

## Enhancing Cancer Research in the Community

### Introduction

The National Cancer Institute Community Cancer Centers Program (NCCCP) completed its fifth year in June 2012 with 30 community hospitals in the network. Working as a learning collaborative, the NCI and the network sites continued to focus on the program's efforts to enhance access, improve quality, and expand research in the community setting – the program's ultimate goal.

This report highlights the network level activities and research partnerships that helped to support the achievement of program goals. To illustrate the NCCCP's progress, we include several stories through the lens of the local community hospitals. Each story reveals how NCCCP research initiatives led to changes at the hospitals, demonstrating that the network sites are able to conduct a broad range of research projects.

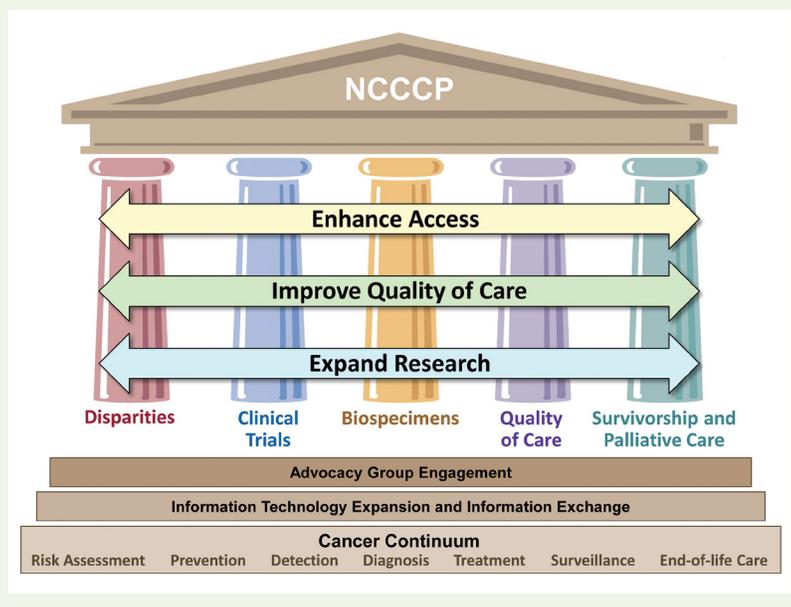
There are many areas of progress throughout the network. The results shared here are based on site self-reported data unless otherwise noted. The report provides several accomplishment overviews, a timeline with program milestones, site stories and quotes from various collaborators. Collectively, these show the contributions of the NCCCP network to the NCI's research mission.

### Enhancing Access

A cross-cutting theme of the program is to reduce healthcare disparities across the full cancer continuum. All NCCCP sites are focused on addressing disparities in each of the program components (i.e., clinical trials, quality of care, survivorship and palliative care, information technology, biospecimens, and communications). From increasing community outreach activities and screening events, to tracking race and ethnicity data, to promoting increased accrual of underserved populations to clinical trials, the network sites are working to enhance access to cancer care and cancer research for underserved populations. In the past year, a rural initiative was launched and three webinars

#### NCCCP Pilot Program Evaluation:

Research Triangle Institute (RTI) International recently completed an independent evaluation of the NCCCP pilot phase (2007-2010). The comprehensive review of the pilot program's 16 community hospitals and RTI's findings are included in a final evaluation report that will be posted to the NCCCP website (<http://ncccp.cancer.gov/about/reports-and-tools.htm>).



*"We have educated 239 Pacific Islander adults who showed significant increases in their knowledge and beliefs about colorectal cancer screening (with knowledge increases predicting intent to get screened). Perhaps most importantly, we learned so much from our NCCCP partner St. Joseph Hospital of Orange about how to create sustainable clinical systems for our medically underserved populations.*

Sora Park Tanjasiri, DrPH, MPH  
**WINCART** CNP Principal Investigator  
**California State University, Fullerton**

were developed by the sites to address challenges and successful strategies for the following areas: frontier and remote access, patient education, and transportation and lodging. Key areas of activity reported by the sites are:

- **Increasing Cancer Disparities Research:** Through formal partnerships with disparities research programs such as NCI Community Networks Program (CNP) grantees and expanded use of evidence-based approaches, the sites were able to conduct a variety of disparities research projects.
- **Engaging Underserved Populations through Community Partnerships:** Sites report that more than 2,400 community partnerships are in place, with many of them serving the following populations: African American (n=251), Hispanic (n=337), rural (n=216), uninsured (n=333), and the poor (n=384). Sites also formed many community advisory boards to help develop strategies to reach minority and underserved communities.
- **Conducting Screening Events:** Between April 2011 and March 2012, sites conducted more than 3,200 screening events (1,974 breast, 498 colon, 208 prostate, 581 other) and screened over 147,000 community residents, helping to bring more patients into the system of care earlier. For the breast cancer outreach events, sites reported 128,371 individuals were screened; 14,635 had abnormal findings and 1,453 were diagnosed with breast cancer.

