Cancer Disparities Research Partnership (CDRP)

Final Program Evaluation Report

Contract No. 263-FQ-609460

June 2010

Submitted to:

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EXECUTIVE SUMMARY

The National Cancer Institute's (NCI) Cancer Disparities Research Partnership (CDRP) Program was created to help reduce the significant negative consequences of cancer health disparities by providing state-of-the-art radiation therapy and radiation oncology clinical trials. The CDRP Program was a 5-year U56 Cooperative Agreement conducted by the Radiation Research Program (RRP) within NCI's Division of Cancer Treatment and Diagnosis (DCTD). The funding mechanism for the CDRP Program was unique in that awards were made to community cancer care facilities that had not traditionally been involved in NCI-sponsored research. Unlike "top down" models where funding is provided to cancer centers and then to disparities sites, CDRP reversed the flow of research dollars with disparities sites choosing their mentoring partner(s).

The CDRP Program sought to build radiation oncology clinical research capabilities in community institutions; prepare scientists in radiation oncology clinical research; increase clinical trial participation of black/African-American, Hispanic/Latino, Native American, Asian, elderly, and low-income populations; provide quality cancer care to disparate populations; and build partnerships between academic institutions and community researchers. A telemedicine system (TELESYNERGY®) was established in grantee and partner institutions to facilitate partnership collaborations for treatment consultations, research, and conferences. A Patient Navigator component sought to facilitate access to radiation oncology services, including clinical trials.[1] The CDRP Program also included community outreach and educational activities to increase knowledge and awareness of cancer and related services and clinical trials.

Six institutions, new to radiation oncology clinical trial research, were awarded CDRP grants. CDRP grantees and target populations were:

CDRP Grantees	Target Population
• Rapid City Regional Hospital Rapid City, South Dakota	American Indian/ Native American
• Laredo Medical Center Laredo, Texas	Hispanic/Latino
• Centinela Freeman Regional Medical Center Inglewood, California	African American Hispanic/Latino
• New Hanover Regional Medical Center Wilmington, North Carolina	African American Urban/Rural Poor
• Singing River Hospital Pascagoula, Mississippi	African American
• University of Pittsburgh Medical Center McKeesport Hospital McKeesport, Pennsylvania	African American Urban/Rural Poor

NCI/RRP reissued the CDRP Program through RFA CA-09-052 in 2008. The RFA invited limited competition applications among U56 grantees to request up to 5-year U54 funding to continue with the implementation of the radiation oncology clinical trials infrastructure to facilitate maximum access and accrual of their minority/underserved populations into all types of NCI cancer clinical trials.

The present evaluation report only covers the CDRP U56 Cooperative Agreement and data on program activities from the beginning of the program through September 2009.

[1] Sites varied in the patient navigator they had; a navigator could be a lay person (e.g., cancer survivors), a professional (registered nurse and/or social worker), or a combination of both.

EVALUATION PURPOSE

The purpose of the evaluation was to measure relevance, effectiveness, and impact of the CDRP Program. A process and outcome evaluation was conducted using a mixed-methods approach of qualitative and quantitative data. Process data provided information on program activities, challenges, outputs, and short-term results. An outcome assessment provided information on project accomplishments and activities that lead to attainment of CDRP intermediate and long-term goals.

An Evaluation Advisory Committee (EAC) was formed by NCI/RRP to provide advice on CDRP programmatic aspects and evaluation. NOVA's evaluation team worked with the CDRP Program Director, RRP-designated staff, CDRP PIs, and EAC in different aspects of the evaluation.

CDRP PROGRAM ACHIEVEMENTS

- ✓ **Building/Stabilizing Clinical Trial Research Infrastructure.** Prior to the CDRP Program, grantees had little or no experience administering Federal grants or conducting radiation oncology clinical trials. The Program helped establish key mechanisms for research (i.e., grant administration, accreditations and affiliations, a review process for research protocols, and capacity building for research). Investigators, research coordinators, research nurses, data managers/coordinators, patient navigators, and grant administrators were hired for the program. Grantees' community hospital administration made in-kind contributions in the form of infrastructure and resources. By the second year of funding, all sites had established their clinical research infrastructure and were able to institute clinical trials.
- ✓ **Clinical Trials.** A total of 452 individual clinical trials were opened as a result of the CDRP Program. All sites became affiliates and opened Radiation Therapy Oncology Group (RTOG)[2] trials (18/452; 19%); but sites most often opened other cooperative group trials (301/452; 67%) (i.e., medical surgical, prevention, and symptom management). Three sites—Laredo, Rapid City, and New Hanover—conducted PI-initiated radiation oncology clinical trials. Such trials were written as the available cooperative group studies were not applicable to the disease state and/or logistical issues facing disparities populations.
- ✓ **Patient Accruals.** A total of 1,644 patients were accrued onto clinical trials[3,4] including substantial numbers of racial/ethnic minorities (331 Hispanics/Latinos, 138 American Indians, and 100 blacks/African Americans) and poor, elderly, and medically underserved.[5] Most patients were enrolled onto other (i.e., non-RTOG) cooperative group trials (60%), followed by investigator-initiated trials (18%), and RTOG trials (10%). Clinical trial eligibility and accrual rates among those eligible were 24 percent and 73 percent, respectively. The most common reason for patient ineligibility was that no study was available to address the patient's tumor type/site (thus a reason for investigator-initiated trials). Eligible patients most frequently refused clinical trial participation due to a combination of reasons (e.g., patients preferred standard treatment, felt overwhelmed, or lacked family support).
- ✓ **Other Clinical Research.** In addition to the 452 clinical trials that were opened, grantees implemented 23 CDRP-related social science studies addressing psychosocial, behavioral, and contextual factors influencing cancer-related outcomes. Social studies focused on topics such as cancer awareness and

[2] The Radiation Therapy Oncology Group is a national clinical cooperative group funded by NCI and that focuses on radiation oncology clinical trials.

[3] Approximately 31 patients were enrolled onto more than one type of trial increasing the total number of patient accruals to 1,678.

[4] Note that many opened trials did not enroll any patients for a variety of reasons (most often due to patient ineligibility).

[5] Definitions of "medically underserved" varied by site to include being poor; having Medicare only; having Medicare with Medicaid supplement; having Medicare and being under age 65, indicating disability; having no health insurance; and being self-pay. Refer to Section 3.7 for individual site definitions.

knowledge among CDRP target populations, access barriers to cancer care, and patient satisfaction with cancer care.

- ✓ **Partnerships/Mentorships.** Partnering with experienced academic research institutions was essential in guiding CDRP sites by advising and collaborating on research studies, expanding local clinical investigators' treatment knowledge and skills, and sharing via tumor boards.[6] Initially, most partner/mentor support involved helping grantees develop their research and grant management capabilities. Later, partnership activities focused on clinical trial research mentoring and collaborations (e.g., planning and implementation of clinical trials, social science studies, and patient navigation), professional training (e.g., new treatments), continuing education, and patient consultations.
- ✓ **TELESYNERGY®.** TELESYNERGY® helped improve communication with NCI staff, partner institutions, and CDRP sites. This system facilitated administrative meetings on program management and grant-related issues, research consultations, tumor boards, training/continuing education, and, to a lesser extent, patient care and treatment consultations. Prior to installation of TELESYNERGY®, most of the activities mentioned did not occur at community grantee sites.
- ✓ **Patient Navigation.** CDRP sites varied in the navigator model implemented, including a lay navigator model, a professional model, or a combination of both. Navigation was implemented differently by sites including whom these services were offered to and what services were available. Some sites offered navigation services to all of their patients, while others only to their targeted CDRP populations; some navigators mentioned clinical trials when they offered navigation services, while others solely addressed patient's barriers to cancer care access and treatment. It was anticipated that patient navigation would have a substantial influence on accrual to clinical trials. However, CDRP grantee staff thought that navigators better served the purpose of guiding patients through the medical system and potentially improving completion of radiation oncology treatment. A total of 3,480 cancer patients was navigated, including substantial proportions of racial/ethnic minorities (53% of navigated patients were blacks/African Americans, Hispanic/Latinos, and American Indians/Alaska Natives) and elderly or medically underserved non-Hispanic whites (64% of navigated white patients were elderly or underserved). Of the 1,644 patients accrued onto clinical trials, 264 (16%) had been navigated.
- ✓ **Community Outreach.** Outreach activities commonly involved education on cancer, clinical trials, and cancer screening through partnerships with community agencies; distribution of program materials; presentations in local organizations; and participation in health fairs, screenings, and conferences. These activities were viewed as essential by CDRP Program staff to increase knowledge about cancer and clinical trials, decrease fear about cancer and treatment, encourage early screenings, facilitate treatment adherence, and increase chances of patient recruitment onto clinical trials. Outreach activities also allowed time to build relationships and trust, viewed as critical to reaching disparities populations, especially in communities for which clinical research is a new endeavor.
- ✓ **New Funding/Professional Development Opportunities.** CDRP grantee sites applied for over 30 new research grants and other supplemental funding and were successful in 23 out of 34 instances; bringing approximately an additional $1.9 million for the program. Three CDRP grantees were awarded NCI Clinical Trials Operations Committee (CTOC) supplemental grants to expand minority accruals in medical and surgical oncology clinical trials. The Program also increased opportunities for professional development as more scientists at grantee and partner institutions become engaged in radiation oncology or other oncology clinical research.

[6] A tumor board is a forum used by doctors of various specialties (e.g., radiation and medical oncology, pathology) to review and discuss the medical condition and treatment options of a patient.

- ✓ **Research Publications and Professional Presentations.** CDRP grantees have published 53 peer-reviewed publications based on their work with the program and have made over 230 presentations at local, regional, national, and international professional meetings as well as presentations/lectures at academic institutions.
- ✓ **Professional Society Programs.** The CDRP Program has resulted in establishment of the NCI American Society for Therapeutic Radiology and Oncology (ASTRO) Disparity Symposium at annual ASTRO meetings since 2003. Based on the CDRP program, ASTRO and RTOG have established working groups focusing on disparities.
- ✓ Exploratory comparative analysis between CDRP grantees and identified comparison sites showed that the CDRP grant might have facilitated some results for grantees. CDRP grantees were more likely than their comparison counterparts to report investigator-initiated trials, offer a wider variety of cooperative group trials, and report open Phase I trials. Importantly, CDRP grantees were also more likely to enroll racial/ethnic minorities to clinical trials.

CDRP PROGRAM CHALLENGES

Special Circumstances—Laredo and Centinela Freeman

- Laredo and Centinela Freeman faced major grant administrative obstacles which resulted in the CDRP grant being relinquished at Laredo (in April 2007) due to inability to recruit a radiation oncologist and Principal Investigator (PI) and transitioned to another institution at Centinela Freeman (hospital closed and it took a few years to attempt to move grant to 21st Century Oncology in August 2008). These obstacles resulted in serious disruptions in program operations (e.g., operational delays, staff turnovers), activation of clinical trials, and patient accrual.

Building/Stabilizing Clinical Trials Research

- Grantees lacked established clinical trial research infrastructures or substantive individual or institutional experience with research and grant administration procedures and regulations.
- PIs with full-time clinical practices had little time for the Program.
- Sites had difficulty recruiting and retaining research project staff (due to the impermanence of employment and low salaries).

Clinical Trials and Patient Accruals

- Sites had difficulty identifying and opening trials that were acceptable to local oncologists, met certain criteria, or were appropriate for their target populations.
- Lack of time and interest in the local medical community (some of it due to the non-revenue-generating nature of NCI studies) were obstacles in some sites.
- Investigator-initiated research may not be realistic for community clinicians with full-time practices considering the amount of time needed to implement this type of research.
- Strict eligibility criteria and related difficulty matching patients served by grantees to studies.
- Sites suffered a shortage of personnel, resources, and staff with specific qualifications.
- Patients often lacked insurance coverage for clinical trials participation.
- Patients were often reluctant to enter a randomized trial.

Partnership/Mentorship

- Academic research institutions received small incentives for partnering with community-based hospitals (i.e., CDRP grantees). The experience, knowledge, time, and other resources provided by the mentors far exceeded any benefits they received from the relationships with CDRP grantees. Nonetheless, partners/mentors were enthusiastic based on the principle of reaching the underserved rather than on financial incentive.

Data Collection/Reporting

- Issues with data collection and reporting included accessibility and usefulness of an existing Web-based CDRP database; lack of data definitions (e.g., "medically underserved" based on income; what services classify as patient navigation); data limitations on reasons why eligible patients opted not to enroll on trials; and inconsistent data collection across sites on patient navigation.

RECOMMENDATIONS

Infrastructure

Need for NCI support to establish research infrastructure

- At the very least, 1 year is needed to develop infrastructure. Prior to award of the RFA, a 1-year grant mechanism (e.g., NIH Clinical Trial Planning Grant Program [R34]) for planning and building research infrastructure should be considered.
- As part of the initial planning grant, NCI needs to provide formal and regular group training, workshops, and advice on establishing research infrastructure and NIH administrative and financial rules and regulations to limit delays resulting from implementation trial and error.
- Funding should be provided for an independent contractor to develop and distribute a CDRP User Manual that addresses building research infrastructure and administering an NIH/NCI grant.
- Sustainable source of support applicable to these settings is needed. There is distrust of government intervention based on a long history of starting then stopping projects.

Need for a minimum of one radiation oncologist in grantee institutions

- Eligibility requirements for RFA application should include having at least one certified radiation oncologist who would function as PI, and another radiation or medical/surgical oncologist serving as co-PI.[7] This would also help buffer the impact of changes in key personnel.

Need for support from the local medical community

- Evidence of support from the local physician referral community (i.e., physicians who would refer patients to the radiation oncologist) should also be required for the application. The mentioning of clinical trials to patients by referring physicians and radiation oncologists was seen as critical in patients' willingness to participate in clinical trials.
- Engaging the medical community and referring physicians on a timelier basis to discuss clinical trials with their patients is critical to successful clinical trial recruitment.

[7] In writing the CDRP U54 RFA, NCI/RRP addressed this recommendation by requiring one radiation oncologist as PI and either a radiation, medical, or surgical oncologist as a co- PI.

Radiation Oncology Clinical Trials

Prioritize cooperative group trials over PI-initiated trials or develop cooperative group trials appropriate to this population

- Investigator-initiated single institution clinical trials may not be feasible for all community-based radiation oncology sites. If this is a key part of the CDRP Program, NCI needs to develop mechanisms to guide and support novice clinical researchers in this effort.
- Implementation of investigator-initiated trials needs to be delayed until later in the grant period (e.g., Year 3 or 4). NCI should continue to require participation in cooperative group trials and may want to give these trials priority over investigator-initiated (or pharmaceutical or industry-supported) trials.
- Investigator-initiated research can be more effectively targeted to the local community's cancer care needs and to address cancer health disparities in the community. Establishing a mechanism for these as cooperative group trials (e.g., a disparities program at RTOG) could allow the development of common protocols, allow for scientific review, and reduce the burden on a single disparities institution.

Partnerships/Mentorships

- Given the time contribution involved in partnerships, increased incentives are needed for the research institution mentors and researchers who agree to mentor/partner with the local grantee. This is not necessarily money but other rewards (e.g., additional TELESYNERGY® equipment and certification, access to minority populations for further research, potential collaborations with key partners and organizations, increased patient referrals, increased publications to bolster academic standing) as partners were very enthusiastic about this effort.
- Grantees recommended more cross-site collaboration (i.e., among CDRP grantees) on program activities as part of the grant. This could be enhanced by cooperative groups and professional societies as was accomplished to some extent by RTOG and ASTRO.

TELESYNERGY®

- Need to develop a plan to promote and increase the use of TELESYNERGY®, including training and highlights of its capabilities. Many of its features were underutilized for varied reasons, including logistical challenges, use of other channels of communication, existing systems in partner institutions, and having to obtain telemedicine privileges prior to use.
- Using the patient camera was at times inconvenient because the equipment was in a location that was not appropriate for patients (usually a conference room). A “miniature version” of the patient camera or a digital camera to take to the examination room was suggested.

Community Outreach and Navigation

More research on patient navigation

- Research evidence related to patient navigation processes and effects needs to be identified. This includes a navigation model that specifies navigator characteristics (e.g., cancer survivor, lay person from the community, nurse), navigation activities (e.g., community outreach, referrals, follow-up through entire diagnosis and treatment), when to begin navigation (e.g., early in diagnosis), and other aspects associated with navigation (e.g., paid staff).
- Navigation needs are likely to vary greatly by community.

Ensuring presence in the community and incentives

- A strong community presence is essential to facilitate referral, recruitment, and enrollment of eligible patients onto radiation oncology clinical trials.
- Provision of incentives for referrals to clinical trials should be considered.

Outreach and navigation as health service issus

- NCI should view issues around outreach and navigation as health services issues as opposed to public health issues. These two program components may have facilitated patient accrual by increasing knowledge about cancer and awareness of locally available treatments and clinical trials. Moreover, these services may have enhanced community perceptions about grantee institutions' commitment in helping patients access cancer care.

Data Collection/Reporting

- Standard operating procedures (SOPs) for collection of CDRP Program data across grantees should be developed. SOPs should cover data on research program structure at the institution (e.g., grants administrator, organizational chart, and relationship with institution administrators), data collection methods for all research (e.g., clinical trials, social science studies, and patient navigation), data storage and security, and transfer of data to NCI.
- Data collection requirements for key program processes and outcomes need to be decided upon and better defined at the outset of the grant.
- Data on patient age at diagnosis and proxy markers of socio-economic status (i.e., highest level of educational attainment and census tract of residence) need to be collected. Age at diagnosis would help to determine whether older patients, as well as adolescents and young adults, who are both underrepresented on NCI-sponsored trials, are able to access appropriate treatment and trials at CDRP sites. Census tract of residence can be used for geocoding to classify patient's site of residence as rural, urban, or suburban, as well as determine the distance between the patient's residence and treatment site.
- Collection of data related to trial eligibility and refusal should be collected in a consistent manner across CDRP sites.
- Data about cultural factors (e.g., cultural backgrounds, individual beliefs, community norms) influencing patient enrollment need to be collected; these data may yield information about differences related to geography or other local demographics.
- Current grantee site databases (e.g., Excel) should be adapted to collect data for the grant and the program, rather than re-entering data into a second central database (i.e., Quarterly Data Reports) for NCI reporting.

Sustainability

- Holding these institutions to the same expectations and standards as major academic medical centers and oncology practices may doom many of them to failure if patient accrual numbers are the key or only metric.
- Leadership at NCI and NIH need to consider additional mechanisms to support disparities communities. While serious performance indicators are necessary, they should account for the realities of resources and personnel available within these communities and the historical level of distrust between many of these communities and federal programs.
- Given resources and support, communities rallied behind the CDRP grantees.

CONCLUSIONS

The CDRP Program was a step toward reducing the negative consequences of cancer health disparities by building clinical research in radiation oncology in community-based institutions that care for a disproportionate share of medically underserved low-income and/or minority populations. CDRP's unique funding mechanism was important as it provided grantees with:

- Resources and support for program activities.
- A leading role in research activities.
- Better access to their target populations resulting in increased minority accruals.
- More chances to positively affect cancer outcomes in their communities.
- More leverage when working with their partners.

The Program accomplished its short-term goals—training community-based clinicians as health disparities researchers and building radiation oncology clinical trial research infrastructure in community-based institutions. According to CDRP grantees, the CDRP Program created a culture of clinical trial research and mindset in community-based institutions and among community physicians where it did not exist before, and it demonstrated that participant enrollment onto clinical trials sponsored by community institutions is possible.

Lessons learned should be applied to future funding mechanisms, realistic timelines, and sustainable support. The uniqueness of the issues in accrual to clinical trials needs to be recognized by NCI and its review boards to allow these communities the opportunity to be successful and to sustain progress.

Cancer Disparities Research Partnership Program Findings

1. INTRODUCTION

1.1 Background

The burden of cancer and cancer disparities still exists despite improvements in overall health and life expectancies resulting from cancer prevention and medical technology advancements. This burden is unequally felt by many population groups in the United States and is exemplified by differences in cancer morbidity and mortality as a function of gender, ethnicity, and socioeconomic status.

Community-based institutions providing cancer services to a disproportionate share of medically underserved, low-income, and/or minority populations are not effectively linked to national cancer research programs. Radiation oncologists in many of these institutions strive to maintain state-of-the-art cancer care (e.g., offering participation in cancer clinical trials to patients) for their communities; however, they often have difficulty starting, developing, and sustaining research programs. Thus, the populations primarily served by these institutions—largely minority, ethnic, and/or low income—do not readily benefit from rapid progress being made in radiation oncology research and may bear an unequal burden of cancer as a result.

Healthcare institutions that predominantly serve populations experiencing the worst consequences of cancer-related health disparities have little involvement in cancer research. In order to develop a stronger national cancer research effort aimed at reducing the disparities of cancer incidence and mortality in those populations, these institutions must increase their participation in cancer research.

1.2 CDRP Program Purpose and Goals

The National Cancer Institute's (NCI) Cancer Disparities Research Partnership (CDRP) Program was a 5-year U56 Cooperative Agreement conducted by the Radiation Research Program (RRP) within NCI's Division of Cancer Treatment and Diagnosis (DCTD). The long-term goal of the CDRP Program is to help reduce the significant negative consequences of cancer health disparities seen in targeted U.S. populations—black/African American, Hispanic/Latino, Native American, Asian, elderly, and low-income—by providing state-of-the-art radiation therapy and radiation oncology clinical trials. This is being accomplished by training new health disparities researchers and by building and stabilizing radiation oncology clinical trials research in community-based institutions caring for a disproportionate share of medically underserved, low-income, and racial and ethnic minority populations.

The CDRP Program had five components: [8]

1. Planning, developing, and conducting radiation oncology clinical trials among members of the CDRP's target community of medically underserved, low-income, and racial/ethnic and other minority populations.
2. Establishing and sustaining partnerships/mentorships between grantee institutions and academic research institutions (i.e., designated NCI comprehensive cancer centers) to promote long-term collaborations (e.g., clinical trials, patient consultations, etc.) focused on radiation oncology clinical research trials and mortality and morbidity in cancer among the targeted population past the life of the

[8] At the start of the CDRP Program, there were only four program components; community outreach activities were not considered a main CDRP component. However, outreach activities soon emerged as an important aspect of building community-based research and were suggested by PIs as a fifth component of the CDRP Program.

grant and strengthen competitive cancer research, research training and career development, education, and outreach capabilities at both institutions.

3. Establishing a telemedicine system (TELESYNERGY®) at each CDRP grantee institution and its primary partner to strengthen partnerships and support for treatment consultations, research consultations, education, and conferences.
4. Supporting a Patient Navigator (PN) program to facilitate access to radiation oncology services, including clinical trials, by addressing barriers (e.g., financial, geographic, cultural) that impact receipt of timely cancer care by patients from target populations.
5. Conducting community outreach activities to increase knowledge and awareness of cancer and the availability of local treatment and clinical trials research.

The five-component model provided a framework to accomplish CDRP goals of building radiation oncology clinical research capabilities in community institutions; preparing clinical scientists in radiation oncology clinical research; increasing participation of medically underserved, low-income, and racial/ethnic minorities in clinical trials; improving the provision of quality cancer care to targeted populations experiencing health disparities; and building partnerships between academic institutions and community researchers. The CDRP Program Conceptual Framework is included in **Appendix A**. The framework lists CDRP-related activities and depicts the actions/causes expected to lead to desired results.

1.2.1 Innovative Funding Model

The CDRP Program was unique in that awards were made to community cancer care facilities that had not traditionally been involved in NCI-sponsored research. Typically, NCI awards funding for clinical trials to institutions with well-established research infrastructures such as academic medical centers with comprehensive cancer centers. Sometimes academic institutions work with community hospitals to accrue patients for clinical trials.

The CDRP Program was funded from September 2002 through September 2008 and had a total 5-year cumulative budget of approximately $25 million. The Patient Navigator Program was a $100,000/year supplement to the original CDRP grant from the NCI Center to Reduce Cancer Health Disparities (CRCHD).

NCI/RRP reissued the CDRP Program through RFA CA-09-052 in 2008. The RFA invited limited competition applications from the currently funded U56 grantees to request up to 5-year U54 funding to continue with the implementation of the radiation oncology clinical trials infrastructure (established previously with U56 funding) to facilitate maximum access and accrual of their minority/underserved populations into all types of NCI cancer clinical trials. The present evaluation report only covers CDRP Program activities under the U56 Cooperative Agreement.

1.3 Community-Based Grantees

Six institutions, new to radiation oncology clinical trials research, were awarded grants for the CDRP Program. Two awards were made in 2002 and four were made in 2003. The grantee sites, their CDRP program names, service areas, and target populations are shown in **Table 1**.

