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# The Development of a Minority Recruitment Plan for Cancer Clinical Trials

**Monica Trevino[1], Susan Padalecki[1,2], Anand Karnad[1,3], Alberto Parra[3], Steve Weitman[1,4], Melissa Nashawati[1], Brad H. Pollock[1,5], Amelie Ramirez[1,5,6] and Ian M. Thompson[1,2]***

[1]*Cancer Therapy and Research Center, University of Texas Health Science Center at San Antonio, San Antonio, USA*
[2]*Departments of Urology, University of Texas Health Science Center at San Antonio, San Antonio, USA*
[3]*Medicine, University of Texas Health Science Center at San Antonio, San Antonio, USA*
[4]*Pediatrics, University of Texas Health Science Center at San Antonio, San Antonio, USA*
[5]*Epidemiology and Biostatistics, University of Texas Health Science Center at San Antonio, San Antonio, USA*
[6]*Institute for Health Promotions Research, University of Texas Health Science Center at San Antonio, San Antonio, USA*

## Abstract

**Background:** Cancer does not occur in all ethnic and racial groups at similar rates. In addition, responses to treatment also vary in certain ethnic and racial groups. For Hispanics, the overall cancer incidence is generally lower yet for some specific tumor types, the incidence rates are higher compared to other populations.

**Objectives:** Although disparities are recognized for treatment outcomes and prevention methodologies for Hispanics and other minority populations, specific recruiting and reporting of minorities remains a challenge. In order to circumvent this problem, the Cancer Therapy and Research Center (CTRC) has developed a new minority recruitment plan for all cancer related clinical trials at this Institute. The overall goal of this initiative is to increase the accrual of minorities in cancer clinical trials by implementing several key interventions.

**Method:** The Cancer Therapy & Research Center (CTRC) at the University of Texas Health Science Center at San Antonio established the Clinical Trials Accrual Task Force to develop and monitor interventions designed to increase accrual to cancer clinical trials, specifically the accrual of minorities with a focus on the Hispanic population that makes up 68% of the CTRC's catchment area.

**Results:** A Minority Accrual Plan (MAP) was implemented in March 2013 as part of the process for initiating and conducting cancer-related clinical trials at the CTRC. The Minority Accrual Plan focuses on Hispanic enrollment due to the characteristics of the South Texas population served by the CTRC but could be easily adapted to other populations.

**Conclusions:** The CTRC has designed a process to prospectively address the challenge of deliberately enrolling minority subjects and accurately accounting for the results by implementing a Minority Accrual Plan for every cancer-related clinical trial at CTRC.

**Keywords:** Minority; Disparities; Cancer; Clinical trials enrollment; Barriers; Accrual

## Introduction

Cancer will be diagnosed in one of two men and one of three women during their lifetime in the U.S. and this disease is now the second most common cause of death [1]. Despite the significant burden of this disease, major improvements in cancer control, including innovations in cancer prevention, early detection, treatment, and supportive care have resulted in improved prognosis for patients confronted with a cancer diagnosis across the age spectrum. For most of these advances, the requisite step prior to the application of the medical intervention is to secure the results from one or more pivotal clinical trials that demonstrate an improved outcome. Prior to the initiation and completion of such pivotal Phase III trials, there may have been a host of preceding clinical studies that examine dosing, toxicity as well as initial efficacy, and the trends in success emerging out of these initial studies would have provided the scientific support for conducting the larger Phase III trials.

The occurrence of neoplastic diseases varies by ethnicity and race. Responses to treatment also vary by ethnicity and race. For example, for patients of Hispanic ethnicity, the overall incidence rates of cancer are generally lower; yet for some specific tumor types, incidence rates are higher compared to other groups. Hispanics have higher incidence and mortality rates than non-Hispanic whites for stomach, liver, uterine cervix, and gallbladder cancers, perhaps reflecting greater exposure to oncogenic infectious agents, lower rates of screening for cervical cancer, differences in lifestyle and dietary patterns, and possibly genetic factors [1]. In the South Texas region served by the Cancer Therapy and Research Center (CTRC) of the University of Texas Health Science Center at San Antonio, hepatocellular cancer (HCC) in particular, is seen at higher rates compared to the rest of the United States. From 1995 through 2006, Latinos accounted for more than one-third of the HCC cases reported in Texas and nearly three-fourths of all HCC cases reported for South Texas. HCC incidence was highest in South Texas Latino men and women (17.3/100,000 and 5.4/100,000), more than 45% and 42% higher than in respective Surveillance, Epidemiology, and End Results (SEER) subjects (SEER 13 grouping) [2]. Likewise, the incidence rates for human papilloma virus (HPV)-associated cervical cancer (2005–2009) were highest among Hispanic women compared to other sub-groups [3], implying an increased incidence in South Texas with its predominant Hispanic population.

