

# US Cancer Centers of Excellence Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials

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**QUESTION ASKED:** What strategies do US cancer centers use to optimize recruitment of racial and ethnic minority groups (REMGs) into clinical trials?

**SUMMARY ANSWER:** Strategies that drive increased participation of REMGs in cancer clinical trials were identified across five broad themes—commitment and center leadership, investigator training and mentoring, community engagement, patient engagement, and operational practices. Specific notable practices included the following: increased engagement of health care professionals; presence of formal processes for obtaining REMG patient/caregiver input on research projects; engagement of community groups; an increase in allocation of resources to improving health disparities; and increased dedication of research staff to REMG engagement.

**WHAT WE DID:** In-depth interviews were conducted with leaders from US cancer centers with above-average recruitment of REMGs into clinical trials to identify specific strategies that were used to facilitate REMG participation.

**WHAT WE FOUND:** We identified leadership, patient engagement, and community engagement practices that facilitate increased accrual of REMGs in cancer trials. In particular, high-recruiting centers excelled in engaging with providers as the most important influencer of patient participation, engaging community leaders and building trust, and seeking dedicated input clinical research programs from REMG patients and caregivers to identify and overcome potential barriers as early as possible.

**BIAS, CONFOUNDING FACTOR(S):** The small sample size, type of cancer center included in the study, and the lack of comparison group could have affected the interpretation of the results.

**REAL-LIFE IMPLICATIONS:** Increased participation of REMGs in cancer research is needed to ensure that medicines developed for and administered to patients with cancer demonstrate their intended benefit in clinical trials that adequately represent the diversity of the US population. Practicing oncologists can help to ensure that all patients can benefit from the newer, increasingly personalized therapies by adopting identified notable practices that increase recruitment of REMGs into clinical trials.

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# US Cancer Centers of Excellence Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials

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## abstract

**PURPOSE** Participation of racial and ethnic minority groups (REMGs) in cancer trials is disproportionately low despite a high prevalence of certain cancers in REMG populations. We aimed to identify notable practices used by leading US cancer centers that facilitate REMG participation in cancer trials.

**METHODS** The National Minority Quality Forum and Sustainable Healthy Communities Diverse Cancer Communities Working Group developed criteria by which to identify eligible US cancer centers—REMGs comprise 10% or more of the catchment area; a 10% to 50% yearly accrual rate of REMGs in cancer trials; and the presence of formal community outreach and diversity enrollment programs. Cancer center leaders were interviewed to ascertain notable practices that facilitate REMG accrual in clinical trials.

**RESULTS** Eight cancer centers that met the Communities Working Group criteria were invited to participate in in-depth interviews. Notable strategies for increased REMG accrual to cancer trials were reported across five broad themes: commitment and center leadership, investigator training and mentoring, community engagement, patient engagement, and operational practices. Specific notable practices included increased engagement of health care professionals, the presence of formal processes for obtaining REMG patient/caregiver input on research projects, and engagement of community groups to drive REMG participation. Centers also reported an increase in the allocation of resources to improving health disparities and increased dedication of research staff to REMG engagement.

**CONCLUSION** We have identified notable practices that facilitate increased participation of REMGs in cancer trials. Wide implementation of such strategies across cancer centers is essential to ensure that all populations benefit from advances in an era of increasingly personalized treatment of cancer.

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## INTRODUCTION

Diverse patient populations in the United States are regularly underrepresented in clinical trials, which stand as the first portal to standard of care and innovative care. Whereas less than 10% of patients with cancer participate in US cancer clinical trials, participation of racial and ethnic minority groups (REMGs) is disproportionately low.<sup>1</sup> For example, African American patients comprise 5% of patients enrolled in clinical trials that support US Food and Drug Administration approval of new drugs but represent 13.3% of the general US population.<sup>2</sup> Cancer is the leading cause of death for Asian Americans,<sup>3</sup> yet this population comprises 3% of cancer clinical trial participants.<sup>4</sup> Hispanics are also similarly underrepresented in clinical trials.<sup>5</sup> These health inequities are

increasingly untenable, with advances in science and technology driving a paradigm shift with precision medicine, especially in cancer.

