Driving Diversity and Inclusion in Cancer Drug Development – Industry and Regulatory Perspectives, Current Practices, Opportunities, and Challenges

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ABSTRACT

In April 2022, the FDA issued draft guidance to help industry develop strategies to improve diversity in clinical trials. Historically, clinical trial sponsors have not systematically incorporated efforts to promote diversity, equity, and inclusion (DEI), particularly during the early design stages of clinical development plans and operational strategies. Unfortunately, a retrospective approach to DEI often results in clinical trial participants not being reflective of the diversity of patients intended to be treated with new therapies. A shift to prospective, intentional DEI strategies for clinical trials, including long-term engagement with diverse patients and communities throughout the development life cycle, is necessary to maximize the benefits and minimize the risks of new drugs and devices for all patients. Sponsors' current practices and opportunities for improving DEI address four major topics: institutional commitment, culture change, and governance; clinical development strategy; setting enrollment goals to ensure trial participant diversity; and development and implementation of the operational strategy. As DEI practices gain wider adoption in clinical trials, shared learning and collaboration among stakeholders on an ongoing and noncompetitive basis will lead to sustainable change. Prioritization of enrollment of diverse populations as an integral part of study start-up planning, clinical trial design, and recruitment capabilities will enhance the clinical development process for oncology therapies. Importantly, these efforts will help provide equitable access to clinical trials and innovative cancer therapies.

Introduction

To meet the needs of all patients, a major shift is needed to prioritize participant diversity in the clinical development of oncology drugs. Prospectively planning clinical trials to include diverse study populations has not been common practice in drug and device development. A more consistent approach is needed to optimize evidence generated to treat diverse populations for which medical products are intended. Many stakeholders in the oncology community have been mobilizing and collaborating to address glaring inequities in health care access and clinical trial participation for historically underserved and underrepresented populations in the United States (1–3). The American Association for Cancer Research (AACR) has promoted initiatives to address disparities in cancer research, including: collaborative workshops with the FDA Oncology Center of Excellence (OCE); the biennial AACR Cancer Disparities Progress Report (3); the annual AACR Science of Cancer Health Disparities conference; and the Minorities in Cancer Research Council. Many from the pharmaceutical industry have also pledged to promote diversity, equity, and inclusion (DEI), including increasing outreach and engagement with underrepresented racial and ethnic minorities for clinical trial participation (4–7).

Racial and ethnic minorities and older adults remain underrepresented in clinical trials of cancer drugs (8). To address this, national programs such as the Cancer Moonshot have prioritized equitable access to clinical research (9). In April 2022, OCE collaborated with all three medical product centers at FDA to issue draft guidance titled, "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials – Draft Guidance for Industry" (10). This guidance recommends that sponsors develop Race and Ethnicity Diversity Plans to enroll representative clinical trial populations, including patients who report Black or African American, Asian, Pacific Islander, or American Indian or Alaskan Native race and Hispanic ethnicity. The draft guidance expands on FDA's guidance documents that recommend that the diversity of participants in clinical trials of FDA-regulated medical products reflects real-world use populations (11). Supplementary Table S1 includes the framework for diversity plans from the FDA draft guidance.

Following the aforementioned draft guidance on diversity plans, AACR convened a series of roundtable meetings in November and December 2022 to discuss current pharmaceutical industry efforts to implement a diversity strategy in cancer drug development. Participants included industry representatives with expertise in regulatory policy, regulatory affairs, clinical development strategy, clinical operations, and diversity and inclusion; representatives from the OCE; and AACR regulatory and science policy staff. The goals of these roundtables were to:

- understand how sponsors design and integrate diversity strategies into clinical development and operational plans;

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- share current practices regarding actionable steps to improve clinical trial diversity; and
- identify key challenges and potential solutions in implementing action plans to improve diversity in clinical trials

Subsequently in December 2022, the 2023 Consolidated Appropriations Act was signed into law. A component of this new legislation requires that drug and device sponsors submit a Diversity Action Plan in the format and manner specified by FDA guidance. These new requirements increase the need for sponsors to design comprehensive strategies for diversity early in clinical development and closely collaborate with FDA and other stakeholders to ensure goals of individual diversity plans are being met. The following sections of this report describe current practices and opportunities to effectively implement diversity strategies and outline ongoing challenges.

