HHS Public Access

Author manuscript

Ann Surg Oncol. Author manuscript; available in PMC 2018 January 18.

Published in final edited form as:

Ann Surg Oncol. 2011 December ; 18(13): 3544–3550. doi:10.1245/s10434-011-1818-9.

Features Associated with Successful Recruitment of Diverse Patients onto Cancer Clinical Trials: Report from the American College of Surgeons Oncology Group

Kathleen M. Diehl, MD, FACS, **Erin M. Green**, **Armin Weinberg, PhD**, **Wayne A. Frederick, MD, FACS**, **Dennis R. Holmes, MD, FACS**, **Bettye Green**, **Arden Morris, MD, FACS**, **Henry M. Kuerer, MD, PhD, FACS**, **Robert A. Beltran, MD, FACS**, **Jane Mendez, MD, FACS**, **Venus Gines**, **David M. Ota, MD, FACS**, **Heidi Nelson, MD, FACS**, and **Lisa A. Newman, MD, MPH, FACS*** **on behalf of On Behalf of the Special Populations Committee of the American College of Surgeons Oncology**

Abstract

Background—The clinical trials mechanism of standardized treatment and follow-up for cancer patients with similar stages and patterns of disease is the most powerful approach available for evaluating the efficacy of novel therapies, and clinical trial participation should protect against delivery of care variations associated with racial/ethnic identity and/or socioeconomic status. Unfortunately, disparities in clinical trial accrual persist, with African Americans (AA) and Hispanic/Latino Americans (HA) underrepresented in most studies.

Study Design—We evaluated the accrual patterns for ten clinical trials conducted by the American College of Surgeons Oncology Group (ACOSOG) 1999–2009, and analyzed results by race/ethnicity as well as study design.

Results—Eight of ten protocols were successful in recruiting AA and/or HA participants; three of four randomized trials were successful. Features that were present among all of the successfully-recruiting protocols were: (i) studies designed to recruit patients with regional or advanced-stage disease (2/2 protocols); and (ii) studies that involved some investigational systemic therapy (3/3 protocols).

Discussion—AA and HA cancer patients can be successfully accrued onto randomized clinical trials, but study design affects recruitment patterns. Increased socioeconomic disadvantages observed within minority-ethnicity communities results in barriers to screening and more advanced cancer stage distribution. Improving cancer early detection is critical in the effort to eliminate outcome disparities but existing differences in disease burden results in diminished eligibility for early-stage cancer clinical trials among minority-ethnicity patients.

Introduction

The clinical trials mechanism is one of the most powerful strategies available for improving the standard of care and survival rates for cancer patients. Participation in a clinical trial

*Corresponding Author: Lisa A. Newman, MD, MPH, FACS, Professor of Surgery, Director, Breast Care Center, University of Michigan, 1500 East Medical Center Drive, Ann Arbor, MI 48109, Tel: 734-936-8771, Fax: 734-647-9647, lanewman@umich.edu.

requires significant trust, compliance, and motivation at the patient level. At the provider level it places substantial demands on time, staffing, and financial resources of the clinical practice. However, the fundamental elements of clinical trial design--standardized delivery of care and follow-up for novel treatments compared to pre-existing approaches--are essential in the effort to make meaningful advances in cancer outcomes.

Findings from an oncology clinical trial cannot be reliably generalized unless the demographic profiles of the study participants and the larger, overall patient population are comparable. Unfortunately, minority racial/ethnic groups have historically been under-represented in cancer clinical trials. Explanations for this accrual disparity include: lack of trust in the healthcare system; socioeconomic disadvantages (since poverty rates are higher among racial/ethnic minorities and they are therefore less likely to receive cancer care in affluent facilities where clinical trials are offered); and lack of awareness of clinical trial benefits. Regardless of explanation, disproportionately low accrual of racial/ethnic minorities raises questions regarding efficacy of the studied treatment across all racial/ethnic and socioeconomic strata.

The American College of Surgeons Oncology Group (ACOSOG) has previously published studies of our accrual patterns related to racial/ethnic identity, and with regard to potential accrual “targets” that account for racial/ethnic distribution of the general cancer population after accounting for particular organ site as well as stage at diagnosis(1, 2). Table 1 summarizes the results of our studies with regard to developing accrual targets for African American and Hispanic/Latino Americans onto breast and thoracic clinical trials, based upon data from general population demographics and the National Cancer Data Base (NCDB). This manuscript describes the racial/ethnic profiles of patients accrued onto the clinical trials of ACOSOG. We compare herein the features of the trials that were most successful in achieving accrual diversity with those that were the least successful.

