NCI Community Cancer Centers Program
Pilot Work Plan and Deliverables Summary

Clinical Trials

INTRODUCTION: The NCI Community Cancer Centers Program (NCCCP) pilot research initiative will explore the development of a national network of community-based cancer centers. The focus of the pilot will be to research how best to accomplish the following:

- increase accruals to NCI-sponsored clinical trials, especially for underrepresented and disadvantaged populations;

- 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;

- increase knowledge of infrastructure requirements, necessary interfaces, and applicability of specific components of caBIG™ 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;

- 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 NCI Best Practices for Biospecimen Resources, thus enabling community hospitals to participate in biospecimen initiatives that will advance the NCI's research agenda.

The NCCCP pilot will incorporate key NCI initiatives into the examination of a model for hospital-based community cancer care to include the four focus areas listed above. In addition, there is interest in exploring the following special areas of interest that could serve to enhance the model:

- Models for effective linkages with NCI-designated cancer centers or academic medical research institutions that would support the program goals;
- Effective linkages with state-sponsored cancer initiatives;
- The potential benefit of participation in healthcare information technology initiatives such as a RHIO (Regional Health Information Organization) or similar initiative;
- Working with providers to examine the potential for the development of new reimbursement models for cancer prevention, screening and treatment;
- Models for survivorship plans that would support the overall goals of the program;
- Exploration of the benefit of linkages with the NCI-sponsored Cancer Expert Corps, a program under development, to bring cancer expertise to locations where there is a gap in a needed service;
- The value of a knowledge exchange network for community hospital-based cancer providers;
- Models for co-investment with the NCI to broaden the effective reach of the NCI research programs;
- Models of multidisciplinary cancer care that incorporate the continuum of services including early detection, prevention, therapy, survivorship follow-up and end-of-life support programs;
- Working with providers that have developed successful approaches for accrual of patients into NCI-sponsored clinical trials. NCCCP pilot sites are not expected to encompass all areas of special interest;
- Programs in locations where the population has significant hardships affecting access to healthcare; and
- Whether selecting a site that is part of a national health system might speed the replication of a successful model.

WORKSCOPE: The organization will participate in routine conference calls with the NCI and SAIC-Frederick staff, to include representatives from the entire pilot group. During the pilot, all trials will be tracked to determine whether there has been an increase in the number of patients accrued to clinical trials, including those who are underrepresented or disadvantaged, with emphasis on minority accrual. It is anticipated that during the pilot, there will be an increase in accrual to all clinical trials including treatment, cancer control and symptom reduction, prevention and behavioral trials, with specific interest to increase accrual to multi-modality trials and NCI-sponsored trials (i.e., CCOP/MB-CCOP, cooperative groups). NCCCP pilot sites will be expected to increase their capability to offer phase II trials and develop protocols for referral of patients for phase I trials to NCI-designated cancer centers or academic medical research institutes. Sites will also be expected to enhance their participation in complex clinical trials including multimodality (i.e., RT plus surgery), and the ability to perform translational research type trials.

There is also interest in exploring successful initiatives with documented results for increasing accrual of patients to clinical trials, with a particular interest in NCI-sponsored clinical trials and recruitment of underrepresented and disadvantaged populations.

During the pilot period, specific research questions will include the following:

- Why are patients deemed ineligible for participation? Information will be tracked by disease, and trial type in order to determine cross-trial factors, including gender, etc.
- What are the minority accrual issues… barriers, new research issues from the community?
- Why are physicians not participating… not randomizing, won't refer?
- What is the level of CIRB utilization… is it working or not and why?
- What problems/solutions have been encountered with respect to phase II study participation?

DELIVERABLES: The organization will provide quarterly reports and a final report to include methods and strategies employed (and resources required) to achieve the required target rate, and those to increase accrual of underrepresented and disadvantaged patients. It is intended that the methods will be replicable for other community cancer programs and be able to be documented and developed into recommendations at the end of the pilot. The pilot sites will also develop a joint report on methods to increase accruals to clinical trials in community cancer centers, including the recruitment of underrepresented and disadvantaged patients. This joint report will be a deliverable from the group, and will be developed through a facilitated group work effort during the pilot. Performance will be measured by assessing how many activities are achieved per year and in what timeframe. Quarterly reports should monitor progress towards achieving year 1-3 activities and should discuss plans for improving performance when achievement of activities is delayed – problems and potential solutions should be highlighted.