Current Practices and Opportunities

It is essential that the evidence base generated for oncology medical products derives from trial participants who reflect the diversity of the population that will use these products following marketing authorization. Diversity in clinical drug development is a broad concept that accounts for the demographic and clinical characteristics of the study population as they are represented within societal, political, economic, and cultural contexts. While this report focuses on diversity as measured by the representativeness of the clinical trial population by race and ethnicity, other demographic factors such as age group, sex, gender identity, and social determinants of health are also important to consider when developing and implementing a diversity strategy. During the roundtable meetings, participants shared their perspectives, provided examples of current practices, and discussed important opportunities to expand these practices. The following summarizes the discussion across four major concepts which highlight critical facets of driving DEI in drug development.

Institutional commitment, culture change, and governance

Sponsor commitment to DEI is foundational to companies' efforts to increase the representativeness of clinical trial participants. Clinical diversity is both a scientific and ethical imperative to improve the generalizability of clinical trial results to the population affected with the disease or condition, and to advance health outcomes for all communities; these principles drive FDA and pharmaceutical industry commitment to DEI in oncology clinical research.

- **Commit dedicated resources to signal sponsor commitment to DEI.** Deliberate organizational commitment and resources increase the likelihood of meaningful change and success. Dedicated people who oversee DEI efforts, along with funding and governance processes should reflect this commitment.
- **Set policy that governs community/external engagement and implement initiatives that promote DEI.** This can be accomplished through establishment of advisory boards comprised of health equity experts, patient advocates, and community leaders that advise on company policy related to DEI and incorporate broad stakeholder voices into the drug development process.
- **Shift culture from a retrospective assessment of trial diversity to prospective planning and benchmark setting.** Culture change can be achieved through training and competency assessments and should be coupled with formal governance structures to ensure comprehensive planning and adherence to achieve the company diversity goals. There should be full integration of DEI staff within clinical development and operational teams and training of staff at all levels to ensure that enrollment of underrepresented minorities becomes a regular part of study planning and recruitment capabilities. This will enable trials to deliver comprehensive datasets that characterize efficacy and safety for intended patient populations.
- **Expand clinical trial infrastructure.** Clinical site selection processes and procedures should evolve to ensure broader access of underrepresented patients to clinical trials. Examples include clinical site contracting frameworks that support the conduct of clinical trials at the point of care, including at community-affiliated sites of larger academic centers.

Considerations for the clinical development strategy

Diversity has not historically been included in clinical development strategies for medicinal products due to a wide range of concerns or assumptions including safety risks, trial eligibility criteria, compliance with protocol-required treatments and evaluations, and impact to timelines. Embedding the DEI strategy within the clinical development strategy will increase access to clinical trials for all communities and provide the opportunity for new therapies to impact a broader population once approved. Assumptions about factors that can impact the diversity of clinical participants should be fully explored and challenged. Refer to **Fig. 1** for an approach to integrate equity in the clinical development plan.

- **Consider the diversity strategy as an integral component of the clinical development plan.** Diversity strategies are as important as other elements of the clinical development strategy that are more typically considered such as dosage evaluation, clinical characteristics, organ site, or comorbid conditions, and therefore, should also be prioritized in the full spectrum of clinical development activities.
- **Assess population-specific factors that could contribute to disparate clinical outcomes and incorporate strategies to address these factors.** Consider variability across the population for disease prevalence, disease course, disease etiologic factors and molecular drivers, and treatment outcomes, among other factors.
- **Identify facilitators and barriers to enrolling a representative population of interest.** An assessment of disease epidemiology and affected populations should occur at the earliest stages of designing the clinical development strategy. These assessments can indicate goals for representation of diverse populations and determine a baseline for measures that should be taken early in the clinical development and operational strategies to enroll a representative population. Early community engagement and educational activities are also important to identify the needs of patients who may experience barriers to trial participation, such as transportation, as well as any available resources in the community that may help alleviate those barriers.
- **Consider early initiation of study logistics to facilitate diversity during clinical strategy development.** Early exploration of the metrics necessary to deliver the defined study demographic representativeness is critical to success. For global trials of drugs being developed to treat diseases that occur less commonly in the United States, prospective planning is needed to ensure that there is sufficient representativeness of U.S. patients and U.S. medical practice to facilitate generalizability and applicability of study results. Adjustments to the operational footprint in the United States and at international sites may be needed.

