

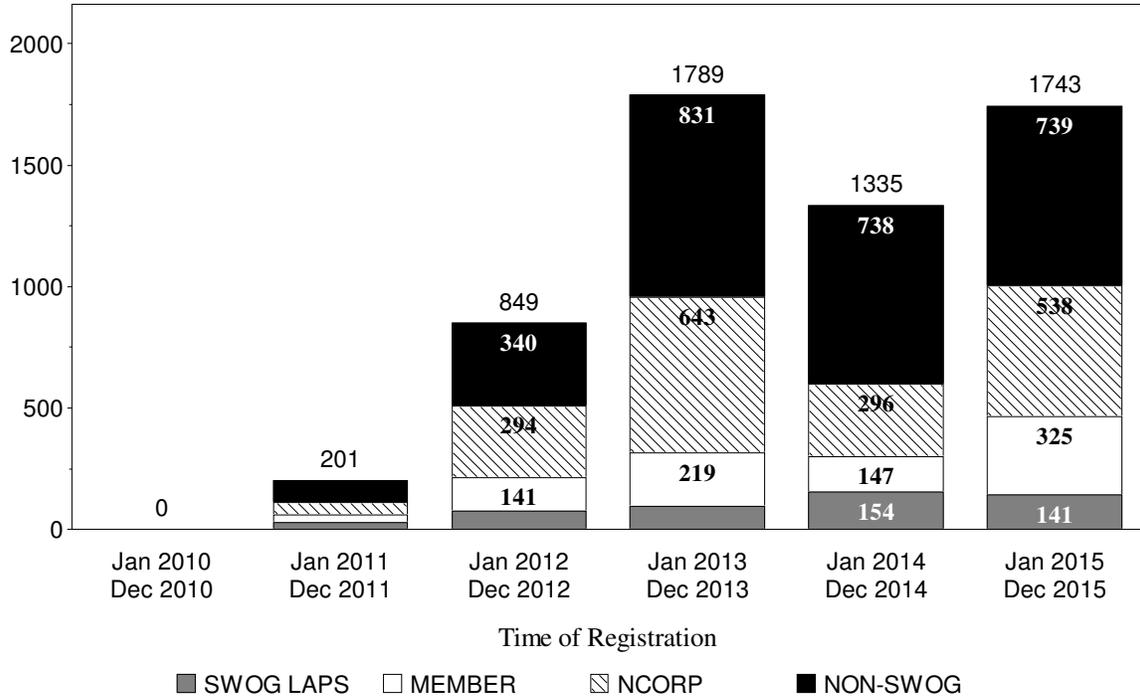
CANCER CARE DELIVERY COMMITTEE

CONTENTS

S1007 Phase III.....	5
S1204 Surveillance	8
S1207 Phase III.....	11
S1415CD Pragmatic Trial.....	13
S1417CD Survey	16

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 2015 Dec 2015	Jan 2015 Jun 2015	Jul 2014 Dec 2014	All Patients
S1007 Breast,Adj,N1,Endocrine+/-Chemo				
Randomization				
Chemo and Endocrine Therapy	239	284	245	2,093
Endocrine Therapy Alone	236	279	243	2,081
	<u>475</u>	<u>563</u>	<u>488</u>	<u>4,174</u>
S1204 Prevalence HIV,HBV,HCV+Cost Eff				
Registration				
HIV, HBV, HCV Prevalence	688	16	2	1,016
A011104 Preoperative Breast MRI*				
Total Registrations	1	0	1	3

* 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

Participants:

SWOG, CTSU (supported by NRG, Alliance, ECOG-ACRIN, CCTG, GEICAM, and UNICANCER)

Date Activated:

01/15/2011

Study Chairs:

K Kalinsky, J Gralow, G Hortobagyi, K Albain

Date Closed:

10/01/2015

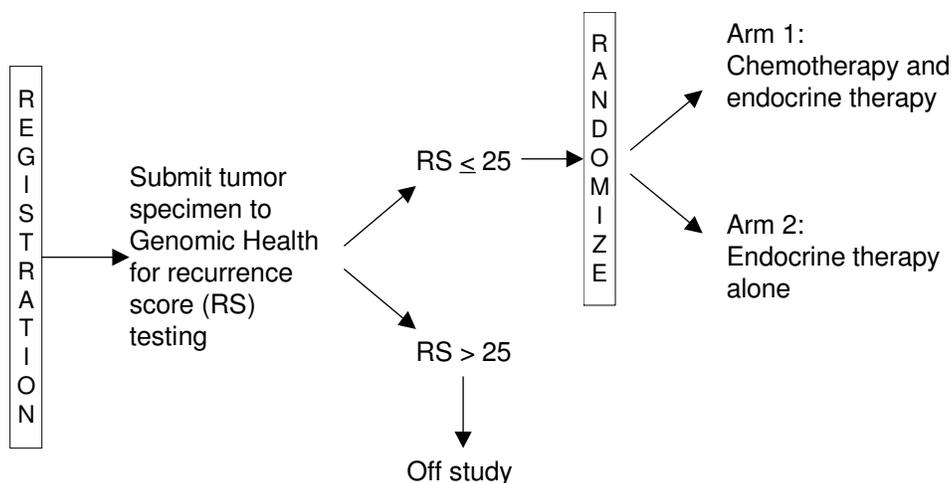
Statisticians:

W Barlow, D Lew

Data Coordinators:

L Kaye, J Scurlock

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 $RS \leq 25$ 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 must have had either breast-conserving surgery with planned radiation therapy or total mastectomy (with or without planned postmastectomy radiation). Patients must have clear margins from both invasive cancer and DCIS; LCIS at the margins is allowed. 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. Patients with a prior diagnosis of contralateral DCIS are eligible if they underwent a mastectomy or lumpectomy with whole breast radiation. Patients with a prior diagnosis of ipsilateral DCIS or invasive breast cancer who received radiation to that breast are not eligible.

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.

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 from UNICANCER in France will be randomized. Annual interim analyses are planned beginning when 24% of the events have been observed, approximately 6.6 years after initiation of the study.

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

Study Chairs:

S Ramsey, R Loomba, R Chugh, D Hershman, J Hwang

Date Activated:

08/29/2013

Statisticians:

J Unger, K Arnold

Data Coordinator:

M Yee

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 solid or hematologic cancer malignancy. Confirmed diagnosis date must be within 120 days prior to first clinic visit as a newly diagnosed cancer patient at the registering clinic. Patients presenting for "second opinions" of confirmed malignancies are eligible, including those who have started cancer treatment at other facilities. Patients must be registered within 90 days after their first clinic visit. Patients must not 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. Patients must have no evidence of disease for a prior malignancy for at least five years prior to randomization except as noted above.

Patients must be 18 years of age or older. Patients must have had their blood drawn for viral status testing for HIV, HBV and HCV or provide acceptable viral status documentation prior to registration, as defined in the protocol. Note that patients must have blood drawn for testing prior to registration for any of the three viruses not covered by the documentation. Patients are allowed to participate in other clinical trials.

Accrual Goals

A total of 3,061 patients will be accrued to achieve 3,000 eligible patients.

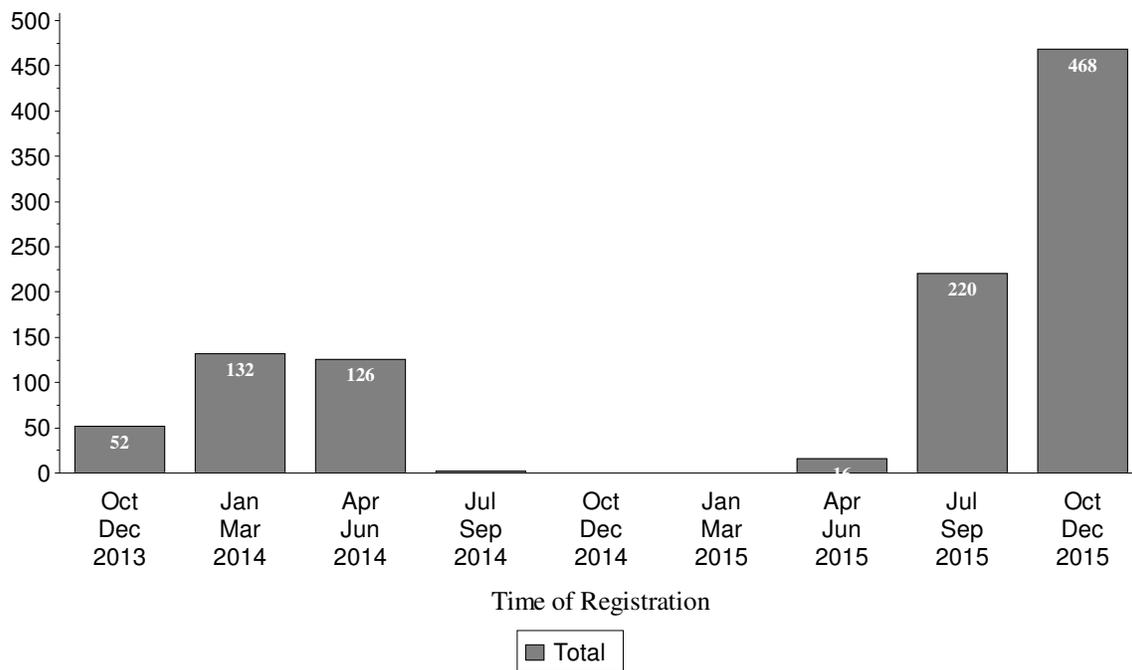
accrual is 1016 patients, 704 of whom were registered after study reactivation.