Without opportunities to participate in clinical trials, REMGs miss the chance to participate in clinical trials that are often standard in oncology practice and are not being included in the populations assessed for safety and efficacy of innovative therapies. Delivering personalized medicines that account for biologic factors, such as genetics, gender, race, and ethnicity, is fundamental to the goal of precision medicine; however, without including adequate representative patient populations, this goal is not achievable.<sup>6-8</sup>

Continued focus on increased participation of REMGs in cancer research is needed to improve our understanding of differences in risk and disease outcomes

## ASSOCIATED CONTENT

### Data Supplement

Author affiliations and support information (if applicable) appear at the end of this article.

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across populations. This work describes a data-driven strategy with which to identify and document notable leadership standards and patient- and community-centered practices that characterize US Centers' of Excellence ability to achieve above-average accrual of REMGs in cancer clinical research. We describe the development of and results from an extensive qualitative and quantitative data assessment conducted by the Sustainable Healthy Communities Diverse Cancer Communities Working Group (CWG) to share best practices and a framework supportive for enhancing REMG participation and inclusion in US cancer research.

## METHODS

The CWG applied criteria (Table 1) that was developed by a focus group of 14 US diversity thought leaders to identify potential US cancer centers of excellence. A cohort of cancer centers that met CWG criteria were invited to share their practices. The CWG conducted a literature review to inform data collection research methodology (Fig 1). Pre- and postinterview surveys and an interview guide were developed to standardize data collection. Surveys were sent to participating cancer centers within 2 weeks of a scheduled interview. The discussion guide included open-ended questions and was used to capture notable practices. The preinterview survey was reviewed in advance of the interview and provided preliminary information that informed the interview. The postinterview survey collected additional clarifying information upon completion and review of the interview. When interviewed, center leaders validated the content of the two survey instruments and discussion guide as being complete for the patient. The discussion guide focused on capturing notable practices covering six major themes: leadership and commitment, operational capabilities, community engagement, patient engagement, investigator training and hiring/mentoring, and recommended sponsor practices for enhanced REMG recruitment. Pre- and postinterview surveys were used to confirm participation eligibility, align on key definitions, and explore emergent themes using consistent definitions (Data Supplement). The preinterview survey,

discussion guide, and postinterview survey are provided in the Data Supplement. Interview notes, provided as a summary document, were sent to each of the center's leaders to validate the accuracy of responses before aggregation of data and notable practices. A single experienced interviewer conducted all interviews and administered all surveys, which were completed between November 2017 and February 2018.

## RESULTS

On the basis of the methods described previously, the CWG selected the following cancer centers: Fox Chase Cancer Center/Temple Health (FCCC; Philadelphia, PA); the Harold C. Simmons Comprehensive Cancer Center/University of Texas Southwestern (Dallas, TX); the Henry Ford Cancer Institute (HFCl; Detroit, MI); the Hollings Cancer Center/Medical University of South Carolina (MUSC; Charleston, SC); the John T. Vucurevich Cancer Institute/Rapid City Regional Hospital (JVCl; Rapid City, SD); The University of Texas MD Anderson Cancer Center (MDACC; Houston, TX); the University of California Davis Comprehensive Cancer Center (UCDCCC; Sacramento, CA); and the Winship Cancer Institute of Emory University (WCI-EMORY; Atlanta, GA). All centers included in the assessment met all criteria for inclusion and represented every major ethnic minority group according to the Health and Human Services, Office of Management and Budget race and ethnicity designations.<sup>11</sup> All centers targeted populations that were consistent with their catchment or service area. Overall, 14 leaders representing eight cancer centers participated in this assessment. Every leader in each of the eight centers participated throughout the assessment. Interviewees were nominated by center leaders according to their expertise relative to the objectives of the assessment, and results were not variable on the basis of the role or function of leaders included in the assessment.

