

NCI Community Cancer Centers Program (NCCCP) Pilot Program Summary

January 2007

Cancer Care in the United States:

- The pace of research in understanding cancer has accelerated in recent years, raising the need for more effective and immediate ways of translating this new knowledge into patient care.
- There is a need for an accessible, national cohort of oncology patients available for clinical trials and follow-up study. This will accelerate the development, testing, and delivery of new treatments.
- National studies have shown that cancer healthcare delivery is inadequate or lacking for large numbers of patients. These include underrepresented and disadvantaged groups, elderly patients, and rural residents.
- There may come a time in the near future when the greatest risk for cancer patients will be their limited access to optimal care.

NCI's Mission:

- NCI's mission is to reduce the burden of cancer by leading an integrated effort to advance fundamental knowledge about cancer across a dynamic continuum of discovery, development and delivery.
- To that end, NCI sponsors many programs, such as the NCI Cancer Centers Program that supports 61 major academic and research institutions throughout the United States. These institutions sustain broad-based, coordinated, interdisciplinary programs in cancer research across the continuum.
- While the NCI Cancer Centers Program makes significant contributions to advances in cancer research, only 16 percent of cancer patients in the United States have access to these centers. The remaining 84 percent are cared for in community hospitals and physician offices.
- For most Americans, especially senior citizens and minorities, who bear a heavy burden of cancer, an NCI-designated cancer center may be too far away, too removed from family and other support systems, or simply out of reach for economic, personal, or other reasons.

The NCI Community Cancer Centers Program (NCCCP):

The NCI is launching the NCI Community Cancer Centers Program (NCCCP) as a pilot program to bring the latest scientific advances and the highest level of innovative and integrated, multi-specialty care to a much larger population of cancer patients.

The program is intended to complement other NCI initiatives in seeking to:

<u>Draw more patients into clinical trials in community-based settings.</u> Clinical trials provide access to cutting-edge advances and state-of-the-art care. They help develop new preventatives, diagnostics, and treatments. Yet only 3 percent of adults with cancer participate in clinical trials. In underserved urban and rural communities, the adult accrual rate is even lower. These groups include populations with disproportionately high cancer rates, so their absence from clinical trials is a significant factor in ongoing healthcare disparities.



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Reduce healthcare disparities. The disparity problem is complex. The NCI is working through this pilot program and a range of other programs to better understand the problem and address the causes. Research confirms that equal treatment at the same stage of disease yields equal outcomes across all populations. Equal access to optimal care could dramatically reduce cancer mortality in the United States.

Prepare sites for standardizing the collection and storage of biological specimens for cancer research. Biospecimens play an important role in translating basic science into cancer treatments because they allow researchers to study cancer cells at the molecular level. But there is no national standard for how these samples are collected and stored. Standardization and making biospecimens more widely accessible would accelerate the translation of research into more effective treatments for patients, including treatments that are personalized for greater efficacy and fewer side effects.

<u>Link sites to national databases supporting basic, clinical, and population-based cancer research.</u>

<u>Explore implementation of electronic medical records.</u> The use of electronic medical records opens broad new avenues for data-intensive research in understanding cancer. Assessing the ability of sites to create and utilize IT infrastructures that are compatible with NCI's cancer Bioinformatics Grid (caBIGTM) could lead to a nationwide repository of data on screened patients, high-risk patients on prevention trials, cancer patients actively being treated, and cancer survivors.

Main Objective:

The overarching goal is to bring science, early-phase clinical research, and optimal evidence-based therapies to patients in their home communities. The pilot will seek to achieve this goal on a limited scale. Pilot sites will also share best practices and refine the overall concept as a prelude to launching a new national network of research-driven cancer care at the community level.

Specific Goals of the NCCCP Pilot:

The focus of the pilot will be to research how best to accomplish the following:

- a) increase accruals to NCI-sponsored clinical trials, especially for underrepresented and disadvantaged populations;
- b) develop new or expanded programs to increase outreach to the uninsured, underrepresented, and disadvantaged populations for prevention, screening, treatment, follow-up care, palliative care, survivorship plans, and end-of-life care;
- c) increase knowledge of infrastructure requirements, necessary interfaces, and applicability of specific components of caBIGTM for community hospital settings, and increase implementation of electronic medical records and exploration of the application of electronic medical records in the provision of cancer care:
- d) increase knowledge of infrastructure requirements, policies and procedures, costs, and other issues (e.g. collaborations or contracts necessary for biospecimen collection, annotation and storage) required for implementation of the *NCI's Best Practices for Biospecimen Resources*, thus enabling community hospitals to participate in biospecimen initiatives that will advance the NCI's research mission.



