Use of the National Cancer Data Base to Develop Clinical Trials Accrual Targets that Are Appropriate for Minority Ethnicity Patients

A Report from the American College of Surgeons Oncology Group (ACOSOG) Special Populations Committee

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BACKGROUND. Disparities in cancer outcome among different subsets of the American population related to ethnic background have been well documented. Clinical trials represent the most powerful strategy for improving cancer treatments, but racial and ethnic minority patients are frequently underrepresented among patients accrued to these protocols. Proof of comparable efficacy for a promising cancer therapy in different groups of patients requires diversity in the clinical trial populations so that study results will be generalizable. Appropriate targets for accrual of minority ethnicity patients have not previously been defined.

METHODS. The National Cancer Database (NCDB) is maintained jointly by the American Cancer Society and the American College of Surgeons. Information submitted by tumor registries throughout the United States represents an estimated 70% of newly diagnosed cancer cases. The authors analyzed NCDB reports on ethnic distribution of patients with breast, prostate, nonsmall cell lung, and colorectal cancer, stratified by stage of disease at diagnosis.

RESULTS. African Americans with cancer of the breast and prostate had the most notable patterns of disproportionate representation among populations with advanced-stage disease. The authors compiled a table of suggested accrual targets for selected solid-organ cancers based on NCDB stage-specific reports.

CONCLUSIONS. Clinical trial results will be more meaningful if participating patients reflect the site- and stage-specific populations that are under study. The authors recommended that clinical trial investigators incorporate accrual targets for minority ethnicity populations into the study design. ***Cancer*** **2006;106:188–95.**

KEYWORDS: National Cancer Data Base, ethnicity, minority, disease stage, breast cancer, prostate cancer, nonsmall cell lung cancer, colorectal cancer.

Well documented, but incompletely understood, disparities are observed in cancer incidence and outcome among different subsets of the American population identified by ethnicity and/or race. Population-based survival data for breast, prostate, lung, and colorectal cancer, as reported by the Surveillance, Epidemiology, and End Results (SEER) Program are shown in Figure 1 and demonstrate notably different mortality rates for some minority ethnicity groups such as African Americans, Hispanic/Latino Americans, Native Americans/Alaskan Natives, and Asian Americans compared with White Americans.[1] Mortality risks from these solid-organ malignancies are higher for patients that self-identify as having an African-American

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TABLE 1
Ethnic Distribution[a] of United States Population, Age 18 Years and Older (Estimated Total Adult Population 209,128,094), and Proportions of Population Subsets with No Health Insurance by Ethnicity

Race/Ethnicity	Proportion of U.S. population, %	Proportion with no health insurance, %	Proportion in poverty, %
White American	72.0	14.2	9.1
African American	11.2	19.4	24.9
Hispanic/Latino	11.0	32.8	22.6
American Indian/Alaska Native	0.7	23.8	25.7
Asian	3.7	18.3	12.6
Native Hawaiian/Pacific Islander	0.1	18.6	17.7

Data taken from U.S. 2000 census.[2–4]

[a] Approximately 0.1% of population is characterized as Other, and 1.3% is categorized as belonging to two or more groups.

background. Racial and ethnic minority patients (hereafter referred to as minority ethnicity) populations are disproportionately represented among the uninsured and the impoverished (Table 1),[2–4] supporting the contention that socioeconomic disadvantages and barriers to healthcare access contribute to these outcome disparities. As demonstrated by Ward et al.,[5] cancer outcomes are consistently worse among socioeconomically deprived subsets within individual ethnic groups, but poverty rates alone do not completely explain variations in cancer burden that are observed among different ethnically defined populations. For example, rates of poverty and lack of healthcare coverage are similarly high among African Americans and Hispanic Americans/Latinos, yet reported cancer mortality rates are lower for the latter group. Other factors that may contribute to group-level mortality differences include disparities in delivery of care, primary ethnicity-related variation in tumor biology and/or drug metabolism, and nutritional/dietary patterns.