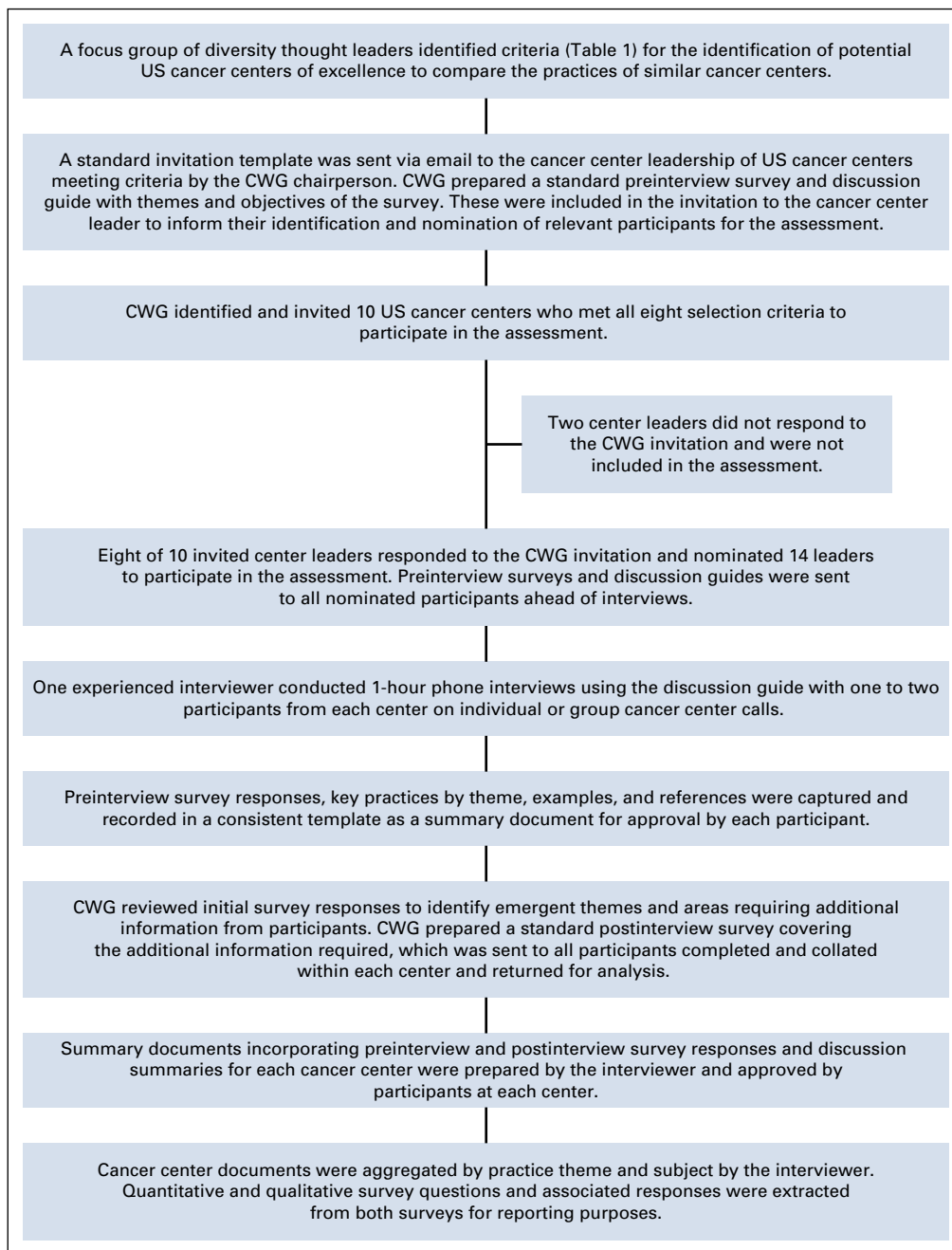
### Summary of Results From Quantitative Surveys

