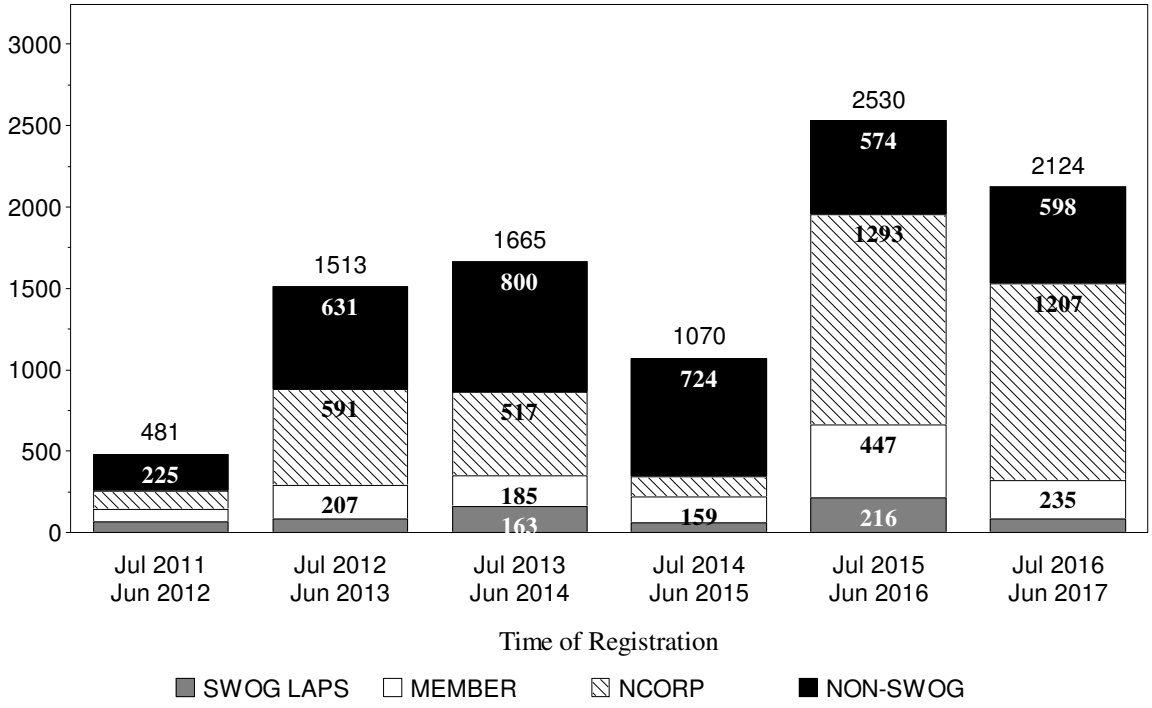
CANCER CARE DELIVERY COMMITTEE

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

	Jan 2017 Jun 2017	Jul 2016 Dec 2016	Jan 2016 Jun 2016	All Patients
S1007 Breast,Adj,N1,Endocrine+/-Chemo				
Randomization				
Chemo and Endocrine Therapy	134	137	116	2,480
Endocrine Therapy Alone	142	137	108	2,468
	276	274	224	4,948
S1204 Prevalence HIV,HBV,HCV+Cost Eff				
Registration				
HIV, HBV, HCV Prevalence	229	706	1,141	3,092
S1415CD TrACER CSF Standing Order Intervention for FN				
Registration				
Cohort	191	48	0	239
Usual Care	100	3	0	103
Intervention CSF for Intermediate Risk	127	8	0	135
Intervention No CSF for Intermediate Risk	85	4	0	89
	503	63	0	566
S1417CD Colorectal, Cost Cohort Study				
Registration				
Observation	53	15	1	69
A011104 Preoperative Breast MRI*				
Total Registrations	3	2	0	8

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

Non-SWOG Studies with SWOG-Credited Registrations

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Studies with Accrual from January 2016 - June 2017

	SWOG Champion	Date Activated	Date Closed	Total Accrued
A011104 Preoperative Breast MRI		02/21/14		172
Most Recent Progress Report				

