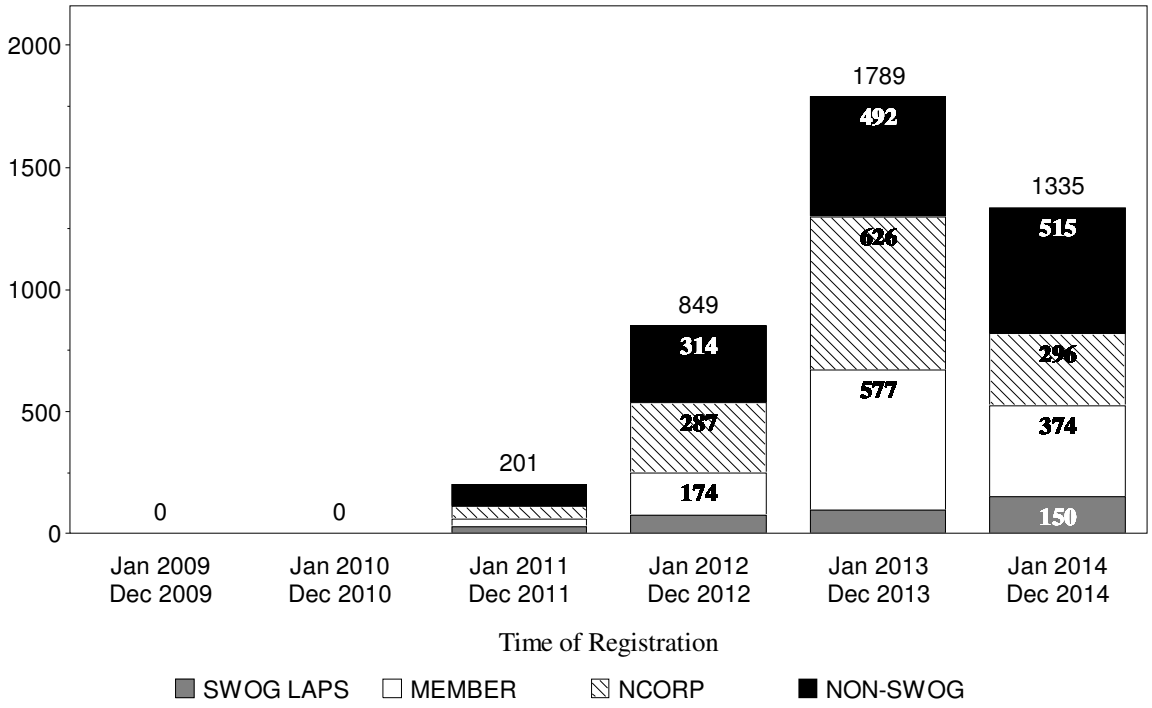
CANCER CARE DELIVERY COMMITTEE

CONTENTS

Patient Registrations to Studies

By 12 Month Intervals
CANCER CARE DELIVERY COMMITTEE



Screening registrations and registrations to Biologic only studies are excluded

Patient Registrations by Study and Arm

CANCER CARE DELIVERY COMMITTEE

	Jul 2014 Dec 2014	Jan 2014 Jun 2014	Jul 2013 Dec 2013	All Patients
S1007 Breast,Adj,N1,Endocrine+/-Chemo				
Randomization				
Chemo and Endocrine Therapy	245	291	291	1,570
Endocrine Therapy Alone	243	294	287	1,566
	488	585	578	3,136
S1105 Breast, Adj, AI Adher, Text-Msg				
Randomization				
Text messaging	0	0	94	360
No text messaging	0	0	97	364
	0	0	191	724
S1204 Prevalence HIV,HBV,HCV+Cost Eff				
Registration				
HIV, HBV, HCV Prevalence	2	258	52	312
A011104 Preoperative Breast MRI*				
Registration				
Total Registrations	1	1	0	2

* For non-SWOG coordinated studies only SWOG registrations are shown.