All of the issues described above are worthy of targeted research; however, one question requiring immediate attention is whether or not standard of care treatment, as well as advanced, investigational therapeutics, can be delivered equitably and with comparable effectiveness to the diverse cancer population in the United States. The clinical trial mechanism should be the appropriate strategy for addressing this question. A well designed prospective, randomized, clinical trial will ensure that cancer treatments are delivered in a standardized fashion to a balanced and representative sample of the cancer population. The importance of achieving this balance in clinical trial enrollment was acknowledged by the National Institutes of Health (NIH) Revitalization Act of 1993,[6] which mandates that the NIH ensure accrual rates of women and minorities onto Phase III clinical trials in numbers that are adequate for analyses. However, there are no universal standards that define optimal accrual proportions. Investigators will typically strive for as much diversity in their patient accruals as possible, but success in this endeavor is typically limited by costs of outreach activities and the extent of diversity in the local patient population where the clinical trial is being offered.

Recent studies have emphasized the challenges of accruing minority ethnicity patients onto cancer clinical trials,[7–16] with most protocols ultimately settling for underrepresentation by these communities. Typically, trialists will use either general population demographics or overall cancer population profiles as benchmarks for defining the optimal ethnic distribution of their study populations. Although it is clearly difficult to achieve accrual patterns that reflect the diversity of these larger populations, some overview analysts have actually reported substantial success when national experience with clinical trials is scrutinized. For example, one study[13] reached the conclusion that as a whole, NCI trials are racially and ethnically representative of the American population, which suggests equal access to NCI clinical trials. This interpretation was based on the ethnic distribution of 99,495 participants accrued to NCI-sponsored cooperative group clinical trials in 1991–1994. Eighty-five percent of these participants were White American; 9.6% were African American; and 5.6% were Hispanic/Latino. These proportions are comparable to general population demographics.

Ethnicity-related variations in incidence and stage distributions for most cancers create a problem that is integrally associated with the disproportionate mortality burden that is observed. Extrapolating from general census data to define accrual targets for cancer clinical trials is, therefore, potentially misleading. For example, African-American women have an overall lower incidence of breast cancer compared with White-American women, yet African-American women are more likely to present with advanced stages of disease. Clinical trials that evaluate promising treatments for high-risk disease should strive for accrual rates that reflect the disproportionately high volume of advanced-stage African-American breast cancer patients. General population and overall breast cancer patient population demographics will yield accrual targets for African-American women that are inappropriately low, as they would not account for the actual profile of American women presenting with advanced stage disease. The goal of this project is to

use data captured and recorded by the National Cancer Data Base (NCDB) for the purpose of defining stage-specific clinical trial accrual targets that more accurately reflect the burden of disease that characterizes different subsets of the American population based on ethnicity and race.

MATERIALS AND METHODS

The NCDB was established in 1989 as a nationwide oncology database. It is maintained as a joint project of the American Cancer Society and the Commission on Cancer of the American College of Surgeons. Information is submitted to the NCDB on an estimated 70% of all newly diagnosed cases of cancer from approximately 1600 hospitals in 50 states (more than 1,000,000 cases per year). The dataset includes demographic, clinical, and health system data elements that are needed to assess quality of care. Hospitals contributing tumor registry information to the NCDB have cancer programs that are approved by the Commission on Cancer, and they are categorized as follows:

1. Community Hospitals Cancer Program (CHCP) accessions are 100–649 cancer cases per year; CHCPs compose 38% of Commission on Cancer-approved programs.
2. Community Hospital Comprehensive Cancer Program (COMP) accessions are at least 650 cancer cases per year; COMPs compose 36% of Commission on Cancer-approved programs.
3. Teaching Hospital Cancer Program (THCP) must be within a facility affiliated with a medical school that participates in resident training in at least four areas, two of which are medicine and surgery; THCPs compose 22% of Commission on Cancer-approved programs.
4. NCI-designated program Comprehensive Cancer Program (NCIP) must take place within a facility that is sponsored by an NCI peer-reviewed Cancer Center Support Grant and is designated by the NCI as a Comprehensive Cancer Center Program; NCIPs compose 2% of Commission on Cancer-approved programs.
5. Network Cancer Program (NCP) occurs within an organization owning multiple facilities that provide integrated cancer care and offering comprehensive services; NCPs compose 1% of Commission on Cancer-approved programs.
6. Hospital Associate Cancer Programs, Affiliate Hospital Cancer Programs, Integrated Cancer Programs, and Freestanding Cancer Center Programs are outpatient and/or lower volume cancer programs; collectively they compose 1% of Commission on Cancer-approved programs.

We compiled information from the NCDB 2001 data collections involving cancer of the breast, prostate, lung (nonsmall cell), and colorectum. These collections involved information submitted on cancer patients from different hospitals as follows:

Breast Cancer: 159,193 cases from 1266 hospitals;
Prostate Cancer: 110,505 cases from 1261 hospitals;
Lung Cancer: 93,573 cases from 1271 hospitals;
Colorectal Cancer: 68,780 cases from 1268 hospitals.

We then evaluated the distribution of patients according to ethnic background for each stage category. The American Joint Commission on Cancer 5th edition staging system was used, as this was the version in effect during 2001, the year of data collection.[17] Information on patient ethnicity is recorded as submitted by the tumor registries for the NCDB participating hospitals and generally reflects self-reported data.

The decision was made before beginning the current study to not test for statistical significance, as the very large sample sizes would have resulted in significant values for absolute differences of relatively small magnitude.

RESULTS

Tables 2–5 reveal ethnic distributions within disease stage and total organ-specific cancer populations according to NCDB reports on breast, prostate, lung, and colorectal cancers, respectively. The most notable disparities were seen for African Americans, who were disproportionately overrepresented in advanced stage categories.

Although African-American women accounted for only 9% of all breast cancer cases in the United States, they represented 14% and 15% of all Stage III and IV breast cancer patients, respectively. In prostate cancer, African-American men represented 12.7% of patients affected, yet accounted for nearly 20% of all Stage IV cases. Similar, but lesser magnitude, patterns of disproportion were observed for nonsquamous cell lung and colorectal cancer patient populations.

Proportions of other minority ethnicity subsets within stage groupings for all four of the cancers evaluated were comparable to their proportions within the total cancer population for each cancer. Hispanic/Latino Americans are estimated to account for 3–4% of breast, prostate, and colorectal cancer populations, and they account for similar proportions within stages of these cancers. Hispanic/Latino Americans account for 2.2% of all lung cancers recorded by the NCDB, and they are estimated to represent 1.7–2.6% of the Stage I–IV disease cases. Native Americans/American Indians account for less than 0.5% of all cases and all stages of breast, prostate, lung, and colorectal cancer.

TABLE 2
Distribution of Patient Ethnicity for Breast Cancer Stratified by Stage of Disease[a]

Group	Proportion of total breast cancer patient population (n = 159,193)	Proportion of Stage 0 pts (n = 26,786)	Proportion of Stage I pts (n = 63,977)	Proportion of Stage II pts (n = 48,555)	Proportion of Stage III pts (n = 9436)	Proportion of Stage IV Pts (n = 5403)
White American	83.1%	82.5%	86.8%	81.1%	77.3%	76.5%
African American	9.0%	9.1%	6.4%	10.4%	14.0%	15.2%
Hispanic/Latino American	3.4%	3.3%	2.7%	4.0%	4.8%	4.2%
Native American	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%
Asian American	2.3%	2.7%	2.1%	2.3%	2.0%	2.0%

[a]Proportions in each column do not sum to 100% because data for unknowns are not shown.