In a 12-month reporting period between 2016 and 2018, centers reported a specific 10% range of accrual and

**TABLE 1.** Cancer Center Selection Criteria

Criteria
Sustained accrual of racial and ethnic minorities in all cancer clinical research of between 10% and 50%
Established minority population $\geq$ 10% of the total site catchment, as confirmed by Sustainable Healthy Communities Cancer Index <sup>9</sup>
Established clinical trial infrastructure, <sup>10</sup> reflecting consistent industry clinical trial operations standards for clinical trial sites
Data infrastructure <sup>10</sup> or previous positive US Food and Drug Administration audit
Provider language and cultural competency reflects demographics of the populations they serve
Existing diversity enrollment program for clinical trials*
Formal community outreach program
Ability to participate in biomarker and metabolism research (eg, tissue correlative laboratories or pharmacokinetics capability)

\*The CWG defined an existing diversity enrollment program as a center having people and processes dedicated to optimizing the goal of diversity and inclusion in cancer clinical trials.



**FIG 1.** Research methodology flow diagram. CWG, Sustainable Healthy Communities Diverse Cancer Communities Working Group.

reported targeted programs for REMGs in their cancer clinical trials. All centers targeted populations that were consistent with their catchment or service area: FCCC, 10% to 20% (African Americans, Hispanic Americans, Asian Americans); University of Texas Southwestern, 30% to 40% (African Americans, Hispanic Americans); HFCl, 30% to 40% (African Americans); MUSC, 20% to 30% (African Americans, Hispanic Americans); JVCl, 10% to 20% (American Indians/Alaskan Natives); MDACC, 10% to 20% (African Americans, Hispanic Americans, Asian Americans); UCDCCC, 30% to 40% (Asian Americans); and WCI-EMORY, 20% to 30% (African Americans, Hispanic

Americans). Overall, the reported percentage of REMG participants accrued in cancer clinical trials for all eight cancer centers ranged from 10% to 40% in this time period. The majority (six of eight centers) used National Cancer Institute grant criteria<sup>12</sup> as a metric scorecard for inclusion of REMGs and captured Office of Minority Health data in the clinical trial database (seven centers and one center unknown degree of capture). Office of Minority Health REMG data were reported by the patient directly (four centers), research staff informed by direct patient query (two centers), or research staff on the basis of visual observation (one center), and one center's reporting varied

by trial. All centers captured REMG data in written format and six centers also had Web-based capture.

### Summary of Results From Qualitative Surveys

Qualitative surveys conducted in each center identified center-reported outcomes and success factors for REMG recruitment in cancer research. All centers reported that the proportion of REMGs included in cancer research and the engagement of health care professionals in the community as partners had increased over time. Centers also reported the establishment of a process for obtaining ethnically diverse patients' and/or caregivers' input on research projects, as well as engagement of community groups to drive REMG participation. The majority (seven centers) also reported an increase in research funds allocated to understanding, addressing, and improving health disparities, and increased dedication of research center staff to REMG engagement (six centers) over the time period. Five centers reported that community-based participatory research strategies are used as a measure of progress to engage REMGs.

### Notable Practices Summary

The qualitative survey identified notable practices across five themes: commitment and center leadership, investigator training and mentoring practices, community engagement, patient engagement, and operational practices, which are listed in [Table 2](#).

### Leadership and Commitment

Commitment from cancer center leadership toward an institutional focus on diversity and physician and patient engagement results in enhanced inclusion of REMGs in cancer clinical research. Health systems and cancer centers that prioritized recruitment of a diverse faculty demonstrated a commitment to health equity. Six of eight centers reported having a standing cancer center leadership advisory committee that focuses on various aspects including, but not limited to, metrics, process improvement, and notable practices. Three centers reported having leadership support for system-wide campaigns and programs that focus on education and the importance of research and collaboration. MUSC leadership noted the expansion of a state-wide program to reduce cancer disparities.

