

Inclusivity in action: HCP perspectives on diversifying clinical trials

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- Survey results highlight HCPs' perspectives on pharmaceutical companies' efforts to diversify clinical trial populations, the perceived barriers to recruitment of diverse participants, and the unmet needs and required resources for improved patient representation
- Medical communications professionals are uniquely positioned to partner with pharmaceutical companies, referring physicians and trial investigators to create and disseminate resources aimed at enhancing clinical trial population diversity

Background

- Racial and ethnic minorities are disproportionately affected by several diseases (eg, diabetes, infectious and autoimmune diseases)^{1,2} yet remain underrepresented in clinical trials and may experience treatment biases³⁻⁸
- Clinical trials that lack diversity perpetuate health inequities in marginalized groups by:
 - Limiting the generalizability of study findings^{9,10}
 - Impacting social, economic, cultural, and environmental determinants
 - Reducing the quality of individual patient care¹¹
- The US FDA has implemented a DAP that encourages sponsors of clinical trials to outline how they will achieve a more diverse participant pool¹²
- Many pharmaceutical companies strive to diversify clinical trial populations through dedicated patient resources aimed at improving representation and identifying unmet needs
- It is unclear how impactful these efforts are and how we as medical communications professionals can support pharmaceutical companies in maximizing such efforts

Methods

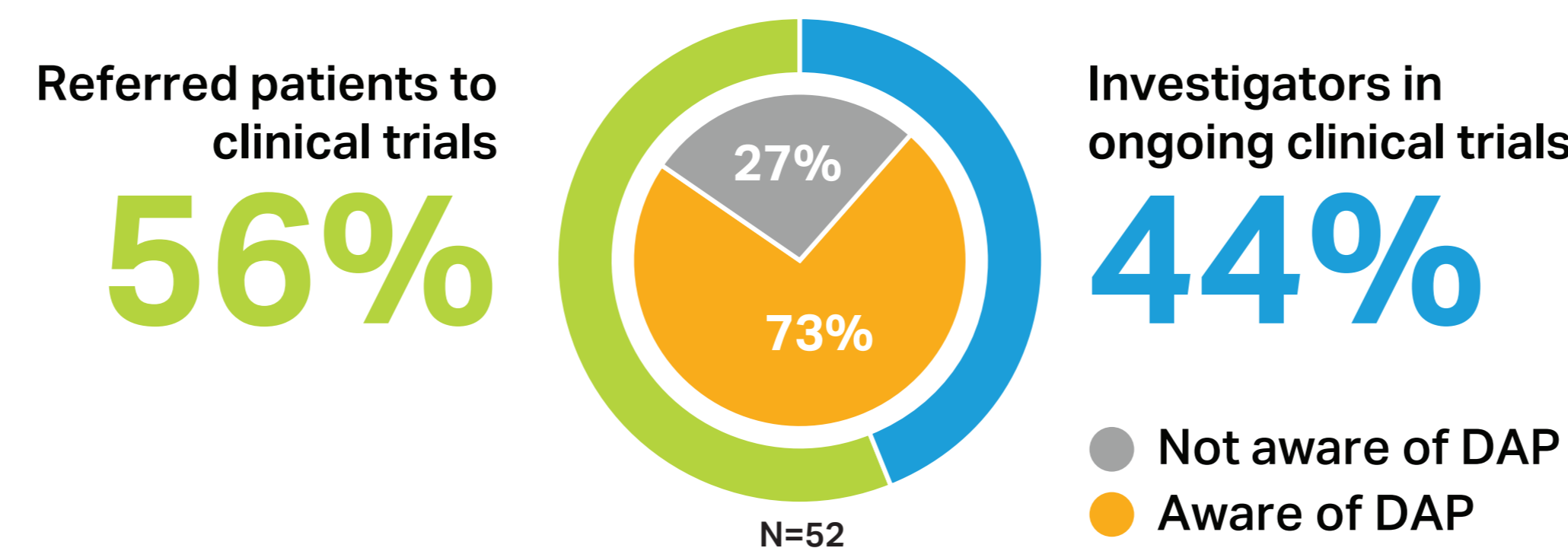
- Using SERMO, we surveyed US HCPs actively involved in clinical trials
- The survey included 3 screening questions and 7 questions examining respondents' perception of
 - Pharmaceutical companies' diversity initiatives in clinical trials
 - Factors influencing diverse recruitment
 - Effectiveness of current initiatives