### **Spartanburg Regional Hospital: Benefitting from Disparities Research Partnerships**

*"We have completely changed the way our hospital connects with underserved populations."*

—James Bearden, MD, FACP, NCCCP Principal Investigator, Spartanburg

With the site's 2010 award for an American Recovery and Reinvestment Act (ARRA) Disparities Project, Spartanburg Regional Hospital formed a formal research partnership with the Community Networks Program (CNP) Center at the University of South Carolina (USC), the South Carolina Cancer Disparities Community Network, to implement the Witness Project® - a culturally informed, community-based breast and cervical cancer education program for African American (AA) women. The initiative promoted the use of community-based participatory research principles and fostered new approaches, most significantly through connections with over 200 faith communities.

"The agendas for our meetings with underserved groups completely changed. We used to organize them like hospital meetings, but we began to structure them more like a church service – with greeters, an opening invocation, and a gospel song. We even began to serve the participants food, rather than have the refreshments available for self-service," explained Lucy Gansauer, NCCCP director at Spartanburg's Gibbs Cancer Center. "We are now modeling all of our community programs based on lessons learned from the CNP partnership," informed Dr. James Bearden, principal investigator (PI) for the NCCCP hospital.

Spartanburg's successful partnership with the CNP led to additional collaborations and funding sources for research studies. "The partnership between USC and Gibbs Cancer Center has emerged as a model in our state," said Dr. James Hébert, the CNP PI. "Our coming together around a shared vision has been pivotal in the planning and implementation of our multi-phased research study to understand the knowledge and attitudes of AA men and women about prostate cancer risk factors, screening, and participation in clinical trials and other research."

Dr. Daniela Friedman, co-investigator and pilot project leader for the CNP study, said that the Gibbs team "played a key role in recruiting 109 AA men and women for the pilot prostate education study and 31 AA men for a second study examining community perceptions about a prostate cancer survey. Without our partnership, it would have been exceedingly difficult to effectively meet project goals."

Noting that the hospital believed it was addressing disparities and conducting outreach efforts before NCCCP involvement, Dr. Bearden acknowledged the significant growth stemming from network participation and the program's requirement to expand partnerships. "It was in Year 3 that the light bulb really turned on and we realized we needed to change the way we were doing things." They are now reaching two-and-a-half times more people than before and are bringing more patients into the system of care earlier through screenings. He continued, "We are seeing the benefits of our engagement with the community and reaching more patients with cancer." As one example, since the expanded navigation and outreach efforts were launched, the mobile mammography program targeted to underserved populations in two counties has seen a 62% increase in the number of individuals (n=2,647) screened from FY11 to FY12. Dr. Mark Monson, Spartanburg's diagnostic radiologist, reports, "The mobile unit is detecting a higher number of patients diagnosed with breast cancer (7.6 per 1000) in this population compared to the hospital's fixed facility mammography locations (4.7 per 1000). We know we are reaching many women who have never been screened before, or were not getting routine screenings."

Using evidence-based approaches and following principles of community-based participatory research can be time-consuming, challenging, and not necessarily profitable, yet the organization is committed to maintaining the required resources after ARRA funding. Dr. Bearden explained, "We realize this is the most effective way to work with our community if we are going to make a change in cancer statistics for underserved populations. Not only are we bringing more underserved patients into the system of care earlier, we are increasing accrual to trials and expanding research opportunities for them."

To improve the quality of cancer care provided in the community setting, NCCCP sites are increasing the use of evidence-based guidelines, utilizing a multidisciplinary model of care, and participating in two national quality reporting initiatives: (1) the American College of Surgeons Commission on Cancer (CoC) Rapid Quality Reporting System (RQRS), and (2) the American Society of Clinical Oncology's (ASCO) Quality Oncology Practice Initiative (QOPI®). The pilot sites were members of the beta test phase for the CoC RQRS, a real-time cancer registry tool to prospectively monitor adherence to National Quality Forum-endorsed measures for breast and colorectal cancers. This effort also laid the foundation for network participation in research projects that are highlighted below. As of June 2012, 18 NCCCP sites are participating in the CoC's RQRS and the other network sites are working towards RQRS participation. For ASCO's QOPI® - an oncology practice-based quality improvement program - participation by the sites is supporting a network data sharing quality initiative. There were 25 sites with affiliated practices participating in QOPI® during the Spring 2012 round of data collection and 11 of those practices had achieved QOPI® certification.

Building network level partnerships and projects helped to advance the NCCCP's goal of improving the quality of cancer care. Significant activities and accomplishments include:

- **Genetics Performance Improvement Project:** Fourteen sites participated in a project aimed at increasing the number of cases referred for genetics counseling services for either breast or colorectal cancer. Collecting and reviewing data monthly, sites were able to identify areas for improvement in the referral process, share data with cancer center management, and chart plans for future enhancements to genetics programs. For example, universal screening for Lynch syndrome is now being implemented at many of the sites and several are focusing on patient education, particularly for colorectal cancer patients, to increase knowledge regarding genetic screening guidelines.
- **Multidisciplinary Care Study:** Sixteen sites are participating in an ARRA-funded quality research study to conduct a preliminary study of the relationship between specific multidisciplinary care (MDC) assessment areas and selected processes and outcomes of cancer care. The study is open for enrollment through September 2012 with data collection continuing through December 2012.
- **ACS RQRS Symptom Surveillance and Disparities Study:** Fourteen sites are participating in the American Cancer Society's Patient-Reported Outcomes study. Working with ACS and the CoC, this project is pilot testing a cost-effective method for collecting patient reported data on symptom experiences and investigating disparities in symptom burden and management.