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, CCTG, GEICAM, UNICANCER)

Study Chairs:
K Kalinsky, J Gralow, P Rastogi (NRG), N Lin (Alliance), L Goldstein (ECOG-ACRIN), S Chia (CCTG), E Alba Conejo (GEICAM), S DeLaloge (UNICANCER)

Statisticians:
W Barlow, D Lew, J Miao

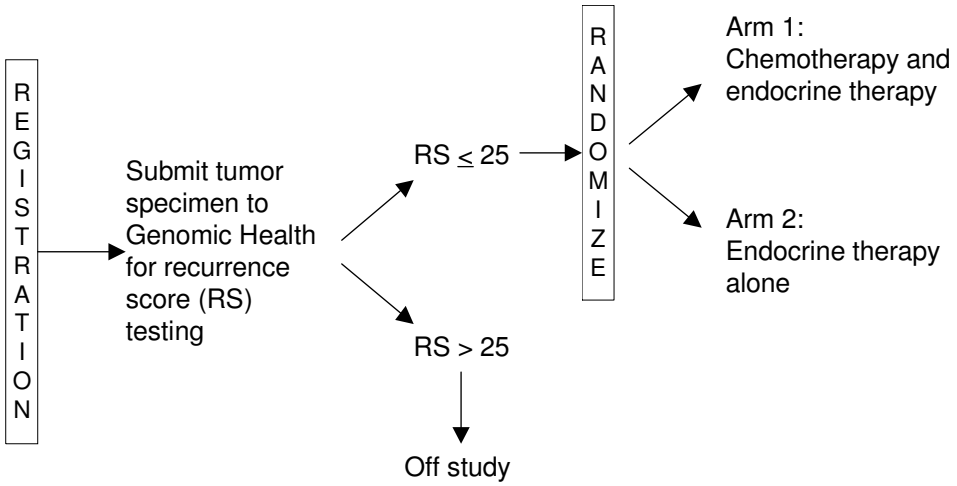
Data Coordinators:
L Kaye, J Scurlock

Date Activated:
01/15/2011

Date Closed*:
10/01/2015

* Open to UNICANCER sites only

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, D Hershman

Statisticians:
J Unger, K Arnold

Data Coordinators:
H Dong, M Yee

Date Activated:
08/29/2013

Date Closed:
02/15/2017

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.

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.