Methods

ACOSOG is a surgically-based clinical trials cooperative group funded by the National Cancer Institute of the National Institutes of Health. We looked at the demographics of participants accrued to ten completed and/or closed ACOSOG studies; we focused on distribution of African American (AA) and Hispanic/Latino American (HA) participants compared to White/European American (WA) participants because the largest magnitude disparities in cancer burden have reported for these population subsets. Racial-ethnic identity was assigned according to patient-reported information ascertained at the time of protocol registration. All of the ACOSOG clinical trials were reviewed and approved by the Institutional Review Boards of the participating cancer-treating facilities.

The ten trials included in this report were selected if they had reached an accrual target of at least 100 participants and were either closed or nearly-closed to further accrual. These ten studies were conducted by the following ACOSOG Committees: Breast (three trials); Sarcoma (two trials); and Thoracic (five trials).

The clinical trials included in this evaluation were categorized by the following protocol features, which were selected because of an a priori concern that these features might be correlated with ability to successfully recruit minority racial/ethnic groups for participation: (i) randomized versus non-randomized study; (ii) protocol designed for early stage disease versus regional and/or locally-advanced disease; and (iii) protocol design featured an investigational drug/systemic therapy in conjunction with surgery versus protocol primarily studying a surgery/surgical staging question.

Accrual rates for the various evaluated ACOSOG protocols were then categorized as being "successful"; "modestly-successful" or "unsuccessful" with regard to proportions of participants self-identifying as being AA or HA. Ranges for these categories were selected as a function of both general population demographics and estimates of the distribution of racial/ethnic minorities within specific cancer type, stratified by stage, and as previously reported(2) as suggested accrual targets for breast and thoracic cancer by ACOSOG. These accrual targets were presented to and promoted among the ACOSOG membership during plenary session lectures at ACOSOG annual meetings, at committee conference calls, and at both disease site committee as well as administrative committee meetings. Accrual targets for sarcoma and esophageal cancers were not previously developed by ACOSOG, and successful accrual diversity for these cancers were defined in correlation with general population demographics.

Early-Stage Breast Cancer Protocols		
	Successful	Unsuccessful
AA	≥11%	<5%
HA	≥5%	<2%
Regionally-Advanced/Node-Positive Breast Cancer Protocols		
	Successful	Unsuccessful
AA	≥14%	<6%
HA	≥5%	<2%
Non-Metastatic Lung Cancer Protocols		
	Successful	Unsuccessful
AA	≥10%	<6%
HA	≥2%	<1%
Metastatic Lung Cancer Protocols		
	Successful	Unsuccessful
AA	≥12%	<6%
HA	≥2%	<1%
Sarcoma, Esophageal Cancer Protocols		
	Successful	Unsuccessful
AA	≥10%	<6%
HA	≥10%	<6%

We then assessed frequency of successful recruitment diversity among protocols characterized by the various protocol features. The overall small sample sizes of evaluated

studies and study features precluded statistical significance testing. The overall small sample sizes of evaluated studies and study features precluded statistical significance testing.

Results

The ten evaluated studies (1999–2009) are described in Table 2, representing breast, thoracic and sarcoma cancer protocols. As shown in Table 3, four studies (40%) were randomized clinical trials; eight (80%) were restricted to participants with early-stage/resectable disease; and three protocols (30%) included the study of some investigational systemic therapy approach.

As shown in Table 4, eight trials (80%) were successful or modestly successful with regard to recruitment of AA and/or HA participants; only one trial (Breast Z1031) was successful in recruiting both AA and HA and two trials were unsuccessful with regard to recruiting both AA and HA participants.

Table 5 summarizes frequency of success/modest success among protocols with particular features. Three-quarters of the randomized trial protocols were successful or modestly-successful in recruiting AA and/or HA participants. Protocol features that were consistently associated with successful recruitment diversity were: (i) studies limited to recruitment of patients with regional or advanced-stage disease (2/2 protocols); and (ii) studies that involved some investigational systemic therapy approach (3/3 protocols).

