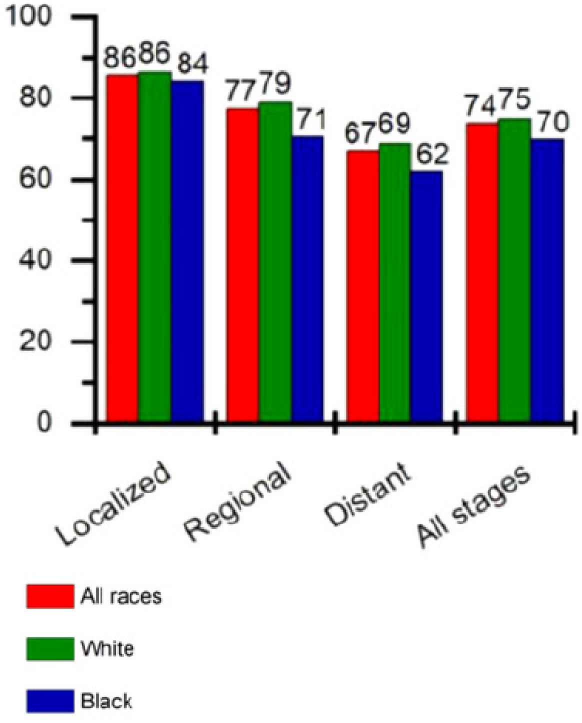
Over the past two decades, there have been major efforts to draw attention to the inequities in medical oncology research. Available data indicates that five-year relative survival rates for all cancer types diagnosed between 2010–2016 disproportionally favor Whites over Blacks, 68% and 63%, respectively (Howlader et al., 2020). Disparities in cancer treatment, a major contributor to diminished outcomes in cancer mortality, may be related to the underrepresentation of ethnic minorities in clinical research. The DRIVE score is an informational tool created to assess how closely a cancer clinical trial reflects the epidemiological demographics of the disease it researches (Birhiray & Birhiray, 2022). Use of the DRIVE Score can inform the medical decision-making of practicing clinicians and further dismantle medical mistrust amongst cancer patients.

Public Problem

Despite significant efforts to address inequities in oncology research, the underrepresentation of minoritized populations in clinical research enforces persisting disparities in cancer treatment and contributes to poorer cancer mortality outcomes (Birhiray & Birhiray, 2023). Clinical trial disparities result in the creation of three main problems of healthcare data: data absenteeism (lack of representation from underprivileged groups), data chauvinism (faith in the size of data without considering quality and contexts), and, in its most extreme form, therapeutic misconceptions (the assumption that approved drugs with promising clinical trial data have demonstrated effectiveness across all patient populations). The DRIVE Score utilizes a six-point system to identify major clinical studies that meet representation goals. This brief will discuss trends in clinical trial disparities, policy considerations, clinical and societal implications, and recommendations.

Trends

Disparities in clinical trials: Race reporting is frequently omitted in clinical trials, resulting in regulatory approval, but this omission is even more prevalent in studies outside regulatory purview. This gap in representation is worse for specific tumor types, particularly in prevalence-adjusted participation for cancers that are more common in African Americans (Al Hadidi et al., 2020). Additionally, in pivotal trials leading to U.S. regulatory approval of immune checkpoint inhibitors, Black patients constituted less than 4% of enrollees. This is particularly problematic because clinical responses to immunotherapeutic agents depend on host and tumor biological interactions that are unique, individual, frequently racially determined, and genetically mediated (Nazha et al., 2019). Pooled data from nine large cooperative group clinical trials in newly diagnosed Multiple Myeloma (MM) over two decades showed only 18% of participants were non-White, which is shocking for a disease with incidence rates in Blacks more than double those seen in Whites (15.9 vs 7.5 cases per 100,000) (Ailawadhi et al., 2018). This trend also extends to mortality (5.6 vs 2.4 MM deaths per 100,000 for African Americans compared with Whites) (DeSantis et al., 2019; Bhatnagar et al., 2017). Siegel et al. (2023) report that outcomes for lymphomas, as well as other high-risk hematologic malignancies, are significantly affected by race (Figure 1).