High REMG recruiting cancer centers model inclusive institutional culture by establishing leadership roles dedicated to diversity issues and minority faculty recruitment. Centers that promote partnerships between faculty and community physicians streamlined access to clinical studies. For example, 30% to 40% of HFCl trial participants were REMGs enrolled through partner research sites. Broad leadership commitment to inclusive patient engagement and outreach to increase the visibility of trials was noted as being key to increasing access and enrollment.

### Investigator Hiring, Training, and Mentoring Practices

Leaders consistently reported a longstanding organizational commitment to quality and diversity in hiring practices, development, and cultural training. Center leaders (HFCl) noted that hiring of research staff that is reflective of the catchment area provides an opportunity to learn and achieve innovative practices. In addition, center leaders (MDACC and WCI-EMORY) noted the importance of developing a diverse faculty reflective of their catchment area and creating an inclusive institutional culture for women and REMGs.

Seven of eight cancer centers noted programs in which junior faculty or students are trained or mentored by senior faculty on aspects of cultural competency and an effective clinical trial discussion approach with patients and care partners. At UCDCCC, senior faculty mentor junior faculty to conduct and generate publications in health disparities research.

### Community Engagement Practices

Having an institutional presence in the community emerged as a fundamental requirement for increasing visibility and developing trustful working relationships with potential research partners. Centers noted the need to invest time and effort with key community representatives to learn about the community, its needs, and potential facilitators and barriers to research participation before approaching communities about research. This upfront investment also enabled researchers to better prepare and engage other relevant staff, such as navigators and financial counselors. Leaders noted that authentic partnerships with communities must extend beyond individual research projects, and that the provision of additional related services is also necessary to build capacity. These services could include multilingual cancer education, describing how research contributes to better care and survivorship as well as access to screening and other preventive health services.

Specific strategies used by multiple institutions to enhance community outreach and engagement included the following:

- Cultural competence training for staff that includes information about motivators, challenges, and barriers to research participation among REMGs
- Community advisory boards composed of diverse stakeholders to guide the development, feasibility, and implementation of research studies
- Lay community representatives—ambassadors—from REMG communities to cultivate community talent and tap into their expertise and networks to reach potential research participants
- Transparency in sharing research findings, potentially via concise, plain language summaries to help participants understand their contributions to science and their community