### Northside Hospital's Quality of Care Research Collaboration

With a grant from the American Cancer Society, Northside is collaborating with Emory University's Winship Cancer Institute on a study aimed at improving the quality of care for breast cancer patients. The goal of the grant is to reduce disparities and eliminate barriers to effective breast cancer care through a multi-level intervention that combines patient navigation and utilization of the CoC RQRS patient management database. RQRS provides Northside's navigators with alerts to trigger patient navigation intervention so staff can more effectively assist patients who are experiencing barriers to care or delays to treatment. Northside has been involved with implementing the research protocol and is providing Winship with access to patients.

*"The NCCCP sites have shared their invaluable experience, insight into best practices, and recommended enhancements, allowing the CoC to develop and improve the Rapid Quality Reporting System for the benefit of the entire community of CoC-accredited cancer programs. The CoC looks forward to continuing its collaboration with the NCCCP sites, sharing the common goal of improving the quality of care provided to cancer patients close to home."*

Erica J. McNamara, MPH, Quality Improvement Information Analyst  
Andrew Stewart, MA, Senior Manager NCDB  
**Commission on Cancer**

The study's goal is to recruit 1,500 breast and colon cancer patients; over 900 patients have completed surveys for this project to date.

- **Completion of the PRO-CTCAE Study:** Five NCCCP sites, along with four NCI-designated Cancer Centers, participated with Memorial Sloan-Kettering in a validation study to test the NCI Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). Dr. Ethan Basch at Memorial Sloan-Kettering Cancer Center was the project PI. The NCCCP sites accrued 536 patients to the study, 25% of them minorities, and all sites met their accrual goals.

*"The side effects of cancer treatment can be as difficult to endure as the disease itself. Many symptoms go under-reported or undertreated, leading to unnecessary suffering, impaired quality of life and functioning, and loss of treatment adherence.*

*The NCCCP is providing a real-world platform for a study of patient-reported symptom experiences. The NCCCP's focus on disparities and the sites' diverse patient populations enhance the ability to accrue samples containing medically underserved groups. The NCCCP's commitment to supporting research in the community setting improves the external validity of research and shortens the distance from research to application. The NCCCP provides a mechanism for conducting research that is fundamental to translating research findings into improved care for cancer patients."*

Tenbroeck Smith, MA, Sr. Behavioral Scientist  
Kevin Stein, PhD, Intramural Research  
Elizabeth Ward, PhD, Intramural Research  
**American Cancer Society**

## Survivorship & Palliative Care

The sites continue to expand survivorship and palliative care services through increased use of patient treatment summaries, implementation of survivorship care plans, integration of palliative care resources in the cancer programs, and incorporation of processes to deliver psychosocial screening, care and referrals. Key activities reported by the sites include:

- **Implementing CoC 2015 Program Standards:** All sites are striving to be early adopters of the 2015 CoC requirements specific to survivorship and palliative care program standards. The new CoC standards are reflective of NCCCP pilot program initiatives.
- **Collaborating with Research Studies:** NCCCP sites have been able to provide extramural research partners with access to community-based clinicians and survivors treated in the community setting.
- **Improving Capacity to Deliver Psychosocial Care:** Sites used an NCCCP-developed tool to assess components of their psychosocial care programs and are using the information to develop processes to address gap areas and implement services, such as distress screening with a standardized tool.

*"As a health services researcher at Memorial Sloan-Kettering Cancer Center, I have excellent opportunities to study how survivorship care is delivered at a large urban comprehensive cancer center. However, it is hard from my vantage point to study how the vast majority of cancer survivors receive care — in the community.*

*Fourteen of the NCCCP sites are participating in a survey of oncology providers to better understand attitudes toward providing survivorship care plans to cancer patients. The investigators at each site have facilitated the enrollment of over 200 oncology providers who have completed the survey — an impressive response rate of over 70%.*

*This will contribute to a high-quality research study from a large, geographically diverse sample. Ultimately, this study will provide critical data elucidating the challenges and benefits of providing survivorship care plans to cancer survivors."*

Talya Salz, PhD, Assistant Attending Outcomes Research Scientist  
Health Outcomes Research Group  
**Memorial Sloan-Kettering Cancer Center**

## Hartford Hospital's Tobacco Cessation Study

*"We learned from NCCCP that success and sustainability comes from embedding change into the care practices of our organization."  
—Andrew Salner, MD, NCCCP Principal Investigator, Hartford Hospital*

After receiving ARRA funds for a project on tobacco cessation, Hartford Hospital's Helen & Harry Gray Cancer Center turned the project into an IRB-approved research protocol. The hospital's evidence-based model for cessation treatment\*, previously developed for cardiac patients and pregnant smokers, was adapted for use with cancer patients and broadened across the organization, to its satellite sites and into physician offices and the community. The hospital's goal was to recruit patients and family members into the study, use the findings to improve the intervention, and ultimately weave the approach into their system of patient care.