TABLE 1 – CDRP PROGRAM GRANTEES, SERVICE AREA, AND TARGET POPULATION

Award Year	Grantee/Principal Investigator (PI)	Service Area Population	Target Population
FY02	Rapid City Regional Hospital Rapid City, South Dakota Program Name: Walking Forward (WF)[a] PI: Daniel G. Petereit, MD	300,000	American Indian/ Native American
FY02	Laredo Medical Center[b] Laredo, Texas Program Name: Evaluating Cancer Disparities Among Hispanic Communities PI: Yadvindera S. Bains, MD	177,000	Hispanic/Latino
FY03	Centinela Freeman Regional Medical Center[c] Inglewood, California Program Name: Urban Latino African American Cancer (ULAAC) Disparities Project PI: Michael L. Steinberg, MD[d]	100,000	African American Hispanic/Latino
FY03	New Hanover Regional Medical Center Wilmington, North Carolina Program Name: Improving Cancer Outcomes for African-Americans PI: Patrick D. Maguire, MD	616,000	African American Urban/Rural Poor
FY03	Singing River Hospital Pascagoula, Mississippi Program Name: The Mississippi/Alabama Radiation Oncology Research Partnership PI: Raymond Wynn, MD[e]	200,000	African American
FY03	University of Pittsburgh Medical Center (UPMC) McKeesport Hospital McKeesport, Pennsylvania Program Name: Radiation Oncology Community Outreach Group (ROCOG) PI: Dwight E. Heron, MD	935,000	African American Urban/Rural Poor

[a] Rapid City changed its CDRP program name early in program development from "Enhancing Native American Participation in Radiation Therapy Trials" to "Walking Forward," which was considered more culturally appropriate for their target American Indian patients.

[b] CDRP grant was relinquished in 2007.

[c] Grant was transitioned to 21st Century Oncology at the Santa Monica Cancer Treatment Center in 2008.

[d] Dr. David Khan is the current CDRP PI and Dr. Michael Steinberg is co-PI.

[e] Dr. Raymond Wynn resigned in 2005 and Dr. W. Sam Dennis became the new PI.

All CDRP grantees received no-cost extensions (NCE) to complete the scope and objectives of their CDRP Programs. Singing River and UPMC McKeesport received NCEs through February 28, 2010; New Hanover and Centinela Freeman's NCE is through August 31, 2010. Rapid City completed its CDRP Program on August 31, 2009.

Two of the awarded institutions, Laredo and Centinela Freeman, faced major grant administrative obstacles, which resulted in the CDRP grant being relinquished at Laredo and transitioned to another institution at Centinela Freeman. Laredo Medical Center relinquished its CDRP grant in April 2007. Beginning in 2004, Centinela Freeman Hospital went through significant changes in ownership and subsequent re-structuring of health care services that ended in the CDRP grant being moved to 21st Century Oncology at the Santa Monica Cancer Treatment Center. NIH/NCI approved the transition of the

grant to 21st Century Oncology in August 2008.[9] More detailed descriptions of related events and challenges faced by these sites are included in Section 3.3 *CDRP Program Challenges and* Section 3.7 *CDRP Site Progress*.

2. CDRP PROGRAM EVALUATION

2.1 Evaluation Purpose and Design

NOVA Research Company (NOVA) was contracted by NCI/RRP to conduct a formal evaluation of the CDRP Program. The purpose of the evaluation was to measure relevance, effectiveness, and impact of the CDRP Program. NCI/RRP was also interested in assessing whether grantee institutions and the CDRP Program as a whole were succeeding in accomplishing their goals.

The evaluation examined processes and outcomes of the Program using a mixed-methods approach of qualitative and quantitative data collection. Process data provided information on main CDRP program activities, challenges, outputs, and short-term results for the purpose of monitoring process and making needed midcourse corrections and program adjustments when needed. An outcome assessment provided information on project accomplishments and activities that lead to attainment of CDRP intermediate and long-term goals.

An Evaluation Matrix was developed that illustrates how process and outcome data collected were going to be used to answer evaluation questions (described below; see **Appendix B**). The evaluation design also involved the collection of comparison data among community-based radiation oncology facilities similar to CDRP grantees.

An Evaluation Advisory Committee (EAC) was formed by NCI/RRP to provide advice on CDRP programmatic aspects and its evaluation. Six members comprised the EAC. Members were selected for their expertise and extensive experience in radiation oncology, clinical trials research, community-based research, and program evaluation.

NOVA's evaluation team worked with the CDRP Program Director (PD), RRP-designated staff, and the EAC to determine what data were appropriate to collect, identify surveys and methods to collect these data, and address other aspects of data collection. Input from the CDRP PD was obtained on all aspects of the evaluation; input from CDRP PIs was also requested when necessary. The performance and management review of NOVA evaluation activities is included in **Appendix C**.

2.1.2 Evaluation Study Questions

Evaluation questions relevant to the CDRP Program were developed to focus the evaluation on program aspects of interest. Five main questions were addressed as part of the evaluation:

1. How does the CDRP Program design contribute to our current knowledge about improving radiation oncology cancer treatment in populations experiencing health disparities and about conducting clinical research in community-based healthcare institutions?
2. Has there been an increase in radiation oncology clinical and translational research with populations experiencing cancer health disparities? How has CDRP affected clinical trial participation by target populations?
3. What is the influence of partnerships between grantee institutions and academic research centers on clinical research and patient outcomes at the grantee sites?

[9] Since most of the grant was under the authority of Centinela Freeman, this report will refer to this site by that name.

4. What is the influence of TELESYNERGY® on building partnerships, facilitating clinical research, and improving treatment outcomes?
5. How has Patient Navigation facilitated access to cancer care and improvement of patient outcomes in the target populations? Has Patient Navigation improved/facilitated participation of minorities in clinical trials?

2.2 Methods and Procedures

Data were collected on various aspects of the CDRP Program. A brief description of all quantitative and qualitative data collection instruments used and procedures to collect these data are provided next.

2.2.1 Quarterly Data Report and Clinical Research Summary Spreadsheet

The Quarterly Data Report was the main source of data collection for the program evaluation.[10] The Quarterly Data Report was used to obtain information on patient screening, patient eligibility/ineligibility, accruals to clinical trials and social science/health services research studies, patients navigated, barriers to care, usage of TELESYNERGY®, partner activities, and outreach efforts. A clinical research summary spreadsheet was also created to capture clinical trial specific data including Institutional Review Board (IRB) approval dates, trial type (e.g., phase, PI-initiated vs. cooperative group, and radiation vs. medical), open and close dates for trials, and accrual numbers to each trial (see **Appendix D** for templates).

Data were completed by CDRP site data managers and/or project managers and submitted to NOVA on a quarterly basis. Data management and quality procedures implemented by NOVA involved a review of quarterly data reports submitted for data discrepancies (e.g., inconsistencies with previous submissions). Quarterly data reports were also cross-checked with data reported in grantees' annual progress reports and other grantee program materials whenever possible. If discrepancies were found, NOVA contacted the data manager and/or project manager at each site for further clarification and/or requested corrections.

Additional data collection. A small survey was used once to collect other data from sites, including information on new researchers, clinical research, partner/mentor activities, and new initiatives (e.g., new grants). Data were completed by CDRP site data managers and/or project managers and submitted to NOVA in February 2007. Data submitted were checked for accuracy with other reports.

2.2.2 Interview Data

Qualitative data on CDRP were collected via in-depth interviews with grantees to gather information about program implementation, challenges, lessons learned, and recommendations. Interviews were conducted to facilitate discussion and opportunities for all program staff to express their thoughts and opinions on the overall CDRP Program and their local programs. Separate interviews were conducted for each CDRP site. NOVA developed semi-structured moderator guides with input from the CDRP PD. NOVA's Evaluation Team conducted interviews with two main groups: CDRP PIs and program staff and CDRP partner/mentor institutions.

[10] Prior to NOVA's evaluation, NCI/RRP had already established a Web-based CDRP database for sites to provide data on all program components. Extracting archival data from this database was problematic because data on program processes and effectiveness were flawed. A decision was made with NCI/RRP to change the data collection/reporting method for the remainder of the grant; sites would discontinue use of the original online CDRP database and would collect data using the quarterly data report template developed by NOVA.

2.2.2.1 Interviews with CDRP PIs and Program Staff

Three sets of interviews were conducted with CDRP PIs, Co-PIs, and program managers/coordinators. The first set of interviews took place in September and October 2006; the second set, in October 2008; and a final set of interviews was conducted between November and December 2009.

The first set of interviews focused on participants' perceptions of the Program's successes, barriers, lessons learned, and best practices during program operations as well as perceived impact of the CDRP Program on radiation oncology research capacity at grantee sites. Interviews were conducted using the video-conferencing feature of TELESYNERGY®, except for one interview that was conducted by telephone. A total of 13 program staff representing the six grantee sites (i.e., Centinela Freeman, Laredo, New Hanover, Rapid City, Singing River, and UPMC McKeesport) participated in the interviews.

The second round of interviews was conducted via telephone. In addition to gathering information about the CDRP implementation and current program status at the time, these interviews focused on plans for sustaining research capacity and the CDRP reissuance. A total of 12 program staff representing five grantees sites[11] (i.e., Centinela Freeman, New Hanover, Rapid City, Singing River, and UPMC McKeesport) participated in the interviews.

The last set of interviews was conducted primarily with CDRP PIs[12] and by telephone. Information was gathered on their overall experience implementing the U56 grant and the reissuance (e.g., overall application process, impact of budget cuts on program design, etc.) of the CDRP Program—the U54 grant.

2.2.2.2 Interviews with CDRP Partners/Mentors

Between February and May 2007, NOVA conducted in-depth interviews with five primary CDRP partner/mentor institutions via telephone (i.e., Centinela Freeman, New Hanover, Rapid City, Singing River, and UPMC McKeesport). Interview questions focused on partners' experience with the overall CDRP Program and partnership/mentoring aspects (e.g., successes, barriers, lessons learned, and recommendations for future programs). Six interviewees representing five CDRP grantee partner sites participated in the interviews. The interviewees and corresponding CDRP grantee partners were University of North Carolina-Chapel Hill (partner for New Hanover); University of Wisconsin-Madison (partner for Rapid City); University of Southern California (partner for Centinela Freeman); Washington University, St. Louis (partner for UPMC McKeesport); and University of Alabama at Birmingham (partner for Singing River).

2.2.3 Annual Progress Reports, Clinical Trials Operations Committee Supplement Progress Reports, and U54 Applications

Qualitative and quantitative data were abstracted from main program reports, including grantee annual progress and final reports submitted to NCI/RRP. Data were also abstracted from CDRP NCI Clinical Trials Operations Committee (CTOC) supplemental awardees' annual reports[13] and from the CDRP sites' U54 grant applications. Data abstracted from these sources focused on progress related to the five program components, overall accomplishments, and challenges meeting CDRP sites' program goals and objectives.

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[11] The Laredo site had already relinquished its CDRP grant (April 2007).

[12] Singing River's PD and co-PIs and UPMC McKeesport's PD also participated in the interview.

[13] As described later in Section 3.1.2 *Clinical Trials*, three CDRP grantees received supplemental grants from the Clinical Trials Operations Committee (CTOC) to expand their clinical trials in medical and surgical oncology. CTOC annual reports were received in 2007 and 2008.

Program written materials. In addition, NOVA reviewed and abstracted data from CDRP PI meeting minutes, presentations, publications, and other project-generated resources (e.g., media articles, brochures) as needed.

2.2.4 Comparison Site Survey

The evaluation also involved the collection of comparison data among community-based radiation oncology facilities similar to CDRP grantees. NOVA gathered information on main project indicators, including the institution's radiation therapy services, involvement in clinical research and related infrastructure, patient characteristics, and patient navigators (see survey used in **Appendix E**).

The CDRP request for applications (RFA) criteria for eligible applicants[14] was used to select these community-based radiation oncology facilities. RRP worked with NOVA and CDRP PIs to identify these sites. Two to three comparison sites were identified for each CDRP site. NCI/RRP was responsible for fielding the survey. Data were collected from comparison sites in Winter 2008 through Fall 2009.

2.3 Data Limitations

The evaluation has a number of limitations that need to be considered when examining evaluation findings and conclusions.

- A main limitation involves the use of self-report data. All data (e.g., quarterly data, annual progress reports) collected by NOVA were reported by CDRP site staff. No other (external) sources of data were available to confirm accuracy of data reported by sites.
- Data on patient screening and eligibility/ineligibility rates were either not collected initially by all sites or collected inconsistently. Regular collection of data on patient screening and clinical trial eligibility across all sites was accomplished by fiscal year (FY) 2007, Quarter 4 of the Program. Findings and implications associated with screening and eligibility data are limited to the period when these data was collected regularly.
- Data on reasons for patients' ineligibility for cancer clinical trials and refusal to participate in a clinical trial among eligible patients were not available at the individual level (cumulative data were reported quarterly). These data was also non-mutually exclusive. As a result, information on the average number of reasons or range of reasons for both patient clinical trial ineligibility and refusal was not available.
- Data on the number of patients accrued and navigated who were non-Hispanic White poor, elderly, and/or underserved were not collected systematically. The Quarterly Data Report Template inquired about patients' race/ethnicity but did not obtain other patient-related data (e.g., patient's age, income). Data included in this report on those patient characteristics (e.g., poverty level, income, elderly, and/or medically underserved) are based on data collected individually by sites for their own monitoring and evaluation.
- There are also issues associated with the time periods of quantitative data included in CDRP grantee annual progress reports. Data in progress reports are reported by program years (i.e., from

[14] Based on the CDRP RFA criteria for eligible applicants, comparison sites had to be from health institutions accredited by the Joint Commission on Accreditation of Health Organizations (JCAHO) or a free-standing cancer center accredited by a nationally recognized accrediting body such as the American College of Radiology, either in the United States or in territories under U.S. jurisdiction. In addition, comparison sites had to be the primary provider of radiation oncology care to one or more populations identified with cancer-related disparities (e.g., African Americans/blacks, Asians, Hispanics/Latinos, Native Americans/Alaskan Natives, Native Hawaiians/Pacific Islanders, and those with low socioeconomic status as defined by the Federal poverty level or the state-defined level, if lower) at a percentage greater than the state average of that population according to the 2000 U.S. Census Bureau statistics, and have a greater cancer incidence and/or mortality than the national average according to the NCI data.

September 1 to August 31), not government fiscal years (i.e., from October 1 to September 30). Many sites reported data one month prior to the actual annual progress report submission, and data reported were not always time stamped.

- Standard definitions for data collection items in the Quarterly Data Report were not developed, which caused some discrepancies and/or misinterpretations in data reporting. Discrepancies were resolved, but commonly included reporting on: (a) the number of patients navigated versus number of patient navigator encounters; (b) how to count patients who are rescreened for trial eligibility; (c) tracking of IRB approval versus open to patient accrual dates for clinical trials; (c) how to count patients who were enrolled onto multiple trials; (d) how to count patients who enrolled again on a clinical trial in a later fiscal year (e.g., a patient may have enrolled on a trial in FY2004 and later enrolled onto another trial in FY2007).
- Three CDRP grantees—Rapid City, Singing River, and UPMC McKeesport—also received CTOC supplemental grants to expand their clinical trials in medical and surgical oncology. This supplement was considered an extension to the original CDRP grant, and, as such, CTOC grantee sites reported CTOC and CDRP program data together in their quarterly data reports. Though efforts to differentiate CTOC-specific data from CDRP-only data were made, this was not always possible for all sites. CTOC-specific data described in this report may sometimes include both CTOC and CDRP data.
- Although some comparison data were collected, a rigorous evaluation of the CDRP Program was not possible. A rigorous evaluation design based on random assignment with control groups would have allowed for causal attributions in outcome changes to the CDRP Program.

  While efforts were made to identify comparison sites similar to CDRP grantees, it is still possible that the comparison sites were fairly unique rendering it too simplistic to attribute any favorable differences among CDRP sites to the CDRP Program.
- This report includes only data on Laredo program activities from 2002 to 2006, as the grant was relinquished in April 2007. Sources of data from this site were limited to annual progress reports, the February 2007 interim survey, and program staff interviews conducted in September/October 2006. Data discrepancies between data reported in annual progress reports and data reported in the 2007 request were never resolved. Thus, data reported by the site were never confirmed.

  Quarterly data reports were not completed or collected from Laredo. Therefore, quantitative data collected on a quarterly basis, such as patient screening and eligibility, navigated patients enrolled on clinical trials, reasons patients refused clinical trial participation and navigation, patient barriers, TELESYNERGY® usage, and community outreach activities, were not available are not included in this report.

2.4 Data Analysis

With the exception of Laredo, all sites received no-cost extensions for the CDRP grant. At the writing of this report, complete CDRP program data were only available for Rapid City because its NCE ended in time to be analyzed. Data from other sites in this report cover the period from the beginning of their CDRP programs through September 30, 2009 because their programs are ending at a later date.[15] As mentioned above, data reported on Laredo's program activities cover only the period from 2002 to 2006.

[15] Rapid City's NCE ended on August 31, 2009; Singing River's ended February 28, 2010; and Centinela Freeman's, New Hanover's, and UPMC McKeesport's NCEs end on August 31, 2010.

2.4.1 Quantitative Data

Analysis of quantitative data was based on quarterly data submitted by sites, quantitative data abstracted from progress reports, and additional data collected (e.g., site queries). Main analyses involved descriptive statistics (e.g., frequencies) on the overall CDRP Program, individual program components, and CDRP grantee sites.

2.4.2 Qualitative Data

Content analysis of the qualitative data collected through interview discussions was conducted. The first two rounds of PI interview data were transcribed verbatim and then coded for analysis by two evaluators. Thematic analyses of coded interviews and summaries were then performed and findings were included in reports. The 2006 and 2008 PI interview reports are included in **Appendix F**. In-depth summaries were prepared with the third round of PI interview data as well as the partner interviews. Qualitative data abstracted from progress reports and other program-related written documents were organized into data abstraction spreadsheets.

3. EVALUATION FINDINGS

Evaluation findings will describe the extent to which CDRP Program goals and objectives were reached and will discuss challenges, lessons learned, and recommendations resulting from implementing the program. Findings will be presented for the overall CDRP Program first, and then for each grantee site.

3.1 CDRP Program Achievements

3.1.1 Building/Stabilizing Clinical Trial Research Infrastructure

The CDRP Program aimed to build and stabilize radiation oncology clinical trial research in community-based institutions caring for a disproportionate share of medically underserved, low-income, and racial and ethnic minority populations. The CDRP Program accomplished its intended goal at all grantee community institutions, with the exception of the program at the Laredo site that had to relinquish its CDRP grant due to unique circumstances (described in Section 3.7; see *CDRP Site Progress*).

Prior to the CDRP Program, grantees had little or no experience administering Federal grants or conducting radiation oncology clinical trials. Two grantees—Rapid City and New Hanover—had experience with clinical trials in research prior to CDRP, but with other disease types. Influence of the CDRP Program was of particular significance in sites where clinical trial research was nonexistent before the Program, as it helped establish key mechanisms for research, such as grant administration, accreditations and affiliations, a review process for research protocols (e.g., IRB, advisory groups, or research foundations), and capacity building for current and future research studies. Building the research infrastructure at grantee sites required learning about Federal regulations and procedures associated with approval of research protocols, grant financial administration, and oversight of a federally funded research grant, including budget management, negotiation of a Facilities and Administrative (F&A) rate, and management of indirect costs.

CDRP grantees also had to recruit and hire staff to support the clinical research infrastructure being built. New researchers and staff, including investigators, research coordinators, research nurses, data managers/coordinators, patient navigators, and grant administrators, were hired and trained (mostly on-the-job training). Hiring and training new staff was done more often than expected as sites experienced frequent staff turnover. CDRP grantees' community hospital administration made in-kind contributions in the form of infrastructure and resources (e.g., office space, staff, employee time, money, and technical support). By the second year of funding, all sites had established their clinical research infrastructure and were able to institute clinical trials.

3.1.2 Clinical Trials

Table 2 displays information on the total number of active (i.e., open to patient accrual) clinical trials by CDRP site in each fiscal year. The overall number of open clinical trials increased consistently through the years, with Rapid City, Singing River, and UPMC McKeesport showing the largest increases over time. An examination of clinical trials across sites shows that Rapid City had the largest number of active trials in any fiscal year. Between 40 and 75 percent of all active trials opened in any fiscal year were at Rapid City. UPMC McKeesport and Singing River also showed increasing numbers of active clinical trials. In the last three years of the Program, these sites contributed between 16 and 37 percent of the total number of active clinical trials in a given year. These three grantees were also successful in applying for and receiving CTOC supplemental grants in September 2006 to help build research capacity. More trials were opened as a result of the supplement because the supplement allowed them to open surgical and medical oncology trial protocols. Rapid City and Singing River received renewals of the CTOC supplemental grants in 2008. Results of the CTOC supplement at grantee sites are discussed in later sections of this report (see *CDRP Site Progress*).

Note: Some clinical trials have been counted more than once. A trial that was initially opened in a given program year and continued to be active in subsequent years was counted each year it was active. For example, a PI-initiated trial at New Hanover was opened in FY2004 and closed towards the end of FY2007. This clinical trial was counted as an active trial in fiscal years 2004, 2005, 2006, and 2007.

TABLE 2 – NUMBER OF CLINICAL TRIALS OPEN PER FISCAL YEAR (AS OF SEPTEMBER 30, 2009)

Grantee Sites	Number of Clinical Trials Open per Fiscal Year (%)					
	FY04	FY05	FY06	FY07	FY08	FY09
Rapid City	48 (75)	52 (63)	76 (55)	98 (48)	101 (42)	94 (40)
Laredo	4 (6)	5 (6)	5 (4)	N/A	N/A	N/A
Centinela Freeman	0 (0)	5 (6)	6 (4)	3 (1)	6[a] (2)	4 (2)
New Hanover	5 (8)	9 (11)	11 (8)	5 (2)	7 (3)	7 (3)
Singing River	0 (0)	1 (1)	20 (15)	40 (20)	39 (16)	61 (26)
UPMC McKeesport	7 (11)	10 (12)	19 (14)	57 (28)	89 (37)	69 (29)
Total[b,c,d]	64 (100)	82 (100)	137 (100)	203 (100[c])	242 (100)	235 (100)

N/A = Not applicable; Laredo's CDRP grant was relinquished in 2007.

[a] After closure of the radiation oncology center in January 2008, no new trials were open until August 2008 (see sections 3.3.2 and 3.7.2 for a description of events).

[b] Trials opened in a given year that remained active (i.e., open to patient accrual) in subsequent years were counted each year they remained open.

[c] Data do not include clinical trials that were opened for follow-up only.

[d] Column percents do not total 100% due to rounding.

Most (over 70%) clinical trials instituted at sites related to their CDRP Programs were Phase II or III cooperative group trials. **Table 3** displays information on the type of clinical trials opened at each site. A total of 452 individual clinical trials (counted once only) were opened among sites as a result of the CDRP Program. Rapid City reported the largest number of active trials, representing almost half of all open clinical trials (214, 47%). UPMC McKeesport and Singing River also reported substantial numbers of active clinical trials (114, 25% and 90, 20%, respectively).

All sites became affiliates and opened Radiation Therapy Oncology Group (RTOG)[16] trials (18/452; 19%); but sites most often opened other cooperative group trials (301/452; 67%) such as ACOSOG, CALGB,

[16] The Radiation Therapy Oncology Group is a national clinical cooperative group funded by NCI that focuses on radiation oncology clinical trials.

CTSU, ECOG, GOG, MCCRC, NCCTG, NCIC CTG, NSABP, and/or SWOG.[17] The majority of cooperative group trials opened included medical and/or surgical oncology treatment (217, 72%) and to a lesser extent, radiation therapy alone or combined chemoradiation (48, 16%). Some of these studies were combined-modality therapy trials (e.g., induction cisplatin/irinotecan followed by combination carboplatin, etoposide, and chest radiotherapy in limited stage small cell lung cancer).

TABLE 3 – TYPES OF CLINICAL TRIALS OPENED BY SITES (AS OF SEPTEMBER 30, 2009)

Grantee Sites	PI-Initiated	Mentor-Initiated	RTOG	Other Cooperative Groups[a]	Pharmaceutical/ Industry	Total (%)
Rapid City	8	1	30	174 (2 R; 22 CR; 118 M/S; 32 CC/P)	1	214 (47)
Laredo	1	1	2	3 (2 CC/P; 1 UNK)	1	8 (2)
Centinela Freeman	0	0	5	1 (1 UNK)	2	8 (2)
New Hanover	1	1	9	7 (7 R/CR)	0	18 (4)
Singing River	0	0	20	63 (5 R/CR; 58 M/S[b])	7	90 (20)
UPMC McKeesport	11[c]	0	22	53 (1 R, 11 CR, 41 M/S)	28	114 (25)
Total	21	3	88	301	39	452 (100[d])

[a] Trial Category for Other Cooperative Groups: R = radiation only; CR = combined chemoradiation; M/S = medical and/or surgical; CC/P = cancer control and/or prevention; UNK = unknown category of trial.

[b] Some medical/surgical oncology trials (n=15) opened at this site are also considered cancer control/prevention trials.

[c] These patients are enrolled on UPMC PI-initiated trials via the University of Pittsburgh Cancer Institute (UPCI).

[d] Column percents do not total 100% due to rounding.

PIs from CDRP and/or partner/mentor sites were encouraged to implement PI-initiated radiation oncology trials because many existing NCI cooperative group trials in radiation oncology were not applicable to the disease state of most patients seen at the sites and because of logistical issues commonly faced by disparities populations (e.g., long treatment duration, no transportation). For example, shorter radiation treatment times were developed in some of Rapid City's protocols to address patients who had long distances to travel or other obstacles preventing optimal cancer care in order to decrease the time burden of treatment. Three sites—Laredo, Rapid City, and New Hanover—designed and conducted PI-initiated radiation oncology clinical trials, with Rapid City implementing the most (six trials compared with only one trial for each of the other sites; see **Table 4**).

Grantees also partnered with other institutions in opening clinical trials. For example, Centinela Freeman collaborated with Louis Warschaw Prostate Cancer Center at Cedars-Sinai Medical Center on the Prostate Patient Profiles Project (P4). UPMC McKeesport opened several UPMC PI-initiated trials via the University of Pittsburgh Cancer Institute (UPCI).

