

COMMENTARY

Reimagining diversity in multiple myeloma clinical trials

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Email: dany.habr@pfizer.com**KEYWORDS**

clinical trials, disparity, diversity, multiple myeloma

Multiple myeloma is primarily a disease of the elderly with a median age at diagnosis of around 66–70 years. It is now also established that it disproportionately impacts ethnic/racial (hereafter referred to as ethnic) minority groups in both incidence and outcome.^{1–4} For instance, monoclonal gammopathy of unknown significance and multiple myeloma tend to occur twice as frequently in African Americans compared to European Americans.⁵ Improvements in multiple myeloma survival with the advent of novel therapies are also less apparent in ethnic minority groups, especially in the older patient population.^{3,5,6} Such ethnic differences in the burden of multiple myeloma cannot be solely attributed to socioeconomic factors and variations in access to care, but may likely also be associated with underlying genetic and biologic differences.¹⁴ To further complicate the picture, elderly patients and ethnic minority groups continue to be underrepresented in cancer clinical trials in general, and multiple myeloma studies in specific.^{7–14} In a recent review of 112,293 patients recruited in 230 oncology trials that led to FDA approvals in the last decade, only 3.1% of patients were blacks and 6.1% were Hispanics (compared to 76.3% whites). This represented no more than 22% and 44% of their expected representation if compared to their proportion of US cancer incidence, respectively.¹¹ The enrollment-incidence disparity for multiple myeloma was second highest among all cancers in blacks and Hispanics, with an enrollment to incidence ratio (i.e., number of those enrolled over those “expected” to be enrolled based on disease incidence across ethnic groups) of 21% for blacks and 4% for Hispanics.¹¹ The enrollment-mortality disparity was equally high.¹¹ Another pooled analysis of 2896 patients from nine

large national cooperative group clinical trials in newly diagnosed multiple myeloma showed that only 18% of participants were non-white.¹⁵ Compared with whites, African-Americans were younger and had more frequent markers of poor risk, while Hispanics had the smallest proportion of patients on trials utilizing novel therapeutic agents.¹⁵ Such disparities between cancer clinical trial participation and the incident disease population appear to be increasing over time and are more prominent in industry-sponsored trials.^{15–17}

Diversity in therapeutic clinical trials that reflects known incidence and burden of cancer in specific age and ethnic groups is crucial for appropriate interpretation of the role of intervention and tailoring management to specific patient needs. In the absence of such data, management strategies would need to be extrapolated from alternate, nonrepresentative patient populations.^{8,18} Over the past decade, there have been several guidance documents, position statements, and recommendations from regulatory agencies and cancer societies, some specifically directed to industry sponsors, to address disparities and underrepresentation of elderly patients and ethnic minority groups in cancer clinical trials.^{1,8,19–28} Recommendations from an FDA-American Association for Cancer Research workshop have also been recently published and dedicated to eliminating disparities in multiple myeloma therapies.²⁹ Success of such measures can only be achieved through partnerships between all stakeholders involved in the clinical trial journey. The pharmaceutical industry plays a key role in this regard not only through adoption of diversity-focused clinical trial recommendations, but through providing innovative

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solutions to address disparities and promote inclusion. We herein elaborate on such potential solutions and directions that can be driven by industry sponsors of multiple myeloma trials (Figure 1). We also share experiences and learnings from our own initiatives directed toward improving diversity in cancer clinical trials across our programs.^{30,31}

1 | BUILDING TRUST THROUGH TAILORED EDUCATION

Proper understanding of the “ins” and “outs” of a clinical trial is key to maximize participation, and wider patient education should start way before eligibility assessment and consenting for individual trials.³²⁻³⁵ Sponsors should design and implement community-directed clinical trial education programs, that are ideally facilitated by community health educators and utilizing concise tools that are directly and appropriately relevant to the age and ethnic minority groups they are targeting.^{22,36-40} This could include testimonials and experiences of previous trial participants that potential future participants can relate to and identify with.⁴¹ Such education campaigns can target collective elderly and ethnic minority groups through centralized channels that they regularly attend and trust.⁴² The use of digital platforms to facilitate community education is also evolving and can maximize reach. Communications must be transparent and address the usual “elephant in the room”, fear of experimentation especially that stemming from historic exploitation of ethnic minorities in medical research.^{32-35,43,44}

2 | OPTIMIZING AWARENESS AND EXPOSURE TO OPPORTUNITY

One key limitation to inclusion in clinical trials is patients’ lack of awareness to opportunities they are eligible for.^{25,45,46} These are sometimes actively “blocked” by treating physicians, investigators and clinical trial staff who withhold presenting trial options to elderly and ethnic minority patients, as they see them as “less promising” participants.^{25,44,47} Suboptimal or ethnically-discordant referring physician-investigator and physician-patient communications can also challenge discussions about clinical trial opportunities.^{48,49} Sponsors should be aware of these barriers and devise specific interventions to address them through soft skill training programs and provision of trial communication tools with appropriate age and ethnic minority group messaging.^{50,51}