With the tobacco cessation study, project leaders recognized that multiple caregivers and non-clinicians would need to make program referral part of their practice to achieve success. "An amazing part of the NCCCP journey," noted Dr. Andrew Salner, "has been that we have learned to think about initiatives such as survivorship care in so many different ways in order to learn how to implement them and help them become part of our routine practices."

A key part of the program success has been the addition of a behavioral psychologist with research experience and the availability of a full-time dedicated smoking cessation interventionist who is able to respond to staff as well as patients. "Physicians are so busy that we wanted to make it easy for them to refer patients," said Dr. Salner. Systematic processes were developed to offer multiple paths for referral and clinical and non-clinical staff were educated about the program. Based on the success to date, hospital management has committed to sustaining the program and the intervention, making it part of their care processes.

*\*Original model selected as one of NCI's Research Tested Intervention Programs: <http://rtips.cancer.gov/rtips/programDetails.do?programId=312134>.*

### Research Project Overview

Use tablet-based intake and a distress thermometer; conduct 90-minute "motivational" and planning interview; encourage use of nicotine replacement therapy and cessation medicines as aids to behavior modification when appropriate.

Perform bi-monthly follow-up calls for telephone support; monitor carbon monoxide levels at 2 and 6 months post-interview.

To date: 100 patients served, 46 enrolled in study (includes 7 family members), 24 completed study, 4 stopped smoking, 7 reduced smoking rates.

## Penrose Cancer Center – Colorado Cancer Coalition Cancer Survivorship Research Study

*"We are responding to the needs of rural and elderly cancer patients with an exportable survivorship program."  
—Judy De Groot, RN, MSN, AOCN, Oncology Nurse Navigator, Penrose Cancer Center*

Recognizing that survivorship programs are often difficult to attend, particularly for patients living in rural communities, Penrose Cancer Center has used its ARRA funds for a state cancer plan collaboration with the University of Colorado Comprehensive Cancer Center (UCCC) in a research study that includes two other community-based cancer centers in Colorado.

The study, called C-STEPS (Cancer Survivorship Telephone Education and Personal Support Program), is a pilot project that aims to provide both psychosocial and health promotion services to cancer survivors without requiring them to return to the treatment institution. According to Kathleen Garrett, program manager at UCCC Cancer Prevention and Control, "A fundamental premise of the C-STEPS project is that it is plausible to develop and deliver a convenient and exportable intervention that does not require return visits, where such visits can pose access barriers."

The C-STEPS research study involves telephone education and support services, based on evidence indicating that the telephone is an effective medium for delivering support interventions to cancer survivors. Judy De Groot, oncology nurse navigator at Penrose, explained that patients, especially those who live in distant rural communities, are "excited about the additional opportunity for post-treatment support."

The study design will allow UCCC to evaluate C-STEPS uniformly across urban and rural geographic areas of Colorado. Kathleen Garrett credits the NCCCP site with advancing the project. She notes, "Fundamental to our success so far in implementing C-STEPS has been our relationship with Penrose. Through our collaboration, we are not only given access to a demographically diverse cancer survivorship population but we are also able to implement this pilot program in a very 'real world' and patient-centered care setting." Additionally, Ms. Garrett attributes the study's successful accrual to the UCCC/Penrose partnership.

Introduction to the C-STEPS program has become a standard part of the survivorship discussion at the NCCCP site and Penrose will continue to offer the program to cancer survivors as part of its care model, even though the project's ARRA funding has ended.

### Research Project Overview

Eligible patients are educated about/offered the C-STEPS program.

C-STEPS psychosocial oncology counselors call consented patients, discuss stress management, provide emotional support, offer suggestions to improve diets and lifestyle choices, and help plan appropriate medical follow up.

Patients complete a questionnaire about their experience with the post treatment support.

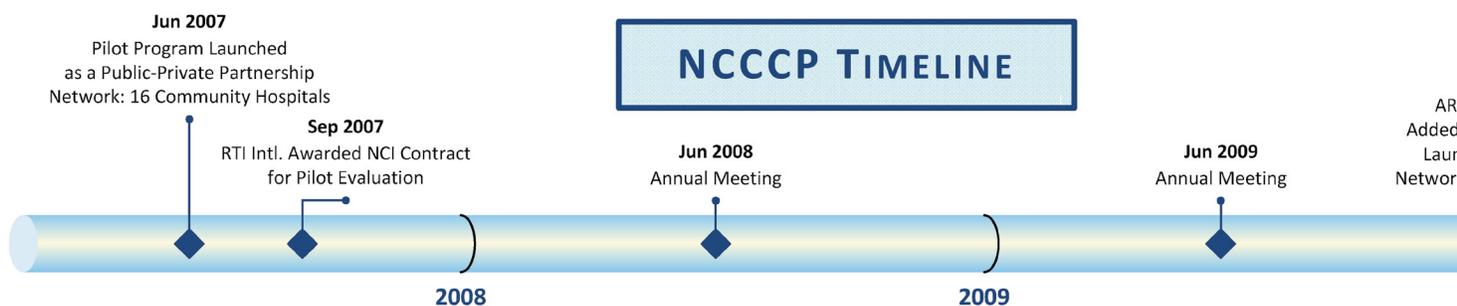
## Expanding Research

With the accelerated speed of scientific discoveries and rapidly changing advances in technology, the NCCCP sites are continuing efforts to become research-ready organizations. The NCCCP has helped participating community hospitals enhance research capacity within their cancer centers. Several external organizations and investigators have reached out to NCCCP sites, developing partnerships for study recruitment and/or research contributions. Additionally, many sites have formed relationships with NCI Community Networks Program (CNP) Centers and are participating in research studies with the goal of reducing cancer health disparities through community-based participatory education, training, and research among racial/ethnic minorities and underserved populations.