[17] ACOSOG=American College of Surgeons Oncology Group; CALGB=Cancer and Leukemia Group B; CTSU=Clinical Trials Support Unit; ECOG=Eastern Cooperative Oncology Group; GOG=Gynecologic Oncology Group; MCCRC= Mayo Clinic Cancer Research Consortium; NCCTG=North Central Cancer Treatment Group; NCIC CTG=Clinical Trials Group of the National Cancer Institute of Canada; NSABP=National Surgical Adjuvant Breast and Bowel Project; SWOG=Southwest Oncology Group.

TABLE 4 – PI-INITIATED RADIATION ONCOLOGY CLINICAL TRIALS (AS OF SEPTEMBER 30, 2009)

Grantee Sites	PI-Initiated Radiation Oncology Clinical Trial
Rapid City	• A Pilot Phase I/II Study of Hypo-Fractionated External Beam Radiation and HDR Brachytherapy for Advanced Prostate Cancer[a] • A Phase II Trial to Evaluate HDR Brachytherapy as Monotherapy for Stage I and II Breast Carcinoma[a] • Phase I/II Trial Examining Dose-Per-Fraction Escalation Using Helical Tomotherapy in the Treatment of Prostate Cancer • Pilot Study of the Helical Tomotherapy Planning and Treatment Delivery Process in Patients Receiving Palliative Treatment for Bone Metastases • Ataxia Telangiectasia Mutation (ATM) Variant in Native Americans: Possible Association with Cancer and Radiotherapy Toxicities • A Phase II Prostate Cancer Trial: Intensity Modulated Radiation Therapy (IMRT) for the Treatment of Pelvic Lymph Nodes and the Prostate to High Dose
Laredo	A Prospective, Randomized Pilot Study of Melatonin vs. Placebo to Reduce Skin Toxicity and Treatment Breaks in Breast Cancer Patients Treated with Conservative Surgery and Radiation Therapy[b]
New Hanover	Phase II Trial of Hyperfractionated Intensity Modulated Radiotherapy (HIMRT) with Concurrent Weekly Cisplatin for Stage III and IVA Head and Neck Cancer

[a] Two separate protocols were written for this clinical trial.

[b] In 2006, the Laredo PI reported opening the trial and awaiting data and safety monitoring board (DSMB) approval. However, the final activation status of this trial was never confirmed.

3.1.3 Patient Accruals

The CDRP Program aimed at enrolling patients from medically underserved, low-income, and racial/ethnic and other minority populations into CDRP-related clinical trials. CDRP grantees were able to enroll a relatively large number of cancer patients onto clinical trials, including substantial numbers of racial/ethnic minorities—American Indians, Hispanics/Latinos, and blacks/African Americans. A total of 1,644 patients were enrolled in clinical trials associated with the CDRP Program through September 30, 2009 (see **Table 5**).[18,19] Most patients accrued to clinical trials were non-Hispanic white (65%), followed by Hispanic/Latino (20%), American Indian/Alaska Native (8%), and non-Hispanic black/African American (6%).

Note: The total number of patients accrued into clinical trials also includes patients that were enrolled into clinical trials prior to CDRP at two sites, but which continued to be opened as part of their CDRP program. At the outset of the CDRP grant, Laredo was already part of NCI's breast cancer prevention trial, Study of Tamoxifen and Raloxifene (STAR) (n=9) and the San Antonio Center of Biomarkers of Risk for Prostate Cancer (SABOR) prostate risk assessment trial (part of NCI's Early Detection Research Network (EDRN) (n = 300). Rapid City had accrued patients to the STAR trial and other cooperative group trials (e.g., RTOG and NCCTG) (n=281) prior to CDRP.

[18] Approximately 31 patients were enrolled onto more than one type of trial increasing the total number of patient accruals to 1,678.

[19] Note that many opened trials did not enroll any patients for a variety of reasons (most often due to patient ineligibility).

TABLE 5 – CUMULATIVE NUMBER OF PATIENTS ACCRUED TO CLINICAL TRIALS BY RACE/ETHNICITY FOR ALL SITES (AS OF SEPTEMBER 30, 2009)

Race/Ethnicity	Total Number of Patients Accrued to CDRP Clinical Trials (%)	
American Indian/Alaska Native	138	(8)
Asian	2	(0)
Native Hawaiian or Pacific Islander	1	(0)
Non-Hispanic Black or African American	100	(6)
Non-Hispanic White	1,071	(65)
Hispanic/Latino	331	(20)
Unknown	1	(0)
Total	1,644[a]	(100[b])

[a] Includes patient accruals to clinical trials opened prior to CDRP: Laredo's accruals to SABOR (n-300) and STAR trials (n = 9) and Rapid City accruals to STAR and cooperative group trials (RTOG and NCCTG) (n=281).

[b] Column percents do not total 100% due to rounding.

Note: Evaluation data on other population characteristics of interest among non-Hispanic whites—specifically, "medically underserved" or "elderly" status—were not collected systematically as part of this evaluation. Although some sites collected these data independently, these data are either missing or collected inconsistently for about 80% of all enrolled non-Hispanic white participants.

Nonetheless, available and complete data on 175 non-Hispanic white participants from two sites (i.e., New Hanover and Singing River) showed that nearly two out of five of these participants (38%) were elderly (65 years old or older) and more than one in four (28%) were considered poor or medically underserved.[20]

Moreover, it is possible that many of the non-Hispanic white participants in Rapid City—which accounted for 73 percent (n = 786) of all CDRP non-Hispanic white patients enrolled into clinical trials—were either underserved or poor. According to the Health Resources and Services Administration (HRSA), all South Dakota residents are officially classified as a "Medically Underserved Population" (MUA).[21] In addition, the U.S. Census classifies the four South Dakota reservation counties served by Rapid City among the ten poorest reservation counties in the U.S.

An examination of patient accrual by clinical trial type and site showed that most patients were enrolled onto other cooperative group trials (e.g., GOG, NSABP, SWOG) (60%), followed by investigator-initiated trials (18%), and RTOG trials (10%; see **Table 6**). CDRP sites were also likely to accrue patients to one or two types of trials. For example, Rapid City accrued mostly to other cooperative group trials and PI-initiated trials; New Hanover accrued mostly to RTOG and PI-initiated trials. Across all sites, Rapid City and Laredo[22] accrued the highest numbers of patients to clinical trials (56% and 19%, respectively).

[20] Definitions of "medically underserved" varied by site to include being poor; having Medicare only; having Medicare with Medicaid supplement; having Medicare and being under age 65, indicating disability; having no health insurance; and being self-pay.

[21] MUAs have shortages of primary medical, dental, and/or mental health providers as well as access barriers to primary medical care services of geographic (a county or service area), demographic (low income, Medicaid-eligible populations), cultural, and/or linguistic nature (Health Resources and Services Administration).

[22].Laredo's accruals to SABOR (n=300) and STAR (n = 9) trials were opened prior to CDRP and accounted for 97% of the site's accruals.

TABLE 6 – CUMULATIVE NUMBER OF PATIENTS ACCRUED AT EACH SITE BY TYPE OF CDRP CLINICAL TRIAL (AS OF SEPTEMBER 30, 2009)

Grantee Sites	PI-Initiated	Mentor-Initiated	RTOG	Other Cooperative Groups	Pharmaceutical / Industry	Total (%)
Rapid City	252	154	45	482	0	933[a] (56)
Laredo	0	0	6	313[b]	3	322 (19)
Centinela Freeman	0	0	17	16	30	63[c] (4)
New Hanover	39	6	50	23	0	118 (7)
Singing River	0	0	18	106	6	130[d] (8)
UPMC McKeesport	10[e]	0	32	58	12	112[f] (7)
Total	301	160	168	998	51	1,678[g] (100[h])

[a] Rapid City accrued 927 patients; 6 patients were on more than one clinical trial and were counted twice. Data includes CDRP prior accrual onto the STAR and cooperative group trials (RTOG and NCCTG) (n= 281).

[b] Includes accruals on prevention trials, STAR (n=9) and SABOR (n=300).

[c] Centinela Freeman accrued 60 patients; 3 patients were on two different types of trials and were counted twice.

[d] Singing River accrued 107 patients; about 20 patients were on two to four different types of clinical trials and were counted every time they participated in a trial.

[e] These patients were enrolled on UPMC PI-initiated trials via the University of Pittsburgh Cancer Institute (UPCI).

[f] UPMC McKeesport accrued 110 patients, 2 patients were on two different types of trials and were counted twice.

[g] This total includes about 30 patients that were counted more than once because they participated in more than one clinical trial. The total number of unduplicated patients accrued was 1,644 (see Table 5).

[h] Column and row percents do not total 100% due to rounding.

Table 7 displays information on patient accrual by fiscal year and type of clinical trial. Fiscal years with the highest patient accruals were 2003, 2004, and 2009, representing more than half (61%) of all patients accrued throughout the CDRP Program; more than 280 patients were enrolled in trials in each of these years. As mentioned above, most patients were enrolled onto other cooperative group trials. Of the 998 patients enrolled to these trials, the majority of patients were on either a cancer control/prevention trial (44%) or a medical and/or surgical oncology trial (41%).

TABLE 7 – CUMULATIVE NUMBER OF PATIENTS ACCRUED IN EACH TYPE OF CLINICAL TRIAL, BY FISCAL YEAR (AS OF SEPTEMBER 30, 2009)

Type of Clinical Trial	FY03[a]	FY04	FY05	FY06	FY07	FY08	FY09	Total (%)
PI-Initiated	0	1	44	78	78	38	62	301 (18)
Mentor-Initiated	0	0	0	0	0	0	160	160 (10)
RTOG	10	7	17	26	34	24	50	168 (10)
Other Cooperative Groups[b]	271	349	39	75	84	98	82	998 (60)
Radiation Only	*1*	*0*	*4*	*20*	*9*	*0*	*3*	*37 (4)*
Radiation/Combined Treatment[b]	*65*	*9*	*14*	*24*	*19*	*13*	*14*	*158 (16)*
Medical/Surgical[b]	*140*	*25*	*24*	*27*	*55*	*79*	*57*	*407 (41)*
Cancer Control/Prevention[b]	*75*	*316[c]*	*6*	*9*	*10*	*11*	*14*	*441 (44)*
Pharmaceutical/Industry	0	0	5	1	8	6	31	51 (3)
Total	281[a]	357	105	180	204	166	385	1,678 (100[d])

[a] Rapid City had approximately 33 active clinical protocols opened during FY03 in which they accrued 281 patients onto the STAR trial and cooperative group trials (RTOG and NCCTG) (n=281).

[b] Rapid City data include patients who were enrolled onto both RTOG and other cooperative group trials. The database structure at this site did not allow segregating the different trial categories (e.g., radiation only, medical/surgical) by only cooperative group trials.

[c] Includes Laredo's accruals to NCI prevention trials, STAR (n=9) and SABOR (300).

[d] Column percents do not total 100% due to rounding.

3.1.3.1 Screening and Eligibility/Ineligibility

Data on patient screening and clinical trial eligibility was also examined. With the exception of one site—Singing River—collection of these data at the beginning of the CDRP Program was inconsistent across sites. Systematic data collection on patient screening and clinical trial eligibility was accomplished by FY2007, Quarter 4 of the Program when the Quarterly Report Template was implemented for all subsequent data collection.

Available data on five of the six grantees (data were not available for Laredo), showed that out of 3,476 patients screened for cancer clinical trials between FY2007, Quarter 4 and FY2009, 819 (24%) met eligibility criteria to participate in available cancer clinical trials (see **Table 8**). Eligibility rates across sites during this time period ranged from 13 to 100 percent (Centinela Freeman had the largest rate; however, this estimate may be misleading because this site did not screen all of its cancer patients). Other than Centinela Freeman, New Hanover and Rapid City had the highest eligibility rates (37% and 29%, respectively) among patients.

TABLE 8 - NUMBER OF PATIENTS SCREENED (SCR) AND ELIGIBLE (ELIG) FOR CANCER CLINICAL TRIALS, BY FISCAL YEAR (AS OF SEPTEMBER 30, 2009)

Grantee Sites[a]	Patients Screened (FY07Q4 - FY09)	Patients Eligible (FY07Q4 - FY09)	Eligibility Rate[b] (%)
Rapid City	1,601	457	29
Centinela Freeman	28	28	100[c]
New Hanover	228	84	37
Singing River	982	166	17
UPMC McKeesport	637	84	13[d]
Total	3,476	819	24

[a] Data were not available for Laredo.
[b] Eligibility rate is based on the number of patients eligible divided by the number of patients screened.
[c] Centinela Freeman did not screen all patients.
[d] Only includes data on the UPMC McKeesport site out of a total of five participating hospital at this CDRP site.

Table 9 displays reported reasons that patients were ineligible to participate in a CDRP-related clinical trial. Common reasons for patients ineligibility to participate in clinical trials were non-mutually exclusive (more than one reason may have been reported for any ineligible patient) and were reported cumulative by sites (not for each individual patient). The most common reason for patient ineligibility was that no study was available to address the patient's tumor type/site (35%). Often this mismatch was a reason for PIs to design and implement investigator-initiated trials. In addition to a variety of other reasons (e.g., patient had prior cancer, trial on hold or closed, past medical history), patients were also ineligible because they presented with very advanced or metastasized cancers (12%).

TABLE 9 –COMMON REASONS PATIENTS WERE INELIGIBLE (AS OF SEPTEMBER 30, 2009)*

Common Reasons for Ineligibility[a]	Total	(%)
No study available addressing tumor type/site	1,238	(35)
Advanced cancer stage	406	(12)
Available trial, but criteria too restrictive	263	(7)
Early stage presentation	241	(7)
Medical comorbidities	186	(5)
Physician preference not to offer	149	(4)
Poor performance status	130	(4)
Patient age	75	(2)
Insurance company denial	31	(1)
Psychological/substance abuse	20	(1)
Other reasons not eligible[b]	780	(22)
Total	3,519	(100)

* Reasons for clinical trial ineligibility were not consistently collected across CDRP sites until FY2007, Quarter 4.

[a] Common reasons for patient ineligibility were non-mutually exclusive.

[b] Other reasons for clinical trial ineligibility included: prior cancer, study participant, or treatment; medical oncologist not an investigator; positive surgical margins; insufficient tissue sample; more than one site or unclear primary tumor; diagnosis is not cancer; trial on hold or closed; patient not evaluated; patient not treated at cancer center; past medical history; missing lab work; estrogen receptor characteristics; tumor size.

The rate of patient accrual into CDRP-related clinical trials was estimated by dividing the number of patients enrolled onto clinical trials (numerator) by the number of patients eligible to participate in clinical trials (denominator). The data presented only cover the period when these data were consistently collected across all sites (FY2007, Quarter 4). As seen in Table 10, CDRP grantees had accrual rates ranging from 52 to 100 percent.

TABLE 10 –PATIENT CLINICAL TRIAL ACCRUAL RATES BY SITE (AS OF SEPTEMBER 30, 2009)

Grantee Sites[a]	Eligible Patients (FY07Q4 - FY09)	Patients Accrued (FY07Q4 - FY09)	Patient Accrual Rate[b] (%)
Rapid City	457	343	75
Centinela Freeman	28	28	100
New Hanover	84	74	88
Singing River	166	87	52
UPMC McKeesport	84	68	81[c]
Total	819	600	73

[a] Data were not available for Laredo.

[b] Accrual rate is based on the number of patients enrolled onto clinical trials divided by the number of patients eligible for clinical trials.

[c] Only includes data on the UPMC McKeesport site out of five participating UPMC hospital sites.

Table 11 displays common reasons eligible patients reported for not participating in clinical trials. Common reasons for refusing trial participation were non-mutually exclusive (more than one reason may have been reported for any eligible patient) and were reported cumulative by sites (not for each individual patient). Most frequently, eligible patients refused clinical trial participation due to a combination of reasons (e.g., patients preferred standard treatment, felt overwhelmed, or lacked family support) (54%). Eligible patients also simply chose not to participate (16%) or their physicians did not recommend that

they participate in a clinical trial (e.g., physician felt patient would not be compliant with therapy, required treatment doses would be poorly tolerated, or patient had a history of substance abuse and physician felt patient would not be a good candidate) (15%).

TABLE 11 –COMMON REASONS ELIGIBLE PATIENTS REFUSED PARTICIPATION IN CANCER CLINICAL TRIALS (AS OF SEPTEMBER 30, 2009)*

Common Reasons for Refusing Cancer Clinical Trial Participation[a]	Total	(%)
Patient refused, unknown reason	159	(16)
Physician preference, not offered to patient	151	(15)
Uninsured or insurance does not cover clinical trials	68	(7)
Patient fear	38	(4)
Physical barrier (e.g., long travel distance, no transportation, poverty, other handicap)	30	(3)
Lack of trust of medical system	20	(2)
Other reasons[b]	558	(54)
Total	1,024	(100[c])

* Reasons for refusing clinical trial participations were not consistently collected across each CDRP site until FY2007, Quarter 4.

[a] Common reasons for refusing trial participation were non-mutually exclusive.

[b] Other reasons included: patient preferred standard treatment, patient did not feel the trial was necessary, patient felt overwhelmed, patient lacked family support, trial treatment not appropriate according to physician, physician was non-participating, patient opted surgery versus radiation therapy, or unknown reason.

[c] Column percents do not total 100% due to rounding.

3.1.4 Other Clinical Research

All CDRP grantees implemented one or more social science studies associated with their CDRP programs. These studies addressed psychosocial, behavioral, and contextual factors influencing cancer-related outcomes. Overall, social science/health services research studies commonly focused on cancer screening, identification of barriers to cancer treatment among target populations, factors influencing clinical trial participation, patient satisfaction, and surveys related to patient navigation and post cancer treatment. Social studies addressed topics such as cancer awareness and knowledge among CDRP target populations (e.g., *Cancer Survey in Colonias: Awareness, Perception, and Knowledge of Cancer among Hispanics in Colonias* conducted at the Laredo site); access barriers to cancer care (e.g., *A Survey of Cancer Patients to Identify Barriers to Cancer Treatment in a Native American Population* conducted at Rapid City); or patient satisfaction with cancer care (e.g., study conducted at Centinela Freeman).

The CDRP grant facilitated the expansion of ongoing or new social/health services studies at sites, and findings were translated into actual practices to improve patient outcomes. For example, UPMC McKeesport expanded its research on health disparities by examining other cancer patient outcomes (e.g., time to initiation of cancer treatment, time to completion of cancer treatment) and patient navigation effects (e.g., comparison of patient outcomes between navigated and non-navigated patients). A clinician at Centinela Freeman was awarded a seed grant for diabetes screening using the CDRP patient navigator model. At New Hanover, results from a behavioral study with cancer patients led to the development of a curriculum module for physicians to enhance interactions with underserved patients.

Table 12 displays information on the type of social and health services studies resulting from implementation of the CDRP Program and the number of participants for each study type. In addition to clinical trials, a total of 23 social sciences studies were conducted as a result of the CDRP Program; most often, these studies addressed knowledge and attitudes about cancer and cancer clinical trials (16) and

were conducted by Rapid City and Singing River (7 each). Over 13,000 patients participated in social sciences studies, with the majority of participants participating in studies focused on knowledge and attitudes about cancer and cancer clinical trials.

TABLE 12 – NUMBER OF PATIENTS ENROLLED ON SOCIAL SCIENCE STUDIES (AS OF SEPTEMBER 30, 2009)

CDRP Grantees	Focus of Social Science Study							
	Knowledge, Attitude, Practice		Behavioral Intervention		Patterns of Healthcare Service Utilization		Total	
	# of Studies	# of Patients	# of Studies	# of Patients	# of Studies	# of Patients	# of Studies	# of Patients
Rapid City	5	1,470	0	0	2	384	7	1,854
Laredo	1	300	0	0	3	266	4	566
Centinela Freeman	3	422	0	0	0	0	3	422
New Hanover	1	260	0	0	1	10	2	270
Singing River	5	10,191	1	51	1	128	7	10,370
UPMC McKeesport	1	135	0	0	0	0	1	135
Total	16	12,778	1	51	7	788	24	13,617

3.1.5 Partnership/Mentorship

Partnerships between CDRP grantee sites and academic medical centers actively involved in NCI-sponsored research were created as part of the CDRP Program. **Table 13** shows the primary and secondary mentor/partners for each CDRP grantee site. CDRP sites worked with one to three partners/mentors. Grantees' relationships with their primary versus secondary partners varied but often included different cooperative group affiliations (e.g., Singing River's RTOG affiliation was with UAB and its SWOG and GOG were through UMMC) and collaborations on different research protocols (e.g., social science studies or patient navigation) available at that institution. In addition to the grantees' primary research partners/mentors, several sites developed additional partnerships. For example, New Hanover conducted interdisciplinary behavioral research with University of North Carolina-Wilmington's (UNC-W) School of Nursing and Department of Psychology.

TABLE 13 – PRIMARY AND SECONDARY MENTOR/PARTNERS OF CDRP PROGRAM GRANTEES

CDRP Grantee	Primary Mentor/Partner	Secondary Mentor/Partner(s)
Centinela Freeman	University of Southern California (USC), Los Angeles, CA	University of California, San Francisco (UCSF), San Francisco, CA RAND Corporation, Santa Monica, CA
Laredo	University of Texas Health Science Center (UTHSC) at San Antonio, San Antonio, TX	MD Anderson Cancer Center, Houston, TX
New Hanover	University of North Carolina-Chapel Hill (UNC-CH), Chapel Hill, NC	
Rapid City	University of Wisconsin-Madison (UW-Madison), Madison, WI	Mayo Clinic, Rochester, MN
Singing River	University of Alabama at Birmingham (UAB), Birmingham, AL	University of Mississippi Medical Center (UMMS), Jackson, MS
UPMC McKeesport	Washington University, St. Louis (WUST), St. Louis, MO	Roswell Park Cancer Center, Buffalo, NY

According to interviewed PIs and partners/mentors, a number of factors influenced the selection of partners/mentors, including shared scientific interest or research benefits, personal interests, investment

in grantee communities, preexisting relationships with PIs and/or other community hospital medical staff, and PI reputation as a highly respected clinician. In addition, New Hanover's partner indicated that, as a state-funded university, their mission included working with community hospitals in the state.

PIs and mentors said that their partnerships for CDRP helped enhance the relationships between their academic institutions and the community hospitals. The nature of the collaboration and the level of interaction grantee community institutions had with their partners varied by site and evolved over time. Initially, most partner/mentor support involved helping grantees develop their research and grant management infrastructure (i.e., grants management and cooperative group affiliations/credentialing). Once the clinical research infrastructure was established, partnership activities generally focused on clinical trial research mentoring and collaborations. These research collaborations involved clinical trials, data analyses, focus groups, publication assistance, cancer education and related professional development (e.g., educational conferences, tumor boards[23], training of medical residents), and patient consultation.

Table 14 shows collaborative research studies conducted between grantee sites and their partners/mentors. Most research collaborations between CDRP grantee sites and their partners involved behavioral research studies (e.g., patient surveys focused on identifying barriers to cancer care), followed by clinical trial research studies. Some sites (e.g., Centinela Freeman and Rapid City) worked with their partners to establish the patient navigator programs at their sites.

TABLE 14 –NUMBER AND TYPE OF COLLABORATIVE RESEARCH STUDIES BETWEEN CDRP GRANTEES AND THEIR PARTNERS (AS OF SEPTEMBER 30, 2009)*

CDRP Grantee	Clinical Trials	Behavioral Research Studies	Other Research Studies	Other (e.g., Focus Groups)
Centinela Freeman	0	5	0	3
Laredo	2	4	2	0
New Hanover	2	2	4	0
Rapid City	5	5	1	0
Singing River	1	2	1	3
UPMC McKeesport	0	1	0	0
Total	10	19	8	6

* Data were consistently collected beginning FY2007, Quarter 4.

Grantee-partner communications about research, consultations about patient treatment, and education varied from regular (e.g., weekly) to occasional contacts that occurred on an as-needed basis. **Table 15** displays the number and type of grantee and partner consultations. The majority of consultations between grantees and partners were related to the conduct of research activities (e.g., planning and implementation of clinical trials, social science studies, and patient navigation), followed by training (e.g., new treatments [e.g., Rapid City staff underwent training by UW-Madison for breast brachytherapy], cultural awareness) or continuing education activities, and patient consultations (e.g., consults during the identification and delineation of a lesion prior to the development of a radiotherapy treatment plan or discussion of a patient's progress during the course of treatment). The substantially higher number of consultations between Rapid City and its partner (UW-Madison) compared with the other grantees and

[23] A tumor board is a forum used by doctors of various specialties (e.g., radiation and medical oncology, pathology) to review and discuss the medical condition and treatment options of a patient.

their partners may be a result of this site's multiple research collaborations (e.g., five clinical trials, five behavioral health studies, and a pathological review study) with its partner, and the fact that the PI had previously been at UW for 5 years.

TABLE 15 – NUMBER AND TYPE OF CONSULTATIONS BETWEEN CDRP GRANTEES AND PARTNERS/MENTORS (AS OF SEPTEMBER 30, 2009)*

CDRP Grantee	Patient Consultations Related to CTs	Research-Related Consultations	Trainings/CE Activities Resulting from Influence of Partnership
Centinela Freeman	7	28	6
Laredo	0	5	57
New Hanover	7	45	16
Rapid City	178	6,616[a]	161
Singing River	13	70[a]	31[a]
UPMC McKeesport	5	14	21
Total	210	6,778[a]	292[a]

* Data from February to June 2007 are currently unavailable and not included in this table.