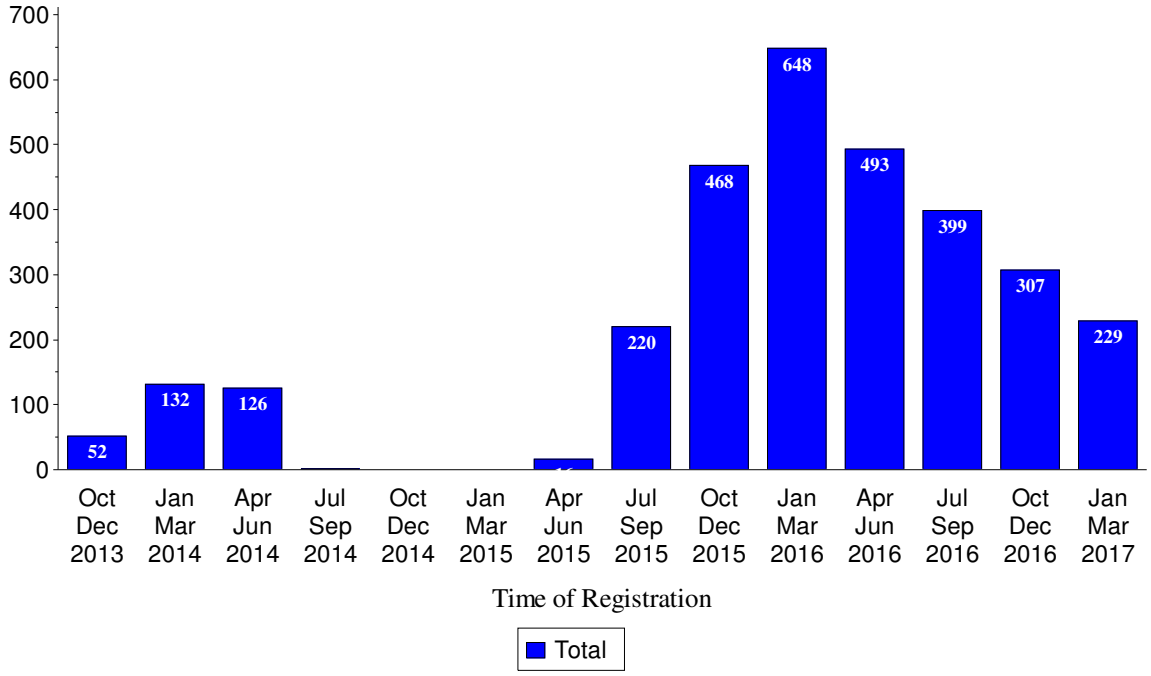
Summary Statement

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. The study closed to accrual on February 15, 2017, with 3092 patients accrued, 2780 of whom were registered after study reactivation.

Thirty-eight patients are ineligible. Seven patients had a cancer diagnosis more than 120 days prior to the first clinic visit, fourteen patients were registered more than 90 days after the first clinic visit, seven patients reported a first clinic visit prior to diagnosis, one patient had a prior cancer diagnosis less than five years ago, one patient did not have cancer, one patient had recurrent cancer, three patients did not have any viral testing done, and four patients had died prior to registration. Three patients are not analyzable due to withdrawal of consent prior to data submission.

Initial Registrations By 3 Month Intervals



Registration by Institution

Registrations ending June 30, 2017

Institutions	Total Reg	Institutions	Total Reg
Kaiser Perm NCORP	624	Desert Hospital	77
Greenville NCORP	542	Boston Medical Ctr	69
Gulf South MU-NCORP	426	Weiss Memorial Hosp/Loyola University	54
MD Anderson CC	354	Boston MC MBCCOP	33
Columbia MU-NCORP	266	Montana NCORP	33
Harrington CC	147	Hines-VA Med Ctr/Loyola University	20
San Antonio, U of TX	146	Sutter Cancer RC	10
VAMC Kansas City	107	St Luke's Mt State/PCRC NCORP	6
Bay Area NCORP	92	**Total (18 Institutions)**	**3092**
Hawaii MU-NCORP	86		

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2017; Data as of July 24, 2017

	Total
NUMBER REGISTERED	3092
INELIGIBLE	38
ELIGIBLE	3054
Analyzable, Pend. Elig.	1
Not Analyzable	3

Patient Characteristics

Registrations ending June 30, 2017; Data as of July 24, 2017

	Total (n=3051)	
AGE		
Median	60.6	
Minimum	18.2	
Maximum	93.7	
SEX		
Males	1209	40%
Females	1842	60%
HISPANIC		
Yes	558	18%
No	2478	81%
Unknown	15	0%
RACE		
White	2281	75%
Black	553	18%
Asian	102	3%
Pacific Islander	12	0%
Native American	20	1%
Multi-Racial	9	0%
Unknown	74	2%

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

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Participants:
SWOG, NRG, CTSU (Supported by Alliance)

Date Activated:
09/03/2013

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

Statisticians:
W Barlow, J Miao, D Lew

Data Coordinator:
I Syquia

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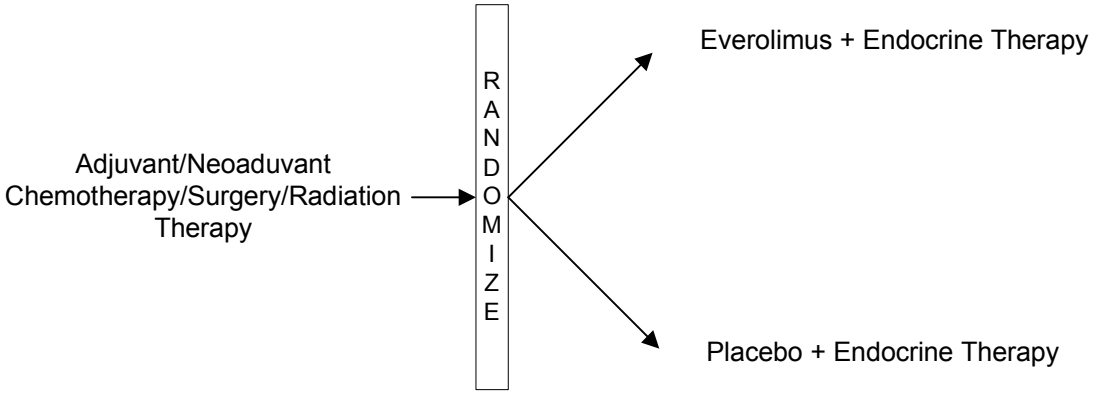