### Biospecimens

Advancement towards complete implementation of *NCI Best Practices for Biospecimen Resources* improved capabilities and contributed to recognition of NCCCP sites as valuable research partners in accruing high-quality specimens. The community hospitals are able to participate in biospecimen initiatives that will advance the NCI research agenda. For example, six sites are participating in biospecimen collection trials for Moffitt Total Cancer Care™ and nine sites have agreements to serve as biospecimen source sites for The Cancer Genome Atlas (TCGA). Other key research capability expansion efforts include:

- CAP Collaboration to Identify the Pre- and Post-analytic Variables Needed for the Creation of High-quality Biospecimens for Patient Care and Cancer Research:** The NCCCP Biospecimens and IT Subcommittees are working with the College of American Pathologists (CAP) to identify all the necessary pre-analytic and post-analytic variables that need to be



#### YEAR ONE: Building Capacity

- Organized network infrastructure and program management/governance
- Launched subcommittee structure
- Worked to establish institutional, management, and medical staff commitment to program goals
- Expanded infrastructure at the site-level
- Developed site-specific work plans for each program component
- Increased site-level relationships with major research institutions
- Formed network collaboration with Commission on Cancer (CoC) to improve quality of care
- Launched NCCCP-ASCO Quality Oncology Practice Initiative (QOPI)
- Developed MDC assessment tool
- Developed model physicians' conditions of participation
- Assessed 'NCI Best Practices for Biospecimen Resources' at site level

#### YEAR TWO: Launching Network-wide Projects

- Adopted uniform definition of healthcare disparities
- Developed and implemented disparities vision work plan
- Increased outreach staff/added patient navigators
- Launched clinical trials screening & accrual log
- Implemented MDC assessment tool
- Expanded number of sites participating in QOPI
- Approved model physicians' conditions of participation for implementation
- Expanded survivorship and palliative care services
- Developed palliative care assessment tool
- Signed network-level MOU with ASCO and NCI to develop requirements for oncology-specific EHR
- Collected biospecimens for The Cancer Genome Atlas (TCGA) [3 sites]

#### YEAR THREE: Expanding Reach

- Launched initiative to expand reach across all systems
- Increased cultural awareness education
- Launched work-group to address disparities
- Promoted evidence-based and community-based care continuum
- Beta tested CoC Rapid Quality Review
- Developed psychosocial care materials
- Developed NCCCP breast cancer survivorship care plan
- Expanded IT capabilities – complete integration connecting with caBIG®
- Completed white paper on oncology-specific EHR
- Complied with ASCO/CAP HER2-ErbB2 fixation breast tissue
- Participated in Moffitt Total Cancer Care

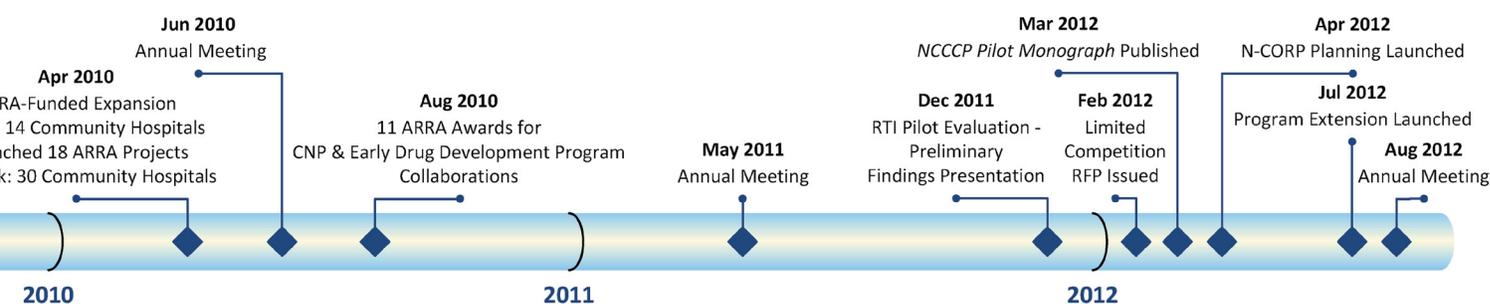
documented in the patient's record in order to create high-quality biospecimens for both patient care and cancer research. This initiative will include working with the major laboratory information system (LIS) vendors to automate the collection of these necessary pre- and post-analytic variable data fields as well as coordination with CAP's electronic Cancer Checklists.