[a] These are estimated numbers.

3.1.6 TELESYNERGY®

A telemedicine system, TELESYNERGY®, was established at each CDRP grantee institution and its primary partner to strengthen their collaboration and support for treatment and research consultations and professional development activities. TELESYNERGY® contains five features: (1) videoconferencing, (2) microscope, (3) patient camera, (4) rad link, and (5) document viewer. Although TELESYNERGY® was utilized in differing ways at grantee sites, the videoconferencing component of TELESYNERGY® was the one most frequently used by all sites.

TELESYNERGY® helped improve communication with NCI staff, partner institutions, and CDRP sites for research and program planning, and enabled educational conferences and tumor boards. More specifically, TELESYNERGY® was used to facilitate administrative meetings on program management and grant-related issues (e.g., consult on building clinical research infrastructure in radiation oncology), research consultations (e.g., to obtain advice on specific research studies), tumor boards, and training/continuing education between grantees and mentor/partner institutions (e.g., patient navigator trainings with USC and Centinela Freeman) and grantees and NCI, and to a lesser extent for patient care and treatment consultations. Prior to installation of TELESYNERGY®, most of the activities mentioned did not occur at community grantee sites.

Over 3,200 sessions using TELESYNERGY® were reported by sites[24] (see **Table 16**) with most (67%) sessions occurring in FY2008. While the frequency of use of TELESYNERGY® varied by site, grantee institutions tended to utilize TELESYNERGY® at least once per week for tumor boards and other activities. TELESYNERGY® was used mainly for patient consultations by one site (i.e., Rapid City)[25] with 70 percent of consultations occurring in FY2008, followed by weekly tumor boards at all sites.

[24] Data on TELESYNERGY® use were consistently collected beginning FY2007, Quarter 4.

[25] Rapid City redeployed one of its TELESYNERGY® units to the Indian Reservations at the Indian Health Service (IHS) hospital and later expanded to two other Reservations. This redeployment resulted in an increase in patient consultations related to cancer care by local physicians.

TABLE 16 – USE OF TELESYNERGY® FOR CDRP GRANTEE ACTIVITIES, BY FISCAL YEAR*

CDRP Grantee Activity	Number Times Used for Activity			
	FY07, Qtr 4	FY08	FY09	Total
Administrative meetings	5	29	28	62
Research consultations	21	8	16	45
Patient consultations	612	2,037	237	2,886[a]
Tumor boards	12	113	108	233
Training/education	5	10	20	35
Other[b]	8	4	14	26
Total	663	2,201	423	3,287

* Data were consistently collected beginning in FY2007, Quarter 4.

[a] 99% of the patient consultations via TELESYNERGY® were conducted by Rapid City.

[b] Includes TELESYNERGY® maintenance and patient rounds.

3.1.7 Patient Navigation

Patient navigation, a main component of the CDRP Program, was expected to facilitate access to radiation oncology services and clinical trials. Most grantees felt that the navigation process was of great benefit to patients by improving patients' cancer care experience, including increased screening rates, likelihood that patients would complete treatment, and awareness of cancer treatment options (including clinical trials). For example, Petereit et al. (2008) found that American Indians who were not navigated during radiation treatment required three additional days to complete treatment compared with those who were navigated. The role of navigators was essential in building trust in the communities and establishing rapport with patients. Navigators were instrumental in certain sites such as Rapid City, where they helped ease concerns of tribal health councils to endorse clinical trials. Although the specific duties of the navigation staff differed across sites, the primary role of the navigator was to help guide (i.e., navigate) patients through the screening and treatment process and address barriers to care such as transportation and insurance that might have otherwise kept patients from completing treatment.

Sites varied in the navigator model employed to assist patients, including a lay navigator model, a professional model, and a combination of both. Centinela Freeman used a lay navigator model that consisted of locally trained community lay health workers as navigators. Laredo, New Hanover, Singing River, and UPMC McKeesport used a professional approach with navigators who tended to be registered nurses and/or social workers. Rapid City used a combination of lay and professional navigators that included community members and a nurse.

Rapid City's navigation model of lay and professional staff was novel as it involved the participation of community navigators—"community research representatives"—who were members of the target reservations acting as a liaison between the health professionals and the community. This site's professional navigator—a nurse patient navigator—was embedded at the hospital cancer center. Several grantees mentioned the importance of having patient navigators who were part of the community they served. The number of active navigators at each grantee site ranged from 1 to 25, many of whom were volunteers.

Centinela Freeman and Singing River Hospitals provided navigation to all cancer patients entering their hospitals, while the other four sites navigated only their targeted CDRP populations. **Table 17** shows the number of patients receiving navigation services by site and fiscal year. A total of 3,480 cancer patients were navigated with increasing numbers of patients being navigated over the years. UPMC McKeesport reported the highest number of patients navigated (i.e., 846 patients), with navigation services being

offered at four out of five of its participating sites. Singing River's navigation model changed in fiscal years 2008 and 2009 from having a nonprofessional staff to using a social worker; this change was associated with an increase in patients being navigated.

TABLE 17 – NUMBER OF NAVIGATED PATIENTS PER FISCAL YEAR (AS OF SEPTEMBER 30, 2009)*

Grantee Sites	FY04	FY05	FY06	FY07	FY08	FY09	Total
Rapid City	35	77	56	66	184	211	629
Laredo[a]	183	74	90	NA	NA	NA	347
Centinela Freeman	NA[b]	80	146	166	90	127	609
New Hanover	2	17	103	117	87	48	374
Singing River	NC	NR	NR	208	142	325	675
UPMC McKeesport	NA[b]	96	165	252	217	116	846
Total	220	344	560	809	720	827	3,480

NA = Not Applicable; NC = Data not collected by CDRP site; NR = refers to data not received.

* Data were consistently collected beginning in FY2007, Quarter 4.

[a] Laredo data are unconfirmed.

[b] Patient navigation program was not active until 2005 .

Table 18 provides a breakdown of numbers of patients navigated by patient race/ethnicity. CDRP sites appeared to reach targeted populations of ethnic minorities by providing navigation services to blacks/African Americans, Hispanics/Latinos, and American Indians/Alaska Natives (53%). Most non-Hispanic white navigated patients were considered either underserved or elderly (64%).

TABLE 18 – NUMBER OF NAVIGATED PATIENTS BY RACE/ETHNICITY (AS OF SEPTEMBER 30, 2009)*

Race/Ethnicity	Cumulative Navigated Patients Number	(%)
American Indian/Alaska Native	352	(10)
Asian	30	(1)
Non-Hispanic Black or African American	1,032	(30)
Non-Hispanic White	1,620	(47)
Non-Hispanic Whites Considered Elderly[a]	*669*[b]	*(41)*
Non-Hispanic Whites Considered Underserved[c]	*367*[b]	*(23)*
Hispanic/Latino	442	(13)
Unknown		(<1)
Total	3,480	(100[d])

* Data were consistently collected beginning in FY2007, Quarter 4.

[a] Elderly = age 65 or older.

[b] These data were not available from Rapid City, where 279 non-Hispanic whites were navigated.

[c] Depending on CDRP site, underserved was defined as either being poor; having Medicare only; having Medicare with Medicaid supplement; having Medicare and being under age 65, indicating disability; having no health insurance; and being self-pay.

[d] Column percents do not total 100% due to rounding.

Patient navigation may have also facilitated access to and participation in clinical trials among some patients. Depending on each CDRP site, some navigators were expected to discuss clinical trials with patients while others may have only promoted clinical trials through outreach educational activities on cancer and cancer clinical trials. **Table 19** displays information on the number of patients who were navigated and enrolled onto a clinical trial. Of the 1,644 patients accrued to clinical trials, 264 (16%) received navigation services. The majority of navigated patients who were also enrolled into clinical trials were racial/ethnic minorities (58% were American Indian, black/African American, and Hispanic/Latino)

TABLE 19 – TOTAL NUMBER OF PATIENTS NAVIGATED AND ENROLLED IN A CLINICAL TRIAL (AS OF SEPTEMBER 30, 2009)*

Race/Ethnicity	Patients Navigated and Enrolled on CT[a] Number	(%)
American Indian/Alaska Native	80	(30)
Asian	2	(1)
Non-Hispanic Black or African American	66	(25)
Non-Hispanic White	108	(41)
Hispanic/Latino	7	(3)
More than One Race	1	(<1)
Total	264	(100)

* Data were consistently collected beginning in FY2007, Quarter 4.

[a] Data from the Laredo site not available.

Patient navigator activities commonly dealt with barriers in accessing and receiving cancer care, and navigated patients often had more than one barrier to cancer care. The two most common barriers to cancer care identified by navigators were financial difficulties and transportation issues (see **Table 20**). In addition, combinations of barriers (e.g., literacy, fear of cancer/treatment, lack of trust with hospital and/or

healthcare staff) were also frequently reported across all sites. For some sites (i.e., Centinela Freeman and Singing River), lack of family support and insurance were among patients' top three barriers to care.

TABLE 20 – PATIENT BARRIERS TO CANCER CARE* IDENTIFIED BY PATIENT NAVIGATORS**

Grantee Sites	Financial	Transportation	Housing	Insurance	Family Support	Other[a]	Total
Rapid City	1,711	1,473	723	267	100	2,965	7,239
Centinela Freeman	28	114	4	4	77	62	289
New Hanover	89	153	26	48	16	89	421
Singing River	204	234	32	287	42	290	1,089
UPMC McKeesport	181	203	15	156	6	198	759
Total	2,213	2,177	800	762	241	3,604	9,797

* Barriers to cancer care were non-mutually exclusive (i.e., check all that apply); more than one barrier may have been reported for a patient.

** Data were consistently collected beginning in FY2007, Quarter 4.

[a] Other barriers identified include issues related to literacy, language, patient attitude toward treatment, childcare, religion, fear of cancer/treatment or radiation, lack of trust in hospital/cancer center, lack of trust with physicians/other healthcare staff, lack of knowledge for decision-making related to care, need for housing during radiation therapy, need for psychiatric counseling, and nutrition.

Information about refusal of navigation services was not consistently collected by grantees. These data were collected by Centinela Freeman which had offered navigation services to 614 patients with a 63 percent overall acceptance rate. Main reasons patients refused navigation at this site were lack of interest, family concerns about care, and patients' decisions to pursue alternative care.

3.1.8 Community Outreach

While grantees were developing their grants administration processes and joining cooperative research groups, they also began community outreach activities to educate potential patients and their families about cancer treatment and clinical trials soon to be available at their local community hospitals. Patient navigators, cancer survivors, clinical and program research staff, hospital educators, and PIs were involved in conducting outreach activities.

Outreach activities varied among sites but commonly included creating partnerships with community agencies (e.g., cancer coalitions and local American Cancer Society chapters) in providing education and cancer screening to address disparities; designing and distributing program materials (e.g., brochures, flyers/posters, fact sheets, and videos) about cancer and cancer clinical trials; making presentations on cancer screening and clinical trials in churches and at other local organizations; and participating in local health fairs, screenings, legislative events, seminars, and conferences. These activities were viewed as essential by CDRP PIs and other program staff to increase knowledge about cancer and related clinical trials, decrease fear about cancer and treatment, encourage early screenings, facilitate treatment adherence, and, ultimately, increase chances of patient recruitment onto clinical trials.

Grantees acknowledged the relevance of the CDRP Program's outreach and education activities on cancer and clinical trials in the community. Innovative outreach strategies were critical to Singing River in reaching their target population in particular after the devastation of Hurricane Katrina. With a large percentage of Singing River's population living in Federal Emergency Management Agency (FEMA) trailers, Singing River integrated cancer prevention/early detection into a program built around stress reduction through healthy lifestyles. They also implemented an annual partnership workshop/retreat to discuss and plan strategies for conducting cancer clinical trials. CDRP outreach educational activities also

seem to have enhanced health literacy around cancer in targeted communities. This is epitomized by Dr. Daniel Petereit, PI at Rapid City, who said: "*Clinical trials, tomotherapy, brachytherapy—all of these terms that people would normally never hear of—they now know about. In the past, a lot of the American Indians were at the bottom of the barrel when it came to access and knowledge about some of the best cancer treatments. Now they are at the front of the line."*

Table 21 summarizes the wealth of community outreach work conducted by grantee sites. The data presented only cover the period when these data were consistently collected across all sites (FY2007, Quarter 4). With the exception of Centinela Freeman and UPMC McKeesport, the number of outreach activities conducted by CDRP sites increased yearly. Over 33,000 people were reportedly reached through community outreach. The greatest number of participants reached by sites' outreach efforts was during FY2008. This was largely due to numerous health fairs, screening events, and meetings that sites participated in or conducted that year. Rapid City, New Hanover, and Singing River were the largest contributors to the high numbers of people reached through community outreach efforts. It is possible that the number of FTEs available for these efforts (and paid for by the grant) at these three sites in addition to their commitment contributed to their community outreach success.

TABLE 21 – NUMBER OF OUTREACH EVENTS/ACTIVITIES* AND ESTIMATED NUMBER OF PARTICIPANTS, BY FISCAL YEAR (QUARTER 4, FY07 THROUGH QUARTER 4, FY09)**

Grantee Sites[a]	Qtr 4, FY07		Qtrs 1 - 4, FY08		Qtrs 1 - 4, FY09		Total	
	# Activities	# Participants	# Activities	# Participants	# Activities	# Participants	# Activities	# Participants
Rapid City	43	1,163	432	7,495[b]	578	4,417	875	11,740[b]
Centinela Freeman	2	300	0	0	0	0	2	300
New Hanover	5	675	33	6,548	34	2,587[b]	72	9,810[b]
Singing River	20	622	62	5,500	89[b]	3,007	171	9,129[b]
UPMC McKeesport	4	430[b]	15	1,120	7	553	26	2,103[b,c]
Total	74	3,190[b]	542	20,663[b]	708[b]	10,564[b]	1,146	33,082[b]

* Events/activities included, but were not limited to, various meetings and presentations (e.g., tribal meetings), posters, radio broadcasts, health fairs, focus groups, and screening events.

**Data were consistently collected beginning in FY2007, Quarter 4.

[a] Laredo data are not available.

[b] These are only estimates provided by sites.

[c] According to UPMC McKeesport staff, a number of outreach activities were conducted before FY2007, Quarter 4 data reporting.

3.1.9 New Funding/Professional Development Opportunities

CDRP grantee sites continued to seek opportunities for new grants related to cancer and other diseases and areas of professional development during the CDRP Program. CDRP grantee sites applied for over new research grants and other supplemental funding and were successful in 23 out of 34 instances (68%) ; bringing approximately an additional $1.9 million for the program. As mentioned earlier, three CDRP grantees were awarded CTOC supplemental grants and two received CTOC renewals to expand minority accruals in medical and surgical oncology clinical trials. Other awards included funding for breast cancer navigation and screening/outreach at Rapid City, state health funds [from tobacco settlement and State Health Improvement Plan (SHIP)] at UPMC McKeesport, funds to carry out stroke/rehabilitation and Alzheimer/memory disorder studies at Centinela Freeman, palliative care work and patient transportation

funding at Singing River, and a grant focusing on survivor education for Black clergy [funded by the Lance Armstrong Foundation] at New Hanover.

The CDRP Program has facilitated an environment for learning and training by increasing opportunities for professional development at the grantee institutions and their academic partners. More scientists are becoming engaged in radiation oncology or other oncology clinical research. An exemplar is the New Hanover site and one of its partners, the Coastal Area Health Education Center (AHEC):

> *"*[Because of the CDRP Program] *we are now selecting projects for residents to work on around cancer. So we have huge cancer databases and because of the need to publish around cancer and cancer disparities, we're changing the focus of some of our scholarly activities for residents to make them more geared toward cancer disparities." – New Hanover Grants Administrator*

Rapid City has partnered with the University of Wisconsin School of Medicine and Public Health in promoting academic opportunities among postdoctorates (e.g., analyzing data and authoring and publishing papers on program results). Singing River collaborates with Mississippi Gulf Coast Community College (MGCCC) in a mentorship program for honor students in biology/health care each semester with an emphasis on development of research projects. Singing River is working with two community college students to develop a research study evaluating the impact of nutrition and exercise interventions for patients on active cancer treatment.

Sites have been actively trying to find ways of maintaining the research infrastructure established at their community-based institutions. Efforts have involved seeking commitment from their institutions to sustain the built infrastructure and applying for outside funding to support continuing clinical research efforts. Many grantees have begun seeking research funding from sources outside their parent institutions. An illustration is UPMC McKeesport, who will receive funding from the State Health Improvement Program (SHIP) in Pennsylvania to continue their research-related outreach activities. Singing River received a commitment of hospital support for the navigation component once their grant ends in February 2010.

3.1.10 Special Accomplishments

3.1.10.1 Research Publications and Professional Presentations

CDRP site staff have published over 50 peer-reviewed publications (see **Appendix G**) based on their work with the CDRP program (see **Table 22**). They also made multiple presentations at local, regional, and national and international professional meetings as well as presentations/lectures at academic institutions. A total of 28 presentations were made at ASTRO, 2 at the American Society of Clinical Oncology (ASCO), 3 at RTOG, and 71 at other national meetings[26].

[26] The total number of presentations at academic institutions is not reported because these data was not available from all sites.

TABLE 22 – NUMBER OF CDRP-RELATED PUBLICATIONS BY GRANTEE SITE (AS OF SEPTEMBER 30, 2009)

Grantee	Number of Publications
Laredo	1
Rapid City	23*
Centinela Freeman	8
New Hanover	4
Singing River	3
UPMC McKeesport	14
Total	53
* Includes 3 book chapters.	

3.1.10.2 Professional Society Programs

The CDRP Program has resulted in establishment of the NCI American Society for Therapeutic Radiology and Oncology (ASTRO) Disparity Symposium at annual ASTRO meetings since 2003. In addition, various CDRP PIs have organized educational panels on cancer disparities research at annual ASTRO meetings since 2006.

3.1.10.3 Special Appointments

PIs at UPMC McKeesport and Rapid City have taken on committee chairmanships associated with their work on the CDRP Program. Dwight Heron was invited to chair the Special Populations Subcommittee of the RTOG. This committee plays an active role in evaluations and strategies to reach unrepresented populations in national RTOG clinical trials. All CDRP PIs have agreed to form the core membership of this committee. Daniel Petereit was appointed co-chair of the Radiation Oncology Committee of NCCTG, which is a national clinical research group sponsored by NCI. Through these committee chairmanships, these PIs hope to effect change. For instance, they are encouraging changes in study protocols to facilitate recruitment of underserved populations for clinical trials because of what they perceive to be excessively strict eligibility requirements for many clinical trials. In addition to PI appointments, the Grants/Program Director at Singing River was appointed to the Community Advisory Board for the Gulf Coast Trans-Disciplinary Research Recovery Center for Community Health (TRHCCC) research grant involving Baylor, MD Anderson, University of Miami, and University of Texas-Galveston.

3.1.10.4 Acknowledgments

Other special accomplishments where CDRP PIs have been nationally recognized include a nomination of the New Hanover site for the 2009 ASCO Clinical Trial Participation Award and recipient of the 2010 ASCO Clinical Trial Participation Award; an invitation to Daniel Petereit to present results of the CDRP Walking Forward Program at the International Conference on Translational Research (ICRT) in Geneva, Switzerland; and PIs at New Hanover and Rapid City being asked to be Community Clinical Oncology Program (CCOP) reviewers for new 2010 submitted applications.

3.1.10.5 CDRP Project-Generated Resources

Multiple CDRP project-generated resources were designed and either implemented and/or distributed by CDRP sites. In general, these resources include research materials (e.g., surveys, data collection templates), program monitoring aides (e.g., program forms, navigators' forms), patient management tools (e.g., patient toolkit), and outreach/media materials (e.g., flyers, brochures, newsletters). Additional information on these resources at each site is included under *CDRP Site Progress*.

3.1.11 Funding Mechanism

CDRP's funding mechanism was unique because it reversed the flow of research dollars by providing funds directly to community institutions rather than to institutions with established research experience and resources (e.g., academic medical centers). This innovative funding strategy allowed community-based grantee institutions to develop an infrastructure for conducting local radiation oncology clinical trials. This mode of funding was also important in providing grantees with resources and support, a leading role in research activities, better access to their target populations, and more leverage when working with their partners.

3.2 Outcomes Among Comparison Sites

In order to measure the effectiveness of the CDRP Program, evaluation activities also involved the collection of outcome data among non-CDRP-funded community-based radiation oncology facilities similar to CDRP grantees. These facilities (hereafter, "*comparison sites"*) were identified based on criteria stated in the original CDRP RFA (see Section 2.2.4). Comparison sites were identified for each CDRP site except Laredo, as its CDRP grant ended earlier and support from program staff in identifying a similar community-based institution was not possible.

Results from comparative analyses between CDRP grantees and comparison sites showed similarities and a few differences in services, receipt of Federal funding for research, and certain program characteristics.[27]

Both comparison sites and CDRP grantees provided radiation therapy for cancer treatment and had one or more radiation oncologist and radiation oncology/medical physicist at their institutions.[28] With regard to receipt of Federal funds for cancer clinical research, all comparison sites except Singing River reported having conducted NCI and/or other federally funded research in cancer clinical trials in the last five years.[29] In comparison, only two CDRP grantees—Rapid City and New Hanover—had experience with clinical trials in research prior to CDRP. The CDRP grant and the CTOC supplemental grant are the only federally-funded research conducted by CDRP grantees during the past 5 years.

Comparison sites were also asked about the availability of patient navigation services at their sites. Only comparison sites for Centinela Freeman, New Hanover, and UPMC McKeesport had patient navigators or oncology case managers at their institutions. Prior to the CDRP grant, CDRP sites did not have patient navigators at their institutions.

3.2.1 Clinical Trials

The comparison site identified for Singing River reported no clinical trial activity (i.e., no clinical trials open for patient enrollment) at the time of survey completion. All remaining comparison sites reported having NCI-funded clinical trials open at the time of survey completion. While all CDRP grantees also had opened pharmaceutical/industry trials, only comparison sites for Centinela Freeman, Rapid City, and UPMC McKeesport had this type of funded clinical trials open.

Table 23 shows the type of open clinical trials at comparison and CDRP grantee sites. With the exception of Singing River's comparison site (which reported no active clinical trials), CDRP grantees and their corresponding comparison sites had opened radiation oncology clinical trials. With regard to nonradiation oncology clinical trials that were active, CDRP grantees and their counterparts tended to be similar, with a few exceptions. Only Rapid City had surgical and other types of oncology clinical trials active, but its

[27] Some of the data from Rapid City's comparison site were missing and are reported accordingly.
[28] Data on number of radiation oncologists/medical physicists were unavailable for Rapid City.
[29] Related data were unavailable for Rapid City.

comparison site did not. On the other hand, the comparison site for New Hanover had open medical oncology trials, but its CDRP counterpart did not.

TABLE 23 – TYPE OF OPEN CLINICAL TRIALS AT CDRP GRANTEE AND COMPARISON SITES

Type of Clinical Trials Open at Institution	CDRP Grantee/Comparison Site (CS) (Y = Yes and N = No)									
	Centinela Freeman		New Hanover		Rapid City		Singing River		UPMC McKeesport	
	Grantee	CS	Grantee	CS	Grantee	CS	Grantee	CS	Grantee	CS
Radiation oncology	Y	Y	Y	Y	Y	Y	Y	NA	Y	Y
Medical oncology	N	N	N	Y	Y	Y	Y	NA	Y	Y
Surgical oncology	N	N	N	N	Y	N	Y	NA	Y	Y
Combined modality oncology (e.g., surgical plus radiation)	N	N	Y	Y	Y	Y	Y	NA	Y	Y
Other types of oncology	N	N	Y	Y	Y	N	Y	NA	N	N

NA = Not applicable.

An examination of active cooperative group clinical trials at comparison and CDRP grantee sites showed that CDRP grantees were more likely to report PI-initiated trials and to offer a wider variety of cooperative group trials than their counterparts (see **Table 24**).

Only CDRP grantees—New Hanover, Rapid City, and UPMC McKeesport—had PI-initiated clinical trials; with the exception of the comparison site for New Hanover, none of the comparison sites reported having active PI-initiated trials. In addition, Rapid City, Singing River, and UPMC McKeesport grantees had a wider variety of cooperative group trials active than did their counterparts. Only the comparison site for New Hanover had more types of cooperative group trials open than its corresponding CDRP grantee.

TABLE 24 –TYPE OF COOPERATIVE GROUP TRIALS OPENED AT CDRP GRANTEE AND COMPARISON SITES

Type[a] of Cooperative Group Trial Open	CDRP Grantee/Comparison Site (CS) (Y = Yes and N = No)									
	Centinela Freeman		New Hanover		Rapid City		Singing River		UPMC McKeesport	
	Grantee	CS	Grantee	CS	Grantee	CS	Grantee	CS	Grantee	CS
CALGB	N	N	Y	Y	Y	Y	Y	NA	Y	N
ECOG	N	N	Y	N	Y	Y	Y	NA	Y	Y
GOG	N	N	N	Y	Y	Y	Y	NA	N	N
NSABP	N	N	N	Y	Y	Y	Y	NA	Y	Y
NCCTG	N	N	N	N	Y	Y	Y	NA	N	N
RTOG	Y	Y	Y	Y	Y	Y	Y	NA	Y	Y
SWOG	N	N	N	Y	Y	Y	Y	NA	Y	Y
PI-Initiated	N	N	Y	Y	Y	N	N	NA	Y	N
Other	N	N	N	N	Y	N	Y	NA	Y	N

NA = Not applicable.