In addition to the significantly increased rates of certain tumors among Hispanics of South Texas, there is also evidence that efficacy of

***Corresponding author:** Ian M. Thompson, Cancer Therapy and Research Center at the University of Texas Health Science Center, 7979 Wurzbach Road, San Antonio, TX 78229, USA, E-mail: ThompsonI@uthscsa.edu

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early detection, prevention, and treatment interventions are different for this ethnic group. For example, as part of the activities of the National Cancer Institute (NCI)-funded *Redes En Acción* research network, two groups of women who received abnormal screening mammogram results were compared: those who had the use of patient navigators (trained health workers that act as liaison to help cancer patients "navigate" barriers of culture, language, and access to cancer care) vs. those who did not. The results showed that the time to diagnosis was notably shorter in the navigated group (mean, 32.5 days vs. 44.6 days for the control group) [4]. Of importance to the risk of cervical cancer, investigators from the Centers for Disease Control and Prevention found significant differences in HPV serotypes in Hispanic and non-Hispanic women, which led them to conclude that age and racial/ethnic differences in HPV-type distribution may have implications for vaccine effectiveness [5].

Differences in treatment outcomes related to ethnicity have also been reported in pediatric acute lymphoblastic leukemia, where lower adherence to oral mercaptopurine in Hispanic children is associated with increased rates for disease relapse [6]. Further, triple negative breast cancer occurs more commonly in non-Hispanic black and Hispanic women in areas of low socioeconomic status [7]. These unique challenges such as higher rates of specific types of cancers among Hispanics or differences in the effectiveness on the application of cancer control measures – provide a strong rationale for ensuring adequate representation of Hispanics and other ethnic and racial groups in cancer clinical trials. In 2012, Hispanics made up approximately 16.7% of the US population, or about 50 million people [8]. A recent report indicates that minorities represent less than 30% of those enrolled in clinical trials sponsored by the National Institutes of Health (NIH), and that African Americans make up approximately 15% of those minority participants [9]. In contrast, one report estimated that Hispanic representation in NIH studies was at 7.6% for all research participants [9], and an earlier report on industry-sponsored studies found that only 3% of participants were Hispanic [10]. This underrepresentation of Hispanics is of particular concern in Texas, where Hispanics represented approximately 40% of the population in 2012, and are projected to constitute nearly 60% of the population by the year 2040 [11,12]. While the importance of accrual of minorities to clinical trials is critical for the health of South Texans in general and for Hispanics in particular, the goal to increase minority representation is in the best interest of the country due to the anticipated increase in the overall Hispanic population [13]. The Hispanic population is expected to comprise a substantially larger percentage of the total population in 2025 compared to 1995, increasing from 21% to 32% in the West and from 9% to 15% in both the South and Northeast [14].

With the CTRC's particular focus on clinical trials addressing a range of issues related to cancer, and the special responsibility for the population of South Texas, a plan was developed to significantly increase minority accrual to cancer-related clinical trials being conducted at this National Cancer Institute-designated Cancer Center. Herein, we describe a program developed specifically to achieve this goal.

## Methods

In early 2012, the CTRC established the Clinical Trials Accrual Task Force. This group was tasked with developing and monitoring the interventions designed to increase accrual to cancer-related clinical trials with a special focus on increasing accrual of ethnic and racial minorities. Appointed as Chair of the Task Force was the Associate Director for Cancer Prevention and Health Disparities at CTRC and Director of the Institute for Health Promotion Research, a research entity of UTHSCSA that investigates the causes of and solutions to the unequal impact of cancer and chronic diseases among Hispanics to improve Hispanic health in San Antonio and South Texas. Additional members of this Task Force included the CTRC Director as well as a broad representation from stakeholders in the clinical trials community, including the CTRC's Phase I program, Cancer Center Administration, Biostatistics and Informatics Shared Resource, Clinical Trials Office, Patient Referrals, Quality Assurance division, and clinical research physicians.