S1007 Phase III

Coordinating Group: SWOG

A Phase III Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer

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Participants:
SWOG, CTSU (supported by NRG, Alliance, ECOG-ACRIN, NCIC CTG, GEICAM, and UNICANCER)

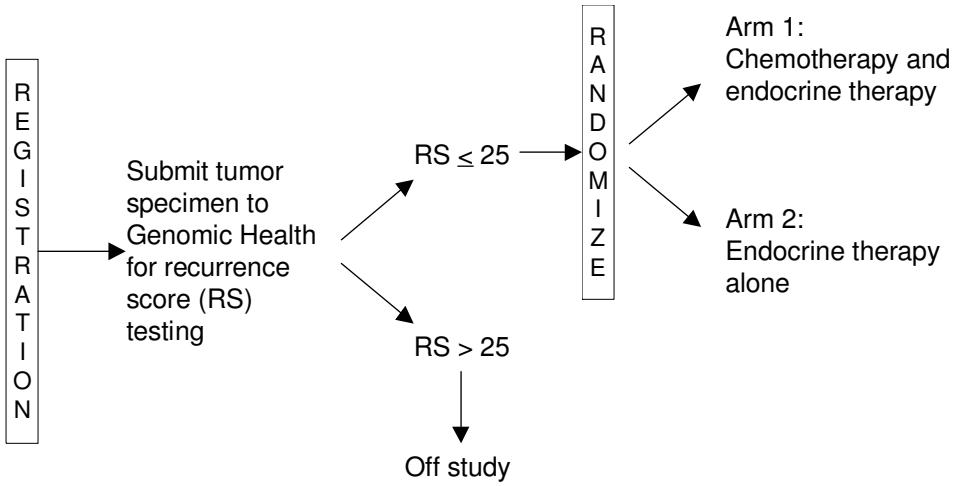
Date Activated:
01/15/2011

Study Chairs:
J Gralow, G Hortobagyi, K Albain

Statisticians:
W Barlow, D Lew

Data Coordinators:
J Barce, L Highleyman

SCHEMA



Objectives

To determine the effect of chemotherapy in patients with node-positive breast cancer who do not have high Recurrence Scores (RS) by Oncotype DX®. In patients with 1-3 positive nodes, and hormone receptor (HR)-positive, HER2-negative breast cancer

with RS ≤ 25 treated with endocrine therapy we will test whether the difference in disease-free survival for patients treated with chemotherapy compared to no chemotherapy depends directly on the magnitude of RS. If benefit depends on the RS score, the trial will determine the optimal cutpoint for recommending chemotherapy or not.

To compare overall survival (OS), distant disease-free survival (DDFS) and local disease-free interval (LDFI) by receipt of chemotherapy or not and its interaction with RS.

To compare the toxicity across the treatment arms.

To perform other assays or tests (in particular the PAM50 risk of relapse score), as they are developed and validated, that measure potential benefit of chemotherapy and compare them to Oncotype DX®.

To determine the impact of management with Oncotype DX® on patient-reported anxiety (co-primary Health-Related Quality of Life [HRQL] outcome) prior to screening, after disclosure of test results, and during the randomized trial.

To determine the impact of Oncotype DX® on the initial management cost of node-positive, HR-positive, HER2-negative breast cancer.

To compare patient-reported utilities (e.g. QOL) for those randomized to chemotherapy versus no chemotherapy.

Using modeling and DFS information from the trial, to estimate the cost-effectiveness of management with Oncotype DX® versus usual care.

To determine the role of other assays (e.g. PAM50) as predictors of DFS, DDFS and LDFI for patients randomized to chemotherapy versus no chemotherapy.

To determine the impact of treatment with chemotherapy versus no chemotherapy on patient-reported fatigue and cognitive concerns (secondary HRQL outcomes).

To determine the impact of management with Oncotype DX® on patient-reported decision conflict, perceptions regarding Oncotype DX® testing, and survivor concerns prior to screening, after disclosure of test results, and during the randomized trial (secondary HRQL outcomes).

Patient Population

Patients must be women with a histologically confirmed diagnosis of node-positive (1-3 nodes) invasive breast carcinoma with positive estrogen and/or progesterone receptor status, and negative HER-2 status. HER-2 test result negativity must be assessed as per ASCO/CAP 2013 guidelines using IHC, ISH or both. If HER-2 IHC is 2+, evaluation for gene amplification (ISH) must be performed and the ISH must be negative; ISH is not required if IHC is 0 or 1+. Patients with equivocal HER-2 are not eligible. Patients with multifocal, multicentric, and synchronous bilateral breast cancers are allowed. Patients must not have inflammatory breast cancer and must not have metastatic disease. Patients with a prior diagnosis of DCIS are eligible if they received mastectomy alone (i.e., no therapeutic radiation or endocrine therapy).