[a] CALGB = Cancer and Leukemia Group B; ECOG = Eastern Cooperative Oncology Group; GOG = Gynecologic Oncology Group; NSABP = National Surgical Adjuvant Breast and Bowel Project; NCCTG = North Central Cancer Treatment Group; RTOG = Radiation Therapy Oncology Group; SWOG = Southwest Oncology Group.

With regard to phase of trials opened, CDRP grantee and comparison sites (except for the Singing River comparison site, which reported no active trials) reported both Phase II and III trials. However, only CDRP grantees (e.g., Rapid City and UPMC McKeesport) were more likely to also report having Phase I trials open.

Comparison sites were also asked about patient accrual onto clinical trials in the last 12 months. Data from CDRP grantees covering the period from October 1, 2008 through September 30, 2009 were used for comparative analyses. As seen in **Table 25**, CDRP grantees were able to enroll more than twice (54%) the number of patients enrolled by their counterparts. Cross-site analyses showed that only comparison sites for Centinela Freeman and New Hanover accrued more patients than their corresponding CDRP grantees. However, these results need to be considered with caution. The question in the comparison site survey used for this analysis, "*How many patients have been enrolled in clinical trials during the past 12 months?"* did not specify enrollment to cancer clinical trials; it is possible that comparison sites included accrual to other types of trials.

TABLE 25 – NUMBER OF PATIENTS ENROLLED TO CLINICAL TRIALS* IN PAST 12 MONTHS

CDRP Grantees	# of Patients[a] Enrolled on Clinical Trials at CDRP Grantee Site	# of Patients Enrolled on Clinical Trials at Comparison Site
Centinela Freeman	28	40
New Hanover	36	96
Rapid City	251	30
Singing River	37	NA[b]
UPMC McKeesport	33	12
Total	385	178

* Patient enrollment by CDRP grantees includes enrollment to radiation, medical, and surgical oncology and cancer control/prevention trials. The question in the comparison site survey did not specify enrollment solely to *cancer* clinical trials.

[a] Data reported are from October 1, 2008 to September 30, 2009.

[b] The comparison site reported no open clinical trials.

Table 26 shows the percentage of patients enrolled onto clinical trials during the past 12 months broken down by race/ethnicity. Across all comparison and CDRP grantee sites, patients enrolled on clinical trials were mostly white and black/African American. However, CDRP grantees were more likely to enroll racial/ethnic minorities compared with their counterparts.

TABLE 26 – NUMBER OF PATIENTS ENROLLED TO CLINICAL TRIALS IN PAST 12 MONTHS

Population Race/Ethnicity	Percentage of Patients Enrolled on Clinical Trials at CDRP Grantee and Comparison Sites (CS)									
	Centinela Freeman		New Hanover		Rapid City		Singing River		UPMC McKeesport	
	Grantee	CS	Grantee	CS	Grantee	CS	Grantee	CS[a]	Grantee	CS
Non-Hispanic White	14	10	92	99.5	80	98	86	NA	94	100
Non-Hispanic Black or African American	61	80	8	.5	0	0	14	NA	6	0
Hispanic/Latino	18	8	0	0	0	0	0	NA	0	0
American Indian/Alaskan Native	0	0	0	0	20	2	0	NA	0	0
Asian	4	0	0	0	0	0	0	NA	0	0
Native Hawaiian or Other Pacific Islander	4	0	0	0	0	0	0	NA	0	0
More Than One Race	0	2	0	0	0	0	0	NA	0	0
Total	100[b]	100	100	100	100	100	100	NA	100	100

NA = Not Applicable.

[a] No clinical trials were opened at site; thus, no patients were enrolled onto clinical trials.

[b] Column totals do not add to 100% due to rounding.

3.3 CDRP Program Challenges

3.3.1 Special Circumstances—Centinela Freeman

Centinela Freeman hospital was unexpectedly sold to Prime Healthcare Services, Inc., in November 2007. The PI and co-PIs had little notice about the hospital sale, and to compound matters, Prime was not interested in continuing the grant. Prime then closed the hospital and the radiation oncology department in January 2008. The PI and co-PIs then focused their efforts on searching for ways of continuing radiation oncology care for their patients and identifying another NCI-appropriate institution to house the grant. This situation caused serious disruptions in program operations, including a 4-6 month operational delay; the need to conduct the grant from a rented medical office and send patients to the Santa Monica Cancer Treatment Center (SMCTC), owned and managed by 21st Century Oncology, for radiation oncology care; and staff turnovers (e.g., only the administrative assistant and some patient navigators stayed).

In addition, Dr. Steinberg resigned as PI and assumed the co-PI role for the program because he became Chairman of the Radiation Oncology Department at the University of California, Los Angeles. Consequently, Dr. Khan, the prior co-PI, then became the new PI for the ULAAC program. In August 2008, NIH approved transition of the CDRP grant from Centinela Freeman to 21st Century Oncology operating at SMCTC. However, no new trials could be opened and no new patients were enrolled onto any studies until NCI paperwork was completed.

3.3.2 Building/Stabilizing Clinical Trials Research in Community-Based Institutions

One of the biggest challenges faced by CDRP grantees was establishing necessary research and administration infrastructure to conduct radiation oncology clinical trials. The following paragraphs describe common challenges among CDRP grantees.

- Because grantee sites are community-based health organizations engaged primarily in provision of healthcare and treatment (and not necessarily research), most did not have the benefit of an existing clinical trial research framework (e.g., IRB and Data Safety Monitoring Board) or substantive individual or institutional experience with research and grant administration procedures and regulations. The hurdles involved in meeting all requirements of a federally funded grant were more than most grantees had anticipated. Many grantees reported struggling with unfamiliar grant-related concepts like negotiating F&A rates and establishing a Federal-wide Assurance (FWA) for protection of human research subjects. In addition to facing other administrative barriers, PIs had to educate their parent institutions/hospitals about federally funded clinical research.
- Inadequate time for PIs with full-time clinical practices and difficulties recruiting and retaining research project staff were cited as challenges among grantees. Recruitment of experienced research staff was challenging because of the isolated locations of several sites and a limited pool of qualified applicants. As a result, implementation of clinical trials was delayed at most sites. After clinical research infrastructure was established, most grantees reported issues with retaining staff for a grant-funded position due to the impermanence of employment as well as staff going to the private sector for higher pay.
- Unique and serious circumstances—resignation of the grant PI at the Laredo and Singing River sites, sale of the hospital and transition of the CDRP grant at Centinela Freeman, and other unforeseen events—also affected some grantees' ability to become fully operational.

3.3.3 Clinical Trials and Patient Accruals

CDRP grantees mentioned several issues around clinical trials and related patient accruals. Although the relevance of these issues varied by individual site, in general, they addressed the type of clinical trials (e.g., cooperative group, PI-initiated), resources involved to start a trial, and challenges with recruitment.

- Sites faced challenges related to identifying and opening trials that were acceptable to local oncologists, met certain criteria, or were appropriate for their target populations. For example, Rapid City encountered issues with opening a stage III non-small cell lung cancer trial through RTOG/NCCTG; oncologists at this site's institution would not open the trial because it did not meet National Comprehensive Cancer Network (NCCN) treatment standards. Other challenges with opening trials included getting specialists from multiple areas to work together to select appropriate trials and opening a PI-initiated trial based on an existing protocol when working with small sample sizes typically seen at a community-based facility.
- Some sites reported disinterest among the medical community in clinical research and difficulties associated with outreach to this group. Lack of time and interest among members of the medical community were obstacles, particularly when discussing non-revenue-generating trials such as NCI studies.
- The biggest challenges affecting clinical trial accrual were eligibility issues and the difficulty of matching patients to studies (e.g., no studies available to address tumor types). Comorbidities, late-stage presentation, and insurance issues were main obstacles preventing patients from enrolling in trials. More importantly, strict trial requirements (e.g., restrictions on age, specific disease stage, no prior treatment, or lab parameters) made it difficult to match patients to clinical trials.
- Sites faced challenges in opening certain trials because they did not have enough personnel, resources, and specific staffing necessary for a selected trial. Participation in cooperative group studies required grantees to apply for membership into cooperative groups. Technical (e.g., specific computer software) and staffing (e.g., full-time physicist at the institution) requirements delayed obtaining membership in cooperative groups. UPMC McKeesport experienced issues with

coordination and logistics of conducting cancer clinical trial research because of the four health systems at five physical treatment centers that comprised this site. Coordination of clinical trials across these centers required an enormous amount of time and resources that was not anticipated by the grantee.

- Insurance coverage for clinical trials participation was problematic in several CDRP locations. A major employer in Pascagoula, MS, had an insurance plan that explicitly denied coverage for clinical trials. Singing River staff worked with the employer and the clinical trial exclusion was lifted in 2007. UPMC McKeesport has a large elderly population covered by Medicare HMOs; these patients are responsible for 20 percent of the costs associated with treatment under a trial (as opposed to full coverage for standard treatment).
- Reluctance to enter a randomized trial due to loss of control over care was also mentioned as a reason for patient refusal of enrollment onto a trial. This is not seen as a problem specific to the medically underserved but, rather, an overall challenge to clinical trial recruitment. Lack of understanding of clinical trials had an effect on accrual efforts in UPMC McKeesport. Despite increased outreach and education efforts, grantees still faced issues related to other priorities in the community and lack of knowledge and misinformation surrounding clinical trials. At Singing River, outreach efforts were complicated by the community's focus on post-Katrina recovery, where it took 2 years for people to focus on other topics and recovery is ongoing.

3.3.4 Partnership/Mentorship

The main challenge with partnerships discussed by grantees centered on lack of funds allocated to partners. There was a general feeling across grantee sites that the experience, knowledge, time, and other resources provided by the partners far exceeded what partner institutions were getting out of the relationship. TELESYNERGY® equipment installed at partner institutions was considered a tangible benefit of partnership with a CDRP grantee; however, it was still not considered to be a completely equitable exchange.

3.3.5 TELESYNERGY®

Commonly reported challenges with TELESYNERGY® included underutilization of the system due to familiarity and comfort with other methods of communication in the past, the process of obtaining telemedicine privileges at grantee institutions, and physical location (i.e., in a conference room) of the system being unsuitable for patient examinations. Also, technical issues (i.e., connection issues) were reported initially, but were resolved.

3.3.6 Data Collection/Reporting

- There were issues with the existing Web-based CDRP database. Grantees had problems entering and tracking information and were unclear about the intended purpose of some data being collected. On the other hand, some information of interest and value to sites was not being collected. Grantee staff recommended redesigning this database, which resulted in the development of the Quarterly Data Report.
- One of the challenges facing grantees was defining "medically underserved" based on income. The collection of income data can be difficult due to the sensitive nature of the subject.

  "We don't have income [data] *because we were told initially we shouldn't ask that by the locals out here. We do have where they're from and we do have from this IMU or Index of Medically Underserved … that's the Medicare database that goes to every county in South Dakota. And so*

anybody that lives out here, it comes from an area where there is an IMU score." – Daniel Petereit, Rapid City

- CDRP grantees also had difficulty capturing the full picture of why an eligible patient may not have gone on trial. For example, in many cases there were multiple reasons for a patient being ineligible, but sites often reported only a single reason.
- Sites were often not able to link patient outcomes directly to navigation activities. Data to support the benefits of patient navigators were not consistently collected across sites and were mostly anecdotal. This was further complicated by the fact that navigation means different things to different people, such as eliminating barriers (e.g., lack of insurance) to medical care, ensuring completion of cancer treatment, navigating the health system, and providing emotional support to patients and their families.

3.4 Best Practices and Lessons Learned

3.4.1 Best Practices

- CDRP's nontraditional funding model has been fundamental in developing clinical trial research capacity at community-based hospitals that care for a disproportionate share of underserved ethnic and racial minorities and the poor.
- Partnering with experienced academic research institutions has been beneficial in guiding CDRP sites at various levels, by: advising and collaborating on research studies, expanding local clinical investigators' treatment knowledge and skills, and sharing via tumor boards. Many PIs found that having a second partner with specific expertise (e.g., Mayo Clinic's [Rapid City's partner] research with Native Americans) was valuable.
- Given that clinical trial research is new to most of the grantee localities, community outreach activities helped the target population gain knowledge about cancer, become aware of locally available treatments, and be exposed to the purpose and availability of clinical trials. Theories such as Diffusion of Innovation support the long-term impact of community outreach activities on willingness to participate in research. Outreach messages, communicated over a period of time among members of a similar social system (e.g., CDRP-targeted populations), is likely to result in awareness, interest, evaluation, trial, and adoption of clinical trials. In addition, patient navigation demonstrated to these local communities that the grantee institutions are vested in helping patients eliminate or cope with common barriers to cancer care services.
- Certain program aspects and strategies that appeared to have facilitated patient accrual into trials included, but are not limited to: (1) having Phase II and novel treatment trials; (2) having an appropriate research infrastructure in place (i.e., research nurses, navigators, etc.); (3) having a match between characteristic of the cancer experienced by most patients at a site and trials offered; (4) maintaining the presence of the program in the community via outreach efforts; and (5) engaging community/referring physicians early in the program.
- Institutions where community-based radiation therapy programs operate are continually faced with maintaining services while funding the facility. Clinical research is not part of the primary mission of these institutions. Research programs such as CDRP often function with minimal support from the institution. Continued commitment and perseverance from program investigators are critical in ensuring the success of a program such as CDRP.

3.4.2 Lessons Learned

Based on experiences during the CDRP grant, much has been learned about implementing and maintaining the CDRP Program. Lessons learned range from characteristics and/or minimum requirements of grantee sites to conducting cancer clinical trials.

- Several issues related to existing resources and characteristics of potential applicants should be considered when selecting grantee sites.
  - There is a need for at least two radiation oncologists for a program such as CDRP. Two of the sites, Singing River and Laredo, only had one certified radiation oncologist, who also happened to be the CDRP PI. Both of these PIs resigned from the grantee institution, disrupting program operations and potential continuation of the program. The grantee institutions had to search not only for a new radiation oncologist to provide patient care, but also for one who was capable and willing to function as a research PI. As described earlier, the resignation of the PI was a major complication for the Laredo site, which had to relinquish their CDRP grant because they were unable to hire a suitable candidate for the position.
  - Another issue related to choosing grantees is the number of hospitals involved in any single CDRP site. This must be carefully examined when determining feasibility of the proposed plan for a multisite grantee. For example, the UPMC McKeesport site involved five community hospitals in rural Pennsylvania that are part of the University of Pittsburgh Medical Center system. Each hospital has an independent IRB and administration that had to be dealt with so that research activities could occur, which led to delays in implementing some clinical trials.
- For community-based hospitals with little or no experience conducting clinical trials, there is a steep and lengthy learning curve as they develop needed research infrastructure. All CDRP sites reported that coordinated guidance with details on developing structures for federally funded grants administration and conduct of clinical trials was needed.
- Experienced research support staff (e.g., research coordinator, grants administrator, research nurses) facilitated building and maintaining community-based clinical trials. Because of the geographic location of many of the CDRP sites, these types of experienced personnel were not readily available and difficult to recruit. This situation was compounded by the relatively high staff turnover at sites. Therefore, several sites had to train support staff as part of their infrastructure development. PIs found that a qualified research nurse is needed from the beginning of the grant.
- Investigator-initiated research may not be realistic for community clinicians with full-time practices, considering the amount of time needed to implement this type of research. Although the CDRP grant includes funding for part of the PIs' time, this may not be enough to cover the time required to launch and manage such research efforts. On the other hand, for institutions that can develop this capacity (i.e., dedicated research time and money for PI research in addition to clinical workload), investigator-initiated research can be more effectively targeted to the local community's cancer care needs and to address cancer health disparities in the community.
- Academic research institutions received small incentives for partnering with community-based hospitals. Partners with the greatest time and resource involvement tended to have one or two researchers who championed the CDRP concept and gave freely (uncompensated) of their expertise and time.
- While TELESYNERGY® and its features provide the capability of real-time interactions (e.g., viewing and discussing the same medical images, patient consultations), many of these features were underutilized. Reasons for underutilization included logistical challenges (e.g., system was located in a room that was not conducive to patient examinations), use of other channels of communication

(e.g., e-mail, phone, and site visits), partner institution telemedicine systems already in place, and the need to obtain telemedicine privileges prior to use (medical billing issue).

- Community outreach and education on cancer and cancer clinical trials are key activities needed prior to clinical trial recruitment. The patient navigator program furthered awareness of available cancer care services and research while helping the target populations overcome or reduce barriers to care. Increasing awareness and knowledge of cancer treatment and clinical trials and building trust in the community are considered crucial first steps in recruiting patients for trials.
- Engaging the medical community and referring physicians on a timelier basis to discuss clinical trials with their patients is critical to successful clinical trial recruitment.
- Patient navigation was initially anticipated as having a big influence on accrual to clinical trials. For example, if more patients were navigated earlier in the cancer care process, more patients would enroll on clinical trials. However, patient navigators better served the purpose of guiding patients through the medical system and potentially improving completion of radiation oncology treatment. On the other hand, the mentioning of clinical trials to patients by referring physicians and radiation oncologists was more critical in patients' willingness to participate in clinical trials.
- Navigation needs are likely to vary greatly by community (e.g., local patient barriers, geographical distance of residence and treatment, SES levels, population characteristics).

3.5 Recommendations

The following recommendations address radiation oncology research infrastructure, radiation oncology clinical trials, partnerships/mentorships, TELESYNERGY®, patient navigation, outreach, and CDRP data collection.

3.5.1 Infrastructure

3.5.1.6 3.5.1.1 More Time for Creating Infrastructure

Most sites indicated that they needed additional time to develop their infrastructure. Prior to award of the RFA, at the very least, a 1-year grant mechanisms (e.g., NIH Clinical Trial Planning Grant Program [R34]) for planning and building research infrastructure should be considered.

3.5.1.7 3.5.1.2 NCI Support to Establish Research Infrastructure

- As part of the initial planning grant, NCI needs to provide formal group training, workshops, and advice on establishing research infrastructure and complying with NIH administrative and financial rules and regulations to limit delays resulting from implementation trial and error. NCI could provide some in-service training to new grantees via Webcam/TELESYNERGY®. Following that, routine group meetings and conferences would provide a vehicle to improve program-wide communication and resolve outstanding issues and concerns in a proactive manner.
- Funding should be provided for an independent contractor to develop and distribute a CDRP User Manual that addresses building research infrastructure and administering an NIH/NCI grant.
- For the experienced oncologist who is a novice researcher, guidance is needed on the type of research support staff required and their roles and responsibilities. Sustainable source of support applicable to these settings is needed. There is distrust of government intervention based on a long history of starting then stopping projects.

3.5.1.8 3.5.1.3 Need for a Minimum of One Radiation Oncologist in Grantee Institutions

Eligibility requirements for RFA application should include having at least one certified radiation oncologist who would function as PI, and another radiation or medical/surgical oncologist serving as co-PI.[30] This would help buffer the impact of changes in key personnel as experienced by Singing River and Laredo. Evidence of support from the local physician referral community (i.e., physicians who would refer patients to the radiation oncologist) should also be required for the application.

3.5.1.9 3.5.1.4 Program Champions

Because the PIs at CDRP sites are radiation oncologists in community-based hospitals that are not research centers, these PIs need to be constant champions of the CDRP initiative (i.e., bringing access to clinical trials to underserved populations).

3.5.2 Radiation Oncology Clinical Trials

3.5.2.10 3.5.2.1 Prioritize Cooperative Group Trials Over PI-Initiated Trials Or Develop Cooperative Group Trials Appropriate to This Population

- Investigator-initiated single institution clinical trials may not be feasible for all community-based radiation oncology sites. If this is a key part of the CDRP Program, NCI needs to develop mechanisms to guide and support novice clinical researchers in this effort. Implementation of investigator-initiated trials needs to be delayed until later in the grant period (e.g., Year 3 or 4). NCI should continue to require participation in cooperative group trials and may want to give these trials priority over investigator-initiated (or pharmaceutical or industry-supported) trials.
- Establishing a mechanism for investigator-initiated trials as cooperative group trials (e.g., a disparities program at RTOG) could facilitate the development of common protocols, allow for scientific review, and reduce the burden on a single disparities institution.

3.5.3 Partnerships/Mentorships

3.5.3.11 3.5.3.1 Incentives

Given the time contribution involved in partnerships, increased incentives are needed for the research institution mentors and research hers who agree to mentor/partner with the local grantee. This is not necessarily money but other rewards (e.g., additional TELESYNERGY® equipment and certification, access to minority populations for further research, potential collaborations with key partners and organizations, increased patient referrals, increased publications to bolster academic standing) as partners were very enthusiastic about this effort.

For example, McKeesport staff thought that providing a much needed monitor to Roswell Park would be a good incentive for their clinical trial mentor. According to WF staff, their partner the University of Wisconsin was very supportive of this partnership for the following reasons: (1) Increased access and accrual to minority populations that helped UW core grant renewal; (2) establishment of a relationship between the Department of Human Oncology and the School of Public Health. Walking Forward in Rapid City facilitated this relationship; (3) UW is currently assessing the “lessons learned” with their partnership in SD, and applying them to the tribal communities of Wisconsin. New Hanover thought that academic partner benefits would also include: telemed conferences for patients that may be reimbursed, & increased professional publications .

[30] In writing the CDRP U54 RFA, NCI/RRP addressed this recommendation by requiring one radiation oncologists as PI and either a radiation, medical, or surgical oncologist as a co- PI.

3.5.3.12 3.5.3.2 Cross-Site Collaborations

Grantees recommended more cross-site collaboration (i.e., among CDRP grantees) on program activities as part of the grant. This could be enhanced by cooperative groups and professional societies as was accomplished to some extent by RTOG and ASTRO.

3.5.4 TELESYNERGY®

Some grantees felt that they did not need to use all of the TELESYNERGY® features and recommended to "omit the use" of some of its components. Others had plans to expand its use. Grantees noted the inconvenience of using the patient camera because the equipment was in a location that was not appropriate for patients (usually a conference room). A "miniature version" of the patient camera or a digital camera to take to the examination room was suggested.

3.5.5 Patient Navigation

Research evidence related to patient navigation processes and effects needs to be identified. This includes a navigation model that specifies navigator characteristics (e.g., cancer survivor, lay person from the community, nurse), navigation activities (e.g., community outreach, referrals, follow-up through entire diagnosis and treatment), when to begin navigation (e.g., early in diagnosis), and other aspects associated with navigation (e.g., paid staff).

3.5.6 Community Outreach and Navigation

3.5.6.13 3.5.6.1 Ensuring Presence in Community

Emphasis should be placed on ensuring that the grantee (i.e., local cancer center where radiation therapy is provided) has or develops a strong community presence to facilitate referral, recruitment, and enrollment of eligible patients into radiation oncology clinical trials. In addition, provider incentives for referrals to clinical trials should be considered.

3.5.6.14 3.5.6.2 Outreach—Health Service Issue

NCI should view issues around outreach and navigation as health services issues as opposed to public health issues. These two program components may have facilitated patient accrual by increasing awareness, education, and the importance of screening.

3.5.7 Data Collection/Reporting

- Standard operating procedures (SOPs) across all CDRP grantees need to be developed for collection of CDRP program data. SOPs should cover data on research program structure at the institution (e.g., grants administrator, organizational chart, and relationship with institution administrators), data collection methods for all research (e.g., clinical trials, social science studies, patient navigation), data storage and security, and transfer of data to NCI. When the Laredo CDRP site closed, data that had not been sent to NCI were lost and submitted data could not be confirmed and validated.
- Data collection requirements for key program processes and outcomes need to be decided upon and better defined at the outset of the grant.
- Data on patient age at diagnosis and proxy markers of socio-economic status (i.e., highest level of educational attainment and census tract of residence) need to be collected. Age at diagnosis would help to determine whether older patients, as well as adolescents and young adults, who are both underrepresented on NCI-sponsored trials, are able to access appropriate treatment and trials at CDRP sites. Census tract of residence can be used for geocoding to classify patient's site of

residence as rural, urban, or suburban, as well as determine the distance between the patient's residence and treatment site.

- Collection of data related to trial eligibility and refusal should be collected in a consistent manner across CDRP sites.
- Data need to be collected about cultural factors (e.g., cultural backgrounds, individual beliefs, community norms) influencing patient enrollment, as collecting these data across sites may yield information about differences related to geography or other local demographics.
- Current grantee site databases (e.g., Excel) should be adapted to collect data for the grant and the program, rather than re-entering data into a second central database (i.e., quarterly data reports) for NCI reporting.

3.5.8 Evaluation of Program Success

Grantees were frustrated by NCI's focus on accrual rates as the measure of success of the program. Interviewees said that accrual is the wrong metric to use for community-based hospitals. They argued that some of their greatest challenges to accrual (i.e., late-stage presentation and comorbidities) can only be addressed by greater outreach, education, and screening efforts.

Dollars per accrual is not a fair metric for community-based programs. Grantees believe that it will always cost more per patient to accrue at the community level due to the additional time necessary to enroll patients in that type of setting. Cost per patient may appear inflated at a community center where staff cost is spread across a much smaller patient population compared with a large academic center.