TABLE 3
Distribution of Patient Ethnicity for Prostate Carcinoma Stratified by Stage of Disease[a]

Group	Proportion of total prostate cancer patient population (n = 110,505)	Proportion of Stage I pts (n = 2689)	Proportion of Stage II pts (n = 87,298)	Proportion of Stage III pts (n = 8900)	Proportion of Stage IV pts (n = 5879)
White American	79.9%	80.5%	80.4%	81.4%	71.9%
African American	12.7%	11.5%	12.4%	11.1%	19.6%
Hispanic/Latino American	3.7%	3.7%	3.6%	3.8%	4.7%
Native American	0.1%	0.2%	0.1%	0.2%	0.2%
Asian American	1.5%	2.1%	1.5%	1.5%	1.7%

[a]Proportions in each column do not sum to 100% because data for unknowns are not shown.

TABLE 4
Distribution of Patient Ethnicity for Nonsmall Cell Lung Cancer Stratified by Stage of Disease[a]

Group	Proportion of total lung cancer patient population (n = 93,573)	Proportion of Stage I pts (n = 21,704)	Proportion of Stage II pts (n = 7304)	Proportion of Stage III pts (n=24,460)	Proportion of Stage IV pts (n = 33,975)
White American	84.4%	87.7%	86.7%	83.7%	82.9%
African American	10.2%	8.0%	9.1%	11.0%	11.3%
Hispanic/Latino American	2.2%	1.7%	1.8%	2.3%	2.6%
Native American	0.2%	0.2%	0.1%	0.2%	0.2%
Asian American	1.7%	1.3%	1.2%	1.7%	2.0%

[a]Proportions in each column do not sum to 100% because data for unknowns and in situ lesions are not shown.

Asian Americans are estimated to account for 1.5–2.7% of these cancers and their stage groups.

DISCUSSION

The NCDB reports reveal several disparities in proportions of minority ethnicity patients presenting with advanced stages of the most common solid-organ malignancies, such as breast, prostate, nonsquamous cell lung, and colorectal cancer (Fig. 1). These patterns are most notable for African Americans. We believe that this disproportionate representation should be considered in the design of cancer clinical trials. Prospective planning of appropriate accrual "targets" for minority ethnicity patients will strengthen the likelihood that trial results will be generalizable and meaningful for the entire population of cancer patients. Ideally, the study patient population will reflect the stage-specific patient population for which the protocol is designed.

Table 6 summarizes the ethnic distribution for patients accrued onto various clinical trials as reported by disease sites and accrual intervals. In con-

TABLE 5
Distribution of Patient Ethnicity for Colorectal Cancer Stratified by Stage of Disease[a]

Group	Proportion of total colorectal cancer patient population (n = 68,780)	Proportion of Stage 0 Pts (n = 5012)	Proportion of Stage I pts (n = 14,339)	Proportion of Stage II pts (n = 18,067)	Proportion of Stage III pts (n = 15,474)	Proportion of Stage IV pts (n = 11,495)
White American	82.4%	80.6%	84.5%	84.0%	81.5%	79.6%
African American	10.9%	12.5%	9.3%	9.4%	11.5%	13.4%
Hispanic/Latino American	3.0%	2.4%	2.8%	3.3%	2.9%	3.2%
Native American	0.2%	0.2%	0.2%	0.1%	0.2%	0.2%
Asian American	2.1%	2.3%	1.9%	1.8%	2.5%	2.2%

[a]Proportions in each column do not sum to 100% because data for unknowns are not shown.