Patients must have had either breast-conserving surgery with planned radiation therapy or total mastectomy (with or without planned postmastectomy radiation), with clear margins. Patients must have undergone axillary staging by sentinel node biopsy or axillary lymph node dissection. Patients with positive sentinel node are not required to undergo full axillary lymph node dissection. This is at the discretion of the treating physician. Patients with micrometastases as the only nodal involvement (pN1mi) are not eligible. Patients must not have begun chemotherapy or endocrine therapy for their breast cancer prior to registration. Patients must be able to receive taxane and/or anthracycline based chemotherapy. Patients must not have received an aromatase inhibitor (AI) or a selective estrogen receptor modulator (SERM) such as tamoxifen or raloxifene within five years prior to registration. Partial breast irradiation (including brachytherapy) is not allowed. Radiation in the opposite breast is acceptable.

Registration of patients who have not yet undergone Oncotype DX® screening must occur no later than 56 days after definitive surgery. For all patients, randomization (Step 2 Registration) must occur within 84 days after definitive surgery. If the Oncotype DX® Breast Cancer Assay has not been performed, patients must be willing to submit tissue samples directly to Genomic Health for testing to determine Recurrence Score value. If the Oncotype DX® Recurrence Score is already known and is 25 or less, the patient must be randomized (registered to Step 2) immediately following initial registration. If the Oncotype DX® Recurrence Score is already known and is greater than 25, the patient is ineligible.

Patients must have a Zubrod performance status of 0-2 and must not require chronic treatment with systemic steroids (inhaled steroids are allowed) or other immunosuppressive agents.

Stratification/Descriptive Factors

Patient randomization will be stratified by the following factors: (1) Recurrence Score: 0-13 vs 14-25; (2) menopausal status: pre vs post; and (3) type of nodal dissection: axillary lymph node dissection (with or without sentinel node mapping) vs sentinel node biopsy without axillary lymph node dissection.

Cancer Control Credits

No cancer control credits are awarded for this study.

Accrual Goals

The accrual goal for the randomized trial is 4,000 eligible patients, which will require approximately 9,400 women to be screened for inclusion. An additional 1,000 eligible patients will be randomized by UNICANCER (France).

Summary Statement

For the current status of this study, please refer to the Breast chapter.

S1204 Surveillance

A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients

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Study Chairs:
S Ramsey, R Loomba, R Chugh, D Hershman, J Hwang

Statisticians:
J Unger, K Arnold

Data Coordinator:
M Yee

Date Activated:
08/29/2013

Date Closed*:
12/15/2014

*Temporary closure

Objectives

Among newly diagnosed cancer patients presenting to SWOG-affiliated community and academic oncology clinics, estimate the prevalence of human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) infection.

Evaluate known sociodemographic, clinical, and behavioral factors that are significantly associated with previously undiagnosed HIV, HBV, and/or HCV infection in a population of people with newly diagnosed cancer.

Among patients who are identified as having HIV, HBV, and/or HCV, evaluate the timing and type of treatments received, both for the viral infections and the cancers.

Evaluate type and rate of cancer treatment-related adverse events in patients with HIV, HBV, and/or HCV infection.

Determine the cost-effectiveness of (1) routine, universal screening and (2) risk factor-directed screening of newly diagnosed cancer patients for HIV, HBV and/or HCV versus current care.

Create a biorepository of stored serum for future translational medicine studies that may include identifying genomic and viral factors that increase the risk of serious adverse effects among participants infected with HIV, HBV, and/or HCV being treated for invasive cancers.

Patient Population

Patients must be presenting for evaluation or treatment for the first diagnosis of a new cancer malignancy (including hematologic). Confirmed pathologic diagnosis must be within 120 days of registration. Patients presenting for "second opinions" of confirmed malignancies are eligible, including those who have started cancer treatment at other facilities. Individuals are ineligible if they have been diagnosed with a malignancy other than the current malignancy within the past five years, with the exception of basal cell or squamous cell skin cancer, in situ cervical cancer, or in situ breast cancer. Individuals are eligible if they have had no evidence of disease for a prior malignancy, except as noted above, for at least five years prior to randomization.