> *"That's the bottom line I think from the NCI's perspective … basically getting down to how many dollars does it cost to put a patient on a clinical trial. Even though there's merit to that and everyone is accountable, if I sit in my office all day and don't have people in the field, they're not going to come in with earlier stages of cancer. The most important part of putting people on clinical trials is to influence the stage at which they present, which moves things upstream to more cancer screening initiatives, which we're doing, getting out in the community. … That's where you're going to get the most bang for your buck; it's going to be in cancer screening and education in this particular population." – Daniel Petereit, Rapid City*

3.5.9 Sustainability

- Holding these institutions to the same expectations and standards as major academic medical centers and oncology practices may doom many of them to failure if patient accrual numbers are the key or only metric.
- Leadership at NCI and NIH need to consider additional mechanisms to support disparities communities. While serious performance indicators are necessary, they should account for the realities of resources and personnel available within these communities and the historical level of distrust between many of these communities and federal programs.
- Given resources and support, communities rallied behind the CDRP grantees.

3.6 Conclusions

Given the projected cancer rates for 2010, a large percentage of cancer patients will continue to be treated in community-based centers. Because most community-based centers are not linked with the national clinical research enterprise, these community patients may not benefit from progress being made in cancer research in radiation oncology, thus continuing to perpetuate cancer health disparities in these populations. CDRP was a step toward reducing the negative consequences of cancer health disparities

by building and stabilizing clinical research in radiation oncology in community-based institutions that care for a disproportionate share of the medically underserved low-income and/or minority populations, whether rural or urban. CDRP provided funding for community-based grantee institutions to develop an infrastructure to conduct local radiation oncology clinical trials. This unique funding mechanism was important in providing grantees with:

- Resources and support for program activities.
- A leading role in research activities.
- Better access to their target populations resulting in increased minority accruals.
- More chances to positively affect cancer outcomes in their communities.
- More leverage when working with their partners.

The CDRP Program accomplished its short-term goals—training community-based clinicians as health disparities researchers and building radiation oncology clinical trial research infrastructure in community-based institutions. As a result of the CDRP Program, the following occurred:

- Establishment of a sustainable clinical trial research infrastructure in community-based institutions.
- Increased numbers of patients enrolled from targeted populations.
- Implementation of research studies in other clinical areas.
- Creation and/or enhancement of long-term partnerships with major academic institutions.
- Improved communication with NCI staff, partner institutions, and CDRP sites for research and program planning, educational conferences, and tumor boards facilitated by TELESYNERGY®.
- Increased community awareness on cancer and cancer clinical trials and establishment of a foundation of trust among target populations through community outreach efforts and patient navigation.
- Publications and presentations on the CDRP Program and related components by CDRP grantee institutions.
- Increased current knowledge about conducting clinical trials and providing treatment in populations experiencing cancer health disparities and in community-based healthcare institutions.

According to CDRP grantees, the CDRP Program created a culture of clinical trial research and mindset in community-based institutions and among community physicians where it didn't exist before, and it demonstrated that participant enrollment onto clinical trials sponsored by community institutions is possible.

CDRP grantees faced several challenges because their primary mission is provision of patient care, not clinical research. For example, community institutions faced a steep learning curve in terms of understanding the research world (e.g., IRBs, FWAs). As these researchers continue to gain experience, efforts by researchers and their parent institutions will need to center on stabilizing and sustaining the CDRP Program and other new programs in order to achieve long-term goals of reducing cancer health disparities in grantee communities by providing state-of-the-science cancer care.

Lessons learned should be applied to future funding mechanisms, realistic timelines and sustainable support. The uniqueness of the issues in accrual to clinical trials needs to be recognized by NCI and its review boards to allow these communities the opportunity to be successful and to sustain progress.

The CDRP Program was approved for reissuance (U54 implementation grant) in 2008 and awards were made to grantees in 2009. Sites are continuing to strategize plans to secure additional funding to continue the CDRP endeavor after NCI funding ends. One of the noteworthy implications of the clinical trial research infrastructure that is now in place is that these community institutions will have the capability to continue with research efforts after the CDRP Program ends.

3.7 CDRP Site Progress

Rapid City, Centinela Freeman, Laredo, New Hanover, Singing River, and UPMC McKeesport had similar program goals and objectives for the CDRP Program. The main goal was to create a clinical trial infrastructure to improve access and accrual into radiation oncology clinical trials while addressing issues of cancer disparities and reducing barriers to care among minority and underserved populations in regions served by CDRP sites. Increased access to clinical trial research and quality cancer care was expected to result in lower cancer mortality rates in target populations. The five integrated components of CDRP served as the main vehicle in reaching this goal. All CDRP grantees made some level of progress in meeting their overall goal and objectives. The following summarizes each CDRP grantee's progress.

3.7.1 Rapid City Regional Hospital

3.7.1.1 Research Activities

Basic clinical research infrastructure elements (e.g., hospital IRB) were already present at Rapid City prior to its CDRP program. This grantee was a member of the North Central Cancer Treatment Group and was accruing patients to this cooperative group before the CDRP Program. Nonetheless, the Rapid City CDRP Program, Walking Forward (WF), still faced multiple challenges with its research infrastructure and, in particular, reaching its program target population—American Indians/Native Americans.[31] Challenges included obtaining tribal endorsements for the CDRP Program; processing multiple IRB approvals from tribal councils to open research protocols; addressing cancer barriers within the community; administrative barriers; a shortage of medical oncologists; and lack of clinical trial interest among medical oncologists. A main strategy that was critical in overcoming challenges at this site involved extensive outreach and educational efforts to disseminate information on cancer, clinical trials, and the CDRP WF program that helped establish a much-needed trust between the Indian Reservation population and WF.

In an effort to expand its clinical trial portfolio, Rapid City joined the Wisconsin Oncology Network. The CTOC grant received in September 2006 and renewal in 2008 also allowed the site to expand its menu of clinical trials to include medical and surgical oncology trials. For example, since award of the CDRP grant in 2002 and prior to CTOC funding, approximately 34 medical/surgical oncology trials were opened at Rapid City. After CTOC funding, over 60 medical/surgical oncology trials were opened. CTOC funding was also used to hire more research staff (e.g., research nurse) to help with clinical trial accrual efforts.

More than 90 clinical trials were opened at the site between fiscal years 2007 and 2009. Open trials included six[32] PI-initiated Phase II and III radiation oncology treatment trials aimed at reducing critical barriers to clinical trial participation among Native Americans (e.g., geographical distance and long treatment duration for American Indians living on outlying Reservations). Other trials opened were Phase II and III cooperative group trials (in particular ECOG, GOG, NCCTG, RTOG, and SWOG) with medical, surgical, and/or radiation oncology components, and cancer control and prevention trials. The most

[31] American Indian and Native American are used interchangeably in describing Rapid City's program target population.

[32] Two protocols (i.e., one targeting non-Native Americans and one targeting Native Americans) were written for two of these PI-initiated clinical trials.

frequently opened trials at Rapid City were other cooperative group and RTOG trials (30 and 174, respectively, representing 95% of all trials opened at this site—see **Table 3**).

Rapid City was rather successful accruing patients onto cancer clinical trials, with more than 900 patients participating in available trials (see **Table 27**).[33] An illustration is the accrual to one of the site's PI-initiated trials, the Ataxia Telangectasia Gene Mutation (ATM) study, which had a lower participation refusal rate than originally anticipated, accruing a total of 154 Native American participants. Rapid City accrued most of its patients in FY03 and FY09 (57% of total accruals). As seen in **Table 27**, most patients (52%) were enrolled onto other cooperative group trials (e.g., NCCTG), followed by investigator-initiated trials (27%), and a mentor-initiated trial in collaboration with New York University (17%). In addition, of the patients enrolled onto an RTOG or other cooperative group trial, most (60%) received medical and/or surgical oncology care.

Available CTOC data from Rapid City indicated that approximately 52 new patients were accrued to medical/surgical oncology trials during CTOC funding (i.e., September 2006-October 2009); all were non-Hispanic whites.

In addition to clinical trials, Rapid City conducted several social science studies to better understand barriers to cancer care and assess the effectiveness of various methods in addressing barriers in the population it served. Examples of these studies include a community survey used to identify and document barriers to timely and effective cancer screening, diagnosis, and treatment among the American Indian community; a cancer patient survey administered to all cancer patients presenting at Rapid City's cancer center to measure medical mistrust and satisfaction with healthcare; and a survey among men who were screened for prostate cancer on the Cheyenne River Reservation.

TABLE 27 – RAPID CITY: NUMBER OF PATIENT ACCRUALS, BY FISCAL YEAR AND TYPE OF CLINICAL TRIAL (AS OF AUGUST 31, 2009)

Type of Clinical Trial	FY03[a]	FY04	FY05	FY06	FY07	FY08	FY09	Total N (%)
PI-Initiated	0	0	33	67	62	32	58	252 (27)
Mentor-Initiated	0	0	0	0	0	0	154	154 (17)
RTOG	10	1	9	5	9	5	6	45 (5)
Other Cooperative Groups[b]	271	34	28	43	40	33	33	482 (52)
Radiation Only	*1*	*0*	*4*	*10*	*3*	*0*	*3*	*21 (4)*
Radiation/Combined Treatment	*65*	*4*	*6*	*8*	*11*	*3*	*9*	*106 (22)*
Medical/Surgical Only	*140*	*25*	*24*	*21*	*28*	*26*	*23*	*287 (60)*
Cancer Control/Prevention	*75*	*6*	*3*	*9*	*7*	*9*	*4*	*113 (23)*
Pharmaceutical/Industry	0	0	0	0	0	0	0	0 (0)
Total	281	35	70	115	111	70	251	933[c] (100[d])

[a] Rapid City had approximately 33 active clinical protocols opened during FY03. Prior to the CDRP Program, the site accrued patients onto the STAR trial and cooperative group trials (RTOG and NCCTG) (n=281).

[b] Data include patients who were enrolled onto both RTOG and other cooperative group trials. Rapid City's database structure prevented the classification of the different trial categories (e.g., radiation only, medical/surgical) by only cooperative group trials.

[c] Six of the 927 patients were on two different types of trials.

[d] Column percents do not total 100% due to rounding.

[33] Note that many opened trials did not enroll any patients for a variety of reasons (most often due to patient ineligibility).

3.7.1.2 Reaching the Target Population

Rapid City Regional Hospital serves approximately 100,000 Native Americans from surrounding communities and Reservations including Pine Ridge, Cheyenne River, and Rosebud. The Pine Ridge Reservation is currently the poorest county in the United States and suffers from some of the highest cancer mortality rates. Health clinics on these three reservations are supported by the Indian Health Service (IHS). Rapid City works closely with IHS in providing health care services and is the primary provider of radiation oncology care for the Native American population in this region. According to CDRP WF program staff, as a result of the program, American Indians now constitute approximately 10% of their patient population presenting for cancer, compared with 9% in 2001.

Rapid City successfully enrolled a relatively large number of participants into CDRP-related clinical research and other program activities. Only for Native Americans, the Rapid City WF program reported a clinical trial accrual rate of 25 percent, including cancer treatment and control, which compares favorably to the national average of less than 1 percent (Kanekar & Petereit, 2009). **Table 28** shows the numbers of patients who participated on clinical trials, took part in social science studies, and were navigated, broken down by race/ethnicity. A total of 927 unduplicated patients were enrolled on clinical trials, 1,854 participated in social science studies, and 629 were navigated. The majority of patients enrolled on clinical research was non-Hispanic whites (85% on clinical trials), while those navigated or on social science studies were primarily Native Americans (55% and 86%, respectively).

The relevance of patient accrual into CDRP program research activities at this site was augmented by the fact that most participants were likely to be medically underserved, poor, and/or racial/ethnic minorities. While data are not available on the number of non-Hispanic whites who were considered elderly or underserved in the entire sample, available data on CTOC-related medical/surgical oncology trial participants (52) indicated that all were considered medically underserved or poor non-Hispanic whites, and 65% were elderly (i.e., 65 or older). In addition, information from HRSA and the U.S. Census indicates that South Dakota residents tend to be medically underserved and/or poor (i.e., four Reservations served by site are considered poor) populations.

TABLE 28 – RAPID CITY: CLINICAL TRIALS, SOCIAL SCIENCE STUDIES, AND PATIENT NAVIGATION PARTICIPATION, BY RACE/ETHNICITY (AS OF AUGUST 31, 2009)

Race/Ethnicity	Clinical Trials		Social Science Studies		Patient Navigation	
	N	(%)	N	(%)	N	(%)
Non-Hispanic White[a]	786	(85)	258	(14)	279	(44)
Non-Hispanic Black or African American	1	(0)	0	(0)	0	(0)
Hispanic/Latino	2	(0)	0	(0)	0	(0)
American Indian/Alaska Native	138	(15)	1,596	(86)	347	(55)
Other	0	(0)	2	(0)	3	(1)
Total (%)	927[b]	(100)	1,854	(100)	629	(100)

[a] Data on age and "medically underserved" or "poverty" status were not consistently collected at this site.

[b] These data include accruals in the STAR trial and cooperative groups (RTOG and NCCTG) trials (n=281) prior to the CDRP Program.

From FY2007, Quarter 4 through FY2009,[34] 29 percent of patients seen at Rapid City's cancer center were eligible for cancer clinical trials. The most common reasons why patients at Rapid City were

[34] Data on patient eligibility and estimates on eligibility and accrual rates only cover the time period when these data were collected regularly across all sites, beginning in FY2007, Quarter 4.

ineligible for clinical trials were that no studies were available to address the patient's tumor type/site, the patient was ineligible due to other reasons (missing lab work or tumor size), and the patient presented with an advanced cancer stage. However, three out of four eligible patients (75%) participated in a clinical trial. Common reasons why eligible patients reported not participating in clinical trials were that the treatment being offered on a clinical trial was not appropriate, the patient chose standard or other treatment, and the patient chose not to participate (i.e., simply refused) for unknown reasons.

3.7.1.3 Working with Partner/Mentor

At the beginning of the grant, Rapid City partnered with the University of Wisconsin (UW) as primary partner/mentor and the Mayo Clinic as secondary partner/mentor. Rapid City had a good and fruitful relationship with UW—five clinical trial protocols and five social science/health services research studies were conducted in collaboration with this partner. Program staff training and education activities were also provided by UW in areas such as breast brachytherapy and IMRT via tomotherapy, fractionated stereotactic radiosurgery, and image-guided prostate radiotherapy. The PI also identified new partners at the UW School of Public Health for the social science aspects of the program (e.g., analysis of surveys). On the other hand, Rapid City's partnership with the Mayo Clinic was not as productive. Partnership activities mainly focused on the NCCTG disparity committee as both the Rapid City and Mayo Clinic PIs are co-chairs.

3.7.1.4 TELESYNERGY®

TELESYNERGY® was initially installed at Rapid City Regional Hospital and its CDRP partner, UW, and was routinely used as a means of partner communication on a quarterly basis. However, TELESYNERGY® was underutilized over time and was redeployed to one of the Indian Reservations at the IHS hospital and later expanded to two other Reservations. This redeployment resulted in an increase in patient consultations related to cancer care. In general, TELESYNERGY® was primarily used at Rapid City for patient consultations. Since July 2007,[35] more than 2,800 patient consults were conducted via TELESYNERGY®. Other uses for the system were for research consultations (e.g., advice on specific research studies), training and education (e.g., program staff training), and TELESYNERGY® maintenance. A total of 2,897 sessions was reported by Rapid City during the CDRP Program. The positive experience using TELESYNERGY® resulted in the expansion of telemedicine at outpatient clinics at Rapid City's parent organization, Regional Health. Regional Health was also awarded a telemedicine grant from the Centers for Medicare and Medicaid Services to provide diabetes education and management.

3.7.1.5 Patient Navigation

The WF patient navigator program included navigation services for cancer patients and community outreach. Patient navigators were present at the hospital to assist cancer patients in overcoming barriers to care (e.g., providing financial and social support) and facilitate cancer treatment. In addition, four community research representatives (CRRs; i.e., patient navigators who are Native American) were situated on the four Reservations served by Rapid City to conduct community education and outreach on cancer awareness, screening, and clinical trials. Navigators were critical in building the necessary trust and partnerships within the communities and with the various tribal health councils in order to endorse clinical trials. In addition, Rapid City instituted a breast cancer patient navigator program, funded entirely by the hospital, based on the success of its WF program. The hospital-based breast cancer navigator provided assistance to all patients.

[35] Data were not consistently collected until FY2007, Quarter 4.

All American Indian patients presenting at Rapid City's cancer center were offered patient navigation services. Six hundred twenty-nine patients were navigated as a result of the WF program; 87 (14%) of those patients were enrolled on a clinical trial. Of the 87 patients that were navigated and enrolled onto clinical trials, 92 percent (i.e., 80 out of 87) were Native American.

3.7.1.6 Community Outreach

Outreach activities were crucial in facilitating access to cancer treatment and providing clinical research information to the target population. Throughout the duration of the WF program, more than 11,000 people (e.g., tribal, research, and/or general community members) were reached through various meetings (e.g., tribal council), health fairs, and presentations focusing on cancer awareness, clinical trials, survivorship, healthy lifestyles, compliance, navigation, human papillomavirus (HPV) vaccine, and other cancer-related topics that were generally conducted by CRRs and patient navigators.

3.7.1.7 Project-Generated Resources

Research and program monitoring resources. Several surveys and data collection tools were developed as part of the WF program at Rapid City. These included a community survey to identify and document barriers to timely and effective cancer screening, a pre- and post-navigation survey to obtain patients' experiences with medical care before and after presenting at the cancer center, and a cancer patient survey (version for American Indians and non-American Indians) to gather information about medical mistrust and satisfaction with healthcare. Data collection instruments included a patient contact sheet used for navigation and a cancer clinical trial participation tracking form.

Outreach/media resources. A series of slide presentations was developed as part of the WF program educational modules for CRRs to provide basic information to Reservation communities on cancer, cancer screening, and treatment options, including clinical trials. Other resources included a program brochure, two fact sheets (one on TELESYNERGY®), and flyers on the WF program, cancer awareness, and navigation. Several publications in peer-reviewed journals (see listing in **Appendix G**) and newsletters in Rapid City's local media (e.g., *Rapid City Journal* newspaper) were published from the CDRP Program.

3.7.1.8 Conclusions

Despite initial institutional and community challenges (e.g., educating hospital administration about federally funded research, cancer barriers in the community, and tribal endorsements) faced by the site, Rapid City's WF program was successful in expanding access to cancer treatment and clinical trials; in particular, for American Indians. Community outreach and patient navigation activities appear to have been particularly effective in that endeavor. The efforts of dedicated and culturally trained staff, working with individual cancer physicians, to increase clinical trial awareness, provide adequate staffing, and encourage local oncologists to enroll patients contributed to clinical trial accrual and provision of cancer care to this underserved population.

Rapid City's WF program accomplishments have been recognized nationally and internationally for success in recruiting American Indians on cancer clinical trials and facilitating access to cancer care services. The PI has been appointed chairman of the NCCTG committee and was invited to present findings on the WF program at the International Conference on Translational Research in Geneva, Switzerland. Moreover, Rapid City's WF program activities expanded the research literature on: community-based participatory research to improve health disparities; barriers to care among Native Americans presenting for cancer treatment; conduct of clinical trials and community education, as well as implementation of patient navigation, among Native American populations; and advanced technologies

for cancer treatment. WF program staff generated over 20 publications and made multiple presentations at meetings such as ASTRO, AACR, RTOG, NCCTG, and Spirit of Eagles.

3.7.2 Centinela Freeman Regional Medical Center

3.7.2.1 Research Activities

Centinela Freeman was able to establish its clinical trial research infrastructure (including a physician-comprised Medical Advisory Board), implement a patient navigator program, and develop various quality assurance instruments (e.g., cancer post-treatment survey) and other resources (see *Project-Generated Resources* below) as a result of their CDRP program—Urban Latino African American Cancer (ULAAC) Disparities Project.

However, unforeseen and ongoing hospital administration changes after award of the grant in 2003 prevented the ULAAC program from becoming fully operational. In 2004, the Daniel Freeman Memorial Hospital (DFMH) was sold to local investors and reorganized under Centinela Freeman Health Systems (CFHS). Significant administration changes within CFHS resulted in a delay in program operations of 15 months to navigate patients and 18 months to open clinical trials. In 2007, Centinela Health Medical Center (CHMC) and the radiation oncology services were purchased by Prime Health Systems (Prime). Within 3 months of purchase, DFMH was closed, CHMC cancelled all managed care contracts, and the Radiation Oncology Department was closed (at the end of January 2008). These major changes and disruptions prompted the PI and co-PI to search for appropriate locations to house the grant, see patients, and refer patients for treatment. After DFMH closed in 2008, the ULAAC program experienced an additional 4-6 month operational delay. The program was then conducted from a rented medical office; patients were sent to the Santa Monica Cancer Treatment Center; and navigation services continued with navigators having to transport patients from their homes to the SMCTC.

The site also experienced continuous staff turnovers, mostly due to the transitions in ownership and subsequent program changes. After the hospital closed, most ULAAC staff resigned (only the administrative assistant and some patient navigators stayed). In addition, Dr. Steinberg resigned as PI and assumed the co-PI role for the program because he became Chairman of the Radiation Oncology Department at the University of California, Los Angeles (UCLA was one of this grantee's partners). Consequently, Dr. Khan, the prior co-PI, then became the new PI for the ULAAC program.

In spite of the major changes and related challenges described, Centinela Freeman was able to activate 8 clinical trials, 5 of which were RTOG trials, and enroll 63 patients onto cancer clinical trials (see **Table 29**). Most clinical trial patients (35, 56%) were enrolled prior to closure of the radiation oncology program at Centinela Freeman in 2008, and most were enrolled in either RTOG trials (27%) or other cooperative group trials (25%) providing radiation oncology only. According to the PI, Centinela Freeman enrolled more patients onto RTOG trials in less than 2 years as part of their CDRP program than its academic partners, UCLA and USC, accomplished combined.

In August 2008, NIH/NCI approved transition of the CDRP grant to 21st Century Oncology, which owns and manages SMCTC, Inc. However, no new trials could be opened nor patients enrolled onto any studies until NCI paperwork was completed. In September 2008, the AIM trial, an industry-sponsored trial, was opened at the SMCTC, where approximately 28 patients were accrued in 8 months (shown in FY09 in **Table 29**). A clinical research coordinator was provided by Calypso Medical Technologies, sponsor of the AIM trial, in order to facilitate patient accrual at SMCTC. A clinical research associate was hired in July 2009 and two new RTOG protocols were submitted to the IRB for approval.

TABLE 29 – CENTINELA FREEMAN: NUMBER OF PATIENT ACCRUALS, BY FISCAL YEAR AND TYPE OF CLINICAL TRIAL (AS OF SEPTEMBER 30, 2009)

Type of Clinical Trial	FY05	FY06	FY07	FY08	FY09	Total N (%)
PI-Initiated	0	0	0	0	0	0 (0)
RTOG	5	8	4	0	0	17 (27)
Other Cooperative Groups	0	10	6	0	0	16 (25)
Radiation Only	*0*	*10*	*6*	*0*	*0*	*16 (100)*
Radiation/Combined Treatment	*0*	*0*	*0*	*0*	*0*	*0 (0)*
Medical/Surgical	*0*	*0*	*0*	*0*	*0*	*0 (0)*
Cancer Control/Prevention	*0*	*0*	*0*	*0*	*0*	*0 (0)*
Pharmaceutical/Industry	2	0	0	0	28	30 (47)
Total	7	18	10	0	28	63[a] (100[b])

a Three of the 63 patients were on two different types of trials.
[b] Column percents do not total 100% due to rounding.

Centinela Freeman conducted various social science studies on patients' levels of satisfaction with cancer care. These studies were conducted with navigated patients who were administered quality assurance tools—Patient Satisfaction Survey, Cancer Post Treatment Survey, and Quality Assurance Patient Evaluation Survey.

3.7.2.2 Reaching the Target Population

Centinela Freeman was the primary provider of radiation oncology services in its community/service area of Inglewood, CA, a southern suburb of Los Angeles. In 2002, about 45 percent of its patient population was African American and 45 percent were Hispanic/Latino.

Table 30 displays Centinela Freeman's ULAAC program success in recruiting minority patients—in particular, blacks/African Americans—into clinical trials (68%) and social science studies (76%), and providing them with navigation services (75%). To a lesser extent, Hispanics/Latinos were also reached by and recruited onto these program components (10%-15% of participating patients were Hispanic/Latino). The program was also able to reach populations of elderly and underserved non-Hispanic whites; of the 64 non-Hispanic whites who received navigation services, 59% were elderly and 41% were considered underserved (i.e., poor or having Medicaid only).

TABLE 30 - CENTINELA FREEMAN: CLINICAL TRIALS, SOCIAL SCIENCE STUDIES, AND PATIENT NAVIGATION PARTICIPATION, BY RACE/ETHNICITY (AS OF SEPTEMBER 30, 2009)

Race/Ethnicity	Clinical Trials		Social Science Studies		Patient Navigation	
	N	(%)	N	(%)	N	(%)
Non-Hispanic White	8	(13)	49	(12)	64	(11)
Non-Hispanic Whites Considered Elderly[a]	0		DNC		38 (59%)	
Non-Hispanic Whites Considered Underserved[b]	0		DNC		26 (41%)	
Non-Hispanic Black or African American	41	(68)	320	(76)	455	(75)
Hispanic/Latino	9	(15)	42	(10)	74	(12)
American Indian/Alaska Native	0	(0)	0	(0)	0	(0)
Other	2	(4)	11	(3)	13	(2)
Total (%)	60	(100)	422	(100)	609	(100)

DNC = Data not collected.

[a] Elderly = age 65 or older.

[b] Centinela Freeman defined underserved as being poor or having Medicaid only.