Objectives

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.

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 or MammaPrint and grade, number of positive nodes, and prior therapy. Patients with micrometastases as the only nodal involvement (pN1mi) 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 be at least 18 years of age, have a Zubrod performance status of 0-2, and have 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.

Stratification/Descriptive Factors

Patient randomization will be stratified by risk level as described in the protocol based on Recurrence Score or MammaPrint 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 Phase III

Coordinating Group: SWOG

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 – Trial Assessing CSF Prescribing Effectiveness and Risk (TrACER)

Participants:
SWOG, CTSU

Date Activated:
09/01/2016

Study Chairs:
S Ramsey, D Hershman

Statisticians:
A Bansal (UW), W Barlow, K Arnold

Project Manager:
K Watabayashi (HICOR)

Data Coordinators:
J Patterson, H Dong

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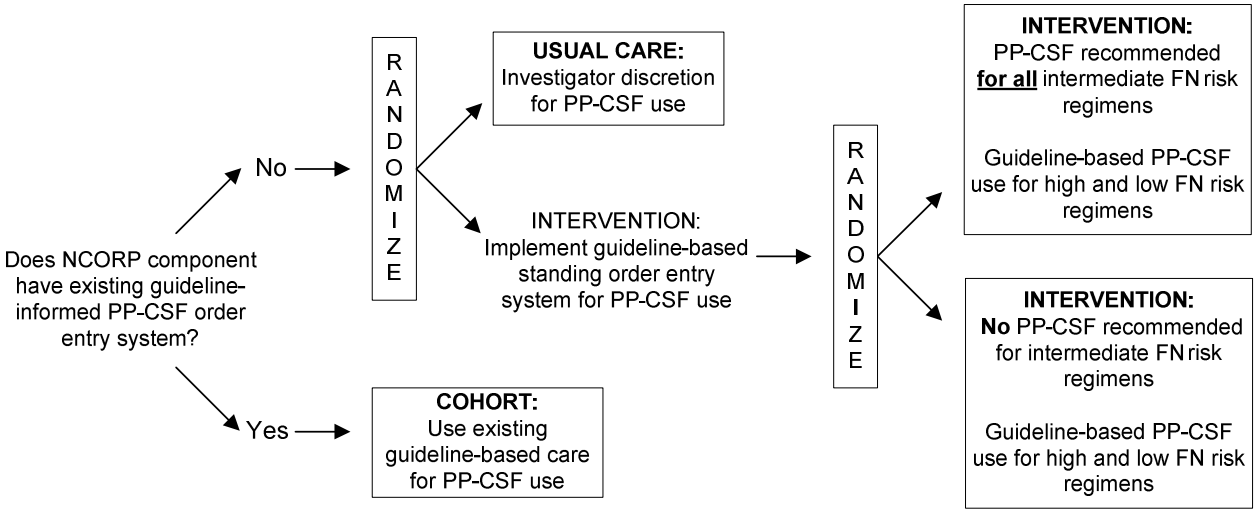


Randomization is at the NCORP component level. All patients at participating components will be subject to the PP-CSF use care as determined by component assignment (Usual Care, Intervention, or Cohort). Only consented patients registered to the study will participate in the data collection.

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 (HRQL) 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 (HRQL) 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).

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 be receiving or planning to receive concurrent radiation therapy during systemic treatment. 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 was activated on September 1, 2016, at limited institutions. As of June 30, 2017, 566 patients have been registered.