Patients must be 18 years of age or older. Patients must have had their blood drawn for testing for HIV, HBV and HCV prior to registration. Patients who have had HIV, HBV and/or HCV testing within 60 days prior to registration and who do not wish to be retested are eligible, provided supporting documents can be obtained confirming viral test results for all three viruses. Patients who are viral positive for either HIV, HBV, and/or HCV and who do not wish to be retested are eligible, provided documentation of

viral load within 120 days prior to registration can be obtained. Note that these patients must be tested for or provide current viral load for all three viruses to be eligible. All documentation must be obtained prior to registration. Patients are allowed to participate in other clinical trials.

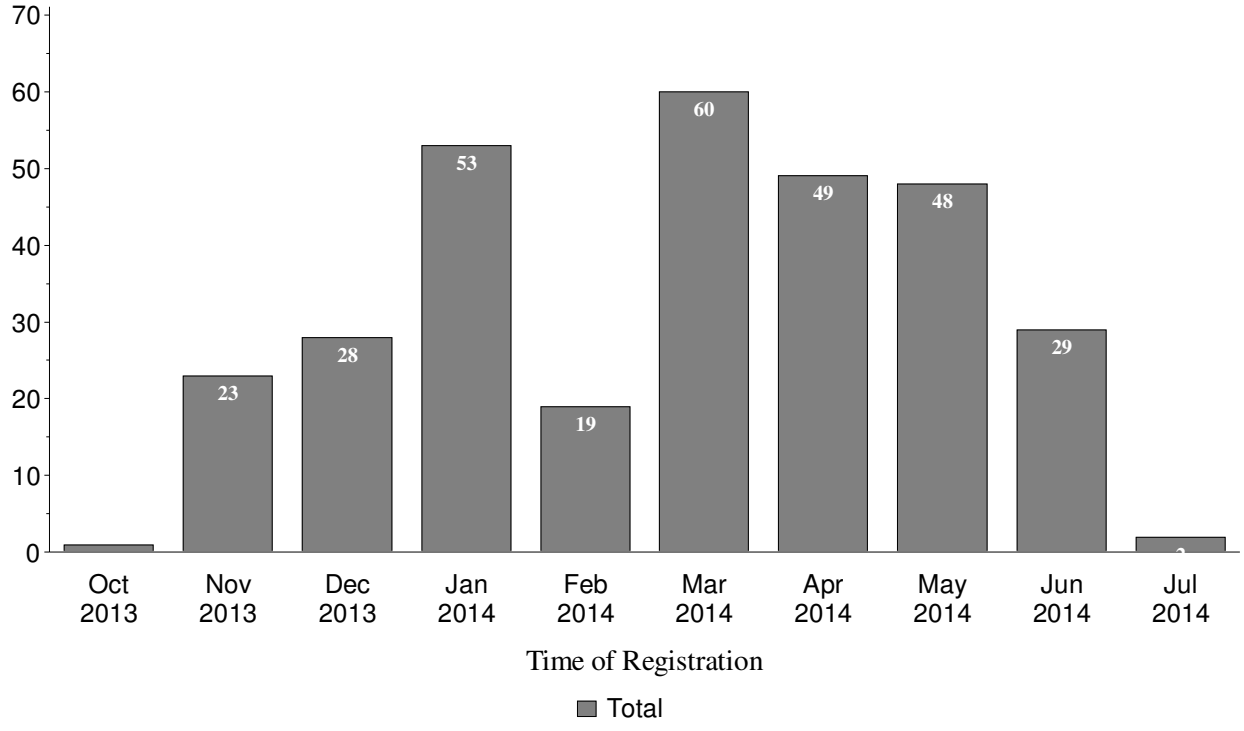
Cancer Control Credits
No cancer control credits are awarded for this study.

Accrual Goals
A total of 3,000 eligible patients will be accrued.

Summary Statement
This study opened to accrual to the run-in phase in limited institutions on August 29, 2013.

Accrual to the run-in phase ended July 25, 2014 with 312 patients accrued. The study is temporarily closed to accrual while data from the run-in phase are evaluated. A major protocol revision is in process in anticipation of study reactivation to complete enrollment.