Limited time and capacity are also recognized as common barriers to recruitment by investigators and clinical trial staff.^{33,52} Sponsors can play an important role by offering trainings and pragmatic solutions that can improve clinical trial diversity by changing recruitment behaviors and optimizing elderly and ethnic minority participant identification.⁵³⁻⁵⁵ This can be achieved through training dedicated nurses or redesigning electronic health records to notify clinical trial staff of potential trial participants attending routine clinics, through algorithms that take into consideration the needs to achieve diversity in recruitment.⁵⁶ Specialized recruitment coordinators (navigators) can also be funded by sponsors to support clinical trial staff in patient identification and managing the case mix.⁵⁷

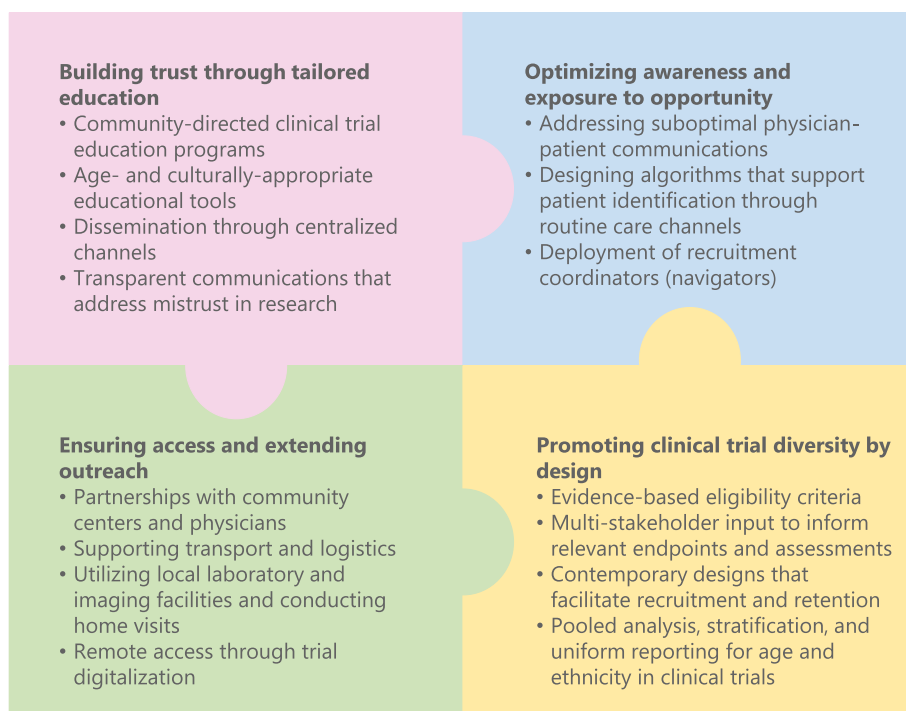


FIGURE 1 Key considerations for the pharmaceutical industry to promote diversity in multiple myeloma clinical trials

3 | ENSURING ACCESS AND EXTENDING OUTREACH

Limited access to clinical trials can often be driven by where the patients live, considering a large proportion of elderly and ethnic minority patients live in community settings far from clinical trial sites in city centers.^{32-35,44} Partnerships between designated cancer centers and smaller community-based healthcare facilities remain essential and have already shown promise in improving diversity in cancer clinical trials.⁵⁸⁻⁶² Seeking support from community-based physicians to inform appropriate outreach tactics for patients under their care is essential, and should be considered by sponsors as early as possible in clinical trial planning to achieve recruitment targets for underrepresented populations.²⁷ The aforementioned recruitment coordinators can also support with referrals and handling logistics for community-based patients being considered for clinical trials conducted at city centers.⁶³ This should be coupled by strategies that support financial coverage for routine care costs, time lost, and travel needs for patients and their care providers especially in such scenarios when study sites are far from home; considering that free access to healthcare remains one of the key drivers for ethnic minority groups to participate in clinical trials.^{27,32-35,64}

Ease of access to clinical trials can also be achieved through bringing the trials closer to where patients reside. For instance, sponsors can use local laboratory and imaging facilities, patient shipping, and home visits to optimize patient experience, especially for the elderly.^{19,65,66} The use of technology to facilitate remote monitoring and trial assessments would also ensure convenience for patients through reduction of site visit requirements.^{19,21,24,67,68}

4 | PROMOTING CLINICAL TRIAL DIVERSITY BY DESIGN

Sponsors should rely on data from early phase, real-world evidence, and translational studies to arrive at contemporary clinical trial designs that ensure suitability for and appropriate representation of elderly and ethnic minority groups.^{8,19,21,24,27,65} Seeking input from geriatric oncology specialists, community-based physicians, patient representatives and caregivers during various phases of study design can help ensure appropriate trial eligibility and assessment criteria are in place.^{21,22,24}