Results

Demographics

- The survey was conducted from December 18-19, 2023; 76 HCPs were screened, 52 qualified based on the screener questions and were included in the results
- Respondents were from a wide spectrum of specialties, including oncology, pulmonology, ophthalmology, neurology, hematology, dermatology, and cardiology
- Nearly 70% of respondents or their patients were involved in investigator-initiated trials; 54% were involved in trials sponsored by large-sized pharmaceutical companies
- HCPs perceived that large-sized (annual revenue, >\$5B USD) and mid-sized (annual revenue, \$0.5B to \$5B USD) pharmaceutical companies were primarily involved in initiatives targeted at increasing diversity in clinical trials

Respondents were screened based on their involvement in clinical trials and awareness of the FDA DAP

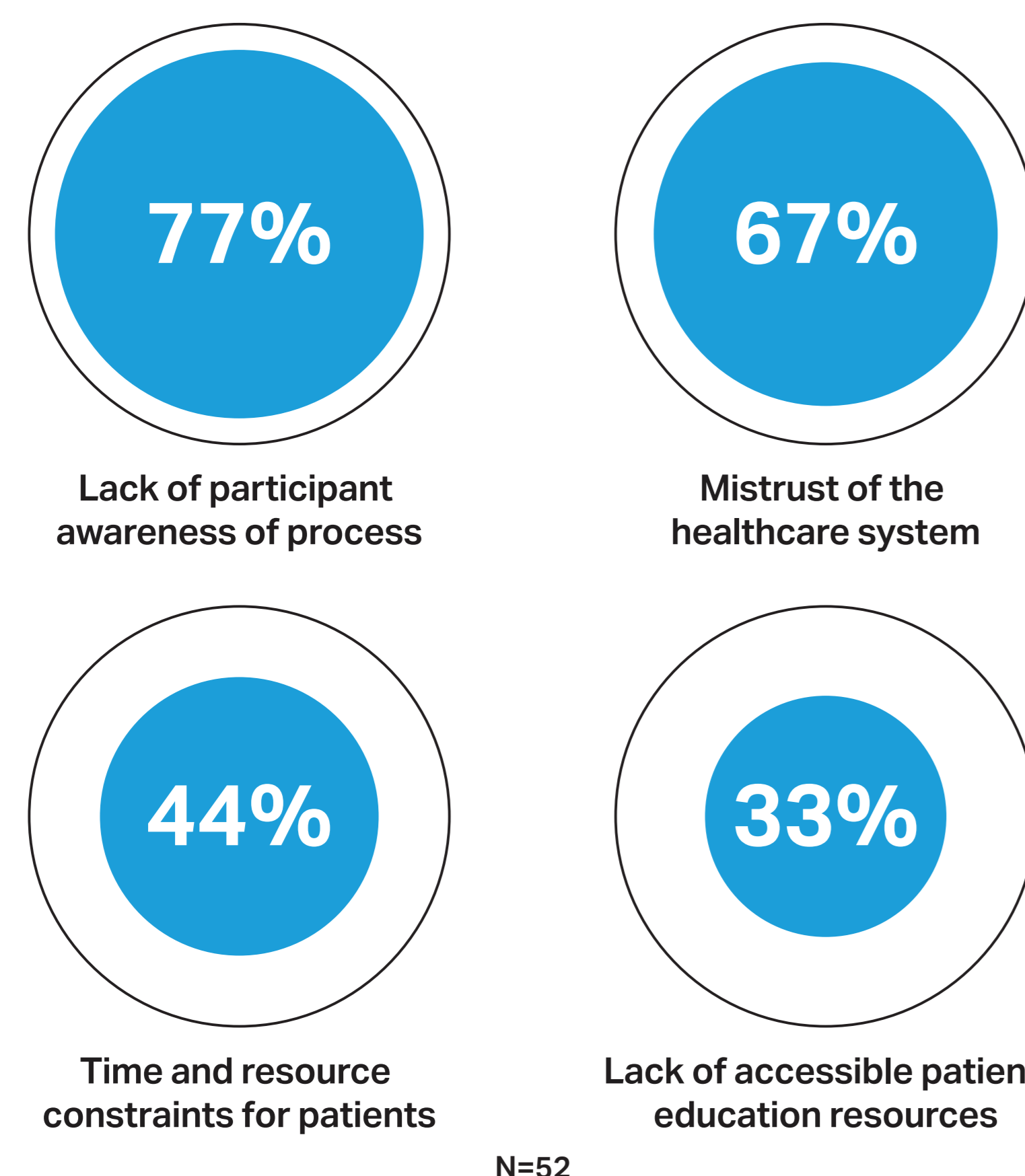


Influencers for Clinical Trial Enrollment

Rank	Influencer	Impact
1	Referring physicians	Were ranked as individuals who had the most influence on clinical trial enrollment
2	Trial investigators	
3	Patients	
4	Pharmaceutical companies/sponsors	
5	Study site coordinators	

Barriers to Improving Representation in Clinical Trials

In your experience, what are the primary barriers to recruitment of diverse populations at your clinical trial sites?