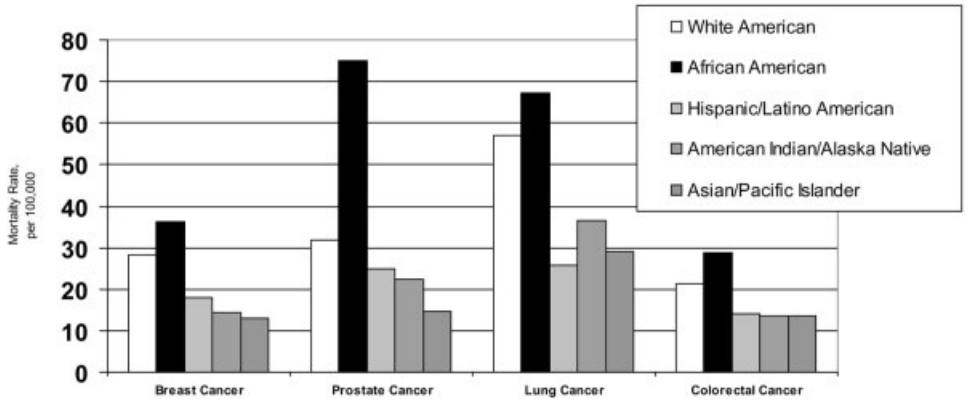

FIGURE 1. Five-year survival rates from breast, prostate, nonsmall cell lung, and colorectal cancer for White Americans, African Americans, and Hispanic/Latino Americans. Data taken from SEER*Stat Database.[1]

trast, Table 7 demonstrates some suggested accrual targets for the four solid-organ malignancies that we evaluated in the current study. These accrual targets are based on assessment of overall organ site-specific distributions of patients by ethnic background, as well as stage-specific distributions within particular cancers. For advanced stages of cancer where a minority ethnicity group is overrepresented, we recommend that a protocol strive for an accrual that matches this relatively higher proportion. For early stage disease, where the minority ethnicity population is underrepresented, we recommend using the proportion contributed by that group to the total cancer-specific population. Use of NCDB reports allows clinical trialists to incorporate ethnicity-specific accrual targets into protocol design and to plan for adequate resources to meet these goals. Focused NCDB reports can also facilitate design of clinical trial accrual targets that account for regional variation in cancer burden.

A few comments are necessary regarding the minority ethnicity populations that are evaluated in this project. The terms *Asian Americans* and *Pacific Islanders* are frequently grouped together in reporting of cancer statistics, and these population subsets are actually comprised of many different communities with disparate languages, cultures, and ancestries. The same is true for *Native Americans/Alaskan Natives*, and *Hispanic/Latino Americans*. For the purpose of streamlining accrual target recommendations, these oversimplifications were used in this report also, and a thorough review of issues that more accurately describe the heterogeneity of these populations is beyond the scope of this article. Clinical trial investigators should be cognizant of possible variations in outreach needs for subsets within these communities, based on linguistic issues, culture, and/or socioeconomic differences.

The importance of ethnic diversity in the study of human disease through clinical trials is not a new concept, and it is certainly not limited to the study of cancer. These issues, and the challenges of addressing them, are apparent in medical literature concerning cardiovascular diseases,[18–20] heart failure trials,[21] mental health trials,[22–24] and infectious disease studies,[25] among others. Hussain-Gambles et al.[9] provided a concise list of barriers that prevent minority ethnic-

TABLE 6
Ethnic/Racial Distributions of Patients Accrued to Cancer Clinical Trials According to Selected Reported Studies

Study (accrual yrs)			White American	African American	Hispanic/Latino American	Asian American/ Pacific Islander	American Indian/ Alaska Native
Tejeda et al.[16]		Breast	86.8	10.0	3.2	NR	NR
Review of NCI-funded clinical trials		Prostate	82.8	14.7	2.5	NR	NR
(1991–1994)		Lung	88.7	9.8	1.4	NR	NR
		Colorectal	88.4	8.4	3.2	NR	NR
Hutchins et al.[10]		Breast	NR	10	NR	NR	NR
SWOG clinical trials		Prostate	NR	21	NR	NR	NR
(1993–1996)		Lung	NR	13	NR	NR	NR
		Colorectal	NR	8	NR	NR	NR
Swanson et al.[15]			90[a]	10.5	0.4	0.04	< 0.01
Literature review of treatment trials (1973–1998)							
Sateren et al.[13]			80.1	9.4	6.7	2.1[b]	0.6
Review of NCI-funded clinical trials (1998–1999)							
Newman et al.[12]		Breast	86.3	7.7	2.5	2.2	0.06
ACOSOG clinical trials		Lung	89.7	5.0	0.5	1.5	0.09
(1998–2003)		Colorectal	79.7	11.6	5.8	4.3	1.4
Murthy et al.[11]	Accrual by yr	1996	83.0	11.0	3.7	2.1	0.3
Review of NCI-funded trials		1999	86.0	9	3.0	1.5	0.5
(1996–2002)		2002	86.6	7.9	3.0	2.2	0.3
	Accrual by site (2000–02)	Breast	87.2	7.0	3.2	2.3	0.3
		Prostate	80.3	15.5	2.3	1.3	0.2
		Lung	89.7	7.4	1.4	1.3	0.3
		Colorectal	87.8	6.9	3.1	1.9	0.3