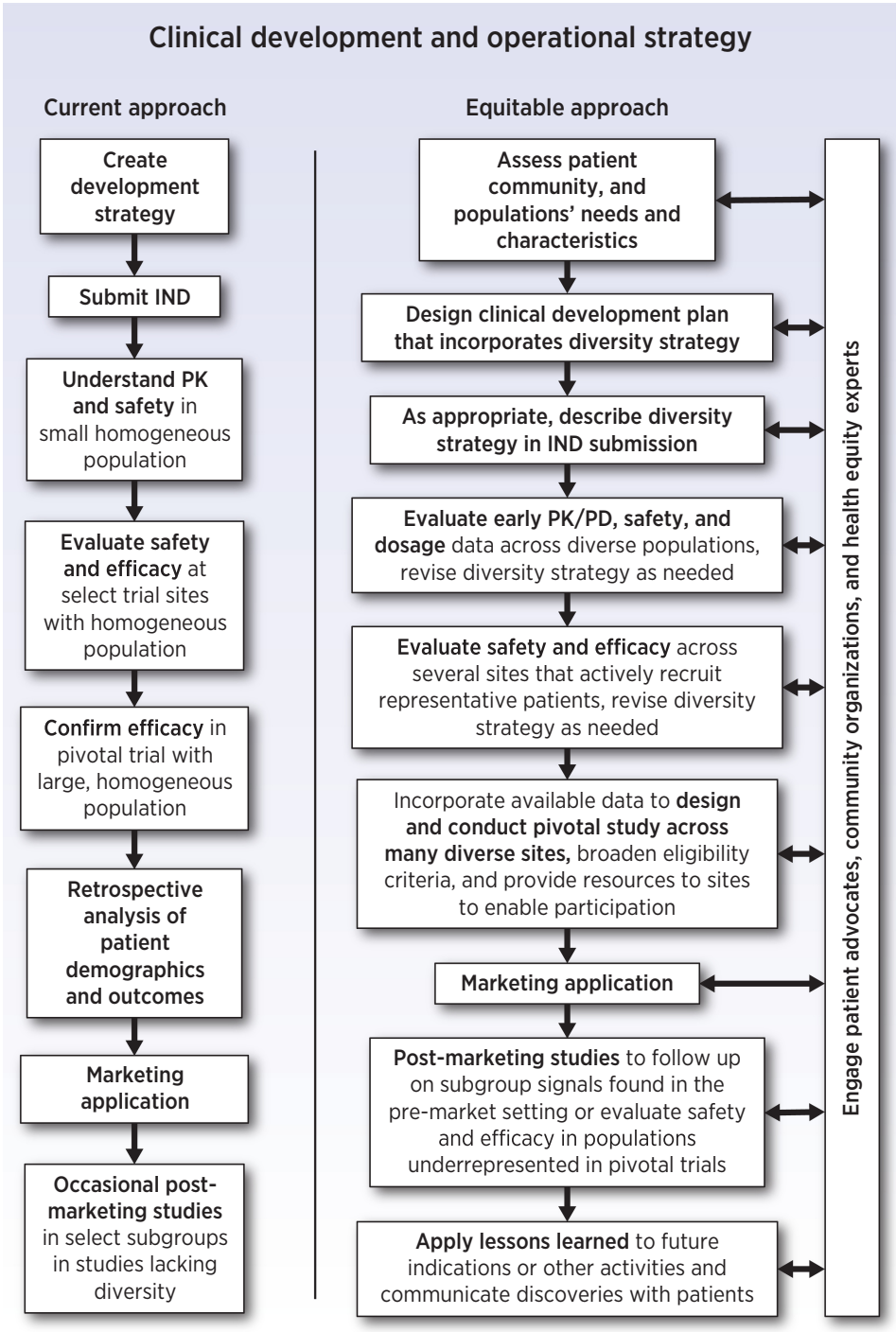

Figure 1.
Clinical development and operational strategy workflow. The left side of the flow chart summarizes common strategies for clinical development of oncology therapies, which frequently view DEI issues from a retrospective lens. On the right, we propose a new paradigm to prospectively integrate DEI through the development and implementation of a diversity strategy, long-term engagement with communities and patients, addressing common barriers to trial participation, and fostering a continuous learning environment to apply knowledge to improve future studies. IND, Investigational New Drug Application; PK, pharmacokinetics; PD, pharmacodynamics.