Discussion

The National Institutes of Health (NIH) Revitalization Act of 1993(3) mandates that the NIH-funded investigators accrue women and minorities onto clinical trials in numbers that are adequate for analyses. Furthermore, many prominent cancer support and funding organizations such as the American Cancer Society and Susan G. Komen for the Cure aggressively advocate in favor of outreach to racial/ethnic minority communities for clinical trial participation.

Past atrocities and abuses of human rights in the conduct of clinical research, such as the notorious “Tuskegee Study of Untreated Syphilis in the Negro Male”, have left a legacy of mistrust regarding the healthcare delivery system. This fear of clinical research is pervasive, and it has been documented among potential clinical trial participants of all racial/ethnic backgrounds for both cancer and non-cancer clinical trials, but it is particularly pronounced among racial/ethnic minorities(4–6) (7) (8–10) (11) (12). Improving successful accrual diversity will require education and behavior modification at both the physician-provider and patient levels. Patients must be educated regarding the safety and advantages of clinical trial participation: enrollment in a clinical trial can serve as a safeguard to insure delivery of well-monitored and standardized care that is free of physician/provider bias and discriminatory practices. Physicians must be educated regarding the critical importance of diversity in 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 their ethnic background and/or socioeconomic status. Balanced presentation of all treatment options (including clinical trial participation) is seminal to the ethical practice of oncology(13, 14).

The findings summarized in this manuscript confirm that eligible AA and HA patients commit to clinical trial participation in robust numbers when given the opportunity.

Cultural competence(15) must be apparent throughout the various stages of protocol design, initiation, and interpretation of results. Unfortunately, several investigators are reporting deficiencies in these areas. Adams-Campbell et al(16) 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(17) reported that African American breast cancer patients were significantly less likely to be offered a clinical trial compared to 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.

Governmental support for healthcare outreach programs will hopefully strengthen relationships between oncology providers and racial/ethnic minority populations. On June 29, 2005, President Bush signed into law the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 (P.L. 109-18). The concept of patient navigators was first introduced by Dr. Harold P. Freeman, as a strategy for improving delivery of comprehensive cancer screening, diagnostic, and treatment services. Use of navigators has been shown to improve breast cancer outcomes by strengthening mammography utilization and yielding earlier detection of disease; these trained patient assistance programs can also be utilized to improve recruitment and retention of diverse patient populations onto clinical trials(18, 19).

Many regulatory practices are now federally-mandated as a direct consequence of past misbehaviors by clinical trialists. Non-compliance with these regulations may result in punitive action, such as monetary fines and forced closure of research programs. Ability to continue offering clinical trial participation therefore requires substantial time and staff resources, leaving only the most affluent health care facilities with the infrastructure to maintain regulatory compliance. Poverty is clearly associated with diminished effectiveness of “basic” cancer screening/early detection programs(20, 21), and it is intuitively clear that financial support for clinical trial implementation is less likely to be available in public/safety-net institutions. Since AA and HA are over-represented among the impoverished and the under-insured, they are therefore also less likely to have access to private/university/academic centers where clinical trials are more commonly offered. This is an especially tragic result, because the contemporary clinical trials mechanism actually represents the “safest” strategy for racial/ethnic minority patients to receive standardized and appropriately monitored care. The clinical trial setting also provides more expedient opportunities to receive novel cancer treatments that might be otherwise unavailable either because of prohibitive costs or limited availability.

ACOSOG has previously suggested that cancer clinical trials should consider using accrual targets for racial/ethnic minorities to improve the generalizability of study findings. ACOSOG has furthermore suggested that these targets should be defined by distribution of racial/ethnic minorities by cancer type and cancer stage because of well-documented variations in cancer burden. Our current analyses of ACOSOG accrual patterns suggest that there is ample room for improving the diversity of cancer clinical trial participants, but we have also shown that these clinical trial targets are indeed achievable. The ten ACOSOG

trials meeting the selection criteria of having at least 100 participants and being closed or nearly-closed represented approximately half of all ACOSOG protocols activated during the development of this report. While the total number of trials evaluated is relatively small, the patterns for accrual success are nonetheless relevant and promising with regard to future clinical trial recruitment efforts.