Initial Registrations By 1 Month Intervals



Registration by Institution

Institutions	Total Reg
Greenville NCORP	108
MD Anderson	74
Bay Area NCORP	41
Columbia MU-NCORP	38
Boston MC MBCCOP	34
Hawaii MU-NCORP	11
St Luke's Mt State/PCRC NCORP	6
Total (7 Institutions)	**312**

Registration, Eligibility, and Evaluability

Data as of February 24, 2015

	Total
NUMBER REGISTERED	312
ELIGIBLE	312

Patient Characteristics

Data as of February 24, 2015

	Total (n=312)	
AGE		
Median	57.8	
Minimum	21.9	
Maximum	89.0	
SEX		
Males	103	33%
Females	209	67%
HISPANIC		
Yes	83	27%
No	229	73%
RACE		
White	227	73%
Black	52	17%
Asian	15	5%
Pacific Islander	3	1%
Native American	1	0%
Unknown	14	4%

S1207 Phase III

Coordinating Groups: SWOG and NRG

Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and Her2/neu Negative Breast Cancer.

e3 Breast Cancer Study - evaluating everolimus with endocrine therapy

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Participants:
SWOG, NRG, CTSU

Date Activated:
09/03/2013

Study Chairs:
M Chavez MacGregor, P Ganz (NRG), L Pusztai, P Rastogi (NRG)

Statisticians:
W Barlow, D Lew

Data Coordinators:
J Barrett, I Syquia

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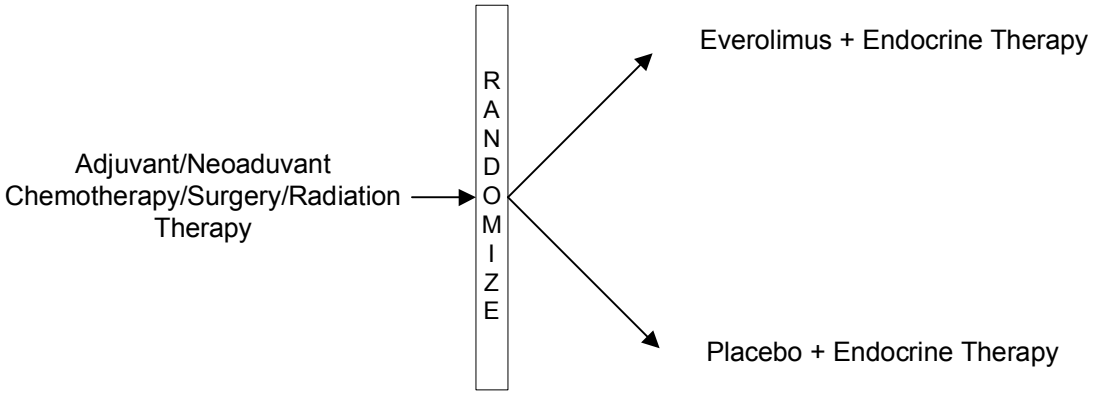

Objectives

To compare whether the addition of one year of everolimus (10 mg daily) to standard adjuvant endocrine therapy improves invasive disease-free survival (IDFS) in patients with high-risk, hormone-receptor (HR) positive and HER2-negative breast cancer.

To compare whether the addition of one year of everolimus to standard adjuvant endocrine therapy improves overall survival (OS) and distant recurrence-free survival (DRFS) in this patient population.

To evaluate the safety, toxicities, and tolerability of one year of everolimus in combination with standard adjuvant endocrine therapy and compare it with standard adjuvant endocrine therapy plus placebo in this patient population.

To determine whether the benefit of one year of everolimus use in addition to standard adjuvant endocrine therapy varies by recurrence score (RS), nodal status, or other commonly used prognostic factors.

To evaluate adherence to 1-year treatment of everolimus in comparison to placebo in addition to standard adjuvant endocrine therapy in this patient population.

To collect specimens in order to evaluate biomarkers of therapeutic efficacy.