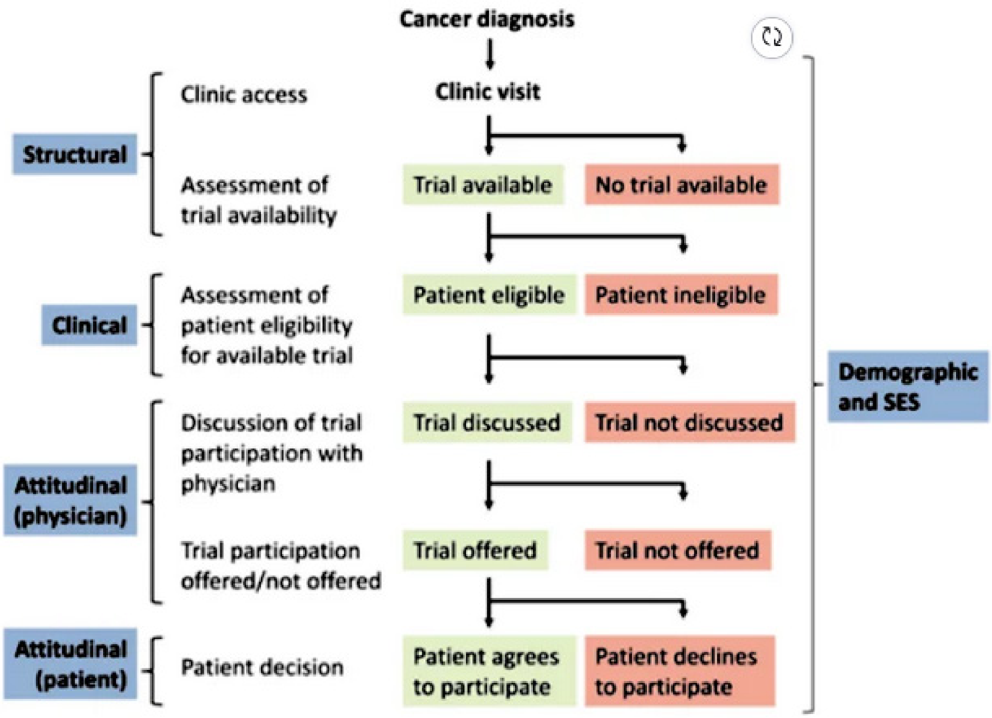


Lymphoma survival. Five-year relative survival for selected cancers by race and stage at diagnosis, United States, 2012 to 2018. White and Black race categories are exclusive of Hispanic ethnicity. Reproduced with permission from Siegel RL, Miller KD, Wagle NS, Jemal A. Cancer statistics, 2023. *CA Cancer J Clin. 2023;73(1):17-48*[23]

Figure 1

Barriers to participation in clinical trials:
Barriers to participation in clinical trials (Figure 2) typically disproportionately affect minority patients, which ultimately results in delayed accrual, delayed generation of clinical data, and reduced generalizability of such data to all persons, thereby promoting outcome disparities (Unger et al., 2016). Access to a clinic can be influenced by various structural factors, including transportation, travel costs, insurance coverage, and childcare availability.

Furthermore, a physician's decision or preference is a primary reason for nonparticipation in patients for whom a protocol is available, and the patient was eligible. Lastly, patients may experience unease or fear about the prospect of participating in clinical trials, including residual mistrust of medical science due to past abuses such as the infamous Tuskegee Syphilis Study or the history of human experimentation with radiation following World War II (Birhiray & Birhiray, 2023).