ACOSOG accrual sites are widely-distributed throughout the United States. Specific details regarding accrual patterns for all ACOSOG trials by race/ethnicity, type of practice and characteristics of ACOSOG investigator are unavailable at this time for this particular manuscript, however these features have been previously analyzed and reported by Leitch et al(22) in a study of the ACOSOG Z0010 Breast Sentinel Lymph Node trial. Leitch et al reported that nearly half of participating surgeons represented academic programs; nearly one-third represented community practices; and 75% of minority patients were accrued by one-quarter of participating surgeons.

Accrual patterns from the ACOSOG protocols suggest that minorities may well be seeking out otherwise-unavailable treatments through the clinical trials process, since the study of Gleevec for GIST's had the most impressive accrual diversity. Gleevec did not receive FDA approval for this hereto-fore highly-fatal cancer until after the trial results were released.

Trials for early-stage cancers (especially operable thoracic tumors) were less likely to be successful in accruing AA and HA patients. This suggests that failure of cancer screening and early detection efforts among racial/ethnic minority communities may be yielding an inherently smaller pool of racial-ethnic minorities that are eligible to participate in clinical trials designed for early-stage disease. This was readily apparent in the ACOSOG Breast trials. The Z0010 trial had the earliest stage disease eligibility, requiring patients to have small, lumpectomy-eligible tumors, and clinically node-negative disease; this trial accrued fewer than 10% AA and HA participants. In contrast, the ACOSOG breast cancer trials for node-positive and/or locally advanced disease (Z0011 and Z0031) included larger proportions of AA and HA patients. Efforts to improve cancer surveillance and earlier detection are obviously essential for improved outcome (above all) as well as improved and more representative clinical trial eligibility. These observations also suggest that the development of additional clinical trials for women with later stage cancer could expand clinical trial opportunities for racial/ethnic populations that tend to present with more advanced disease.

The disparity in estimates for proportion of Hispanic/Latino Americans in the general U.S. population compared with the proportion of Hispanic/Latino Americans with a cancer diagnosis is noteworthy, and correlates with the notably lower proportion of Hispanic/Latino Americans accrued onto clinical trials. For example, SEER data as well as the NCDB indicate that Hispanic/Latino 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, accounting for more than 13% of the current population and projected to account for 24% by the year 2050(23). This disproportionately low frequency of Hispanic/Latino Americans among the cancer patient population may be a reflection of differences in self-reported racial/ethnic identity related to demographics ascertained by the

U.S. Census versus data obtained by cancer registries and clinical trialists. These differences made it more difficult to select accrual targets that are both achievable and representative of the cancer population as well as the general population. We suggested accrual targets of at least 5% for Hispanic/Latino Americans onto most cancer clinical trials. While this target is greater than the average 2–3% accrued onto past trials, investigators should consider the likelihood that Hispanic/Latino Americans will comprise a significantly larger proportion of the future cancer patient population as the Hispanic/Latino population expands and as ascertainment of racial/ethnic identity by cancer registries becomes more robust.

ACOSOG recognizes the widespread difficulties associated with recruitment of diverse patient populations onto their clinical trials. This cooperative group has worked aggressively to address and overcome barriers to accrual diversity through several strategies. The Education Committee develops patient-oriented printed materials regarding ACOSOG protocols, and these materials are reviewed by the Special Populations and Patient Advocates Committees. Unfortunately, these materials are not routinely available in non-English languages. The Patient Advocates and Special Populations Committees also work together closely by meeting at the ACOSOG Annual Meetings, and by implementing a luncheon speaker series designed to inform the ACOSOG membership regarding disparities in oncology. This speaker series emphasizes the importance of using the clinical trial mechanism to improve our understanding of cancer risk and outcome disparities, and has included topics such as geriatric oncology; the cancer burden of Hispanic/Latina communities; disparities in thoracic oncology; and use of genotyping/Ancestry Informative Markers in clinical trials. The possible existence of geographic variation in accrual diversity is another important and relevant issue, but unfortunately these data were not uniformly available for all ACOSOG protocols. Discussions at ACOSOG meetings however, indicated relatively greater success in recruiting Hispanic/Latina patients from southwest sites in the United States (unpublished data).