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. Following a temporary closure to evaluate the run-in data and implement protocol modifications, the study reopened to accrual on May 1, 2015. As of December 31, 2015, total study

SWOG sites interested in participating must have submitted the S1204 Site Application. However, due to strong site participation, as of October 23, 2015, no new S1204 Site Applications will be accepted. Approved sites may apply to add additional clinics. Participating sites must agree to the site requirements, as listed in Section 4.0 of the protocol.

Initial Registrations By 3 Month Intervals



Registration by Institution

Registrations ending December 31, 2015

Institutions	Total Reg	Institutions	Total Reg
Greenville NCORP	207	Boston MC MBCCOP	33
MD Anderson CC	167	Hawaii MU-NCORP	33
Columbia MU-NCORP	135	Desert Hospital	18
Kaiser Perm NCORP	93	Hines-VA Med Ctr/Loyola University	11
Gulf South MU-NCORP	76	Montana NCORP	10
San Antonio, U of TX	68	VAMC Kansas City	9
Bay Area NCORP	67	St Luke's Mt State/PCRC NCORP	6
Harrington CC	43	Sutter Cancer RC	1
Boston Medical Ctr	39	Total (17 Institutions)	1016

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2015; Data as of February 15, 2016

	<u>Total</u>
NUMBER REGISTERED	1016
ELIGIBLE	1016
Analyzable, Pend. Elig.	228

Patient Characteristics

Registrations ending December 31, 2015; Data as of February 15, 2016

	<u>Total (n=1016)</u>	
AGE		
Median	58.3	
Minimum	20.1	
Maximum	90.0	
SEX		
Males	366	36%
Females	650	64%
HISPANIC		
Yes	257	25%
No	754	74%
Unknown	5	0%
RACE		
White	749	74%
Black	184	18%
Asian	46	5%
Pacific Islander	3	0%
Native American	3	0%
Multi-Racial	1	0%
Unknown	30	3%

S1207 Phase III

Coordinating Group: SWOG

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

Participants:
SWOG, CTSU, NRG

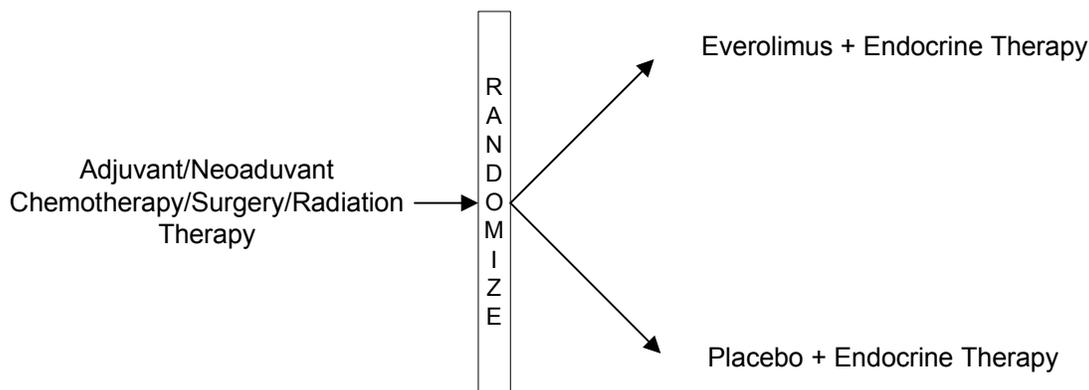
Date Activated:
09/03/2013

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

Statisticians:
W Barlow, D Lew

Data Coordinators:
J Barrett, I Syquia

SCHEMA



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 eligible, and will be categorized as node-negative.