Model pathway of trial enrollment process. SES, socioeconomic status. Reproduced with permission from Unger JM, Cook E, Tai E, Bleyer A. The role of clinical trial participation in cancer research: barriers, evidence, and strategies. *Am Soc Clin Oncol Educ Book. 2016;35:185-198.*[32]
Figure 2

Policy Considerations

Two large-scale federal acts in recent history have been the Food and Drug Omnibus Reform Act (FDORA) of 2022 and Project Equity. FDORA requires the pharmaceutical industry to create prospective diversity plans and have major public hearings with the intent of enhancing diverse clinical trial enrollment. Project Equity is a "public health initiative established by the U.S. FDA Oncology Center of Excellence, to ensure that the data supporting approval of oncology medical products adequately reflects the demographic representation of patients for whom the medical products are intended." (Fashoyin-Aje et al., 2023)

Under FDORA, the FDA was working on a guidance document draft titled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies." Only a few days after taking office, President Donald Trump signed an executive order halting all federal DEI programs. This guidance document draft, which had been in progress since June 2024, was quietly removed from the FDA website shortly after (Grossi, 2025).

On May 19, 2023, the FDA released several documents regarding clinical trials, addressing the validity of clinical trials and ethical concerns for patients. One such document, Good Clinical Practice E6(R3) Draft Guideline, outlines quality standards for trials involving human participants, stating, "the use of innovative clinical trial designs and technologies may help include diverse patient populations, as appropriate, and enable wider participation" (Food and Drug Administration, 2023).

DRIVE is a strategic framework for promoting representative enrollment in clinical trials. This initiative addresses the inherent safety and efficacy concerns that arise when studies are conducted in populations that do not reflect the different patient groups these treatments are intended to serve. Generalizability, the ability to infer treatment effects for the entire population from a study population, and transportability, the ability to apply treatment effects from one group to another, are critical for ensuring equitable and effective care. To uphold these principles, "Clinical Trial Excellence" has been defined as studies that successfully meet these diversity and representation benchmarks. The DRIVE Initiative (2025) aims to establish measurable standards for representation, advocate for policy changes, and promote inclusive research practices that improve clinical outcomes for all patients, regardless of background.

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Implications

Application of the DRIVE scoring method allows researchers and providers to efficiently evaluate whether a cancer therapy is supported by broadly applicable data, thereby promoting inclusive and equitable healthcare practices. A DRIVE Score also allows patients further autonomy in shared decision-making by providing them with a mechanism to assess if their treatments were studied in patients who reflect similar biopyschosocial backgrounds.

The DRIVE Score is robust in nature, basing its disease epidemiology calculations on non-normalized data obtained from the Surveillance Research Program at the National Cancer Institute's (2025) SEER*Explorer Cancer Statistics Network; however, its utility is limited by a lack of research data published in a scorable format. A score can only be calculated when data is provided in a SEER-compatible format (such as classifying participants as "non-Hispanic Black" rather than simply "Black") this designation is important because, without it, some patients may be inaccurately accounted for when establishing a score. In March 2024, the U.S. Office of Management and Budget (OMB, 2024) issued revised guidance for Statistical Policy Directive Number 15 (SPD 15), which introduced an integrated race and ethnicity question as well as mandated more detailed data collection (e.g., checkboxes and write-in responses). This change to data collection is essential to broader implementation of the DRIVE Score for two reasons: first, it ensures respectful and accurate data collection reflecting patient and research participants' self-identification; second, it standardizes data analysis into a format compatible with the DRIVE scoring methodology. Medical societies like the American Society of Clinical Oncology (ASCO) or the American Society of Hematology (ASH) act as international bodies for medical professionals to collaborate. These bodies serve to call attention to and address the research insufficiencies that contribute to health disparities in cancer. By enforcing a standard in their publications for reporting and scoring patient demographic data with the DRIVE Score, they encourage greater transparency amongst their members and champion valid, reliable data.

Alternatively, academic research institutions are the sites for groundbreaking and practice-changing medicine. Research protocols informed by the DRIVE Score metric would allow principal investigators to prospectively develop achievable, flexible, and monitorable accrual goals that consider the diversity of the intent-to-treat population. Furthermore, a knowledge and understanding of the patients most impacted by a given disease can aid in developing culturally sensitive study materials that increase overall research accrual.

Recommendations/Call to Action

- Adoption of Project Equity and FDORA by the global regulatory community through International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) policy initiatives on broadening eligibility criteria in clinical trials.
- Widespread utilization of the DRIVE Score among academic centers and community physicians, with a commitment to implementing the other aspects of the DRIVE Initiative in due time.

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