- Enhancing Tissue Management Infrastructures:**  
 Sites are improving local standard operating procedures and enhancing infrastructures to extend capabilities, improve quality, and expand participation in national biospecimen initiatives and research efforts, including participation in the national case report form harmonization effort being led by NCI.

*"Our cancer center's participation in NCCCP has significantly enhanced our organization's research commitment to supporting translational science. Our ability to contribute specimens to TCGA and partner with the Wistar Institute, the University of Delaware and the Kimmel Cancer Center at Thomas Jefferson University are directly related to NCCCP network participation.*

*We have collected over 3,000 high-quality biospecimens for more than 15 different cancer types, showing that community hospitals can be a valuable research partner for the NCI and other academic research programs."*

Nicholas Petrelli, MD  
 Bank of America Endowed Medical Director  
**Helen F. Graham Cancer Center at Christiana Care**



**ing Network Projects**  
 e and ethnicity data collection  
 ication and developed webinars  
 underserved accrual  
 ordinated care across cancer  
 porting System (RQRS)  
 rix  
 treatment summary and  
 eted deployment plans for  
 ogy-specific EHR  
 R-PgR guidelines for formalin-  
 er Care™ [5 sites]

**YEAR FOUR: Driving Progress Through Partnerships**

- Increased community outreach activities, screening events, and patient navigation services
- Formed relationships with Community Networks Program (CNP) institutions
- Partnered with NCI-designated Cancer Centers to offer Phase I/II trials [12 sites]
- Continued expansion of CT infrastructure, increased Cooperative Group membership
- Doubled participation in QOPI
- Continued beta testing RQRS [16 sites]
- Implemented cancer genetic counseling assessment tool, promoted evidence-based approaches for genetic testing and counseling
- Added 27 new disease-specific MDCs since pilot launch
- Increased use of patient treatment summaries
- Increased participation in biospecimen research programs; 8 sites implemented NCI Best Practices

**YEAR FIVE: Enhancing Cancer Research in the Community**

- Partnered with CNPs (9 sites) and launched several disparities research projects
- Expanded network initiatives to increase underserved accrual
- Increased collaborations for early phase trials
- Expanded site participation in QOPI and RQRS
- Completed Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) national validation study
- Launched ACS RQRS Patient-Reported Outcomes study (14 sites)
- Continued MDC research study (16 sites)
- Participated in Memorial Sloan-Kettering study about survivorship care plans (14 sites)
- Continued oncology-specific EHR expansion efforts
- Participated in Moffitt Total Cancer Care™ (6 sites)
- Served as biospecimen source sites for TCGA (9 sites)

## Clinical Trials

Newly identified cancer molecular subtypes and new knowledge about cancer genetics are driving changes in the infrastructure required to conduct early-phase clinical trials. One of the NCCCP goals has been to increase capacity for the community hospitals to participate in early phase trials, thereby offering more treatment options to patients closer to their homes. Collaborations with NCI-designated Cancer Centers, Cooperative Groups, industry partners and access to more Phase II trials on the Cancer Trials Support Unit have helped sites participate in more Phase II trials. Combined with the program's disparities focus, NCCCP sites are also working on approaches to increase patient participation in clinical trials – particularly for patients from underserved populations – to provide a broader base for cancer research. Over the past year, the sites broadened their clinical trials portfolios and opened more early phase trials. Also of note, the network sites:

- **Focused Efforts of the Clinical Trials Underserved Accrual Working Group:** Emerging from a special session on underserved accruals at the 2011 NCCCP Annual Meeting, this group established metrics and began to collect data in three specific areas: (1) physician and community outreach related to clinical trials, (2) navigator/clinical trials research team coordination, and (3) strategies to translate informed consent documents to other languages. Emphasis on these metrics is improving awareness and focusing efforts to promote underserved accruals at the site level; for example, navigators are attending MDCs. The metrics will continue to be refined and monitored over the coming year.
- **Increased Racial Minority Accruals to Clinical Trials:** Along with an increased number of overall accruals to clinical trials, sites have increased racial minority accruals to NCI-sponsored Division of Cancer Prevention (DCP) and Cancer Therapy Evaluation Program (CTEP) treatment, prevention, and supportive care/quality of life trials. The NCCCP-developed Minority/Rural Matrix has guided sites in the identification of their minority/underserved populations and helped to assess their strengths and weaknesses related to reaching and accruing these patients.
- **Developed a Clinical Trials Best Practice Matrix:** This tool contains nine elements for sites to assess their clinical trials infrastructure. The sites completed the matrix in spring 2011 to establish a baseline assessment and then again in June 2012. An analysis of results using site self-reported data has shown that sites increased their mean score on the tool from 19 to 21 (possible score range: 9 – 27) and early findings suggest that sites with a mean score of 21 or above have twice the average number of accruals compared to sites with lower mean scores. Additionally, over the past year, the number of sites with a Level I rating (the lowest of three level ratings) for their underserved accrual and outreach decreased by 50%. The matrix is being evaluated for possible tool validation and broader dissemination for community cancer centers to use as a roadmap for program improvement.