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 must be offered the opportunity to participate in the Behavioral and Health Outcomes (BAHO) substudy (patients who have already started endocrine therapy are eligible for the BAHO study).

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.

Accrual Goals

The accrual goal is 1,900 patients. Interim analyses are planned for after approximately 40%, 60%, and 80% 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.

S1415CD Pragmatic Trial

Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia – Pragmatic Trial Assessing CSF Prescribing Effectiveness and Risk (TrACER)

Study Chairs:

S Ramsey, D Hershman, G Lyman, S Sullivan

Statisticians:

A Bansal (UW), W Barlow, K Arnold

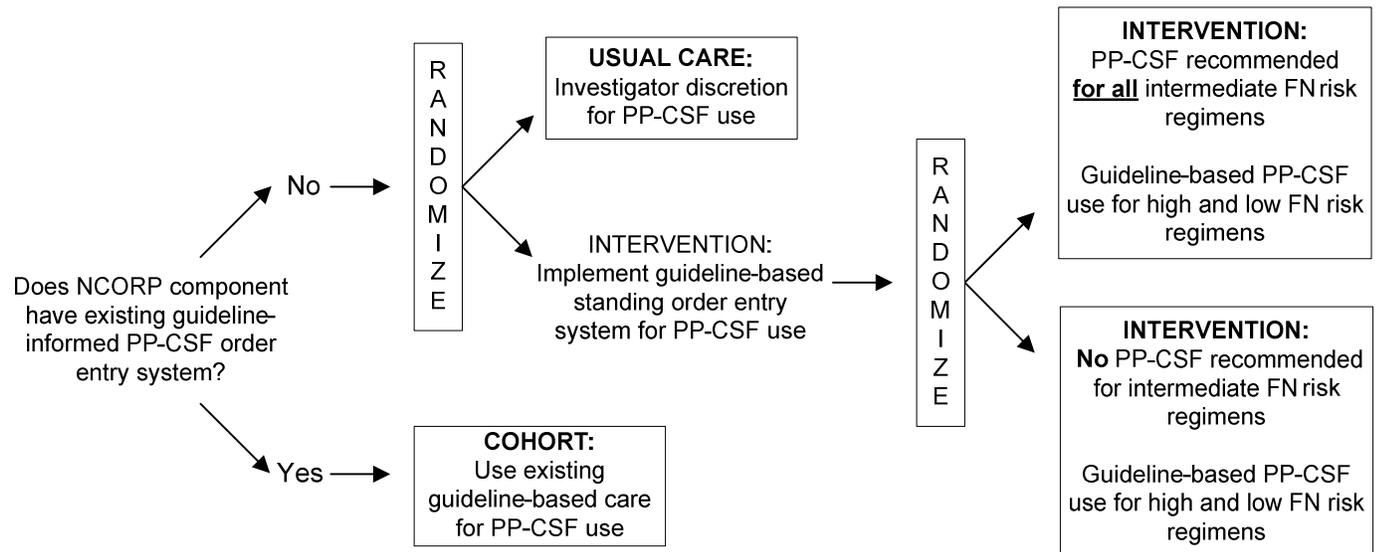
Project Manager:

K Watabayashi (HICOR)

Data Coordinator:

M Yee

SCHEMA



Randomization is at the NCORP component level. All patients at participating components will be subject to the PP-CSF use care as determined by component assignment (Usual Care, Intervention, or Cohort). Only consented patients registered to the study will participate in the data collection.

Objectives

To compare the use of primary prophylactic colony stimulating factor (PP-CSF) according to recommended clinical practice guidelines among patients registered at Intervention components versus Usual Care components.

To compare the rate of febrile neutropenia (FN) among patients registered at Intervention components versus Usual Care components.

