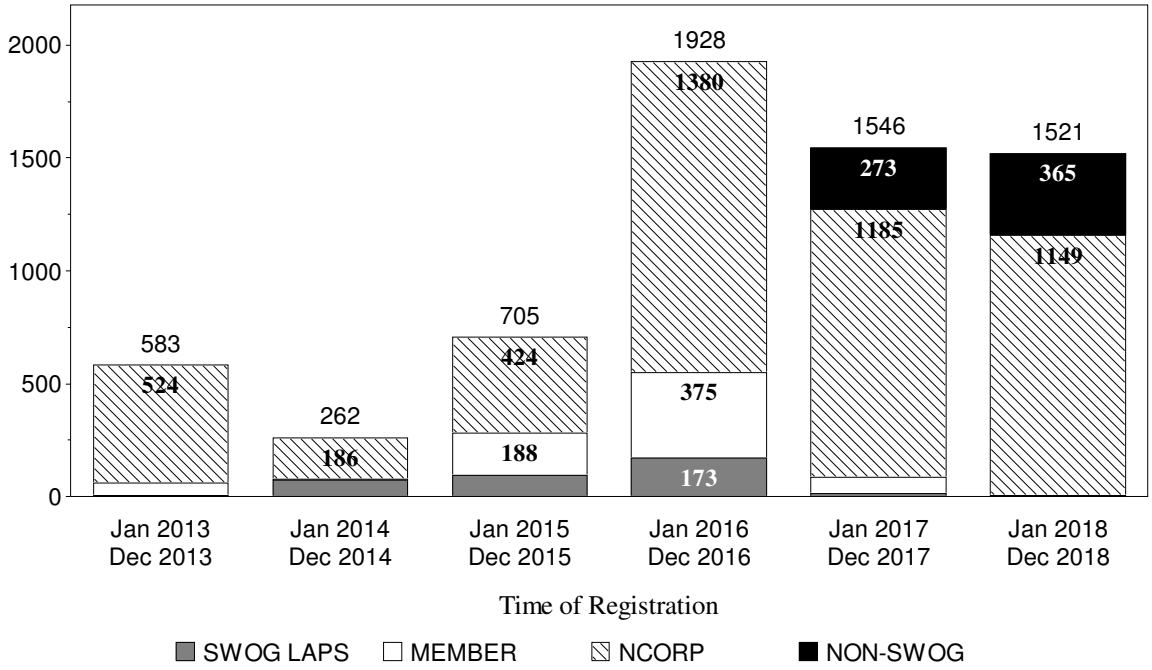
CANCER CARE DELIVERY COMMITTEE

CONTENTS

Patient Registrations to Studies

by 12 Month Intervals
CANCER CARE DELIVERY COMMITTEE
As Primary Committee



Screening registrations and registrations to Biologic only studies are excluded.

Patient Registrations by Study and Arm

CANCER CARE DELIVERY COMMITTEE

	Jul 2018 Dec 2018	Jan 2018 Jun 2018	Jul 2017 Dec 2017	All Patients
S1007 Breast,Adj,N1,Endocrine+/-Chemo				
Randomization				
Chemo and Endocrine Therapy	0	0	67	2,547
Endocrine Therapy Alone	0	0	68	2,536
	0	0	135	5,083
S1415CD TrACER CSF Standing Order Intervention for FN				
Registration				
Site assigned to Cohort	107	144	131	620
Site randomized: Control	102	104	140	450
SiteRand Int Risk: CSF	180	250	218	783
SiteRand Int Risk: No CSF	175	181	182	627
	564	679	671	2,480
S1417CD Colorectal, Cost Cohort Study				
Registration				
Observation	89	122	81	361
S1703 Met Breast, STM-monitoring v Usual Care				
Initial Registration				
Screening	9	0	0	9
Randomization				
Control (Usual Care)	1	0	0	1
Intervention (STMDDM)	1	0	0	1
	2	0	0	2

Non-SWOG Studies with SWOG-Credited Registrations

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Studies with Accrual from July 2017 - December 2018