In summary, our study of accrual patterns onto ACOSOG clinical trials demonstrated that successful recruitment of minority racial/ethnic groups is indeed feasible, regardless of whether the protocol involves randomization and regardless of whether an investigational therapeutic drug is being offered. Trial eligibility limited to early-stage disease appears to be a significant barrier to clinical trial participation. Efforts to improve early detection of cancer in racial/ethnic minorities must be strengthened, and outreach to diverse patients for clinical trials evaluating locally advanced stages of disease should continue.

References

1. Newman LA, Hurd T, Leitch M, Kuerer HM, Diehl K, Lucci A, et al. A report on accrual rates for elderly and minority-ethnicity cancer patients to clinical trials of the American College of Surgeons Oncology Group. J Am Coll Surg. 2004; 199(4):644–51. [PubMed: 15454152]
2. Newman LA, Lee CT, Parekh LP, Stewart AK, Thomas CR Jr, Beltran RA, et al. 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 Population Committee. Cancer. 2006; 106(1):188–95. [PubMed: 16333856]
3. NIH Revitalization Act. Public Law. 1993:103–43.
4. Peterson ED, Lytle BL, Biswas MS, Coombs L. Willingness to participate in cardiac trials. Am J Geriatr Cardiol. 2004; 13(1):11–5. [PubMed: 14724396]

5. Beswick AD, Rees K, Griebsch I, Taylor FC, Burke M, West RR, et al. Provision, uptake and cost of cardiac rehabilitation programmes: improving services to under-represented groups. Health Technol Assess. 2004; 8(41):iii–iv. ix–x, 1–152.
6. Bartlett C, Davey P, Dieppe P, Doyal L, Ebrahim S, Egger M. Women, older persons, and ethnic minorities: factors associated with their inclusion in randomised trials of statins 1990 to 2001. Heart. 2003; 89(3):327–8. [PubMed: 12591845]
7. Heiat A, Gross CP, Krumholz HM. Representation of the elderly, women, and minorities in heart failure clinical trials. Arch Intern Med. 2002; 162(15):1682–8. [PubMed: 12153370]
8. Alvidrez J, Arean PA. Psychosocial treatment research with ethnic minority populations: ethical considerations in conducting clinical trials. Ethics Behav. 2002; 12(1):103–16. [PubMed: 12171080]
9. Miskimen T, Marin H, Escobar J. Psychopharmacological research ethics: special issues affecting US ethnic minorities. Psychopharmacology (Berl). 2003; 171(1):98–104. [PubMed: 14624328]
10. Miranda J, Nakamura R, Bernal G. Including ethnic minorities in mental health intervention research: a practical approach to a long-standing problem. Cult Med Psychiatry. 2003; 27(4):467–86. [PubMed: 14727681]
11. Gifford AL, Cunningham WE, Heslin KC, Andersen RM, Nakazono T, Lieu DK, et al. Participation in research and access to experimental treatments by HIV-infected patients. N Engl J Med. 2002; 346(18):1373–82. [PubMed: 11986412]
12. Hussain-Gambles M, Atkin K, Leese B. Why ethnic minority groups are under-represented in clinical trials: a review of the literature. Health Soc Care Community. 2004; 12(5):382–8. [PubMed: 15373816]
13. Leffall LD Jr, Organ Claude H Jr. Honorary/Sandoz Nutrition Lectureship. Ethics in research and surgical practice. Am J Surg. 1997; 174(6):589–91. [PubMed: 9409578]
14. Leffall LD Jr. Ethics in surgical research. Surgery. 1998; 123(6):603–5. [PubMed: 9626309]
15. Betancourt JR. Cultural competence--marginal or mainstream movement? N Engl J Med. 2004; 351(10):953–5. [PubMed: 15342800]
16. Adams-Campbell LL, Ahaghotu C, Gaskins M, Dawkins FW, Smoot D, Polk OD, et al. Enrollment of African Americans onto clinical treatment trials: study design barriers. J Clin Oncol. 2004; 22(4):730–4. [PubMed: 14966098]
17. Simon MS, Du W, Flaherty L, Philip PA, Lorusso P, Miree C, et al. Factors associated with breast cancer clinical trials participation and enrollment at a large academic medical center. J Clin Oncol. 2004; 22(11):2046–52. [PubMed: 15082724]
18. Freeman HP, Muth BJ, Kerner JF. Expanding access to cancer screening and clinical follow-up among the medically underserved. Cancer Pract. 1995; 3(1):19–30. [PubMed: 7704057]
19. Vargas RB, Ryan GW, Jackson CA, Rodriguez R, Freeman HP. Characteristics of the original patient navigation programs to reduce disparities in the diagnosis and treatment of breast cancer. Cancer. 2008; 113(2):426–33. [PubMed: 18470906]
20. McGinnis LS, Menck HR, Eyre HJ, Bland KI, Scott-Conner CE, Morrow M, et al. National Cancer Data Base survey of breast cancer management for patients from low income zip codes. Cancer. 2000; 88(4):933–45. [PubMed: 10679664]
21. Stewart AK, Bland KI, McGinnis LS Jr, Morrow M, Eyre HJ. Clinical highlights from the National Cancer Data Base, 2000. CA Cancer J Clin. 2000; 50(3):171–83. [PubMed: 10901740]
22. Leitch AM, Beitsch PD, McCall LM, Posther K, Newman LA, Herndon JE 2nd, et al. Patterns of participation and successful patient recruitment to American College of Surgeons Oncology Group Z0010, a phase II trial for patients with early-stage breast cancer. Am J Surg. 2005; 190(4):539–42. [PubMed: 16164916]
23. U.S. Census Bureau. Population Division, Population Projections Branch Maintained By: Information & Research Services Internet Staff (Population Division). available at http://www.census.gov/ipc/www/usinterimproj/. In: Created: March 18, 2004
24. McKinnon, J. Current Population Reports, Series P20-541. U.S. Census Burueau; Washington, D.C: 2003. The Black Population in the United States: March 2002.
25. Ramirez, RR., de La Cruz, GP. Current Population Reports, P20-545. U.S. Census Bureau; Washington, D.C: 2002. The Hispanic Population in the United States: March 2002.