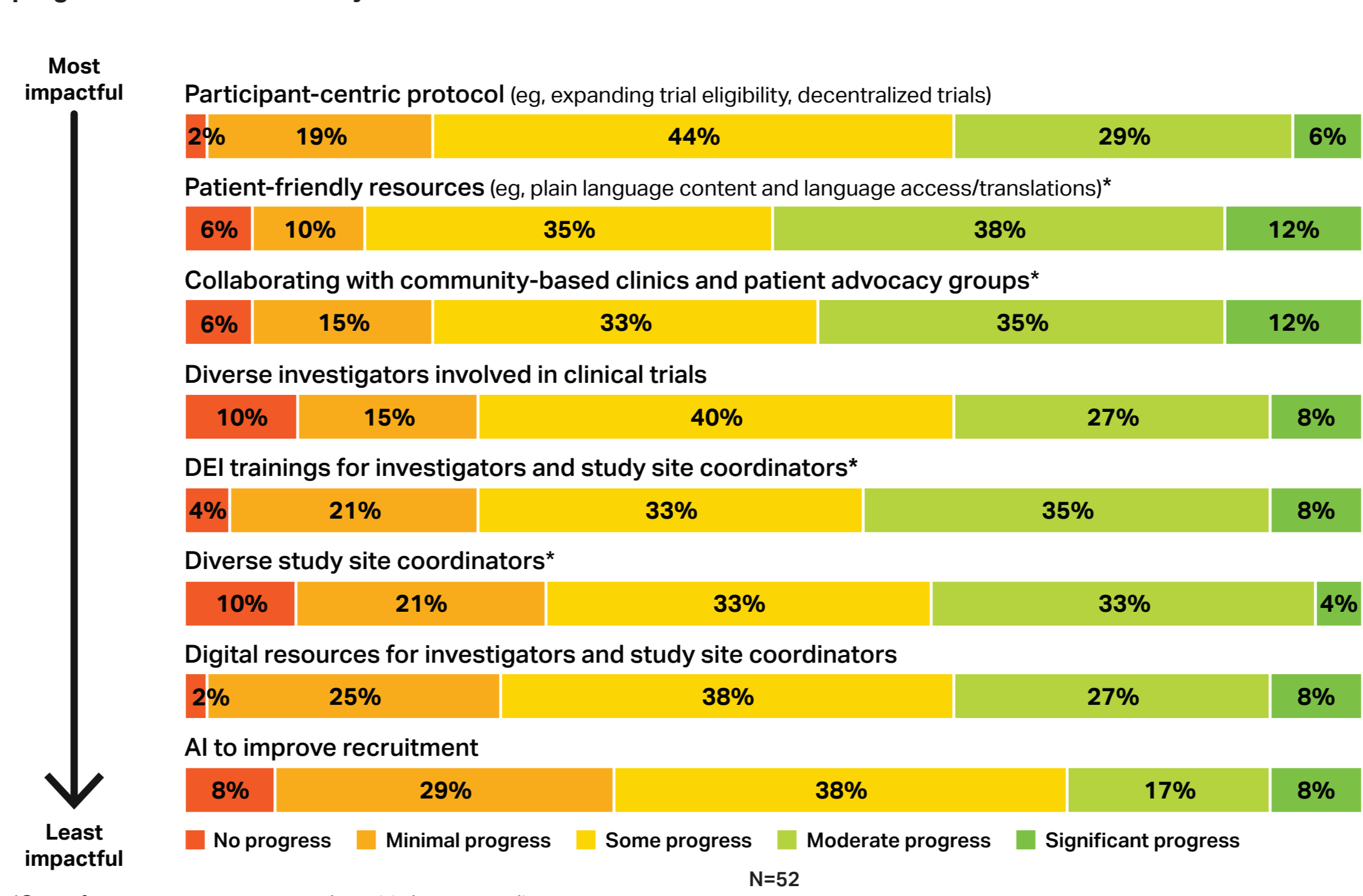


- Diverse health/religious beliefs, clinical trial protocol, and provider awareness were noted as additional barriers to diverse clinical trial recruitment

Current Efforts to Improve Clinical Trial Diversity

Initiatives focused on diversifying demographic factors (race, sex, age [55%-88%]) and socioeconomic status (55%) were believed to have the greatest impact on representation

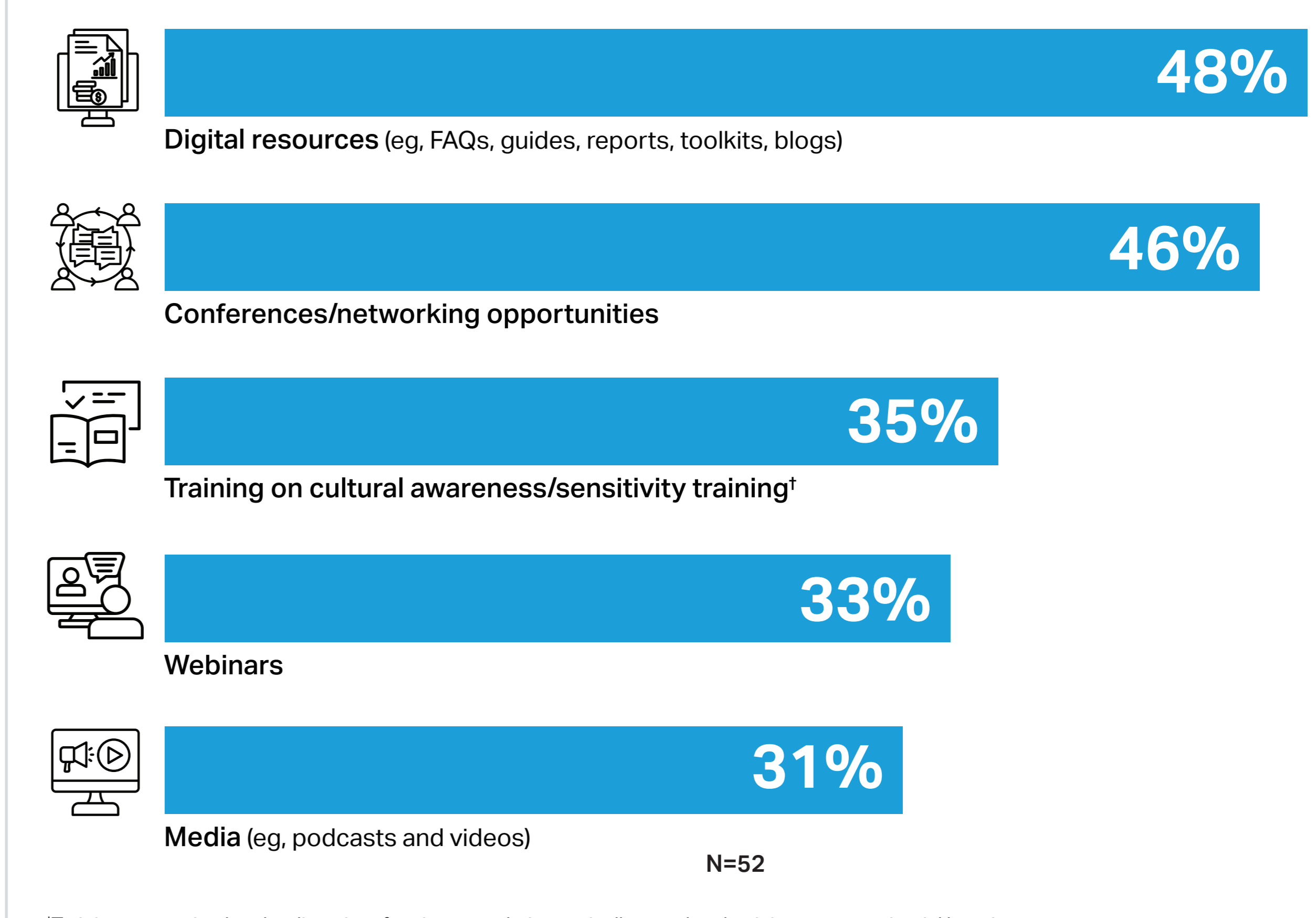
In your opinion, for the initiatives listed below, to what extent do you believe pharmaceutical companies are making progress to enhance diversity in clinical trials?