	SWOG Champion	SWOG Accrual Jul 2018 Dec 2018	SWOG Accrual Jan 2018 Jun 2018	SWOG Accrual Jul 2017 Dec 2017	SWOG Total	Total Accrued
A011104 Preoperative Breast MRI Date Activated: 02/21/14 *Most Recent Progress Report*		5	2	4	19	267
A191402CD PROS, Testing Decision Aids for Minority Men Date Activated: 07/14/17 *Most Recent Progress Report*		8	5	2	15	138
ACCL16N1 Guideline Consistent Treatment AYA ALL Date Activated: 12/18/17 *No Progress Report Available*	A Advani, K O'Dwyer, D Hershman	34	0	0	34	141
EAQ162CD CCD, Financial Burden, Colon & Rectal Cancer Date Activated: 05/17/18 *Most Recent Progress Report*		11	0	0	11	166

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, D Hershman

Statisticians:
J Unger, K Arnold

Data Coordinator:
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, describe the timing and type of treatments received (if any), both for the viral infections and the cancers.

Describe the type of adverse events possibly attributable to the patient's viral status in patients with HIV, HBV, and/or HCV infection.

Using simulation modeling that is directly informed by the data obtained from this study, determine the cost-effectiveness (expressed as cost per infection detected and cost per year of life gained) 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-four patients were ineligible. Thirteen patients were registered more than 90 days after the first clinic visit, seven patients had a cancer diagnosis more than 120 days prior to the first clinic visit, four patients reported a first clinic visit prior to diagnosis, three patients did not have any viral testing done, one patient had a prior cancer diagnosis less than five years ago, one patient did not have cancer, one patient had recurrent cancer, and four patients had died prior to registration. Three patients were not analyzable due to withdrawal of consent prior to data submission.

The results of this trial were published in JAMA Oncology on January 17, 2019. Analysis results for the primary objective and selected prespecified secondary objectives are shown in Table 1: Analysis Results.

At the time of analysis for the primary publication, 3051 patients were deemed eligible. Since that time, there has been further clean-up of data resulting in an additional four eligible patients. Eligible patients may not have had viral status determined for all three viruses. A total of 3050 patient had HBV viral status established, 2990 patients had HCV viral status established, and 3045 patients had HIV viral status established. Viral infection rates are reported separately by virus type.

The observed infection rate for chronic HBV was 0.6% (95% CI, 0.4%-1.0%) and 6.5% (95% CI, 5.6%-7.4%) for previous HBV. Eight patients with chronic HBV (42.1%; 95% CI, 20.3%-66.5%) were newly diagnosed through the study.

The observed infection rate for HCV was 2.4% (95% CI, 1.9%-3.0%). Twenty-two patients with HCV (31.0%; 95% CI, 20.5%-43.1%) were newly diagnosed through the study.