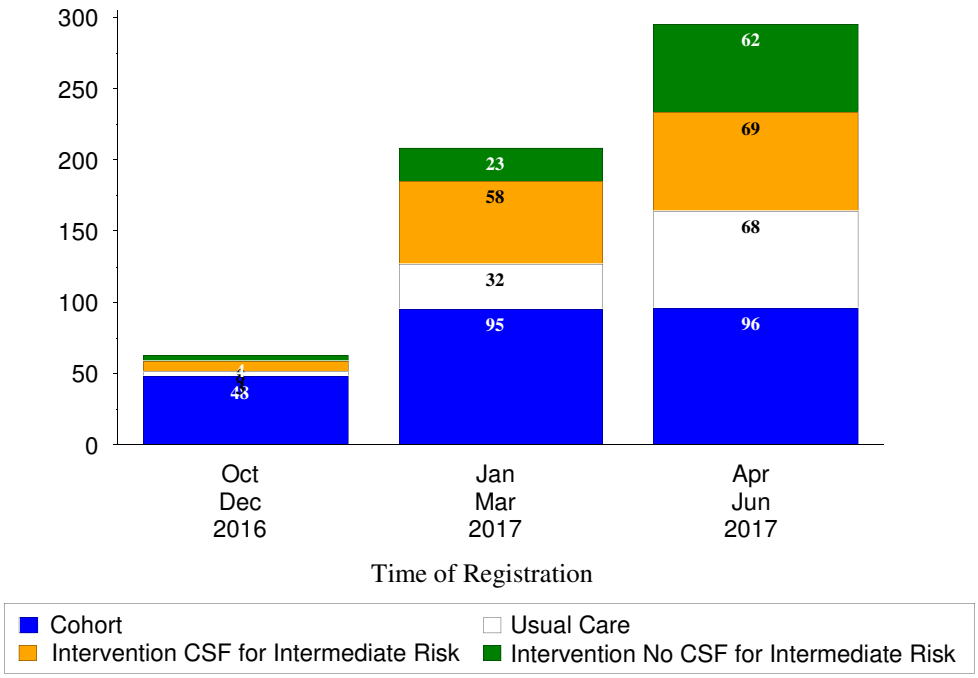
For this study, a component is defined as a site or group of sites in the same administrative network that all share one paper or electronic medical record and order system. Component randomization is complete, with eight components randomized to Usual Care and 24 components randomized to Intervention. As of June 30, 2017, 19 of the Intervention components have completed updating their standing order systems and are open. All of the Usual Care and Cohort components are open.

Eight patients are ineligible. Two patients had systemic therapy within 180 days of registration, one patient planned to have concurrent radiation therapy, one patient did not have the correct cancer type, two patients planned to have regimens not listed in Appendix 18.1, and two patients had regimens listed in Section 18.1 with planned dose reductions that were too deviant from the standard regimen dosing. Three patients are not analyzable because they never started systemic therapy. Eleven patients are off treatment, including two who have withdrawn consent for any further follow-up.

Adverse events shown are those attributable to PP-CSF (first cycle only). Among 129 patients who have had adverse events assessed in the Cohort group, two patients reported Grade 3 bone pain, one of whom also reported Grade 3 arthralgia, and one patient reported Grade 3 back pain and chest wall pain. Among 49 patients who have had adverse events assessed in the Usual Care group, one patient reported Grade 3 arthralgia and bone pain. Among 41 patients who have had adverse events assessed in the Intervention No CSF for Intermediate Risk group, three patients reported Grade 3 bone pain, one of whom also reported Grade 3 arthralgia, and one patient reported Grade 3 febrile neutropenia. No Grade 3 or higher events were reported in the Intervention CSF for Intermediate Risk group.

Revision #3 clarified eligibility requirements.