- **Consider data external to the trial to inform patient selection decisions and the operational tactics needed.** Analyses of real-world data or screen failure data from previous trials can identify opportunities to improve site selection, broaden eligibility criteria, and increase the pool of eligible patients. Although such analyses can be limited due to heterogenous collection, they can be useful in the early planning stage. Improving data collection to characterize reasons for ineligibility and trial dropout can also support inclusion-focused modifications to study protocols.

- **Design clinical development plans to include ongoing data review to inform broadening the study population in real time.** Some sponsors may assume there is tension between the goals of enrolling a diverse population, timely completion of the trial, and maintaining participant safety; this can be managed by incorporating data-informed decision points where eligibility criteria may be re-assessed to optimize the diversity of the study population in real time. When appropriate, a potential solution could be to allow trial continuation at select clinical sites that

demonstrate high enrollment of participants who are members of underrepresented populations, without delaying the primary analysis.

- **Plan for and incorporate all aspects related to enrolling an appropriately diverse population in clinical trials.** Study budgets and study timelines should consider strategic goals for diversity including participant recruitment and retention, support for trial-related costs for patients and measures to minimize participant burden; such measures could include accounting for the costs of digital health tools; data collection at local laboratory and imaging facilities; and the costs of comparator drugs.

Setting enrollment goals

Sponsors are employing various approaches to set enrollment goals for racial and ethnic diversity, including based on the epidemiology of the disease or by the distribution of race and ethnicity in the general population. Some sponsors set benchmarks based on the goal to improve from their company-specific historical clinical trial data, while other sponsors have prioritized enrollment goals for specific trial phases or for specific indications with high representation of racial and ethnic minorities. Companies have also taken varied approaches to setting enrollment goals for trials that enroll in the United States as well as internationally.

- **Utilize a multifactorial approach to setting enrollment goals.** Setting enrollment goals requires understanding of the distribution of the disease or condition in the United States population in the context of multiple factors, including the clinical intent of the medical product, disease prevalence, and the study population for whom the drug is being investigated. Additional considerations may include the complexity of trial designs, such as platform trials with multiple biomarker-informed arms. Sponsors often develop global clinical plans and may need to reconcile several factors, including regional regulatory requirements, medical practice, health care infrastructure, and clinical site capabilities. The complex interplay of these factors requires careful consideration and justification when setting enrollment goals in order to meet the expectations of FDA.
- **Identify sources of data characterizing the distribution of the population for a given indication.** Data from large epidemiological databases, such as the Surveillance, Epidemiology, and End Results (SEER) Program and the National Cancer Database, are available for most cancers. However, these sources are not currently designed to describe populations that are defined by specific features or biomarkers. Available estimates in these settings are sometimes based on limited data from registries or previous trials, but this is not optimal as these sources may themselves lack racial and ethnic diversity. Careful consideration and integration of all available data sources is needed to optimize the goal setting process and to understand why data may be conflicting between sources. Noncompetitive collaborations across all stakeholders will be crucial to optimize sources of data and implement population-level analyses for biomarkers or other features.

Developing and implementing operational strategies

Operational strategies should be developed concurrently with clinical strategies to facilitate understanding of diversity goals, opportunities, and challenges to be addressed. Early development and implementation of the clinical development operational strategy should include input from community, investigators, and patient stakeholders. **Table 1** includes anonymized examples of how sponsors have developed and implemented operational strategies as well as addressed the major categories described above.

Table 1. Examples from sponsors' current practices to facilitate clinical trial diversity.