**TABLE 2.** Summary of Notable Practices of Centers on the Basis of Practice Themes

Cancer Center Summary of Notable Practices								
Practice Theme	FCCC	UTSW	HFCI	MUSC	JVCI	MDACC	UCDCCC	WCI-EMORY
<b>Leadership and commitment</b>	Leadership advisory committee; "Be the Breakthrough" campaign	Leadership advisory committee; "Count Me In" campaign	Leadership advisory committee; employees in leadership reflect diversity in community (hiring practices acknowledged by Diversity) <sup>13</sup>	Leadership advisory committee; collaboration with South Carolina State University to reduce cancer disparities (CPACHE)	Leadership advisory committee; extensive tumor registry of AIs; documentation and publication of cancer disparities in AIs; "Walking Forward Program" <sup>14</sup> to drive trials uptake in AIs	Leadership advisory committee; "Moon Shots Program" <sup>15</sup> focusing on innovation, scale, and collaboration	Extensive registry for HCC covering 25 years and 15 REMGs <sup>16</sup>	Regular leaders' review of accrual data, including REMGs, and action
<b>Investigator training and mentoring practices</b>	Fellows and residents shadow senior physicians to learn how to introduce a clinical trial	Training of fellows coordinated with research patient navigator with prescreen before clinic to ensure consistency of process	Provides mandatory cultural competency training to its entire workforce, including physicians	Developed cancer research training for historically black colleges; has summer student training programs with impact measurement by follow-up; shared development of research protocols with investigators and the community	Ongoing cultural awareness training for researchers and staff; weekly research staff meeting to share practices and successes; focuses on the next generation of physicians and how to give back to the community; celebrates small wins to motivate staff	Longstanding commitment to the hiring and development of women and REMGs to drive faculty diversity	Senior faculty mentor junior faculty to conduct and generate publications in health disparities research; careful selection of interns to assure faculty diversity	Attracts investigators that reflect diversity in cancer research (patients see themselves in the team)
<b>Community engagement</b>	Community ambassador program; community advisory council; described as trusted brokers to patients and care partners	Community research registry; Spanish language validation; partnerships with community constituencies are considered critical to ensure trust and education of patients and care partners	Partnering physician framework for community and private physicians to access trials; framework for credentialing of community physician researchers; community-based tumor boards with a trials participation option within the treatment plan for newly diagnosed patients; partnership with Sisters Network <sup>17</sup>	Community-based navigator program for African Americans <sup>18</sup> ; community outreach train-the-trainer program; research focus on community needs; annual targets and metrics for community-based education; citizen's advisory board; trusted stakeholders are critical to ensure success	Community navigation leaders' and tribal leaders' input into research projects for acceptance, enrollment and institutional review board approval; described as trust brokers; research center measures trust between community navigators and patients as part of the continuum of care	Annual targets and metrics for community partnership growth and onboarding; health educators in the community used as full-time staff; Project CHURCH, a research partnership with faith-based organizations; "Mano a Mano", a Mexican American Health Study established in 2001	Trains bilingual/bicultural lay health workers; community navigators help with translating institutional review board forms; leverages community relationships to promote biospecimen contribution; lay health workers are described as trusted stakeholders	Engages community leaders and social workers early to help patients navigate the health care delivery process; encourages research coordinators to keep close contact and to increase reminders with more vulnerable patients between visits

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**TABLE 2.** Summary of Notable Practices of Centers on the Basis of Practice Themes (continued)  
**Cancer Center Summary of Notable Practices**

Practice Theme	FCCC	UTSW	HFCI	MUSC	JVCI	MDACC	UCDCCC	WCI-EMORY
<b>Patient engagement</b>	Only the HCP has a discussion with the patient about clinical trial availability and eligibility at the time of treatment options discussion; developed "PRE-ACT (Preparatory Education About Clinical Trials)," <sup>19</sup> a decision tool for clinical trial participation; established clinical trial navigators	Only the HCP has a discussion with the patient about clinical trial availability and eligibility at the time of treatment options discussion; has volunteer research participant registry, "MYCHART" (patient portal for consent and sign up)	Only the HCP has a discussion with the patient about clinical trial availability and eligibility at the time of treatment options discussion; uses "Game On Cancer" philanthropic apparatus for travel/logistics support	Only the HCP has a discussion with the patient about clinical trial availability and eligibility at the time of treatment options discussion; employs a comprehensive lay clinical trial patient navigation process	Community research representatives on reservations act as focal points for questions, updates, and for referral to care for patients; Clinical Trials Education for Native Americans (CTENA) curriculum <sup>20</sup> focusing on the availability of trials	Only the HCP has a discussion with the patient about clinical trial availability and eligibility at the time of treatment options discussion; uses culturally sensitive and health literate information from the National Cancer Institute Web site to educate the patient on clinical trials	Only the HCP has a discussion with the patient about clinical trial availability and eligibility at the time of treatment options discussion; generates in-language and culturally sensitive educational materials around trial participation and patient preferences; practices '4 Ts' principles (trust, transparency, time, and talent)	Only the HCP has a discussion with the patient about clinical trial availability and eligibility at the time of treatment options discussion; cross-department coordination and processes to overcome financial challenges; engages social workers early in the health care delivery process to help the patient navigate the process and to assess resources needed; engages a family member or friend in addition to the patient to serve as a second set of ears and reinforcement regarding the trial process; has lay navigator survivors (and clinical trial participants) available in the clinic to talk to patients