- Participant-centric protocol and patient-friendly resources were ranked as the most impactful tools to improve clinical trial representation
- Digital resources for investigators and study site coordinators, as well as use of AI for patient recruitment, were identified as strategies that could be developed further to enhance diversity in clinical trials

Effective Resources for Improved Representation

Based on your experience, what format of resources would be most helpful to patients and physicians to build awareness and improve representation in clinical trials?



- Training on the FDA DAP, utilizing external resources to improve accessibility, case studies and regional learning forums/roundtables were identified as additional helpful content formats for building patient and physician awareness

Discussion

- While HCPs acknowledge the efforts by pharmaceutical companies that are primarily aimed at improving demographic and socioeconomic diversity among trial participants, significant barriers to diverse trial recruitment remain, including a lack of awareness and mistrust of healthcare systems
- Our analysis highlights the importance of participant-centric protocols and patient-friendly resources for improving clinical trial representation

Recommendations for our industry to help enhance clinical trial diversity

Patient-Friendly Resources

- **Engaging Formats:** Utilize visuals, infographics, and explainer videos
- **Accessibility:** Ensure multilingual and plain language content
- **Expanding Reach:** Offer resources through multichannel platforms
- **Patient Connection:** Create and feature compelling narratives and testimonials from diverse participants
- **Collaboration:** Partner with patient advocacy groups for development and dissemination

Trainings and Education

- **Building Cultural Competency:** Cultural competency/sensitivity training for all stakeholders (pharmaceutical companies, physicians, investigators) to ensure materials resonate with diverse audiences and avoid unintentional bias
- **Addressing Bias:** Training that addresses implicit bias, social determinants of health, and specific needs of different ethnicities
- **Data-Driven Advocacy:** Data or statistics that highlight the benefits of diverse clinical trial populations for both patients and pharmaceutical companies

Leveraging AI for Inclusive Eligibility Criteria¹³

- **Human Oversight and Diverse Data:** Human oversight and diverse/representative data sets are required to avoid perpetuating biases
- **Success Stories:** Case studies that demonstrate effective utilization of AI to optimize eligibility criteria and diversify enrollment
- **Ethical Considerations:** Ensure transparency in communicating how AI is used to optimize inclusion/exclusion criteria, and adhere to best practices when communicating in publications