Initial Registrations By 3 Month Intervals



Registration by DM Institution

Registrations ending June 30, 2017

Institutions	Total Reg
Heartland Cancer Research NCORP (HEARTLAND)	93
Cancer Research for the Ozarks NCORP (OZARKS)	67
Wichita NCI Community Oncology Research Progr (WICHITA)	36
Novant Health Forsyth Medical Center (SCCC)	35
Greenville Memorial Hospital (GREENVILLE)	30
Columbia University Minority Underserved NCO (COLUMBIA)	29
Pacific Cancer Research Consortium NCORP (PCRC)	27
Southeast Clinical Oncology Research (SCOR) Cons (SCCC)	27
Iowa-Wide Oncology Research Coalition NCORP (IWORC)	24
Saint Luke's Mountain States Tumor Institute (PCRC)	23
Baptist Health System/Mid South Minority Unde (BAPTIST)	21
Carle Cancer Center NCI Community Oncology Rese (CARLE)	18
New Mexico Minority Underserved NCORP (NEWMEXICO)	18
Cancer Care Specialists of Central (HEARTLAND)	17
Sanford NCI Community Oncology Research Progr (SANFORD)	16
Montana Cancer Consortium NCORP (MONTANA)	13
Hawaii Minority Underserved NCORP (HAWAII)	12
Essentia Health NCI Community Oncology Resea (ESSENTIA)	10
Catholic Health Initiatives NCORP (CORA)	8
Gulf South Minority Underserved NCORP (GULFSOUTH)	8
Michigan Cancer Research Consortium NCORP (MCRC)	7
Columbus NCI Community Oncology Research Pro (COLUMBUS)	4

Institutions	Total Reg
MultiCare Tacoma General Hospital (NORTHWEST)	4
Bay Area Tumor Institute NCORP (BATI)	3
Cancer Center of Kansas - Wichita (WICHITA)	3
Georgia NCI Community Oncology Research Progr (GEORGIA)	3
Marshfield Clinic - Weston Center (WINCORP)	3
Northwest NCI Community Oncology Research P (NORTHWEST)	3
Cancer Research Consortium of West Michigan NCO (CRCWM)	2
Carle Cancer Center (CARLE)	1
Wisconsin NCI Community Oncology Research Pro (WINCORP)	1
Total (31 Institutions)	**566**

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2017; Data as of July 28, 2017

	TOTAL	Cohort	Usual Care	Intervention CSF for Intermediate Risk	Intervention No CSF for Intermediate Risk
NUMBER REGISTERED	566	239	103	135	89
INELIGIBLE	8	2	2	3	1
ELIGIBLE	558	237	101	132	88
Analyzable, Pend. Elig.	5	1	2	0	2
Not Analyzable	3	3	0	0	0

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending June 30, 2017; Data as of July 28, 2017

	Cohort (n=234)		Usual Care (n=101)		Intervention CSF for Intermediate Risk (n=132)		Intervention No CSF for Intermediate Risk (n=88)	
AGE								
Median	59.4		60.5		61.8		59.8	
Minimum	25.8		36.3		22.5		30.9	
Maximum	91.2		86.2		88.4		80.6	
SEX								
Males	52	22%	23	23%	36	27%	11	13%
Females	182	78%	78	77%	96	73%	77	88%
HISPANIC								
Yes	5	2%	4	4%	4	3%	12	14%
No	229	98%	96	95%	122	92%	72	82%
Unknown	0	0%	1	1%	6	5%	4	5%
RACE								
White	208	89%	79	78%	107	81%	61	69%
Black	22	9%	15	15%	19	14%	5	6%
Asian	1	0%	2	2%	4	3%	8	9%
Pacific Islander	0	0%	1	1%	1	1%	1	1%
Native American	0	0%	0	0%	1	1%	3	3%
Multi-Racial	1	0%	0	0%	0	0%	1	1%
Unknown	2	1%	4	4%	0	0%	9	10%
FEBRILE NEUTROPENIA RISK								
Low	44	19%	23	23%	37	28%	22	25%
Intermediate	96	41%	41	41%	65	49%	32	36%
High	94	40%	37	37%	30	23%	34	39%