TIMELINE – MAJOR ACTIVITIES AND SAMPLE METRICS:

YEAR 1
Obtain baseline metrics – complete a baseline assessment survey
Develop the more detailed clinical trials work plan, in conjunction with the NCI Advisory Committee's Clinical Trials subcommittee
Increase in number of trials open in 2 of the 3 types of protocols – treatment, prevention, cancer control
Implement patient/physician log for all screened cancer pts and high risk individuals – collect reasons why patients don't participate in trials (reasonable to do identical survey across all pilot sites)
Increase in number of physicians participating in trials at each site

Investigate to develop new trial partnerships (e.g., CCOPs, Groups, Phase 2)
Assess new IRB processes (regional IRB and NCI CIRB)
Implement or improve programs to increase minority accrual
Assess navigator's outreach needs and their ability to accommodate expansion of program's types of clinical trials
Develop timelines for protocol receipt to activation and from IRB receipt to approval
Develop or improve communications in-house regarding clinical trials
Develop/enhance process for eliciting ongoing feedback related to clinical trials to include community oncologic and general practitioners, lay community minority representation, related health practitioners (e.g., nursing/CRAs, radiology, pathology and surgery), advocates
Perform baseline self-assessment survey on clinical trials (once again this would best be done uniformly across the pilot sites to permit cross-site comparisons) – Examples • Is there adequate financial support? • Is there adequate dedicated staff (physician, nursing, CRA)? • Does the organization culture/infrastructure support clinical trials?
Participate in the formal program evaluation
YEAR 2
Open at least one phase 2, specimen acquisition-rich trial
Demonstrate capacity to do multi-modality trials
Design, analyze, and implement plan to increase percentage of patients going on trial – based upon patient/physician log-survey
Increase minority accrual by >5%
Demonstrate improvement in protocol/IRB timelines (receipt to approval)
Increase number of collaborations (e.g., CCOPs, Cooperative Groups, phase 2, Industry) by showing an increase in number of trials open of all 3 types (treatment, prevention, cancer control)
Demonstrate active participation in a collaborating organization (e.g., Cooperative Groups, NCI-designated Cancer Centers, CCOPs) by starting or increasing activity in management activities (e.g., member disease-oriented, underserved population or cancer control committees, audits, DMC)
Participate in the formal program evaluation
YEAR 3
Increase overall annual accrual
Increase minority accrual by >15%
Increase number of open trials – in all three domains

Improve protocol/IRB approval timelines
Demonstrate quality data via an audit (by an external agency)
Increase number of staff dedicated to clinical trials (e.g., physician, nursing/CRA, pharmacy)
Re-do self-assessment survey regarding clinical trials and compare to baseline – sorted by new staff and pre-existing staff
Prepare report on effective methods that led to success
Participate in the formal program evaluation

Sample Metrics (*Final metrics for each pilot organization will depend on the capabilities of each site and will be formalized in Year 1, as the work plan is developed in conjunction with the NCI Program Advisory Committee's Clinical Trials subcommittee.*)

AREA	YEAR 1	YEAR 2	YEAR 3
Community Input	Establish process for obtaining input/support for trials including minority and community input.	Utilize input from this process for CT expansion	Initiatives launched based on feedback and tracked for increase in trials – progress measured
Trial Types	Conduct baseline CT assessment (i.e. types, #s, accruals to each type)	Expand to include another trial type	Repeat baseline CT assessment and show increased activities and accruals
Trial Complexity	Investigate expansion in CT complexity	Open phase 2 trial or multimodal trial	Demonstrate success in conducting more and complex trials via audit by external reviewers
CT Infrastructure	Assess infrastructure and staff dedicated to working on clinical trials, education for new staff	Increase MD participation and RN/CRA staff to support expansion	Demonstrate increased staffing committed and infrastructure support to CTs
Protocol Activation Timeliness	Collect protocol timeline data to analyze to improve timeliness of system	Implement methods to streamline protocol activation process	Demonstrate improvement in protocol timelines
Infra-structure	Increased MD participation and RN/CRA staff to support expansion	More MDs are registered NCI investigators and offering trials	Demonstrate increased staffing commitment and infrastructure support to CTs
Accrual Tracking	Implement data collection to assess reasons pts not on trials	Analyze reasons and implement solutions for why pts aren't going on trials	Demonstrate increased accrual
Protocol Activation	Collect protocol/IRB timeline data to analyze system performance timeliness	Implement methods to streamline protocol activation process	Demonstrate improvement in protocol timelines
Communication	Assess methods to identify patients for offering trial participation	Implement systems to better identify eligible patients for trials	Demonstrate systems improvement in identifying patients for trials