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Pilot Overview:

Pilot sites will be community hospital-based cancer centers offering multi-specialty cancer care (medical, surgical, and radiation oncology) under one administrative, medical structure and with a qualified physician director with cancer expertise. Pilot sites will see at least 1,000 new cancer cases each year. Sites will have experience conducting clinical trials and will have a track record of providing leadership within their communities in providing healthcare outreach programs to serve the needs of underrepresented and disadvantaged populations. Additional baseline criteria are outlined in the RFP.

Pilot Deliverables:

By the end of the pilot, the NCCCP sites will offer more comprehensive and integrated services such as:

- Expansion of integrated multi-specialty cancer care (medical, surgical, radiation oncology) through new or expanded approaches introduced to improve coordination (e.g., patient navigators, information technology, multi-disciplinary disease-specific planning committees).
- A physician director with cancer expertise devoting most of his or her time to the program
 to provide leadership to coordinate the many components of an NCCCP program, oversee
 quality of care, and expand accruals to clinical trials.
- Medical staff credentialing specifically for the cancer program to improve care by including only physicians with appropriate expertise and active cancer practices in the cancer center.
- Increased use of evidence-based guidelines for cancer care leading to improvements in care because NCCCP sites will be following guidelines for cancer care that have been developed by nationally recognized cancer organizations or groups (e.g., NCCN, ASCO, American College of Surgeons Commission on Cancer).
- Enhanced linkages with NCI-designated Cancer Centers for referrals and research support.
- Expanded programs and new approaches to build a community infrastructure to address the unmet health needs of the community and to reduce cancer healthcare disparities.
- Addition or expansion of genetics and molecular testing on site or through a formal specimen referral to approved labs to offer the most comprehensive approach to risk assessment, treatment and follow-up care.
- Expansion of clinical research through new or improved approaches to increase accrual of patients to clinical trials, especially phase II trials.
- Addition or expansion of palliative care by incorporating national best practices including programs for pain and symptom management into the care model.
- Introduction of survivorship plans into the initial care plan for patients for ongoing support through treatment, for follow-up care, with symptom management, and, if needed, for hospice or end-of-life care. An individual is considered a cancer survivor from the time of diagnosis, through the balance of his or her life. Survivors also include affected family members, friends and care givers.



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- Completion of a detailed assessment with recommendations on IT infrastructure requirements, necessary interfaces, and applicability of specific components of caBIGTM for community hospital settings to support NCI research goals. Implementation of electronic medical records and tumor registry.
- Completion of a detailed assessment with recommendations on the necessary infrastructure requirements, policies and procedures, cost and other implementation issues necessary for the establishment of a biospecimen resource that is compliant with NCI's Best Practices for Biospecimen Resources enabling community hospitals to participate in biospecimen-dependent scientific initiatives that will advance the research mission of NCI.

Results from the pilot program will help provide recommendations to develop a community-based platform and information network for expanded cancer research with access to a greater number and cross section of patients. This will lead to the rapid translation of newly discovered biomarkers (diagnostics) and the sophisticated, molecularly targeted therapies of the future and will speed the development of new cancer drugs, reduce the cost of drug approvals, and provide the best possible care for the greatest number of patients.

Additional Areas of Exploration for the NCCCP Pilot:

The 3-year pilot will also examine other issues that could improve the effectiveness of an NCCCP program or enhance other cancer prevention, screening and treatment initiatives. For example:

- How innovative integrated models for multi-specialty care may improve care to cancer patients.
- How different models for effective linkages between NCCCP sites and NCI-designated cancer centers may enhance the care and clinical trials provided in community-based cancer centers and enable appropriate referrals for more complex care.
- How an NCCCP program may benefit from program linkages or cooperative efforts with state or other publicly-sponsored cancer programs.

Pilot Evaluation:

• The success of the pilot will be determined through an independent evaluation by outside experts who will conduct quantitative and qualitative data analyses. The NCI will negotiate a separate evaluation contract for this purpose. An evaluation oversight committee comprised of external experts with experience in cancer program evaluation will serve for the three years of the pilot. Results of the evaluation will be used to refine the program concept and identify critical factors to include in launching a nationwide program intended for 2010.



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Pilot Program Management:

- SAIC-Frederick, Inc., under contract with NCI, will competitively solicit with the intent to subcontract with approximately six institutions for the 3-year pilot to test and refine the concept of community cancer centers.
- NCI-Frederick is a Federally Funded Research and Development Center (FFRDC) that can provide quick response and flexible capability in meeting the federal government's research and development goals. SAIC-Frederick, Inc. is the operations and technical support prime contractor for this FFRDC.
- The anticipated funding level totals \$9 million over three years. During the past two years, NCI leadership has reduced or phased out programs to allow the redeployment of resources, to initiate new programs, or to increase support to existing programs, in order to continue to make strategic investments such as this.

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