NCI: National Cancer Institute; SWOG: Southwest Oncology Group; ACOSOG: American College of Surgeons Oncology Group.
[a] Estimated value based on reported data.
[b] 1.5% Asian American and 0.6% Hawaiian/Pacific Islander.

TABLE 7
Suggested Accrual Targets for Minority-Ethnicity Patients by Stage-Specific Protocol Eligibility

Cancer		African American	Hispanic/Latino American	Asian American/ Pacific Islanders	American Indian/ Native American
Breast	DCIS/Early-stage/Node-negative	≥ 11%	≥ 5%	≥ 3%	≥ 0.5%
	LABC/Node-positive/Stage IV	≥ 14%	≥ 5%	≥ 3%	≥ 0.5%
Prostate	Stages I–III nonmetastatic	≥ 12%	≥ 5%	≥ 2%	≥ 0.2%
	Stage IV metastatic	≥ 19%	≥ 5%	≥ 2%	≥ 0.2%
Lung	Stages I–III nonmetastatic	≥ 10%	≥ 2%	≥ 2%	≥ 0.2%
	Stage IV metastatic	≥ 12%	≥ 2%	≥ 2%	≥ 0.2%
Colorectal	Stages 0–II	≥ 10%	≥ 5%	≥ 3%	≥ 0.2%
	Stages III/IV	≥ 12%	≥ 5%	≥ 3%	≥ 0.2%

DCIS: ductal carcinoma in situ; LABC: locally advanced breast cancer.

ity individuals from optimally using the clinical trials mechanism. These barriers are

1. fear or mistrust,
2. inappropriate exclusion criteria,
3. poorly designed protocols,
4. inadequate access to clinical trials,
5. costs associated with interpretation or translation services required for informed consent,
6. sociocultural barriers, and
7. stereotypes or cultural myths.

Overcoming these factors will require education and behavior modification at both physician–provider and patient levels. Patients must receive education on the safety and advantages of clinical trial participation; enrollment in a clinical trial is actually a safeguard that ensures well monitored and standardized care that is