Abbreviations: AI, American Indian; CAPACHE, Comprehensive Partnerships to Advance Cancer Health Equity; FCCC, Fox Chase Cancer Center/Temple Health; HCC, hepatocellular carcinoma; HCP, health care provider; HFCI, Henry Ford Cancer Institute; JVCI, John T. Vucurevich Cancer Institute/Rapid City Regional Hospital; MDACC, MD Anderson Cancer Center; MUSC, Hollings Cancer Center/Medical University of South Carolina; REMG, racial and ethnic minority group; UCDCCC, University of California Davis Comprehensive Cancer Center; UTSW, Harold C. Simmons Comprehensive Cancer Center/University of Texas Southwestern; WCI-EMORY, Winship Cancer Institute/Emory.

Using these strategies was reported as a means to enhance recruitment efforts and to strengthen community partnerships, often described as trusted brokers, with patients and care partners. Although community education and outreach can increase a community's understanding of research, leaders noted that the actual invitation to participate in a specific study must remain in the hands of an investigator or study coordinator involved in the study—and in the case of an intervention treatment study, ideally the physician caring for the patient.

### Patient Engagement Practices

Leaders noted that a provider's recommendation is the most important factor that influences a patients' willingness to participate in clinical research. The provider is ultimately responsible for discussing with the patient their potential eligibility for a specific clinical trial at the time patients make decisions on treatment as part of holistic discussions on the current standard of care and the most appropriate treatment approach.

Three additional notable practices reported by all centers included engaging the patient in trial participation decision making; ensuring the availability of culturally appropriate, ethnicity-specific, and cognitively empowering materials; and earning the trust of the patient.

According to the leaders, for patients to make an informed decision regarding the choice to participate in clinical research, study materials (for example, educational pamphlets) must be both culturally and linguistically accessible and user friendly. This includes information produced in various formats (for example, print, audio, or video) and in common and lesser-known languages of REMG communities. Furthermore, leaders noted that patients are more likely to engage in clinical research if providers and researchers take the time to build trusting relationships with patients and their families.

## DISCUSSION

Engaging REMGs in cancer research requires both institutional- and community-based strategies. This work identifies practices in the areas of leadership commitment, standards, and patient- and community-centered practices that characterize centers of excellence with respect to recruiting REMGs to cancer clinical trials. Major findings were captured in pre- and postinterview surveys and expanded on during all leader interviews. In particular, these centers achieved sustainable high recruitment of REMGs by excelling in:

1. Strategic engagement with providers, as they are the most important influence on whether the patient is recruited and participates in clinical trials
2. Community leader engagement as a core center function which results in trust and engagement with REMGs and their care partners

3. Seeking dedicated input into cancer clinical research programs, such as feasibility of implementation, from REMG patients and caregivers.
4. Establishing clear, cross-cancer center leadership commitment to quality and hiring practices to ensure that the composition of research staff represents the population served, allied with a corresponding development and training culture

Leading centers demonstrate an early focus and long-term commitment to physician training and cancer research. At FCCC, fellows, residents, and medical staff receive cultural competence training, learning about how religion and health literacy, for example, affect the patient experience and participation in research. Several cancer centers, including MUSC, have long-standing research and training programs that are affiliated with minority-serving institutions that train future researchers and providers in health disparities.<sup>21</sup> Similarly, the Asian American Network for Cancer Awareness Research and Training enables a mentoring research culture in which junior faculty at UCDCCC focus on disparities and the importance of health equity in research.<sup>22</sup>

An example of how to develop a sustainable, 20-year cancer disparity research culture is from JVCI, which includes a collaborative approach with the community and perseverance.<sup>23</sup> JVCI has fostered trust among the American Indian tribal communities with frequent trips, listening, and hiring of American Indian staff from the local communities. Together with research center staff, they have developed successful interventions to increase REMG recruitment to cancer trials by demonstrating cultural competency and authentically meeting the needs of the community.<sup>24</sup>