*"Discovery and development of newer therapies for patients with cancer is the main goal of the University of Wisconsin Carbone Cancer Center Phase I Research Program. Our partnership with NCCCP site Sanford Medical Center has allowed us to provide early phase clinical trial options to Sanford Medical Center and the under-represented population that they serve. The future of cancer therapy involves genotyping tumors and personalizing therapy, thus including under-represented populations will allow us to better understand and tailor treatments for individual patients."*

George Wilding, MD

Director, **University of Wisconsin Carbone Cancer Center**

## St. Joseph's/Candler: A Multi-faceted Approach to Promoting Underserved Accrual to Clinical Trials

*"To get the patients who are most difficult to reach on clinical trials, we needed a cross-cutting tactical plan that was monitored weekly."  
—H.A. Zaren, MD, FACS, NCCCP Principal Investigator, St. Joseph's/Candler*

"It all begins with knowing who you serve," said Dr. Zaren, NCCCP principal investigator for the Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph's/Candler. Spanning a 28 county service area, with 21 of those classified as largely rural, the population of the hospital's primary service area of Chatham County is 40% African American. The hospital sponsors two clinics that provide access to the underserved and conducts many outreach activities, yet new strategies were needed to increase accrual of underserved patients to trials.

"We began," explained Dr. Zaren, "by identifying the barriers and then used a cross-cutting approach to develop a tactic for each barrier." Adding patient navigators, supporting culturally appropriate education on clinical trials, and building partnerships with community based volunteer lay navigators has helped to improve the patient knowledge base which, in turn, has increased the number of patients screened for trials. Partnerships with community organizations and many African American churches are strategic methods for reaching patients and increasing African American accruals.

The cancer center launched systematic efforts to link patients to 'medical homes' and to convince physicians that patients seen in outpatient settings need access to cancer screenings. The hospital committed to minimizing physician risk by taking responsibility for follow up required for patients with a positive screening test. The Cancer Center Medical Staff Conditions of Participation, instituted as part of the NCCCP program, also required physicians to give a percentage of their time to treatment of the uninsured. An American Cancer Society patient resource navigator, whose salary is split between the ACS and the cancer center, assists the private practice offices within the cancer center to help underserved patients link with resources.

To address barriers created by limited transportation resources, particularly for patients in rural areas, the hospital responded by providing two vans and has plans to buy a third – offering free rides to patients as far away as 120 miles for appointments and treatments. Improving access to care is essential, but getting underserved patients on clinical trials required more engagement with primary care physicians, specialists, and community groups through an ongoing campaign.

Dr. Zaren explained, "I regularly visit primary care physicians (PCPs) in their offices, even those in distant locations, to inform them about open trials and the eligibility criteria." By working closely with the Magnolia Coastal Area Health Education Council, Dr. Zaren launched CEU-based webinars on disparities and clinical trials to educate and engage PCPs.

St. Joseph's/Candler promotes underserved accrual by employing cross-cutting measures to reinforce the topic at every opportunity. Eileen Dimond, NCI Clinical Trials lead for the NCCCP, attributes the site's progress with this difficult area to the hospital's "multi-faceted approach to create a culture for addressing the underserved." Noting that underserved accrual is a standing agenda item at all program, clinical, and staff meetings, Dr. Zaren explained that metrics are continually reviewed to monitor progress. In 2011, 46% (19 of 41) of patients accrued to Cooperative Group trials at St. Joseph's/Candler were from rural locations, compared to 28% (13 of 45) in 2010. "We are very proud of our success," he added, "but we continue to strive for more. To advance cancer treatments for all patients and ensure that the results can be generalized to broader populations, we must all work to ensure that we increase accruals of underserved patients to clinical trials."

Barriers to Underserved Accruals
Patient knowledge base
Lack of regular source of medical care/no medical home
Medical staff reluctance to assume liability for patients screened without access to treatment
Fear of job/payment loss – if being on a clinical trial requires time away from work
Transportation, especially for rural patients
Results
The percentage of rural patients accrued to Cooperative Group trials went from 28% to 46% in one year

## Information Technology

Information technology (IT) initiatives are addressing program goals by integrating IT activities across program components to speed the incorporation of NCCCP data collection needs within technology expansion plans at the sites. During the past year, the IT Subcommittee gave special attention to the technical work required to support the disparities and biospecimen activities, and also focused resources on technology expansion to meet the U.S. Department of Health & Human Services “meaningful use” timelines. Key projects to support research expansion include:

- **Enabling Race and Ethnicity Data Capture:** All sites successfully implemented mandatory system configurations that required the collection of race and ethnicity data according to the Office of Management and Budget (OMB) guidelines.
- **Enhancing Local Data Warehousing:** Sites worked collaboratively to define an initial list of community-based oncology outcomes data elements mapped to common systems, locally addressing common data integration issues. Four sites created or expanded local data warehouses that reflected considerations from this work.
- **Improving and Sharing System Documentation:** IT representatives worked to improve and share system documentation and code, collaborating to share experiences and resources in expansion activities, testing and improving local installations of NCI open source solutions to enhance the deployment experience nationally.