To enable dedicated support for this effort, the CTRC established the position of Coordinator for Minority Programs and a bilingual individual was appointed to this position. This Coordinator was tasked with tracking minority accruals across all cancer sites and clinical entities as well as implementing the interventions designed by the Clinical Trials Task Force (Task Force) for the purpose of increasing minority representation in clinical trials accruals.

After initial organizational meetings, the Task Force discovered that very few clinical studies had a pre-determined plan for ensuring maximum participation by ethnic and racial minorities. Consequently, the Task Force established new guidance that would mandate a Minority Accrual Plan (MAP) to be developed prior to CTRC approval and activation of each new clinical trial, both therapeutic and non-therapeutic. The Minority Accrual Plan (MAP) includes 1) a minority accrual projections template; and 2) a clinical investigator checklist of tools for the recruitment of minorities. The purpose of the minority accrual template and checklist of tools is to assist clinical investigators in determining whether or not they are meeting the NIH and NCI guidelines and recommendations for the inclusion of minorities in clinical trials and to also assist them in maximizing their efforts towards improving the enrollment of minority patients.

Study design of any clinical trial at CTRC will adhere to the following guidelines: a) Detailed estimate of accruals including Hispanics; b) major focus of recruiting Hispanic patients; c) plans to circumvent barriers for enrollment of minorities with special emphasis on Hispanics. With this objective included in the planning phase/study design of a clinical study, it is expected that the goal of increasing minority participation will be attained.

The Coordinator of Minority Programs, in collaboration with the Protocol Review Committee (PRC) and the Operations and Logistics Committee (O&L), will monitor clinical trial accruals by gender, race, and ethnicity and compare projected numbers with actual numbers. If there are any inconsistent results, the Coordinator of Minority Programs will assist individual clinical investigators to develop and implement appropriate recruitment strategies, including those targeting minority and other priority populations.

## Results

The CTRC implemented its Minority Accrual Plan (MAP) in March 2013 through a broad announcement to all Cancer Center members. To assist investigators in the development of the MAP, an online two-pronged approach was developed, namely, the Minority Accruals Projection Template and the Minority Accruals Clinical Trials Toolbox. Each element of the MAP is described in more detail below.

### Minority accrual projections template

At the time of submission of all cancer-related clinical trials to the Protocol Review Committee (PRC) of the CTRC, a completed Minority Accrual Projections Template (Table 1) is required. This template,

which breaks down the subject accruals by race, ethnicity and gender, is consistent with the National Cancer Institute's race, ethnicity, and national origin common data element definitions. The trial investigator provides the estimated accrual numbers for each category. If the accrual expectations are inconsistent with a reasonable estimate of the patient population seen by the clinical entity or partially based on population incidence and failure rates from front-line therapy, then the investigator may be asked to justify these variations to the PRC and a revised set of estimates may be developed. Importantly, these estimates become part of the regular PRC review of trial accrual numbers by race and gender on the regularly scheduled accrual review (at 6 month intervals for investigator initiated studies and annually for all other trials). If total accrual expectations are not being met or if minority accrual expectations are not being achieved, the investigator will be asked to present plans to remedy the poorer than expected study accrual.

## Minority accrual plan investigator toolbox

In addition to the minority accrual projections, all clinical trials at the CTRC are now required to have a Minority Accrual Plan Investigator Toolbox. As part of the toolbox, the investigator must detail the steps to be taken to overcome enrollment barriers and ensure optimal participation by ethnic and racial minorities. A specific focus on Hispanic patient enrollment is warranted, considering the characteristics of the South Texas population that is served by the CTRC. The Minority Accrual Plan (MAP) must include the specific steps that are to be taken to achieve minority accrual goals.

The toolbox provides investigators with a broad range of tools that can be incorporated into the operations of a clinical trial prior to study activation. Elements of the Toolbox (Table 2) include the provision of bilingual research coordinators, consent forms and other materials translated into Spanish, points of contact for Spanish-language media, as well as website materials in both English and Spanish. To further facilitate these efforts, translation services for all materials, including web services, are provided to CTRC members at no charge. The Coordinator of Minority Programs provides day-to-day assistance to study team members with all elements of the Tool Box.