Patient Population

Patients must have histologically confirmed invasive breast carcinoma with positive ER and/or PgR status and negative HER-2, for whom standard adjuvant endocrine therapy is planned. Patients must not have metastatic breast cancer. Patients with multifocal, multicentric, synchronous bilateral, and primary inflammatory breast cancers are allowed. Patients must be high risk as defined in the protocol, based on Recurrence Score and grade, number of positive nodes, and prior therapy. Patients with micrometastases as the only nodal involvement (pN1mi) are not eligible.

Patients must have completed either breast-conserving surgery or total mastectomy with negative margins and appropriate axillary staging. Patients must have completed appropriate radiation therapy as described in the protocol. Patients must have completed standard neoadjuvant or adjuvant taxane and/or anthracycline based chemotherapy prior to randomization. Patients may have started endocrine therapy at any time after the diagnosis of the current breast cancer. Patients must not be receiving or planning to receive trastuzumab. Concurrent bisphosphonate therapy is allowed. Patients must not have prior exposure to mTOR inhibitors.

Patients must have a Zubrod performance status of 0-2 and adequate hematologic, hepatic, renal, and cardiac function. Patients must not have received immunization with an attenuated live vaccine within seven days prior to registration. Patients must be able to take oral medications. Patients at NCORP institutions who have not already started endocrine therapy must be offered the opportunity to participate in the Behavioral and Health Outcomes (BAHO) substudy.

Stratification/Descriptive Factors

Patient randomization will be stratified by risk level as described in the protocol based on Recurrence Score and grade, number of positive nodes, and prior therapy.

Cancer Control Credits

The NCI Division of Cancer Prevention has not assigned cancer control credits for registration to this study. There are potential cancer control credits for the BAHO portion of this study.

Accrual Goals

The accrual goal is 3,500 eligible patients. Interim analyses are planned for after approximately 39%, 60%, and 81% of the events in the control arm have been observed.

Summary Statement

For the current status of this study, please refer to the Breast chapter.

S1417 Surveillance

Coordinating Group: SWOG

Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer

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Participants:
SWOG, CTSU

Study Chairs:
V Shankaran, S Ramsey, D Hershman

Statisticians:
J Unger, A Darke

Data Coordinators:
M Yee, D Liggett

Objectives

To estimate the prevalence of treatment-related financial hardship over 12 months, among patients with newly diagnosed metastatic colorectal cancer (mCRC) treated at SWOG-affiliated NCI Community Oncology Research Program (NCORP) sites and minority/underserved NCORP sites.

To determine whether major financial hardships associated with mCRC treatment are more likely in younger, non-white, unmarried, unemployed, and lower income patients.

To explore whether occurrence of major financial hardship is associated with poorer health-related quality of life over time.

To profile the magnitude and timing of treatment-related changes in patients' income, assets, debt, and employment, and to quantify major out-of-pocket expenses during the 12 months following diagnosis.

To explore the extent to which health insurance factors (e.g., high copayments, deductibles, premiums, loss/change of insurance plan) are associated with treatment-related financial hardship and treatment adherence.

To obtain objective measures of expenses, debt and credit through linkage with individual patient credit reports (TransUnion) at enrollment (baseline) and end of follow up (12 months).

To determine feasibility of recruiting primary caregivers and measuring caregiver burden and caregivers' perceptions about cancer treatment costs.

To determine the feasibility of conducting a prospective multi-site longitudinal cohort study assessing financial outcomes in patients with mCRC undergoing treatment within the NCORP network.

Patient Population

Patients must have newly diagnosed metastatic colon or rectal cancer (de novo metastatic diagnosis or metastatic recurrence after prior treatment for stage I-III disease), with registration within 90 days of diagnosis. Patients must have either initiated systemic chemotherapy at the registering institution or have a plan in place for initiation of chemotherapy. Patients must not have been diagnosed with any malignancy other than colorectal cancer within the past five years, with the exception of basal cell or squamous cell skin cancer, in situ cervical cancer, or in situ breast cancer.

Patients may have received prior chemotherapy, radiation therapy, or surgery for non-metastatic colorectal cancer.

Patients must provide full name and social security number at registration and be able to complete questionnaires in English. Patients must not be currently enrolled in any clinical treatment trials at time of registration. Patients may enroll in treatment trials or other clinical trials following completion of baseline surveys.

Cancer Control Credits

No cancer control credits are awarded for this study.

Accrual Goals

A total of 337 patients will be enrolled to achieve 320 eligible patients.