The use of age-based eligibility criteria in cancer clinical trials is on the decline.⁶⁹ However, general exclusions based on functional status, organ function, and comorbidity continue to limit eligibility of elderly patients. Efforts to revise such criteria and calls to use more evidence-based trial eligibility standards are on the rise.^{8,19,70,71} The use of adaptive clinical trial designs, stratification, hierarchical testing, and pragmatic clinical trials have also been suggested to support inclusion of older patients in cancer clinical trials.^{19,21,24,25,72,73} Functional endpoints and patient-reported outcomes are key in cancer clinical trials evaluating therapeutic benefit in elderly populations but continue to be underutilized.^{8,25,74}

Inclusion of geriatric assessments in such trials would help solidify relevance and optimize recruitment and retention of older patients.^{20,22,25}

Clinical trial protocols and statistical analysis plans should also consider stratification, pooled analysis, and reporting of data per age and ethnic groups to allow appropriate interpretation of results and identification of risk factors for disparate outcomes.^{22,24,27,75,76}

5 | OUR OWN INITIATIVES

At Pfizer, our clinical trial teams benefit from a Diversity in Clinical Trials Center of Excellence (CoE) which provides detailed demographic data on the epidemiology of the disease we are targeting, and thus allowing them to select investigators and sites in an informed manner that ensures our diversity goals are met. This CoE was recently leveraged in the planning and execution of our investigational BCMA-bispecific clinical trials' program "MagnetisMM". We also reinforce a strong collaboration between our clinical development and medical affairs functions, whereby field medical associates who are highly knowledgeable of the multiple myeloma footprint and site diversity potential recommended trial sites that were not originally on the radar of clinical operations teams. This went in parallel with creation of territory-based referral maps that include census diversity data on a county level to help target areas that can refer to clinical trial sites. Proactive outreach was then mediated through dedicated presentations focused on disparities in clinical trials targeting community health advisors and referral centers. We have also conducted regional community advisory boards to discuss illicit biases and how best to overcome them in the community setting. We are also supporting the MagnetisMM program trial sites with additional staffing including community navigators matched to the ethnic minority groups they are targeting. This is coupled with collaborations with various professional associations representative of ethnic minority groups that can support community recruitment. Moreover, we are planning to conduct investigator meetups for best practice sharing to increase diversity enrollment in clinical trials. Recruitment and retention data of the MagnetisMM clinical trials program are monitored regularly and actioned through a designated digital platform that can flag deviations from accrual needs.

This is in addition to other initiatives we have previously introduced, and which will continue to be leveraged for multiple myeloma clinical trials, such as the Blue Button® Program which allows patients in our clinical trials to have access to their clinical data, thus helping build more trust with study participants.^{30,31} Our reliance on telemedicine approaches to effectively run clinical trials in remote settings continues to evolve, especially considering the recent mobility challenges imposed by the Covid-19 pandemic.⁷⁷ We are also regularly partnering with other professional bodies to support diversity in cancer care and research. For example, we have joined other industry partners in the Center for Information and Study on Clinical Research Participation (CISCRP,

www.ciscrp.com), an initiative dedicated to clinical research education and sharing best practices for addressing challenges with clinical trial recruitment. Our Patient Centricity Initiative is based on partnerships with patient advocacy organizations with the aim of promoting health equity, health literacy, and involving patients in clinical research.^{30,31} We have also collaborated with the American Cancer Society to establish the 'Addressing Racial Disparities in Cancer Care Competitive Grant Program' aimed at reducing ethnic disparities in cancer care.⁷⁸ More recently, we have also provided a 3-year, multimillion grant to Columbia University to help establish and expand the Columbia-Pfizer Clinical Trials Diversity Initiative.⁷⁹

Achieving cancer clinical trial diversity should be a shared responsibility by all stakeholders involved. The pharmaceutical industry can play a major role through the design of modern, patient-centric clinical trials and mobilizing resources to support identification, recruitment, and retention of diverse patient populations that are representative of the underlying cancer type the trial is evaluating. Leveraging data from real-world evidence can also be instrumental to confirm effectiveness and risks of approved therapies for ethnic minority and older age groups who are underrepresented in clinical trials.

ACKNOWLEDGMENTS

Medical writing support was provided by Khaled Musallam MD PhD at Evida Medical DMCC and was funded by Pfizer.

CONFLICT OF INTEREST

Dany Habr and Massimo Corsaro are employees of and own stock in Pfizer.

AUTHOR CONTRIBUTIONS

All authors have contributed to conceptualization, critical review, and final approval of the manuscript for submission.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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TRANSPARENT PEER REVIEW

The peer review history for this article is available at: <https://publons.com/publon/10.1002/hon.2997>.

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