To compare the rate of FN among intermediate risk patients registered at Intervention components by component treatment assignment (administer PP-CSF to intermediate risk patients versus not).

To compare the rate of FN among low-risk patients registered at Intervention components versus Usual Care components.

To compare the FN-related health-related quality of life (HRQOL) among low-risk patients registered at Intervention components versus Usual Care components.

To compare patient adherence to PP-CSF prescribing among patients registered at Intervention components versus Usual Care components.

To compare patient knowledge of the indications for, efficacy of, and side effects associated with PP-CSF between the initiation and conclusion of the first cycle of myelosuppressive systemic therapy among patients registered at Intervention components versus Usual Care components.

To compare the proportion of patients completing the initial systemic therapy regimen at planned duration and at planned dose intensity among patients registered at Intervention components versus Usual Care components.

To compare antibiotic use both as prophylaxis and as treatment for FN among patients registered at Intervention components versus Usual Care components.

To compare the rate of FN-related emergency department visits and hospitalizations among intermediate risk patients registered to Intervention components by component treatment assignment (administer PP-CSF to intermediate risk patients versus not).

To compare the FN-related health-related quality of life (HRQOL) among intermediate risk patients registered to Intervention components by component treatment assignment (administer PP-CSF to intermediate risk patients versus not).

To compare overall survival among intermediate risk patients registered to Intervention components by component treatment assignment (administer PP-CSF to intermediate risk patients versus not).

To characterize and descriptively report the differences among Cohort components and the Intervention and Usual Care components, according to the endpoints outlined in Section 10.0.

Patient Population

Patients must have a current diagnosis of breast cancer, non-small cell lung cancer, or colorectal cancer. Cancer may be metastatic or non-metastatic.

Patients must be planning to receive one of the study-allowed regimens as their initial treatment for their current diagnosis. Patients must be registered prior to their first cycle of systemic therapy (chemotherapy, immunotherapy, biologic therapy, or combination regimens). Prior systemic therapy must have been completed at least 180 days prior to registration. Patients must not have any known contraindication to CSFs, including prior hypersensitivity to Escherichia coli-derived proteins, filgrastim, pegfilgrastim, or tbo-filgrastim.

Patients must be able to understand and provide information for the patient-completed study forms in either English or Spanish. Patients may have had a prior malignancy. Patients must not be participating or plan to participate in other clinical trials that involve investigational systemic cancer treatments or investigational uses of CSF.

Stratification/Descriptive Factors

NCORP components eligible for randomization will be randomly assigned to Usual Care or Intervention with stratification by component size (number of patients at that component) and type of NCORP component (minority/underserved vs not).

Accrual Goals

A total of 3,960 patients will be accrued to achieve 3,600 eligible patients. The Intervention components will accrue 2,376 patients, the Usual Care components will accrue 792 patients and the Cohort components will accrue 792 patients.

One interim analysis will be conducted when 360 patients in the intermediate risk group at Intervention components have complete outcome information. A second interim analysis will be conducted when 650 patients in the intermediate risk group at Intervention components have complete outcome information.

Summary Statement

This study will be open to limited SWOG NCORP CCDR components. Components may apply by completing the S1415CD Component application found on the S1415CD protocol page on the SWOG web site. Components which have submitted applications will receive status notifications this spring.

S1417CD Survey

Coordinating Group: SWOG

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

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 incidence of treatment-related major financial hardship over 12 months, among patients with newly diagnosed metastatic colorectal cancer (mCRC) treated at SWOG-affiliated NCI Community Oncology Research Program (NCORP) Cancer Care Delivery Research (CCDR) components.

To describe the association of major financial hardships with mCRC treatment by demographic factors, including age, race, marital status, employment status, and income.

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 registration.

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

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.

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).

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 plan to begin systemic chemotherapy and/or biologic therapy at the registering institution within 30 days after registration. 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, biologic therapy, radiation therapy, or surgery for non-metastatic colorectal cancer.

Patients must provide full name, address, 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.

Accrual Goals

A total of 374 patients will be enrolled to achieve 320 eligible patients.

Summary Statement

This study will open in Spring of 2016. S1417CD is restricted to SWOG-affiliated NCORP CCDR components and does not use the Central IRB (CIRB).