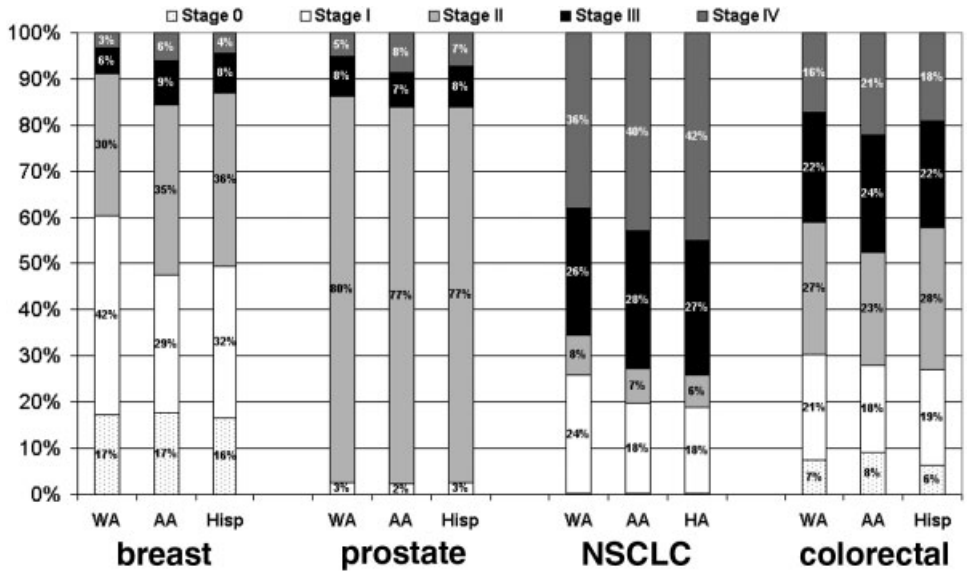

FIGURE 2. Stage distribution of breast, prostate, nonsmall cell lung (NSCLC), and colorectal cancer for White Americans, African Americans, and Hispanic/Latino Americans.

free of physician bias and discriminatory practices in delivery of care. Physicians must have knowledge of the critical importance of ethnic and minority diversity to the implementation of a meaningful clinical trial. The physician must also resist the temptation to assume that a patient will not be interested in a clinical trial because of his or her ethnic background and/or socioeconomic status.

Cultural competence[26] must be apparent throughout various stages of protocol design, initiation, and interpretation of results. Unfortunately, several investigators are reporting deficiencies in these areas. Adams-Campbell et al.[7] demonstrated inherent barriers in clinical trial design that precluded African Americans from being eligible to participate in clinical trials in a Howard University study. Simon et al.[14] reported that African-American breast cancer patients were significantly less likely to be offered a clinical trial compared with their White-American counterparts. Both investigators found that African Americans had relatively high rates of trial participation if they were eligible and if the trial was offered.

Issues pertinent to costs of clinical trial participation are also relevant. Whereas several studies have demonstrated cost efficiency of clinical trials,[27–29] a facility that offers clinical trials must have an infrastructure that can support the safe and well regulated implementation of research protocols. A large proportion of minority ethnicity patients receive routine healthcare as well as cancer care through the so-called "safety-net institutions,", i.e., the publicly funded city and county hospitals.[30] Efforts to conduct clinical research in these settings are often derailed by the overwhelming burden of providing completely uncompensated care to a patient population that has complex and often long-neglected medical needs.

Several potential limitations of this study deserve comment. The NCDB is a powerful resource, and its magnitude suggests that it will accurately reflect cancer patient populations of most practices. The NCDB was not designed as a population-based registry, as was the Surveillance, Epidemiology, and End Results (SEER) Program. However, patterns of cancer patient demographics and stage distributions tend to be similar in reports from the NCDB and the SEER databases, and it is, therefore, reasonable to assume comparable strength for the two registries in reflecting the general cancer population in the United States. Nonetheless, it is possible that cancer information on a significant proportion of indigent patients and, therefore, many minority ethnicity patients is excluded from data collected by the NCDB, because tumor registry data are voluntarily submitted by participating institutions (Fig. 2).

Another limitation is that our accrual targets are based on available current data, and cancer information on some population subsets with rapidly changing demographics will impact future clinical trial needs. For example, SEER data as well as NCDB data indicate that Hispanic Americans account for less than 5% of the cancer population. The Hispanic-American community is one of the most rapidly growing subsets of the American population, and it is projected to account for 24% of the national population by the year 2050.[31] We suggest accrual targets of at least 5% for Hispanic Americans on

cancer clinical trials. Although this target is greater than the average 2–3% accrued onto past trials, investigators should consider the likelihood that Hispanic Americans will compose a significantly larger proportion of future cancer patient populations.

In summary, the challenge of achieving ethnic balance and an appropriate degree of diversity in the clinical trial patient population is a difficult one. Nonetheless, it is a challenge that the oncology community is obligated to address. Otherwise, we will never reach our ultimate goal of minimizing the threat of cancer to the longevity of the individual as well as the strength and productivity of the many communities that compose our society.

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