Synopsis

Accrual patterns from the American College of Surgeons Oncology Group trials demonstrate that African American and Hispanic American cancer patients can be successfully accrued onto randomized clinical trials, but study design affects recruitment patterns.

Table 1

Distribution of African Americans (AA), and Hispanic/Latino Americans (HA) within the U.S. general population, and the cancer population (stratified by stage of disease); accrual targets for AA and HA suggested by the American College of Surgeons Oncology Group (ACOSOG) based upon cancer-specific features, as reported by Newman et al(2).

	General Population(24, 25)	Breast Cancer(2)		Lung Cancer(2)		Suggested ACOSOG Accrual Targets(2)			
		Early-Stage (Clinically node-negative; Stage I/II)	Regionally-Advanced (Node-Positive/Metastatic)	Non-Metastatic	Metastatic	Breast (Early Stage)	Breast (Regionally Advanced)	Lung (Non-Metastatic)	Lung (Metastatic)
AA	13.0%	6.4–14.0%	14.0–15.2%	8.0–11.0%	11.3%	≥11%	≥14%	≥10%	≥12%
HA	13.3%	2.7–4.0%	4.2–4.8%	1.7–2.3%	2.6%	≥5%	≥5%	≥2%	≥2%

Table 2

ACOSOG Protocols evaluated in this report.

Organ Site	Study ID	Description
Breast	Z0010	Prospective study of sentinel node and bone marrow micrometastases in women with clinical T1 or T2 N0 M0 breast cancer
Breast	Z0010	Randomized trial of axillary node dissection in women with clinical T1 or T2 N0 M0 breast cancer who have a positive sentinel node
Breast	Z1031	Randomized phase III trial comparing 16–18 weeks of neoadjuvant exemestane, letrozole, or anastrozole in postmenopausal women with clinical stage II and III estrogen receptor positive breast cancer
Sarcoma	Z9000	Phase II study of adjuvant ST1571 therapy in patients following completely-resected high-risk primary Gastrointestinal Stromal Tumor (GIST)
Sarcoma	Z9001	Phase III randomized double-blind study of adjuvant ST1571 (Gleevec) versus placebo in patients following resection of primary Gastrointestinal Stromal Tumor (GIST)
Thoracic	Z0030	Randomized trial of mediastinal lymph node sampling versus complete lymphadenectomy during pulmonary resection in the patient with N0 or N1 (less than hilar) non-small cell carcinoma
Thoracic	Z0040	Prospective study of the prognostic significance of occult metastases in the patient with respectable non-small cell lung carcinoma
Thoracic	Z0050	Utility of positron emission tomography (PET) in staging of patients with potentially operable non-small cell lung carcinoma
Thoracic	Z0060	Utility of positron emission tomography (PET) in staging of patients with potentially operable carcinoma of the thoracic esophagus
Thoracic	Z4031	Use of proteomic analysis of serum samples for detection of non-small cell lung carcinoma