A recent American Cancer Society report<sup>1</sup> supports center of excellence practices. Complementary recommendations from this report include the following: seek engagement and partnerships with community leaders and community-based organizations, especially those serving REMGs as well as medically underserved communities, to effectively disseminate information about the importance of clinical research participation as a social justice issue; present patients with cancer with specifically identified trial options as part of the physician-patient treatment decision discussion; design patient-centric trials by using patient input during the design and implementation phases; select research sites for multisite trials with diverse patient populations that reflect the broader population with cancer; and provide clinical trial navigation services tailored to REMGs.

It is important to note the limitations that may affect the interpretation of this cross-cancer center assessment. The small sample size may have had an impact on the results reported. Inclusion of additional center types, such as government facilities, independent cancer centers, different health care systems, and additional geographies, may have yielded different findings. Six of the eight centers were



National Cancer Institute-designated cancer centers. This could lead to the suggestion that the notable practices identified are not generalizable or transferable to other US centers because of the level of longstanding National Institutes of Health funding that may allow for capacity building. However, low-cost resource strategies for improved REMG recruitment were recommended by center leaders during interviews. There was no comparison group of like centers in similar geographies with low accrual rates to fully determine and validate the center-reported drivers of success and there was no priority assessment of drivers of success.

While acknowledging the potential limitations of the current report, we encourage cancer center leaders to transparently share and publish approaches and continue to learn from others in the field of diversity and inclusion in cancer research. We suggest that, if, as a result of this assessment and report, all the drivers of success for accrual of REMGs are optimized, it may result in a general trend toward the improvement of accrual rates of diverse populations beyond the current cancer center sample. The hope is that REMG inclusion becomes a routine part of cancer research center activity as a core capability. Engagement of REMGs in nonclinical studies, as well as models of community health assessments and community partner models, are areas worthy of additional exploration as part of an overall cancer center strategy.

CWG industry members' organizations report that they are actively working to establish practices in support or recruitment and retention of REMGs in cancer clinical trials.<sup>25-29</sup> These include:

1. Proactive identification of new trial sites during the selection process to understand their approach and capabilities, asking active investigator sites to recruit a diverse patient cohort and provide their recruitment strategy

2. Careful consideration of protocol inclusions and exclusions, such as non-clinically relevant criteria that disproportionately affect REMGs
3. Discussion of prospective support/logistics measures for patients so that patients understand what is available to them in the recruiting stage
4. During investigator meetings, provide a rationale for the inclusion of REMGs and provide sites that are culturally sensitive and health literate recruitment materials for use by research staff
5. Active engagement by industry-supported patient engagement programs of representative populations of patients and care partners for insights into protocol and feasibility designs
6. Working with patient organizations to share and educate membership about the availability of specific clinical studies

The advent of promising novel therapies, including immunotherapy and recently discovered genetic therapies, create urgency to improve clinical trial enrollment of REMGs and advance the field. It is critical that REMGs and those who are at higher risk of disease or with poor prognosis participate in genetic testing and clinical research programs in cancer trials and other disease areas if we are to achieve benefit for the whole population.<sup>30,31</sup> In conclusion, we have identified leadership, patient engagement, and community engagement practices that facilitate increased accrual of REMGs in cancer trials. To establish a sustainable cancer center inclusion research strategy, it is valuable to consider capabilities and practices that are informed by leading US cancer centers. Continued focus and progress on increased participation of REMGs in cancer research is needed from multiple collaborative stakeholders to continue to improve our understanding of differences in risk and disease outcomes across populations.

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## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

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## AUTHOR CONTRIBUTIONS

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**Accountable for all aspects of the work: All authors****AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST****US Cancer Centers of Excellence Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials**

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