Major concept	Examples from sponsors
Institutional commitment, culture change, governance	Many sponsors have implemented DEI teams to help bring these issues to the forefront when developing new trials. In some instances, programs have been established to encourage cross-functional DEI training for staff in various departments at all levels. Implementing these rotational or cross-functional training programs creates an all-company investment and full integration of DEI principles throughout the ecosystem.
Considerations for the clinical development strategy	Patient panels are an asset in developing protocols that maintain maximum accessibility for trials. Several companies have implemented patient advisory boards to review protocols and provide feedback on inclusion/exclusion criteria. It is critical that these recommended changes be highly considered and detailed reports justifying making or not making changes be tracked and reported back to these advisory boards.
Setting enrollment goals	The availability of quality demographic data for any given disease is often limited. For cancer-related trials, sponsors have used databases such as SEER in conjunction with epidemiological data to determine which populations are affected by a particular disease. In addition, census data can provide valuable insight when identifying sites that serve a more diverse patient population.
Developing and implementing the operational strategy	Partnering with new sites to build up access in areas with underserved and hard-to-reach patient populations can be largely advantageous for hitting diversity enrollment goals. Through partnership programs, companies may help make connections between imaging facilities, testing facilities, and treatment centers, among other critical needs. These partnerships should be long-term and consistent. In addition, sponsors should improve contracting practices to negotiate inclusion of community-affiliated sites of larger academic centers that may serve a more diverse patient population.

- **Use available data and tools to identify opportunities to enroll and retain diverse patients.** Available insurance claims and census data, coupled with geographic information software, use of artificial intelligence, and other data sources can be used to identify where patients receive their oncology care and ancillary health care services. These measures can also help to identify communities where new sites could provide meaningful improvements to clinical trial access. A "diversity score card" containing information such as enrollment and retention data can be implemented at the site level and by the sponsor to assess past performance in enrolling diverse study populations in clinical trials and the potential to meet diversity goals.
- **Expand established partnerships and establish new ones.** Leveraging networks of community hospitals and clinical centers affiliated with major cancer centers that have experience conducting trials is a relatively simple method to increase trial access for historically underrepresented populations. Perhaps more challenging but just as critical to expanding equitable access to clinical trials is establishing new partnerships with clinical sites that serve large proportions of racial and ethnic minority patients. It is essential to enable capacity building through good clinical practice (GCP)-compliant trial infrastructure and staff training, with sufficient lead time for site readiness and site funding to ensure success at the new clinical trial sites.
- **Engage early with sites to align expectations and identify facilitators and challenges to meeting them.** Diversity goals should be discussed with clinical sites early in the site feasibility and selection process to ensure transparency and agreement on necessary resources. Early site capacity assessment using tools such as the Diversity Site Assessment Tool (DSAT; ref. 12) can facilitate alignment between clinical trial site staff and sponsors on diversity goals and the resources needed to achieve them. Recruitment and retention of diverse participants can be greatly aided by funding site staff such as nurse navigators, research coordinators, and study nurses. Additional measures that reduce the burden of clinical trial participation like decentralization of study procedures, study visits, and data collection should also be considered and funded.
- **Streamline and harmonize activities that engage communities and clinical sites.** Streamlining and harmonizing sponsor efforts to engage communities and clinical trial sites help minimize duplicative efforts and reduce clinical site and patient burden. Harmonizing efforts can be an opportunity for noncompetitive collaboration between stakeholders, for example, through consortia.
- **Align diversity and global submission goals to optimize international site selection.** Site selection practices should be optimized to meet goals both inside the United States and internationally. Selection of sites for international clinical trials should also consider potential discordance between regulatory requirements for some international regulatory agencies and FDA expectations for data generalizability and applicability to the U.S. population.
- **Develop and implement monitoring and accountability measures.** Continuously evaluating the accuracy of assumptions made during development of diversity action plans helps keep sponsors and clinical sites accountable and provides the opportunity to identify and address unexpected outcomes early. Real-time site- and study-level monitoring of participant accrual can provide opportunities for early identification of studies and sites that are under- or over-performing relative to pre-study predictions; deploying appropriate support during a trial can leverage the performance of over-performing sites, or address barriers in underperforming sites. Beyond examining trial enrollment status, real-time monitoring also affords the opportunity to evaluate screen-failure data to identify reasons why a trial may not be meeting its targets for enrolling a particular demographic group. When approaching trial completion, comparing enrollment goals to observed enrollment using a Diversity Score Card/Diversity Index can indicate whether additional interventions could be implemented to maximize efficiency, such as maintaining a study open for longer at select sites to enroll more diverse participants.