### Norton Healthcare: Building Information Technology Platforms to Support Research Relationships

*“If we want to make research an integral part of the care we offer, we have to be connected to leading research organizations with a vision to think outside of our organization.”*

—Stephen A. Williams, Norton CEO

The Norton Cancer Institute had already started to invest in cancer research and build connections with the University of Kentucky (UK) when it decided to respond to an RFP for NCCCP selection in 2010. Once it joined the NCCCP network, those relationships were able to expand more rapidly and a combined collaboration with Norton, UK, and Moffitt Cancer Center was formed to enhance biospecimen research opportunities.

“We knew that if we wanted to offer research to our patients we needed to broaden our research infrastructure and connect with regional and national partners. It was important that our IT systems could interface with theirs to facilitate interactions. NCI made the opportunity for technology expansion possible,” said Robert Shaw, president of the Norton Cancer Institute.

“As soon as we joined the NCCCP network,” said Dr. Sandra Brooks, principal investigator and physician director for the NCCCP site, “we became very engaged with the program’s IT pillar. We hired IT expertise to support our cancer center and the needed technology expansion, and we immediately began to explore adoption of the NCI caTissue Suite to support our biospecimen initiatives.”

At the same time, the NCI was implementing a new Clinical Data Management System (CDMS) software package - Medidata Rave® - to facilitate the conduct of clinical research throughout the NCI-supported clinical research enterprise. There were spots for 10 organizations to pilot the CDMS project. Pat Jerus, director of IT at Norton Cancer Institute, explained, “Strategically, we appreciated the importance of aligning NCI standards including harmonization efforts in data with discovery partners.” Norton is the only community hospital in the NCI pilot adoption group.

Standardization across organizations is very challenging, yet the realization of improved technology capabilities and the interchange of research data is essential for the NCI. Norton has contributed by providing improved installation documentation for mutual caTissue Suite deployments, making it available to any site planning similar installations. They also developed new code after working with several other NCCCP sites to validate the work, and provided the code to the NCI Tissue Knowledge Center. The NCCCP IT pillar lead, Brenda Duggan, acknowledged that “Norton’s contributions and leadership provided value to the NCI technology community at large and improved the return on investment for NCI.”

Norton continues to explore ways to reduce barriers to cancer research. A current project is underway to work with NCCCP sites to validate documentation that directs the enabling of barcoding technology integration with caTissue Suite for use by the larger NCI academic research community.

“To work interactively with our research partners,” explained Pat Jerus, “we needed the impetus to be agile. That required getting clinical staff, management, and our legal team on board to strengthen and standardize technology capabilities so that our patients and the research community would all benefit.”

The NCCCP has become a community-based research platform to support a variety of research projects that address NCI priorities and support research across the cancer continuum. The sites are partnering with CNPs to study ways to reduce cancer healthcare disparities, participating in quality of care and survivorship care studies, partnering with organizations for molecular research studies, and collaborating with investigators from NCI’s Early Drug Development Program to conduct early phase clinical trials. The network is a resource for other NCI programs and external organizations, with many sites serving as collaborators on investigator-initiated research studies. To view a snapshot of several network level research partnerships, see Table 1.

**Table 1: Network Level Research Partnerships**

Partner	Overview	Topic
NCI Community Networks Program (CNP)	Partnering with CNPs (9 sites), several for research studies	Reduce cancer health disparities
American Cancer Society	Patient symptom experience and disparities study (14 sites)	Quality of care
Memorial Sloan-Kettering Cancer Center	Validation study of Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (5 sites)	Quality of life management
University of Maryland, Baltimore	ARRA-funded study on the impact of multidisciplinary care on processes and outcomes of cancer care (16 sites)	Quality of care
Memorial Sloan-Kettering Cancer Center	Study of oncology providers’ attitudes towards providing care plans (14 sites)	Survivorship care
The Cancer Genome Atlas	Formal agreements to serve as biospecimen source sites (9 sites)	Cancer genome characterization
Moffitt Total Cancer Care™	Longitudinal observational study (6 sites)	Biospecimen collection for molecular research

## Building on Progress

In July 2012, NCI extended program participation for two more years for 21 of the community hospitals. Located in 16 states across the U.S., the sites will continue to support program initiatives. Building on the success achieved by the network to date, these organizations will further strengthen their capacity to conduct cancer research in the community setting.

### NCI Community Cancer Centers Program 2012 NCCCP Hospitals



## **A Look Ahead: NCI Community Programs**

In April 2012, NCI launched a formal planning and external consultation process to solicit input on its recommendation to combine the institute's three community-based research networks to create a single network that builds on their strengths. The Community Clinical Oncology Program Network, including Community Clinical Oncology Programs (CCOPs), Minority-based Community Clinical Oncology Programs (MB-CCOPs) and Research Bases, and the NCI Community Cancer Centers Program (NCCCP) will be united to create the NCI Community Oncology Research Program (NCORP). The new program will serve as a community platform with a broad research agenda. Types of research could include: clinical trials, health services research, disparities research, outcomes research, biospecimen collection, cost-effectiveness research, comparative-effectiveness research, diffusion and dissemination research, and behavioral research. NCORP will maintain a focus on cancer healthcare disparities across the cancer continuum. NCI is collecting input from internal and external stakeholders and expects to present the finalized concept to the NCI Board of Scientific Advisors next year, with the intent to make awards in mid-2014. The funding mechanism will be Cooperative Agreements awarded by the NCI.