Treatment Summary

All eligible and selected ineligible patients included

Registrations ending June 30, 2017; Data as of July 28, 2017

	TOTAL	Cohort	Usual Care	Intervention CSF for Intermediate Risk	Intervention No CSF for Intermediate Risk
NUMBER ON PROTOCOL TREATMENT	544	229	100	129	86
NUMBER OFF PROTOCOL TREATMENT	11	5	1	3	2
REASON OFF TREATMENT					
Treatment completed as planned	0	0	0	0	0
Adverse Event or side effects	0	0	0	0	0
Refusal unrelated to adverse event	2	0	1	1	0
Progression/relapse	0	0	0	0	0
Death	8	5	0	2	1
Other - not protocol specified	0	0	0	0	0
Reason under review	1	0	0	0	1
MAJOR PROTOCOL DEVIATIONS	0	0	0	0	0

Number of Patients with a Given Type and Grade of Adverse Event

First Cycle Only

Adverse Events Unlikely or Not Related to Treatment Excluded

All Eligible and Selected Ineligible Patients Included

Registrations ending June 30, 2017; Data as of July 28, 2017

	Cohort (n=129) Grade						Usual Care (n=49) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Arthralgia	104	19	5	1	0	0	42	3	3	1	0	0
Back pain	127	0	1	1	0	0	49	0	0	0	0	0
Bone pain	103	17	7	2	0	0	36	5	7	1	0	0
Chest wall pain	128	0	0	1	0	0	49	0	0	0	0	0
Constipation	129	0	0	0	0	0	49	0	0	0	0	0
Diarrhea	129	0	0	0	0	0	49	0	0	0	0	0
Fatigue	128	1	0	0	0	0	49	0	0	0	0	0
Febrile neutropenia	129	0	0	0	0	0	49	0	0	0	0	0
Headache	129	0	0	0	0	0	49	0	0	0	0	0
Mucositis oral	126	2	1	0	0	0	43	3	3	0	0	0
Myalgia	126	3	0	0	0	0	49	0	0	0	0	0
Myositis	127	0	2	0	0	0	49	0	0	0	0	0
Pain in extremity	129	0	0	0	0	0	49	0	0	0	0	0
Vomiting	128	1	0	0	0	0	49	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	82	30	14	3	0	0	31	8	9	1	0	0

	Intervention CSF for Intermediate Risk (n=56) Grade						Intervention No CSF for Intermediate Risk (n=41) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Arthralgia	52	3	1	0	0	0	36	2	2	1	0	0
Back pain	56	0	0	0	0	0	41	0	0	0	0	0
Bone pain	38	9	9	0	0	0	33	3	2	3	0	0
Chest wall pain	56	0	0	0	0	0	41	0	0	0	0	0
Constipation	55	0	1	0	0	0	41	0	0	0	0	0
Diarrhea	54	2	0	0	0	0	41	0	0	0	0	0
Fatigue	56	0	0	0	0	0	41	0	0	0	0	0
Febrile neutropenia	56	0	0	0	0	0	40	0	0	1	0	0
Headache	55	1	0	0	0	0	40	0	1	0	0	0
Mucositis oral	55	1	0	0	0	0	40	1	0	0	0	0
Myalgia	55	1	0	0	0	0	41	0	0	0	0	0
Myositis	54	1	1	0	0	0	36	2	3	0	0	0
Pain in extremity	56	0	0	0	0	0	40	1	0	0	0	0
Vomiting	56	0	0	0	0	0	41	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	35	10	11	0	0	0	27	6	4	4	0	0

S1417CD Survey

Coordinating Group: SWOG

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

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Participants:
SWOG, CTSU

Date Activated:
05/13/2016

Study Chairs:
V Shankaran, S Ramsey

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 components and subcomponents of the NCI Community Oncology Research Program (NCORP).

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.

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 120 days of diagnosis. Patients must plan to begin systemic chemotherapy and/or biologic therapy at the registering institution within 30 days after registration or must have initiated treatment no more than 60 days prior to registration.