Discussion and Next Steps

There are many challenges (**Table 2**) to comprehensively integrate DEI in clinical drug development as needed to meet regulatory expectations and requirements. These hurdles are expected given the profound change to the drug development process and the clinical research ecosystem needed to undo decades-long disparities in clinical trial participation rates among racial and ethnic minorities. Careful consideration of diversity strategies and early engagement with FDA, patient advocates, and community stakeholders can help address some of these issues. Some of the most immediate actions needed include changes to historical clinical development designs and sponsor practices; training diverse and culturally competent clinical trial staff at experienced clinical trial sites; and supporting infrastructure and training at newer, less experienced sites. In addition, defining which financial supports are allowable for patient study-related costs through legislation and regulation would provide needed clarity for trial sponsors to address common barriers to participation. Furthermore, harmonization of international regulations and development of frameworks to facilitate the design and conduct of diverse global clinical trials would decrease the burden of implementing comprehensive DEI initiatives. Effective change management practices, including the analysis of ongoing efforts, and noncompetitive sharing of ideas will be essential for identifying successful strategies to improve DEI in clinical research, including in clinical trials.

Many in the oncology research community have begun implementing strategies to facilitate culture shift from a retrospective view of DEI to one that is prospective and integrated into comprehensive development plans. However, meaningful, sustainable change will require long-term dedicated efforts from sponsors of all sizes, academic researchers, patient advocates, and federal agencies. Any process of this magnitude will require redesigning reward systems that incentivize new behaviors as well as ongoing analyses of metrics of success. Financial incentives from private industry, or federal grants, will be especially important to broaden capacity for conducting clinical trials in the United States and ease the burden of participating in clinical trials. For example, the National Cancer Institute's Cancer Therapy Evaluation Program and Community Oncology Research Program have well-established track records of supporting clinical trial infrastructure and staff across the United States, including at nontraditional community sites; building on this experience could provide a roadmap for additional investments. As discussed at the 2022 AACR Annual Meeting, there could be room for a public-private partnership to combine private and public funds and comprehensively structure reward systems around the goal of expanding equitable access to clinical trials (13). In addition, a public–private partnership, or other form of a multistakeholder consortium, would greatly help with building consensus to address specific policy and regulatory issues;

Table 2. Challenges to designing and implementing a diversity strategy.

Challenges	DEI-centered solutions
Diversity introduces heterogeneity in clinical trials that limits interpretability	Subgroup analysis can reveal clinically meaningful differences that impact patient care and may occur based on sex, age, and ethnicity provided there is sufficient statistical power from diverse patients.
Prioritization of DEI in companies with limited capabilities, resources, and/or experience may be difficult	Capability development approaches and knowledge-sharing to support DEI can serve as a tool for companies with limited resources. Continued noncompetitive collaboration through consortia may enable lower-resource companies to pursue DEI as a priority.
Limited site capabilities and experience may be a barrier to establishing new partnerships or extending clinical sites beyond academic centers	Objective measures to assess site burden and capability allow sponsors to better understand a site's capacity for enrollment and retention. Forming new partnerships with inexperienced clinical sites may require additional training to ensure that trial conduct and data quality are in compliance with regulatory standards. Continued capacity building is essential to long-term success.
Lack of best practice standards for setting enrollment goals	Epidemiologic databases are helpful tools to set enrollment goals. Analyzing data from past trials or performing meta-analysis can also help explore how to best set enrollment targets. Continued conversations with stakeholders and refinement of data collection will be needed to help establish best practice standards.
Inadequate coverage of patient trial-related costs due to unclear compliance requirements	New policies could clarify allowable financial support for trial-related costs. Sponsor payment models that take a comprehensive approach to addressing costs for patients and providers can help alleviate some patient burden for participating in trials.
Slower U.S. site initiation compared to international sites	Sponsors should consider initiatives to define and standardize contracting practices and procedures that lead to lag time in site initiation in the United States. In addition, sponsors should consider utilizing "U.S. tails" that allow the trial to continue after enrollment goals in other countries have been met, to enroll and retain a representative patient population.
Study burden limiting participation of patients from historically underrepresented populations	Decentralization of study procedures, study visits, and data collection are important first steps to reducing trial participation burden. Often, enrolling a diverse patient population can be as simple as ensuring providers regularly offer clinical trials as an option to those patients in historically underrepresented groups.