From FY2007, Quarter 4, through FY2009,[36] 100 percent of the patients seen at Centinela Freeman were eligible for cancer clinical trials. Centinela Freeman did not screen all patients; therefore, data on reasons why patients were ineligible for cancer clinical trials were minimal but included the presence of co-morbidities and being denied insurance coverage for care. Main obstacles to accrual of low-income and minority patients reported by this site included lack of transportation and infrastructure (e.g., instability of health system, hospital closures) to supply clinical trials.

3.7.2.3 Working with Partner/Mentor

Centinela Freeman partnered with three major research institutions for the ULAAC program—University of Southern California (Norris Comprehensive Cancer Center at USC), University of California San Francisco, and RAND. Partner activities involved mostly research consultations and studies (e.g., social science studies with RAND), clinical trial collaboration (i.e., enrolling patients on PI-initiated trials with USC), tumor boards with USC, and mentoring from USC and UCLA about the patient navigator program. Centinela Freeman was able to establish its grants support and management office to provide technical assistance to physicians and other clinicians interfacing with ULAAC with the help of RAND. Unfortunately, the sale of DMFH also disrupted communications with partner institutions. However, Dr. Steinberg's move to UCLA helped to ensure a continued connection between the ULAAC program and UCLA.

3.7.2.4 TELESYNERGY®

TELESYNERGY® was located at the ULAAC site office at DFMH and at its partner site, the Norris Comprehensive Cancer Center at USC. TELESYNERGY® was mainly used for training and education, including continuing education for patient navigators, weekly staff meetings, and tumor boards. A total of 5 sessions was reported by Centinela Freeman.[37]

[36] Data on patient eligibility and estimates on eligibility and accrual rates only cover the time period when these data were collected regularly across all sites, beginning in FY2007, Quarter 4.

[37] Data on TELESYNERGY® use ere not consistently collected until FY2007, Quarter 4.

3.7.2.5 Patient Navigation

The ULAAC program used a lay navigator model to improve cancer care and access to clinical trials among its targeted population. The site implemented a navigation training program that was attended by over 70 navigators. Approximately 12 of these trained navigators became active ULAAC program navigators, some of whom were cancer survivors. The site conducted a study on patient navigation that was published in a peer-reviewed journal (Steinberg et al., 2006). Study findings indicated that navigation had a positive effect on minority and low-income cancer patients' experiences with care as well as reducing barriers to care. A total of 609 patients were navigated at Centinela Freeman. Of the 60 patients accrued to clinical trials, more than half (39, 65%) were navigated.

3.7.2.6 Community Outreach

Community outreach activities were minimal for this site. Prior to closure of the radiation oncology center, the ULAAC program was promoting navigation through poster presentations in the community and provision of information on cancer awareness at community health fairs and clinics. Physicians and navigators took part in conducting outreach activities. However, no additional outreach activities were reported after closure of the hospital.

3.7.2.7 Project-Generated Resources

Research and program monitoring resources. Several resources were generated by Centinela Freeman for the purpose of research and program monitoring. These included a patient toolkit that was used to track appointments, doctor visits, and lab values, and an intake form to collect basic demographic information about the patient; a Patient Care Plan Guide for navigators to use for keeping up with their patients' appointments, physicians, follow-up visits, and scans; three quality assurance tools—Patient Satisfaction Survey, Cancer Post Treatment Survey, and Quality Assurance Patient Evaluation Survey; a patient navigator training manual; and an in-house policy and procedures manual.

Outreach/media resources. Two ULAAC brochures (English and Spanish versions) were developed to disseminate information to oncology patients to increase their awareness of ULAAC program services (e.g., patient navigation, clinical trials). Another ULAAC brochure was developed in 2008 when the hospital changed ownership. Eight publications have been produced on program-related topics, such as patient navigation, radiation therapy, and TELESYNERGY® in peer-reviewed journals (see listing in **Appendix G**).

3.7.2.8 Conclusions

Prior to the DFMH closure in early 2008, the Centinela Freeman ULAAC Program was actively accruing minority patients to clinical research and providing navigation services to patients. Repeated institutional changes and overall hospital instability disrupted the implementation and regular operations of the program. To compound matters, the entire healthcare delivery system in the south central Los Angeles area became uncertain; since 2003, three major area hospitals servicing the program's targeted underserved community have closed. Given this context, efforts by Drs. Steinberg and Khan to identify another radiation oncology center—21st Century Oncology at SMCTC—to which to transfer the CDRP grant are noteworthy. These investigators were able to provide patients a 2-year "lifeline" for care.

An objective of the CDRP Program was to help sites establish sustainable clinical research infrastructures. This site is in the process of building and opening a new cancer center located in El Segundo, which is a joint venture between 21st Century Oncology and physicians. The ULACC program will relocate to this new facility with hopes of becoming operational during 2010. New funding opportunities are also being sought to support the program.

3.7.3 New Hanover Regional Medical Center

3.7.3.1 Research Activities

Prior to the CDRP grant, New Hanover had participated in cooperative group chemotherapy trials (e.g., CALGB, cosponsored by RTOG), some with a radiation therapy component. The CDRP program helped strengthened the infrastructure to support clinical research. Main challenges related to research activities experienced by New Hanover included startup inertia, lack of clinical research interest among referring medical doctors, and personnel turnover. Staff turnover, in particular of qualified research staff (e.g., nurses, clinical research assistants [CRAs]), was a major challenge faced by this site.

New Hanover conducted Phase II and III radiation oncology clinical trials, including the first PI-initiated Phase II head and neck study at the cancer center, along with several cooperative group trials. The PI-initiated trial was originally opened at New Hanover and later opened at its partner, the University of North Carolina-Chapel Hill (UNC-CH).

The number of active treatment trials was fairly low at New Hanover (18, mostly RTOG and other cooperative group trials [9 and 7, respectively]) compared with other sites, which with the exception of Laredo and Centinela Freeman, had 100 or more. **Table 31** provides a breakdown of the number of accruals by fiscal year and type of clinical trials at this site. New Hanover accrued a total of 118 patients to radiation oncology clinical trials.[38] Patients were most frequently enrolled onto RTOG trials (42%), followed by the PI-initiated head and neck trial (33%). New Hanover accrued most of its patients in FY2009, and these were enrolled mostly onto RTOG trials. According to the PI, New Hanover became the highest accruing RTOG site in North Carolina in 2008 and 2009. Twenty-three patients (19%) were accrued to other cooperative group trials that offered combination radiation therapy (i.e., radiation and combined chemoradiation). In addition to clinical trials, New Hanover conducted two social science studies. The first study looked at attitudes and beliefs of African Americans about radiation therapy for cancer. The results of this study led to development of a curriculum for local physicians to improve African Americans' satisfaction with medical care. Another study focused on patients newly diagnosed with head and neck cancer. This is a prospective study that began in 2007 and examines patterns of care for patients receiving therapies other than surgical resection alone. An aim of this study is to use findings for future clinical trials.

[38] Only two trials opened at this site did not enroll any patients.

TABLE 31 – NEW HANOVER: NUMBER OF PATIENT ACCRUALS, BY FISCAL YEAR AND TYPE OF CLINICAL TRIAL (AS OF SEPTEMBER 30, 2009)

Type of Clinical Trial	FY04	FY05	FY06	FY07	FY08	FY09	Total N	Total (%)
PI-Initiated	1	11	11	16	0	0	39	(33)
Mentor-Initiated	0	0	0	0	0	6	6	(5)
RTOG	0	1	2	4	13	30	50	(42)
Other Cooperative Groups	2	7	9	2	3	0	23	(19)
Radiation Only	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*(0)*
Radiation/Combined Treatment	*2*	*7*	*9*	*2*	*3*	*0*	*23*	*(100)*
Medical/Surgical	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*(0)*
Cancer Control/Prevention	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*(0)*
Pharmaceutical/Industry	0	0	0	0	0	0	0	(0)
Total	3	19	22	22	16	36	118	(100)

3.7.3.2 Reaching the Target Population

New Hanover Regional Medical Center serves a population with high percentages of African-American and poor individuals. In the nine counties served by New Hanover, 22.5 percent of the population are African American.

Table 32 shows the numbers of patients who were enrolled on radiation oncology clinical trials, participated in social science studies, and were navigated at this site. Of the 118 patients accrued onto clinical trials, almost four out of five (76%) were non-Hispanic whites; 22 percent were African Americans. Forty-one percent of white patients were elderly and 12% were considered underserved (i.e., having Medicaid or no healthcare insurance). Social science studies included a total of 270 patients, almost evenly split between African Americans and non-Hispanic whites. The majority (55%) of navigated patients were African American. Of the 149 non-Hispanic white patients navigated, 14 were elderly and 58 were considered underserved.

From FY2007, Quarter 4, through FY2009,[39] 37 percent of the patients screened at New Hanover were eligible for cancer clinical trials. The most common reasons why patients at New Hanover were ineligible for clinical trials included trial criteria being too restrictive (e.g., patient's age or stage of cancer) and cancer treatment having been received prior to patient consultation. It is noteworthy that 88 percent of those patients eligible to participate in clinical trials were enrolled onto one. Common reasons why eligible patients reported not participating in clinical trials were physical barriers, such as long travel distances to treatment; lack of transportation; poverty; or other handicap. A number of efforts were implemented to increase minority accruals to radiation oncology clinical trials at this site, including: hiring an additional research nurse to focus on gynecologic oncology trials with a radiation component; opening a new facility in Brunswick County, South Atlantic Radiation Oncology, through a joint venture between its medical doctors and New Hanover Regional Medical Center; contracting with a retired minority physician to conduct community outreach and education; and increasing referring physician awareness of clinical trials by implementing physician outreach strategies.

[39] Data on patient eligibility and estimates on eligibility and accrual rates only cover the time period when these data were collected regularly across all sites, beginning in FY2007, Quarter 4.

TABLE 32 – NEW HANOVER: CLINICAL TRIALS, SOCIAL SCIENCE STUDIES, AND PATIENT NAVIGATION PARTICIPATION, BY RACE/ETHNICITY (AS OF SEPTEMBER 30, 2009)

Race/Ethnicity	Clinical Trials N	Clinical Trials (%)	Social Science Studies N	Social Science Studies (%)	Patient Navigation N	Patient Navigation (%)
Non-Hispanic White	90	(76)	123	(45)	149	(40)
Non-Hispanic Whites Considered Elderly[a]	37	(41%)	DNC		14	(9%)
Non-Hispanic Whites Considered Underserved[b]	11	(12%)	DNC		58	(38%)
Non-Hispanic Black or African American	26	(22)	121	(45)	207	(55)
Hispanic/Latino	1	(1)	10	(4)	11	(3)
American Indian/Alaska Native	0	(0)	0	(0)	4	(1)
Other	1	(1)	16	(6)	3	(1)
Total (%)	118	(100[c])	270	(100)	374	(100)

DNC = Data not collected.

[a] Elderly = age 65 or older.

[b] New Hanover defined underserved as patients having Medicaid or no insurance.

[c] Column percents do not total 100% due to rounding.

3.7.3.3 Working with Partner/Mentor

New Hanover only had one partner—UNC-CH. The partnership with UNC-CH was rather successful and strengthened over time with the CDRP Program. In addition to collaborative treatment planning and patient consultations, partnership activities with UNC-CH included clinical trial collaborations on New Hanover's PI-initiated trial and a multi-institutional chemoradiation trial. At the time of this report writing, other planned clinical trial collaborations with UNC-CH included opening a new, limited multi-institutional trial for patients with squamous cell carcinoma of the head and neck (SCCHN) and a new PI-initiated study evaluating the efficacy and toxicity profile of very-low-dose elective nodal irradiation for patients with T1-4N0-2b SCCHN.

3.7.3.4 TELESYNERGY®

TELESYNERGY® was installed at New Hanover and at the UNC-CH site to support the relationship between the partners and enhance communication. New Hanover added TELESYNERGY® connections that allowed real-time examination and consultation with UNC-CH. TELESYNERGY® facilitated physician interactions with UNC-CH and was also used for tumor board meetings. A total of 138 TELESYNERGY® sessions was reported by this site.[40]

3.7.3.5 Patient Navigation

Initially, navigation services were restricted to patients being considered for radiation oncology clinical trials but expanded after the first program year to include anyone in the target population— African Americans and urban/rural poor—or any patients presenting at the cancer center who were considered underserved.

New Hanover had a Community Advisory Board (CAB) that provided guidance and advice on CDRP activities in the community. The CAB comprised primarily African-American community leaders, some of whom were cancer survivors. Patient navigators worked with CAB members to become advocates for

[40] Data on TELESYNERGY® use ere not consistently collected until FY2007, Quarter 4.

patients' rights, inform the community about cancer and clinical trials, and build trust in African-American communities with regards to clinical research.

While the number of patients navigated steadily increased in the first several years (i.e., fiscal years 2004 through 2007) of the grant, these increments were not sustained over time (e.g., 31% were navigated in FY2007 compared with 13% in FY2009). A main reason for the decline in numbers of patients navigated involved staff issues; two navigators were not good matches for the position, and turnover among navigators hindered the number of patients navigated in subsequent years. A total of 374 patients were navigated at this site; 29 (7%) navigated patients were enrolled on a clinical trial, representing 25 percent of all accrued patients.

3.7.3.6 Community Outreach

Between October 2007 and September 2009, over 9,800 people were reached through various community meetings, health fairs, and presentations focusing on cancer awareness, clinical trials, and survivorship. New Hanover outreach efforts targeted influential community leaders such as black clergy and physicians. The relatively low interest in cancer research among physicians who could potentially refer patients prompted outreach educational efforts on cancer clinical trials directed to this group of physicians. The CAB also helped to facilitate a monthly schedule of outreach events, particularly in churches.

3.7.3.7 Project-Generated Resources

Outreach/media resources. As a result of the CDRP Program, New Hanover developed a patient navigator services brochure and video; a brochure on improving cancer outcomes for African Americans; a Ministers Seminar program notebook; and a participant survey for their Having Faith in Cancer Care seminar for black clergy. In addition, a survey was developed to gather beliefs about health and cancer from participants at the Having Faith in Cancer Care seminar.

3.7.3.8 Conclusions

New Hanover's CDRP program was instrumental in establishing the clinical research infrastructure at its medical center, opening a new radiation oncology facility (South Atlantic Radiation Oncology, in Brunswick County), and opening more cancer clinical trials at this site. Importantly, the site's first PI-initiated head and neck trial and accruals onto this and RTOG trials were largely a result of the CDRP program. CDRP clinical trials outreach efforts to referring physicians seemed to facilitate clinical trial accrual at this site. According to the PI, referring doctors who mentioned clinical trials to patients prior to their visit at the cancer center were a big influence on patient enrollment. Patient navigation services were particularly helpful to African Americans (more than half of navigated patients) and a substantial number of non-Hispanic whites (two out of five navigated patients).

Other program accomplishments included a strengthened partnership with UNC-CH, a publication in a supplemental issue of the *Journal of Clinical Oncology* (based on their PI-initiated head and neck study), and a nomination for the 2009 ASCO Clinical Trial Participation Award and recipient of the 2010 ASCO Clinical Trial Participation Award.

3.7.4 Singing River Hospital

3.7.4.1 Research Activities

The CDRP grant was the first federally funded grant received by Singing River Hospital in Mississippi. Singing River spent the first two years of the grant focusing on regulatory and fiscal processes necessary to set up its clinical research infrastructure. Soon after developing its basic infrastructure, Singing River

dealt with two major issues that affected progress of the program. First, the original PI resigned in 2005 and a new PI, Dr. Sam Dennis, transitioned into the PI leadership role while maintaining a full-time practice.

The program was restructured in the third year to dedicate full-time staff to certain program areas. Standard operating procedures were developed in the same year for research conducted at the hospital. This involved collaboration of various hospital departments (e.g., pharmacy). A Medical Advisory Board comprising other physicians was implemented as a result of the CDRP grant. Within 8 months of the restructuring process, Singing River began enrolling patients to cancer clinical trials.

Secondly, Hurricane Katrina (2005) severely impacted Singing River and the surrounding community in Year 3. The cancer center closed for 3 weeks due to the devastation caused by the hurricane. Because of the research infrastructure already in place for the CDRP Program, Dr. Dennis assumed management of 16 Singing River patients who were participating in several cooperative group clinical trials at a nearby hospital that was severely damaged. Despite major setbacks during the first years of its CDRP program, Singing River recovered and began enrolling patients onto RTOG, other cooperative group, and pharmaceutical/industry trials.

Numerous Phase II and III medical, surgical, or radiation oncology cooperative group trials were opened at Singing River in the last few years of the grant. A total of 90 clinical trials were open at this site as a result of the CDRP Program. The most frequent types of clinical trials opened were non-RTOG cooperative group trials (70%) involving medical and/or surgical oncology care. With award of the CTOC supplement in 2006,[41] the site was able to further expand its clinical research to medical/surgical oncology and fund a second clinical research associate devoted exclusively to screening and case finding. It is important to note that Singing River was conducting approximately 13 medical and surgical oncology clinical trials prior to CTOC funding since it restructured its program in September 2005. During CTOC funding years, Singing River reported opening 45 new medical (chemo only) and 6 new surgical oncology trials.

Table 33 provides a breakdown of the number of accruals by fiscal year and type of clinical trial implemented by Singing River. Singing River accrued a total of 130 patients to cancer clinical trials.[42] The largest number of patients was accrued in FY2008. Most patients were enrolled into other (i.e., non-RTOG) cooperative group trials (82%). To a lesser extent, patients were also accrued into RTOG trials (14%).

[41] Site had CTOC funding from 9/1/2006 – 8/31/2009.

[42] Note that many opened trials did not enroll any patients for a variety of reasons (most often due to patient ineligibility).

TABLE 33– SINGING RIVER: NUMBER OF PATIENT ACCRUALS, BY FISCAL YEAR AND TYPE OF CLINICAL TRIAL (AS OF SEPTEMBER 30, 2009)

Type of Clinical Trial	FY06	FY07	FY08	FY09	Total N	Total (%)
PI-Initiated	0	0	0	0	0	(0)
RTOG	0	8	3	7	18	(14)
Other Cooperative Groups	4	24	48	30	106	(82)
Radiation Only	*0*	*0*	*0*	*0*	*0*	*(0)*
Radiation/Combined Treatment	*0*	*0*	*1*	*2*	*3*	*(3)*
Surgical/Medical	*4*	*21*	*45*	*18*	*88*	*(83)*
Cancer Control/Prevention	*0*	*3*	*2*	*10*	*15*	*(14)*
Pharmaceutical/Industry	1	3	2	0	6	(5)
Total	5	35	53	37	130[a]	(100[b])

[a] Approximately 20 of the 130 patients were on more than one type of trial.

[b] Column percents do not total 100% due to rounding.

CTOC data showed that 87 patients were accrued to medical/surgical oncology trials during CTOC funding (September 2006-October 2009). Note, however, that Singing River program staff credit patient accrual during this time to the CDRP Program only (not CTOC funding). CTOC funding only provided support for one clinical research coordinator for screening/case finding and not patient registration, data management, or any other aspect of patient accrual efforts. According to program staff, having three physicians—one radiation oncologist and two medical oncologists—was particularly effective in accruing patients to clinical trials. Medical oncologists were active participants in SWOG, GOG, NSABP and CTSU studies, and accrued almost 75 percent of research patients over the last 3 program years. The site hired a second radiation oncologist in 2008 to increase accruals to RTOG trials. In 2008, Singing River's CDRP program was integrated with a second Singing River Health System hospital at Ocean Springs, Mississippi. The expansion of clinical services resulted in more allocation of resources for case finding and management of research activities.

In addition to clinical trials, Singing River instituted multiple social science studies, mostly involving surveys and resulting in over 10,000 participants. Results from a study on factors influencing patients to participate in clinical trials were used to develop a Patient Fast Fact Sheet as a recruitment tool. Other studies included a Cancer Risk Quiz to assess community cancer awareness and education and a Cancer Protective Survey, which was implemented at health fairs.

3.7.4.2 Reaching the Target Population

Singing River's population consists of 65-70 percent elderly (i.e., 65 or older) individuals, with 25 percent being black/African American and 75 percent being underserved (underinsured or uninsured). **Table 34** shows the numbers of patients who were enrolled on cancer clinical trials, participated in social science studies, and were navigated at Singing River. The site accrued 107 unduplicated patients onto clinical trials and 10,370 into social science studies, and 675 patients were navigated. The majority of patients participating in these activities were non-Hispanic whites, followed by blacks/African American. Substantial proportions of non-Hispanic whites who were enrolled onto clinical trials and were navigated were elderly or underinsured (79% and 74%, respectively). Data on patients accrued through CTOC funding showed that 87 patients were accrued to medical/surgical oncology trials; the majority were non-Hispanic whites (77%) and 22% were black/African American. Of the white patients, over half were considered either elderly or underinsured/uninsured. Note that the proportion of blacks/African Americans participating in clinical trials (21%) was similar to the proportion of this group in the area (25%). Nearly a

third of all navigated patients were blacks/African Americans (31%), and a relatively large number of Hispanics/Latinos participated in social science studies (281).

From FY2007, Quarter 4, through FY2009,[43] 17 percent of the patients seen at Singing River cancer center were eligible for cancer clinical trials. The most common reasons why patients at Singing River were ineligible for clinical trials included lack of studies that addressed patients' tumor types/sites, physicians not recommending that patients participate in clinical trials, patients considering alternative treatment more appropriate, and other reasons (e.g., prior cancer treatment). Most clinical trial eligible participants, however, participated in a trial (52%). Common reasons why eligible patients reported not participating in clinical trials were that their physicians did not recommend that they participate in a clinical trial (e.g., physician felt patient would not be compliant with therapy, required treatment doses would be poorly tolerated, or patient had a history of substance abuse and the physician felt the patient would not be a good candidate) and insurance not covering participation in clinical trials.

TABLE 34 – SINGING RIVER: CLINICAL TRIALS, SOCIAL SCIENCE STUDIES, AND PATIENT NAVIGATION PARTICIPATION, BY RACE/ETHNICITY (AS OF SEPTEMBER 30, 2009)

Race/Ethnicity	Clinical Trials		Social Science Studies		Patient Navigation	
	N	(%)	N	(%)	N	(%)
Non-Hispanic White	85	(79)	5,515	(53)	459	(68)
Non-Hispanic Whites considered Elderly[a]	29 (34%)		DNC		224 (49%)	
Non-Hispanic Whites considered Underserved[b]	38 (45%)		DNC		116 (25%)	
Non-Hispanic Black or African American	22	(21)	3,198	(31)	206	(31)
Hispanic/Latino	0	(0)	281	(3)	5	(1)
American Indian/Alaska Native	0	(0)	0	(0)	0	(0)
Other	0	(0)	1,376	(13)	5	(1)
Total (%)	107	(100)	10,370	(100)	675	(100[c])

DNC = Data not collected.

[a] Elderly = age 65 or older.

[b] Singing River defined underserved as uninsured or underinsured patients.

[c] Column percents do not total 100% due to rounding.

3.7.4.3 Working with Partner/Mentor

The initial partnership that Singing River had with Mobile Infirmary did not flourish and was terminated at the end of the second program year. On the other hand, the site strengthened its partnership with the University of Alabama and started a new partnership with the University of Mississippi Medical Center. Most interactions focused on research-related issues and less on patient care and consultations. Cooperative group affiliations were the main aspects of the partnership. The site remained an RTOG affiliate through UAB and a GOG and SWOG affiliate through UMMC. Partnership activities increased in the last few years of the CDRP Program to include more patient consultations, training and education, and other research (e.g., planning of a collaborative social science study on bone metastases radiation therapy patterns of care). Singing River also initiated annual partnership retreats with UAB and UMMC to discuss current goals, standard operating procedures, compliance issues, and collaborative research studies.

[43] Data on patient eligibility and estimates on eligibility and accrual rates only cover the time period when these data were collected regularly across all sites, beginning in FY2007, Quarter 4.

3.7.4.4 TELESYNERGY®

Located at Singing River and its partners, UMMC and UAB, TELESYNERGY® was mainly used for administrative and research consultations, and tumor boards. Singing River moved TELESYNERGY® to a conference room to enhance patient case presentations and other medical staff usage. TELESYNERGY® supported patient consultations between Singing River and UMMC (largely due to in-state patient referrals). A total of 81 sessions was reported by Singing River.[44]

3.7.4.5 Patient Navigation

Singing River's navigation model changed in fiscal years 2008 and 2009 from having a nonprofessional staff to using a social worker who was African American. The navigator contacted every new patient referred to the center prior to the patient's first consultation in order to screen patient barriers to treatment. Singing River reported that this change resulted in an increase in patients being navigated and presenting to care on a timelier basis. The patient navigator provided services for drug assistance, financial issues, and social services. Most importantly, post-Katrina, the navigator was critical in helping patients maintain compliance with treatments. Singing River reported that the navigator and patient driver made over 3,300 trips assisting patients, as public transportation did not exist after Hurricane Katrina. The site expanded to two full-time navigators because of the new clinic opened at Ocean Springs. A total of 675 patients were navigated and 106 (16%) of those patients were enrolled on a clinical trial. It is noteworthy that almost all clinical trial participants (106 out of the total 107) had been navigated.