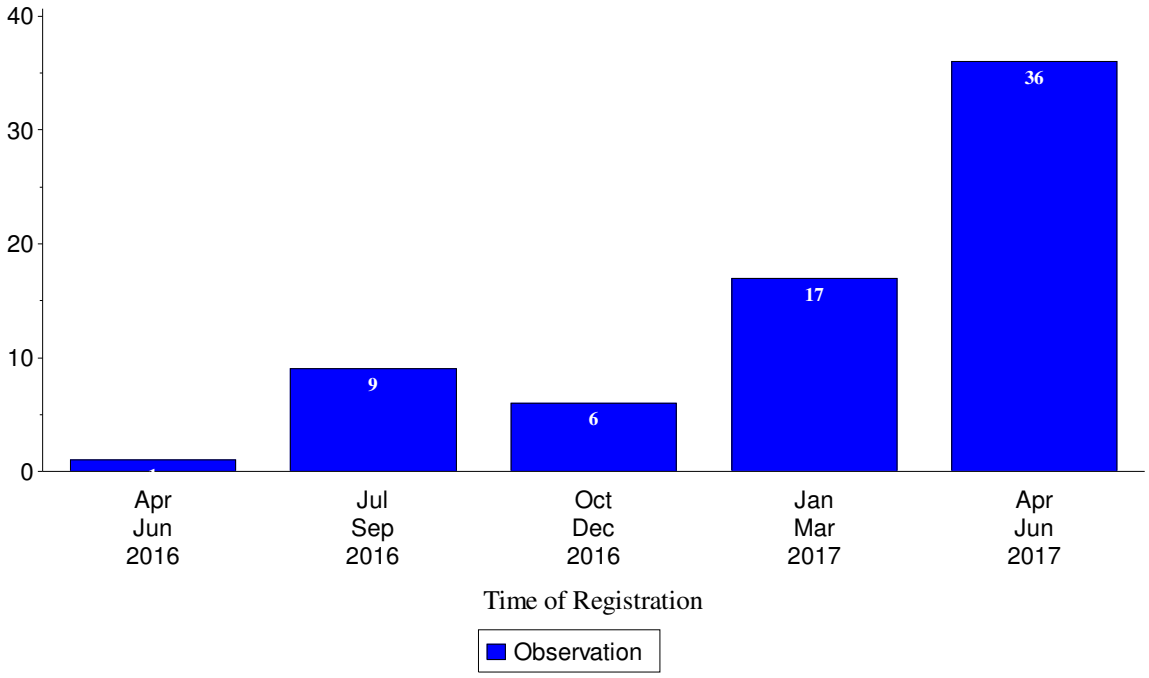
Patients may have received prior chemotherapy, biologic therapy, radiation therapy, or surgery for non-metastatic colorectal cancer.

Patients must provide full name, address, and social security number at registration and be able to complete questionnaires in English.

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

Summary Statement
S1417CD is restricted to NCORP components and subcomponents and does not use the Central IRB (CIRB). This study was activated May 13, 2016. As of June 30, 2017, 69 patients had been accrued. One patient is ineligible due to being diagnosed with metastatic colorectal cancer more than 120 days prior to registration.

Initial Registrations By 3 Month Intervals



Registration by Institution

Registrations ending June 30, 2017

Institutions	Total Reg	Institutions	Total Reg
Columbia MU-NCORP	9	Michigan CRC NCORP	2
Columbus NCORP	8	New Mexico MU-NCORP	2
Heartland NCORP	8	Wichita NCORP	2
CRC West MI NCORP	7	CORA NCORP	1
Greenville NCORP	7	Montana NCORP	1
Southeast COR NCORP	4	PCRC NCORP	1
Kaiser Perm NCORP	3	ECOG-ACRIN	6
Dayton NCORP	2	ALLIANCE	1
Georgia NCORP	2	NRG	1
Hawaii MU-NCORP	2	**Total (19 Institutions)**	**69**

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2017; Data as of July 20, 2017

	Observation
NUMBER REGISTERED	69
INELIGIBLE	1
ELIGIBLE	68
Analyzable, Pend. Elig.	1

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending June 30, 2017; Data as of July 31, 2017

	Observation (n=68)	
AGE		
Median	60.3	
Minimum	28.4	
Maximum	87.3	
SEX		
Males	36	53%
Females	32	47%
HISPANIC		
Yes	5	7%
No	59	87%
Unknown	4	6%
RACE		
White	49	72%
Black	9	13%
Asian	2	3%
Pacific Islander	1	1%
Unknown	7	10%