(Continued on the following column)

sharing best practices; avoiding duplicative efforts; and fostering deeper engagement between industry, academia, agencies, and patients (14). The call for ongoing collaboration on this topic was also echoed at the 2023 AACR Annual Meeting. It is critical for the entire clinical research ecosystem to work together to leverage our collective learning on this subject on an ongoing noncompetitive basis. Fostering these long-term relationships will be crucial to building trust in clinical research as the cancer research community collectively walks the path toward health equity and addresses the damage of decades of discrimination in health care. Ensuring generation of high-quality evidence for new oncology therapies, and the diverse patient community that receives them, is a vital component in reducing disparities in cancer outcomes experienced by underrepresented racial and ethnic minorities. To achieve the goal of the reignited Cancer Moonshot to reduce the cancer death rate by half in 25 years, it will be necessary for all parties in the cancer research community to consider what they can do to ensure that all patients with cancer receive the maximum benefit of novel treatments.

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Note

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References

1. Gormley N, Fashoyin-Aje L, Locke T, Unger JM, Little RF, Nooka A, et al. Recommendations on eliminating racial disparities in multiple myeloma therapies: a step toward achieving equity in healthcare. Blood Cancer Discov 2021;2:119–24.
2. Oyer RA, Hurley P, Boehmer L, Bruinooge SS, Levit K, Barrett N, et al. Increasing racial and ethnic diversity in cancer clinical trials: an american society of clinical oncology and association of community cancer centers joint research statement. J Clin Oncol 2022;40:2163–71.
3. American Association for Cancer Research. AACR Cancer Disparities Progress Report 2022. Available from: https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2022/06/AACR_CDPR_2022.pdf.
4. Rottas M, Thadeio P, Simons R, Houck R, Gruben D, Keller D, et al. Demographic diversity of participants in Pfizer sponsored clinical trials in the United States. Contemp Clin Trials 2021;106:106421.
5. BIO takes on health equity in clinical trials. Available from: https://www.bio.org/press-release/bio-takes-health-equity-clinical-trials.
6. PhRMA. Industry efforts to enhance clinical trial diversity; 2022. Available from: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Campaign-Pages/Clinical-Trial-Diversity/PDF/Company-CTD-Efforts.pdf.
7. Fashoyin-Aje L, Browning-McNee LA, Boehmer J, Pazdur R, Winckler SC. Generating evidence for racial and ethnic minorities during development of oncologic therapeutics; 2023. Available from: https://www.raps.org/news-and-articles/news-articles?author=94a920ad-9ee2–4333-b5fa-30ea6c2b94c5.
8. U.S. Food and Drug Administration. 2015–2019 Drug Trials Snapshots Summary Report; 2020. Available from: https://www.fda.gov/media/143592/download.
9. The White House Office of Science and Technology Policy. Fact sheet: White House announces initial steps for reignited Cancer Moonshot. The White House; 2022. Available from: https://www.whitehouse.gov/ostp/news-updates/2022/03/17/fact-sheet-white-house-announces-initial-steps-for-reignited-cancer-moonshot/.
10. U.S. Food and Drug Administration. Diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations in clinical trials guidance for industry. U.S. Food and Drug Administration; 2022. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations.
11. Fashoyin-Aje L, Beaver JA, Pazdur R. Promoting inclusion of members of racial and ethnic minority groups in cancer drug development. JAMA Oncol 2021;7:1445–6.
12. Diversity site assessment tool – DSAT – Society for Clinical Research Sites. Available from: https://myscrs.org/dsat/.
13. Giusti K, Carpten J. How to reduce racial disparities in cancer. The Hill; 2022. Available from: https://thehill.com/opinion/healthcare/3265475-how-to-reduce-racial-disparities-in-cancer/.
14. U.S. Food and Drug Administration. Moving on equity: OCE expands diversity initiative, a Cancer Moonshot community conversation. U.S. Food and Drug Administration; 2022. Available from: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/moving-equity-oce-expands-diversity-initiative-cancer-moonshot-community-conversation-05042022.