3.7.4.6 Community Outreach

Post Hurricane Katrina, outreach efforts were the most challenging aspect of the CDRP Program for Singing River. Considering that many people still lived in FEMA trailers and were focused on rebuilding, it was difficult for the site to engage the community in cancer-related topics. Instead of focusing on cancer-related messages, Singing River's CDRP program staff decided to conduct outreach activities emphasizing cancer prevention through a stress reduction program. A new outreach coordinator was successful in reaching church communities and promoting cancer awareness. Approximately 164 presentations were given by the outreach coordinator from July 2007 to September 2009, reaching over 6,000 community members, including African-American, elderly, low-income, and cancer survivor populations. In addition to presentations, cancer screening events and media advertisements promoting clinical trials were conducted at this site. Expansion of outreach efforts also included implementing a Legacy Patient Advocacy Program—a patient-peer mentoring system connecting new cancer patients with "veterans"—and a Tobacco Cessation Program, and partnering with Northrop Grumman shipyards (a major employer in the area) for cancer awareness programs and with the YMCA to promote healthy lifestyles with emphasis on nutrition and skin cancer prevention. Among all Singing River's outreach activities, over 9,000 community members were reached.

3.7.4.7 Project-Generated Resources

Numerous program materials and information were developed for clinical research, patient navigation, and outreach efforts at Singing River.

Research and program monitoring resources. Standard operating procedures were developed for the patient navigator program, outreach, regulatory processes, case finding, and case management. The site also developed several databases and tracking logs for administration, clinical trial research (e.g., case finding, study patient accrual listing, study activation list), and reporting purposes.

[44] Data on TELESYNERGY® use were not consistently collected until FY2007, Quarter 4.

Outreach/media resources. Program materials developed for community outreach activities included, but not limited to, brochures and flyers on clinical trials and navigation, outreach presentations for the general public, and meeting and training agendas (e.g., Legacies Advocate training).

3.7.4.8 Conclusions

Singing River is an example of what devastations like Hurricane Katrina can do to a small community site. Yet, more importantly, Singing River is exemplary of how a community hospital can overcome major setbacks. In addition to Katrina, this site experienced other unique challenges, as well as ones similar to those faced by other sites, including change of PIs, the need to engage in community outreach that met the needs of its community, and staff turnover (including change to professional staff navigator). Nonetheless, this site amazingly restructured itself and leveraged resources to establish an active clinical research office and an efficient patient navigation program, and was innovative in conducting community outreach efforts. Accrual rates in clinical trials and behavioral studies reflect the amount of effort the site made towards reaching its programmatic goals and objectives. Singing River was able to enroll and provide navigation services to substantial numbers of patients in its target population, including the elderly, the underserved or uninsured, and/or African Americans. Across all sites, Singing River reported the largest numbers of participants in social science studies, reaching a relatively large number of minority populations. Another notable accomplishment of the site is that the hospital agreed to support patient navigation for the cancer center once the original U56 NCI funding ends. Additionally, papers on improving community access to care and clinical trials, using a Patient Fast Fact Sheet as a recruitment tool for clinical trials, and conducting outcome evaluations of cancer awareness, education, and marketing have been published in peer-reviewed journals.

3.7.5 UPMC McKeesport Hospital

3.7.5.1 Research Activities

The UPMC McKeesport grantee site consists of five collaborating hospitals.[45] This program faced multiple logistical challenges largely due to the coordination of five hospitals (e.g., obtaining multiple hospital IRB approvals, working within multiple hospital policies and procedures). Despite hurdles associated with the complexity of managing five sites, this CDRP grantee was successful in establishing a research infrastructure to initiate clinical trials and other research programs within 18 months after award of the grant. Notably, the site developed a clinical research infrastructure and deployed the necessary resources to support the infrastructure in each partnering hospital.

During the course of UPMC McKeesport's CDRP program—Radiation Oncology Community Outreach Group (ROCOG)—the site experienced delays and obstacles in clinical trial accruals due to physician staffing issues (e.g., obtaining private physician privileges with the health system to accrue patients to clinical trials), the purchase of one of its collaborating hospitals (Mercy Hospital by UPMC Health System) in 2008, and the loss of an investigator at the Mercy site due to the acquisition which resulted in no patient accruals for six months. Another major barrier to accrual was that the State Medicare HMO required patients to pay 20 percent of the cost of their care if they enrolled on a Medicare qualifying trial. If patients chose standard care, they were required to pay very little or nothing. Another limiting factor in accrual was the shortage of available trials that matched their patients' characteristics.

However, once policies and procedures for clinical trials at UPMC McKeesport were finalized, private physicians were given institutional access to put patients on clinical trials. And patient accrual resumed at

[45] The five participating hospitals include UPMC McKeesport Hospital, Jameson Memorial Hospital, UPMC Lee Hospital, Mercy Hospital, and Somerset Hospital/West Penn Allegheny Cancer Center.

Mercy once a radiation oncologist was hired, but radiation oncology at this site was shut down in January 2009.

The site opened a total of 114 clinical trials; most frequently, these were other (i.e.,non-RTOG) cooperative group trials (46%) with radiation therapy and combination trials with radiation components. Other frequently opened trials were pharmaceutical and RTOG trials (25% and 19%, respectively). The CTOC grant received in September 2006[46] provided funding to expand clinical trials to medical and surgical oncology trials at the UPMC McKeesport Hospital only (no medical and/or surgical oncology trials were opened at this hospital prior to CTOC). During CTOC funding, approximately 48 medical/surgical oncology trials were opened. CTOC funding allowed the site to hire a clinical research coordinator to help with clinical trial accrual efforts at the UPMC McKeesport Hospital.

Table 35 provides a breakdown of the number of accruals by fiscal year and type of clinical trial. UPMC McKeesport steadily increased its accrual numbers over the years, with a total of 112 patients enrolled in clinical trials throughout the ROCOG program.[47] More than three-quarters of clinical trial accruals occurred over the last 3 years. Most patients (61%) were accrued to other cooperative group trials with combination radiation and/or medical/surgical oncology components, followed by RTOG trials (29%). Site staff attributed the yearly increase in patient accruals, beginning in FY06, to the CTOC supplement and hiring of a clinical research coordinator. Available data from UPMC McKeesport indicate that approximately 27 patients were accrued to medical/surgical oncology trials during CTOC funding (i.e., September 2006-October 2008).

TABLE 35 – UPMC MCKEESPORT: NUMBER OF PATIENT ACCRUALS, BY FISCAL YEAR AND TYPE OF CLINICAL TRIAL (AS OF SEPTEMBER 30, 2009)

Type of Clinical Trial	FY04	FY05	FY06	FY07	FY08	FY09	Total N	Total (%)
PI-Initiated	0	0	0	0	6[a]	4[a]	10	(9)
RTOG	0	2	11	9	3	7	32	(29)
Other Cooperative Groups	3	1	9	12	14	19	58	(52)
Radiation Only	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*(0)*
Radiation/Combined Treatment	*3*	*1*	*7*	*6*	*6*	*3*	*26*	*(45)*
Surgical/Medical	*0*	*0*	*2*	*6*	*8*	*16*	*32*	*(55)*
Cancer Control/Prevention	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*(0)*
Pharmaceutical/Industry	0	0	0	5	4	3	12	(11)
Total	3	3	20	26	27	33	112[b]	(100[c])

a Patients were enrolled on UPMC PI-initiated trials via the UPCI; there were no CDRP PI-initiated trials implemented at this site.

b Two of the 112 patients were on two different types of trials.

c Column percents do not total 100% due to rounding.

3.7.5.2 Reaching the Target Population

ROCOG targeted three populations—the isolated, rural poor and inner-city, poor African-American communities, as well as elderly. Three of its partnering hospitals, UPMC Lee Hospital, Somerset Hospital, and Jameson Hospital, have service areas that are populated by excesses of poor (often elderly) rural residents. UPMC McKeesport and Mercy Hospitals are in areas with large African-American populations.

[46] The site received two years of CTOC funding.

[47] Note that many opened trials did not enroll any patients for a variety of reasons (most often due to patient ineligibility).

Although it was not initially a target population, the ROCOG program was able to reach the Amish community through community outreach efforts at the Somerset and Jameson sites.

Table 36 shows the numbers of patients who were enrolled on cancer clinical trials, participated in social science studies, and were navigated at UPMC McKeesport. The site accrued 110 patients onto clinical trials; 99 percent of patients accrued were non-Hispanic whites and 9 percent were African Americans. ROCOG staff estimated that of the 99 non-Hispanic white patients accrued to clinical trials, at least half (52%) were either elderly (i.e., 65 or older) or underserved (i.e., having Medicare or Medicaid, having no health insurance, being self-pay, or being disabled). Other clinical research activity at UPMC McKeesport included one social science study that examined methods that radiation oncologists can employ to improve patient satisfaction. Total accrual to this social science study was 135 patients, 96% of whom were non-Hispanic whites and 4 percent were non-Hispanic blacks/African Americans. Most of the 846 patients who were navigated were non-Hispanic whites (79%) and, to a lesser extent, African Americans (19%). At least half of navigated white patients were elderly and one out of four were underserved.

CTOC data on the 27 patients accrued to medical/ surgical oncology trials showed that most were also non-Hispanic white (22) and 5 were black/African American. Forty-five percent of the non-Hispanic whites were elderly and 19 percent were considered medically underserved.

TABLE 36 – UPMC MCKEESPORT (5 HOSPITALS): CLINICAL TRIALS, SOCIAL SCIENCE STUDIES, AND PATIENT NAVIGATION PARTICIPATION, BY RACE/ETHNICITY (AS OF SEPTEMBER 30, 2009)

Race/Ethnicity	Clinical Trials		Social Science Studies		Patient Navigation	
	N	(%)	N	(%)	N	(%)
Non-Hispanic White	99	(90)	130	(96)	669	(79)
Number of Non-Hispanic Whites Considered Elderly[a]	44 (44% of Whites)		DNC		393 (59% of Whites)	
Number of Non-Hispanic Whites Considered Underserved[b]	8 (1% of Whites)		DNC		167 (25% of Whites)	
Non-Hispanic Black or African American	10	(9)	5	(4)	164	(19)
Hispanic/Latino	0	(0)	0	(0)	5	(1)
American Indian/Alaska Native	0	(0)	0	(0)	1	(0)
Other	1	(1)	0	(0)	7	(1)
Total (%)	110	(100)	135	(100)	846[c]	(100)

[a] Elderly = age 65 or older.

[b] UPMC McKeesport defined underserved as patients having Medicare only, having Medicare with Medicaid supplement, having Medicare and being under age 65 with disability, having no insurance, and/or being self-pay. Note: Data were not available from UPMC McKeesport for most non-Hispanic whites due to incomplete patient insurance information.

[c] Navigation services were offered in four of five of McKeesport's community sites.

Data on patient screening and eligibility were only collected at the UPMC McKeesport Hospital (not the other collaborating sites). From FY2007, Quarter 4, through FY2009,[48] 13 percent of the patients seen at this site were eligible for cancer clinical trials. The most common reasons why patients at UPMC McKeesport Hospital were ineligible for clinical trials was that no studies were available to address the patients' tumor types/sites and available trials criteria were too restrictive (e.g., patients' age). More than

[48] Data on patient eligibility and estimates on eligibility and accrual rates only cover the time period when these data were collected regularly across all sites, beginning in FY2007, Quarter 4.

four out of five eligible patients (81%) were accrued onto clinical trials. Most commonly, those eligible patients who did not participate in a clinical trial simply refused to do so.

3.7.5.3 Working with Partner/Mentor

UPMC McKeesport established relationships with its primary and secondary partners, Washington University and Roswell Park Cancer Institute, and had additional local mentors—University of Pittsburgh Cancer Institute (UPCI) and Allegheny General Hospital Cancer Institute. Each of these mentors were NCI-designated cancer centers, RTOG participating institutions, or other NCI-sponsored cooperative group participating institutions. Collaboration with local and academic mentors was primarily in the form of research consultations and advisement and assistance in implementing clinical trials (e.g., advice on study designs and recruitment strategies).

3.7.5.4 TELESYNERGY®

Overall, this site had a total of 3 full systems, one mini system, and helped upgrade the Roswell's equipment. TELESYNERGY® was initially installed at McKeesport and their partner Washington University. Carryover funding enabled installation of a scaled back version of the equipment in Jameson. The Laredo system that became available when this site's grant was relinquished was then installed in Somerset. UPMC McKeesport was able to provide equipment (a Dome monitor) to its other partner Roswell to bring their existing system up to required standards for certification by NCI.

TELESYNERGY® at UPMC McKeesport supported program goals by facilitating communication among this CDRP program's three clinical sites and between sites and their two partner/mentor institutions. The use of TELESYNERGY® at UPMC McKeesport was primarily for cancer research and education, especially tumor boards. UPMC McKeesport designed and initiated a trailer-based system (i.e., mobile TELESYNERGY®) in Year 2, of the program which allowed the system to be moved for conferencing at its other regional facilities. After reorganization of tumor boards and installation of TELESYNERGY®, the site reported an increase in participation of physicians and hospital staff, number of presentations, and continuing education credits. The total number of sessions reported during the ROCOG program was 164.[49]

3.7.5.5 Patient Navigation

This site faced many challenges implementing the navigator program, from acceptance issues by physicians related to the navigator's role or involvement in patients' cancer care processes, and navigator turnover, to difficulty in reaching target minority populations. Despite these challenges, navigators were able to provide services to 846 patients; however, only 3 navigated patients were enrolled on a clinical trial.

Navigation services were offered in four of five of McKeesport's community sites; one site served as a control for navigation. Preliminary study findings on navigation effects indicated that navigation may have helped patients adhere to treatment schedules. Navigators also facilitated transportation services and helped uninsured patients to obtain insurance coverage (e.g., Medicaid), which in turn helped limit hospital losses from providing uncompensated care to cancer patients. By the end of FY2009, navigation programs were sustained at the Mercy and Jameson sites with full institutional support and UPMC McKeesport was in the process of working with the regional health systems to sustain navigation at the other collaborating sites after the CDRP Program.

[49] Data on TELESYNERGY® use were not consistently collected until FY2007, Quarter 4.

3.7.5.6 Community Outreach

Outreach was a critical component in reaching underserved communities and providing cancer education and screening opportunities. UPMC McKeesport conducted a wealth of community outreach work through dissemination of information at health fairs and meetings, and in newspaper articles. In the last four reporting quarters alone, UPMC McKeesport reported reaching over 40,000 community members in Western Pennsylvania, including hundreds of Amish men and women (e.g., breast and prostate screening events held in the Amish communities at the Jameson site).

Community partnerships and relationships with community members played a key role in the site's outreach efforts. For example, UPMC McKeesport ROCOG partnered with Centers for Healthy Hearts and Souls (CHHS), a well-known regional program that provides cardiovascular and diabetes care to poor African-American populations and developed a Cancer 101 program that was delivered to the inner-city African-American population. UPMC McKeesport was invited to lead the Pennsylvania State Health Improvement Plan (SHIP) Cancer Navigator Logic Model, which will help sustain cancer outreach in communities past CDRP. Other sustained outreach efforts included providing mobile education and cancer screening and providing cancer information through a community and physician resource Web site.

3.7.5.7 Project-Generated Resources

Research and program monitoring resources. The site developed several databases for administration and program data reporting purposes. In addition, four surveys were developed on navigation, cancer knowledge, physician satisfaction, and case studies.

Outreach/media resources. UPMC McKeesport developed several brochures for the general public on breast cancer screening and six brochures on cancer types and medical treatment for the Amish community. Information from the American Cancer Society and Cancer Information Service were not culturally sensitive for the Amish population. The new brochures were developed in collaboration with an Amish woman interested in reducing cancer burden in her community. The UPMC McKeesport Project Director reported that these brochures were well received by the Amish community. In addition, three Amish newspaper articles were written about cancer awareness and survivorship. Other project-generated resources included three educational presentations targeting homeless men in McKeesport, and four flyers on mammograms, breast cancer awareness, and navigation recruitment.

3.7.5.8 Conclusions

The UPMC McKeesport site was unique in having five collaborating hospitals comprising the ROCOG program. The complexity of implementing a research program among five locations with little research experience imposed unexpected challenges that were eventually surpassed by the ROCOG. Nonetheless, this site was able to establish the necessary clinical research infrastructure in each partnering hospital and opened radiation therapy and combination trials with radiation components.

The site was particularly successful in reaching non-Hispanic white populations of elderly and underserved and recruiting them into clinical research activities and providing them with navigation services. UPMC McKeesport was less successful in reaching targeted disparate populations of African Americans. However, one unexpected outcome and accomplishment was the site's ability to reach the "hard-to-reach" Amish population through community outreach efforts commonly involving cancer screening activities. Community outreach activities were numerous, diverse (e.g., health fairs, mobile education and screening, physician Web site) and intense in African-American and Amish communities. ROCOG's experience in cancer and clinical trials outreach and navigation resulted in this site being invited to lead the Pennsylvania State Health Improvement Plan Cancer Navigator Logic Model. The

Cancer Navigator Logic Model is the first disease-oriented logic model initiated by the SHIP and will help sustain cancer outreach in communities past CDRP.

Other noteworthy accomplishments by UPMC McKeesport ROCOG include the appointment of this site's PI to chair the RTOG Special Populations Subcommittee and the publication of 14 manuscripts in peer-reviewed journals.

3.7.6 Laredo Medical Center

3.7.6.1 Research Activities

Laredo was awarded the CDRP grant in 2002. During the first program years, Laredo hired its research staff, developed a Data Safety and Monitoring Plan, established an Institutional Biologic Committee to review clinical research protocols, as well as an IRB, and received approval for cooperative group affiliations (e.g., RTOG, CTSU, and SWOG). The site faced several challenges in establishing its infrastructure, including finding qualified research staff, its RTOG application taking 7 months to complete, and finding appropriate trials to open, as the hospital did not have IMRT capabilities. In 2003, the hospital was bought by a for-profit organization; the site had to focus on reorganizing structurally and resubmitting the necessary paperwork for the grant. Once the necessary infrastructure was established, the site opened five clinical trial protocols for accrual, including one PI-initiated trial, and navigation and outreach efforts were under way.

In spring of 2006, the site PI resigned. The hospital administrators worked closely with their partner—University of Texas Health Science Center at San Antonio—to recruit a board-certified radiation oncologist to assume the role of PI and provide radiation therapy. The hospital was unsuccessful in hiring a full-time board-certified radiation oncologist, despite interviews with several favorable candidates. After almost a year of no CDRP program activity, Laredo was unable to continue with the Program. Laredo relinquished its CDRP grant in April 2007.

As mentioned earlier, limited data are available on the site's program activities and these data were never confirmed by the site. Eight clinical trials were activated at this site; these trials tended to be other cooperative group and RTOG trials (3 and 2, respectively). **Table 37** provides the cumulative numbers of patient accruals onto clinical trials from FY2004 to FY2005 at this site. No patients were accrued in prior fiscal years or during FY2006. Patients were enrolled into RTOG, other cooperative groups, and pharmaceutical clinical trials. Although a PI-initiated trial was active, no patient accruals onto it were reported. The majority of patient accruals were to other cooperative group trials (97%); in particular, onto breast cancer prevention (STAR) and prostate risk assessment (SABOR) trials.

TABLE 37 – LAREDO MEDICAL CENTER: CUMULATIVE NUMBER OF PATIENT ACCRUALS, BY FISCAL YEAR AND TYPE OF CLINICAL TRIAL (AS OF JULY 2006)

Type of Clinical Trial	FY04	FY05	Total N	Total (%)
PI-Initiated	0	0	0	(0)
RTOG	6	0	6	(2)
Other Cooperative Groups	310	3	313[a]	(97)
Radiation Only	*0*	*0*	*0*	*(0)*
Radiation/Combined Treatment	*0*	*0*	*0*	*(0)*
Medical/Surgical	*0*	*0*	*0*	*(0)*
Cancer Control/Prevention	*310*	*3*	*313*	*(100)*
Pharmaceutical/Industry	0	3	3	(1)
Total	316	6	322	(100)

[a] Includes accruals on prevention trials, STAR (n=9) and SABOR (n=300) opened prior to CDRP.

3.7.6.2 Reaching the Target Population

Laredo Medical Center serves a community that is 95 percent Hispanic, with more than 35 percent of its residents living in poverty. The Center also serves 40 to 60 *colonias*—unincorporated areas with substantial substandard housing and conditions comparable many third world countries (e.g., no running water, electricity, or telephone service).

Laredo was able to accrue Hispanic/Latino patients into clinical research. **Table 38** shows the numbers of patients who enrolled on radiation oncology clinical trials, participated in social science studies, and were navigated at Laredo. The site accrued 322 patients onto clinical trials; 99 percent were Hispanic/Latino. Several social science studies (e.g., survey on cancer awareness, perception, and knowledge among Hispanics in *colonias*) conducted at the site included a total of 566 study participants; all were Hispanic/Latino. All patients navigated (347) were also Hispanic/Latino.

TABLE 38 – LAREDO MEDICAL CENTER: CLINICAL TRIALS, SOCIAL SCIENCE STUDIES, AND PATIENT NAVIGATION PARTICIPATION, BY RACE/ETHNICITY (AS OF JULY 2006)

Race/Ethnicity	Clinical Trials N	Clinical Trials (%)	Social Science Studies N	Social Science Studies (%)	Patient Navigation N	Patient Navigation (%)
Non-Hispanic White	3	(1)	0	(0)	0	(100)
Non-Hispanic Black or African American	0	(0)	0	(0)	0	(0)
Hispanic/Latino	319	(99)	566	(0)	347	(100)
American Indian/ Alaska Native	0	(0)	0	(0)	0	(0)
Other	0	(0)	0	(0)	0	(0)
Total (%)	322[a]	(100)	566	(100)	347	(100)

[a] Includes accruals on prevention trials, STAR (n=9) and SABOR (n=300) opened prior to CDRP.

3.7.6.3 Working with Partner/Mentor

Partnership activities with the University of Texas Health Science Center at San Antonio initially included grant management support and later focused on research collaborations (e.g., STAR and SABOR trials), educational meetings, and publication assistance (e.g., ASTRO submissions, etc.).

3.7.6.4 TELESYNERGY®

Laredo used TELESYNERGY® for staff training and education (e.g., radiation oncology lecture series), communicating with its partner for grand rounds (i.e., multidisciplinary teaching oriented reviews of patients and treatments) and clinical trial development, and tumor boards. In 2008 (after Laredo relinquished its CDRP grant), TELESYNERGY® equipment at Laredo was transferred to UPMC McKeesport. Data on the number and frequency of sessions held using TELESYNERGY® were not reported or available from the site.

3.7.6.5 Patient Navigation

All patients referred for radiation therapy were offered navigation services. Program staff reported that navigation was important as it provided the patient with an introduction to cancer care and clinical trials and it helped assess the patient for clinical trial eligibility as well as patient barriers. Common patient barriers to care identified by the site were financial and transportation issues.

3.7.6.6 Community Outreach

Outreach activities documented by the site included participation in health fairs, cancer screening activities, local workshops, and national awareness programs. Outreach activities commonly included administration of surveys to assess cancer awareness, knowledge, and screening among Hispanic/Latino populations. Laredo also provided community education through the use of *Promotoras* (i.e., residents of the *colonias* who were trained and served as a liaison between the community and health educators), which was significant in developing trust among Hispanic/Latino communities. Data on the number of outreach events and participants reached were not reported or available from the site.

3.7.6.7 Project-Generated Resources

Other than surveys to identify knowledge and awareness of cancer among Hispanic populations, no additional project-generated resources were reported by the site while it remained an active CDRP grantee.

3.7.6.8 Conclusions

As a result of the CDRP Program, clinical research infrastructure was initially established at Laredo. However, major setbacks prevented the site from ever becoming fully operational and ultimately lead to the grant being relinquished. Despite these circumstances, Laredo was able to reach its targeted population through navigation, cancer education, and outreach efforts, as well as enroll them onto clinical trials and social science studies. Additionally, a manuscript on factors influencing colorectal screening among Hispanics/Latinos living along the Texas-Mexico border was published.

3.8 PI Reflections on the U54 CDRP Continuation Process

As part of the evaluation, it was of interest to learn about the opinions of CDRP grantees regarding the U54 CDRP continuation process. U54 awards were made to CDRP grantees—New Hanover, Rapid City, Singing River, and UPMC McKeesport (phase-out funding)—in 2009. Centinela Freeman did not receive U54 funding but will continue to support program activities under carryover funds from the U56 program.

All CDRP grantees submitted applications for U54 funding. The following reflects all CDRP PI thoughts on the renewal process.

- For the most part, CDRP PIs thought the renewal application process was straightforward and the progress report format used for the application was easy to follow. The fact that unused funds from the U56 grant could not be transferred did not affect aims of the U54 Program for most sites.
- Based on PIs' experience with the U56 Program, most had planned changes for the U54 Program that commonly included earlier program involvement among referring physicians, concentration on opening and expanding trial selection (especially for common disease sites), and creation of new and improvement of existing partnerships. In addition, Singing River is currently in the process of developing an acuity tool to score each study based on time and effort required of research staff.
- As a result of budget cuts for the Program, the most commonly reported impact was the financial burden placed on the hospital to cover staffing and salaries and the challenge of getting the hospital administration involved in continuing to support the CDRP Program knowing funding will most likely end.
- Some PIs felt that the U54 Program goal of becoming a CCOP or Minority-Based Community Clinical Oncology Program (MB-CCOP) site was set too high given the various circumstances and/or challenges faced in the planning phase of the Program.

4. LIST OF APPENDICES

- Appendix A: CDRP Program Conceptual Framework
- Appendix B: Evaluation Matrix
- Appendix C: Performance and Management Review of NOVA Evaluation Activities
- Appendix D: Quarterly Data Report and Clinical Trial and Research Summary Spreadsheet
- Appendix E: Comparison Site Survey
- Appendix F: Reports from In-Depth Interviews with PIs and Partners
- Appendix G: Peer-Reviewed Publications Related to CDRP