Table 3

Demographics of participant accrual, by protocol

Organ Site	Study ID	Brief Description	Protocol Design		Protocol Eligibility		Protocol Features	
			Randomized	Not Randomized	Early stage disease	Regional or locally advanced disease	Investigational systemic therapy + Surgery	Primary surgery study
Breast	Z0010	Prospective study of sentinel node and bone marrow micrometastases		√	√			√
Breast	Z0010	Randomized trial of axillary node dissection	√			√		√
Breast	Z1031	Randomized phase III trial of neoadjuvant aromatase inhibitors	√			√	√	
Sarcoma	Z9000	Phase II study of adjuvant ST1571 therapy		√	√		√	
Sarcoma	Z9001	Phase III randomized double-blind study of adjuvant ST1571 versus placebo	√		√		√	
Thoracic	Z0030	Randomized trial of mediastinal lymph node sampling versus complete lymphadenectomy	√		√			√
Thoracic	Z0040	Prospective study of prognostic significance of occult metastases		√	√			√
Thoracic	Z0050	Utility of positron emission tomography (PET) in NSCLC		√	√			√
Thoracic	Z0060	Utility of positron emission tomography (PET) in esophageal CA		√	√			√
Thoracic	Z4031	Use of proteomic analysis of serum samples in NSCLC		√	√			√

Table 4

Study sizes and race/ethnicity distributions for protocols evaluated in this report.

Organ Site	Study ID	Total Accrual	Race-Ethnicity Distribution N (%)*			Accrual "Success"	
			WA	AA	HA	AA	HA
Breast	Z0010	5539	4814 (87%)	420 (8%)	127 (2%)	modestly successful	unsuccessful
Breast	Z0011	891	732 (82%)	86 (10%)	42 (5%)	modestly successful	successful
Breast	Z1031	377	304 (81%)	55 (15%)	48 (13%)	successful	successful
Sarcoma	Z9000	109	89 (82%)	9 (8%)	2 (2%)	modestly successful	unsuccessful
Sarcoma	Z9001	778	615 (79%)	97 (12%)	34 (4%)	successful	unsuccessful
Thoracic	Z0030	1111	1037(93%)	49(4%)	4 (0.4%)	unsuccessful	unsuccessful
Thoracic	Z0040	1310	1201 (92%)	73 (6%)	12 (0.9%)	modestly successful	unsuccessful
Thoracic	Z0050	445	401 (90%)	36 (8%)	2 (0.4%)	modestly successful	unsuccessful
Thoracic	Z0060	262	243 (93%)	11 (4%)	2 (0.8%)	unsuccessful	unsuccessful
Thoracic	Z4031	1073	981 (91%)	69 (6%)	6 (0.6%)	modestly successful	unsuccessful

*differences between summation of reported race/ethnicities and total accrual population are participants self-recorded as either "Asian American"; "Other" or race-ethnicity "Unknown".

Table 5

Frequency of selected protocol features among "successful" *or* "modestly successful" (for accrual of AA and/or HA; n=8) versus "unsuccessful" (for accrual of both AA and HA; n=3) with regard to accrual diversity

Feature		**Proportion (%) of protocols with selected feature that were "successful" or "modestly successful"**	**Proportion (%) of protocols with selected feature that were "unsuccessful"**
Protocol Design	Randomized n=4	3/4 (75%)	1/4 (25%)
	Not Randomized n=6	5/6 (83%)	1/6 (17%)
Protocol Eligibility	Early stage disease n=8	6/8 (75%)	2/8 (25%)
	Regional or locally advanced disease n=2	2/2 (100%)	0/2 (0%)
Protocol Features	Investigational systemic therapy plus surgery n=3	3/3 (100%)	0/3 (0%)
	Primary surgical study n=7	5/7 (71%)	2/7 (29%)