## Integration into cancer clinical trial approval

All elements of the Minority Accrual Plan process (Minority Accrual Projections Template and Minority Accrual Plan Investigator Toolbox) are integrated into the protocol approval process of the CTRC. Both the projections template and investigator toolbox must be approved by the CTRC's PRC before the study is submitted for approval to the Institutional Review Board (IRB). The inclusion of a Coordinator for Minority Programs in this process is designed to ensure that this

| **Estimated Target Accrual (Total):** Indicate the **total** targeted/planned accrual by **Race & Gender** | | |
|---|---|---|
| **Race** | **% Male** | **% Female** |
| Black or African American | | |
| American Indian or Alaskan Native | | |
| Asian | | |
| White | | |
| Native Hawaiian or Other Pacific Islander | | |
| More Than One Race (Multiracial) | | |
| **Total** | | |
| **Breakdown of subjects**: Indicate the **total** targeted/planned accrual by **Ethnicity & Gender**. | | |
| **Ethnicity** | **% Male** | **% Female** |
| Hispanic or Latino | | |
| Not Hispanic or Latino | | |
| **Total** | | |

**Table 1:** Minority Accrual Projections Template.

| **Tool included in study** | List of Tools and Actions for Increasing Minority Accruals to Clinical Trials | |
|---|---|---|
| Yes<br>No | 1. | Include Clinical Trial information on CTRC website in both English and Spanish |
| Yes<br>No | 2. | Use of Bilingual Research Team Member or Translation services |
| Yes<br>No | 3. | Identification of bilingual Patient Navigator representative of the Target Population. Please Specify: |
| Yes<br>No | 4. | Informed Consent available in Spanish |
| Yes<br>No | 5. | Information Brochures in English and Spanish (IRB approval required) |
| Yes<br>No | 6. | Flyers in English and Spanish (two-sided, printed in English on one side and Spanish on the other) (IRB approval required) |
| Yes<br>No | 7. | Public Service Announcements (PSAs) or Advertisements- Spanish Radio (IRB approval required) |
| Yes<br>No | 8. | PSA's or Advertisements -Spanish newspapers (IRB approval required) |
| Yes<br>No | 9. | PSA's or Advertisements -Spanish Television (IRB approval required) |
| Yes<br>No | 10. | Patient Friendly Fast Facts in English and Spanish (IRB approval may be required) |
| Yes<br>No | 11. | Outreach to advocacy or community organizations (including presentations or awareness campaigns). Please specify: |

**Table 2:** Minority Accrual Plan Investigator Toolbox.

requirement does not delay the approval of clinical trials; instead it is expected that the Coordinator for Minority Programs will improve the time to trial completion by optimizing subject enrollment. To further facilitate the completion of both the projections template and investigator toolbox, all elements are housed online together in the CTRC's Information Data Exchange and Acquisition System (IDEAS) protocol entry and tracking system, which is used by CTRC researchers and related staff to track clinical trial status and accrual, among other functions. Summary reports can be created using the IDEAS system to show the status of the protocols, including actual accruals compared to the expectations of the projections template.

## Discussion

A major responsibility of a NCI-designated Cancer Center is to reduce the burden of cancer for the population served with a specific focus on the unique attributes of a regional population. The high proportion of patients of Hispanic ethnicity in South Texas, with the 'unique' distribution of cancers that are unlike the general US population, as well as the understanding that the US is rapidly approaching the South Texas demographic, makes the improvement of cancer care for this ethnic group a major goal and responsibility.

Historically, the representation and reporting of accrual of Hispanics into cancer clinical trials has been very poor in the United States. In a brief review of 17 major clinical trials published in 2012 and 2013, only two of the 17 trials reported the proportion of participants who were of Hispanic ethnicity; of those that did, the rates were 1.8% and 5.1% [15,16]. The fact that very large clinical trials for cancer prevention, cancer screening, cancer treatment of low-stage disease and treatment of advanced disease across a spectrum of diseases would have little or no information on the impact of the intervention in Hispanic patients implies that, as the US population changes to become one quarter or more Hispanic, little will be known about the application of these interventions on this ethnic group.

Most clinical investigators have little knowledge regarding the importance of minority accrual to the ultimate success of clinical trials or what steps can be taken to improve minority accrual. It is for this reason that CTRC senior leadership opted both to require a proactive approach to recruitment of minorities to clinical trials as well as to create a package of tools that would be available to the study's principal investigator for incorporation into a minority recruitment plan.

The response to this plan has been quite positive, especially as the components in the Minority Recruitment Plan are all established. It will require time to assess the impact of this plan on minority accrual and, depending on the results, additional components may be included as options for the Minority Recruitment Plan.

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