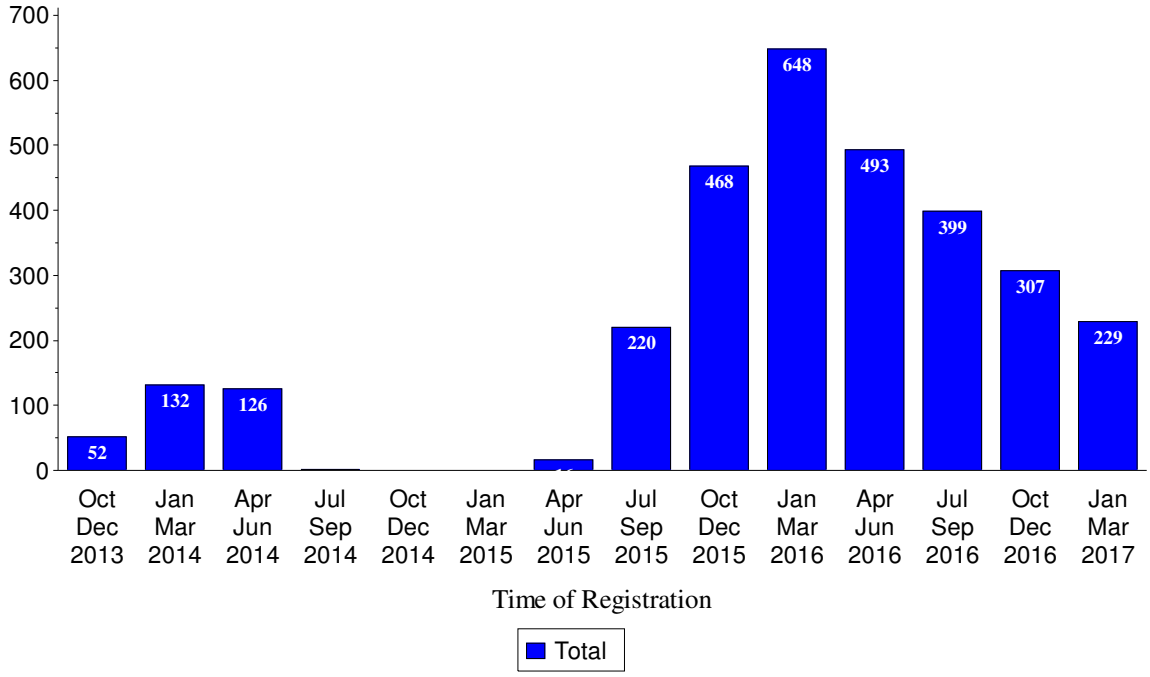
The observed infection rate for HIV was 1.1% (95% CI, 0.8%-1.6%). Two patients with HIV (5.9%; 95% CI, 0.7%-19.7%) were newly diagnosed through the study.

Table 1 also provides infection rates by cancer type.

Among patients with infections, four patients with chronic HBV (21.1%; 95% CI, 6.1%-45.6%) 23 patients with HCV (32.4%; 95% CI, 21.8%-44.5%) and seven patients with HIV (20.6%; 95% CI, 8.7%-37.9%) had no identifiable risk factors.

In summary, the study found that a substantial proportion of patients with newly diagnosed cancer and concurrent HBV or HCV are unaware of their viral infection at the time of cancer diagnosis, and many had no identifiable risk factors for infection. The study authors concluded that screening patients with newly diagnosed cancer to identify HBV and HCV infection before starting treatment may be warranted to prevent viral reactivation and adverse clinical outcomes, but universal screening for HIV infection may not be warranted.

Initial Registrations by 3 Month Intervals



Registration by Institution

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

Data as of January 29, 2019

	Total
NUMBER REGISTERED	3092
INELIGIBLE	34
ELIGIBLE	3058
Not Analyzable	3

Patient Characteristics

Data as of January 29, 2019

	Total (n=3055)	
AGE		
Median	60.6	
Minimum	18.1	
Maximum	93.7	
SEX		
Males	1212	40%
Females	1843	60%
HISPANIC		
Yes	559	18%
No	2481	81%
Unknown	15	0%
RACE		
White	2284	75%
Black	553	18%
Asian	102	3%
Pacific Islander	12	0%
Native American	20	1%
Multi-Racial	9	0%
Unknown	75	2%

Treatment Summary

Patient Status at 1 Year after Regsitration

Data as of January 29, 2019

	Total
NUMBER ON PROTOCOL TREATMENT	0
NUMBER OFF PROTOCOL TREATMENT	3055
REASON OFF TREATMENT	
Treatment completed as planned	2514
Adverse Event or side effects	0
Refusal unrelated to adverse event	1
Progression/relapse	0
Death	540
Other - not protocol specified	0
Reason under review	0
MAJOR PROTOCOL DEVIATIONS	0
LOST TO FOLLOW-UP	0
CONSENT WITHDRAWAL AFTER TREATMENT INITIATION	0

Table 1: Analysis Results

Classified by Virus Type

	Chronic HBV		Previous HBV		HCV		HIV	
	Rate*	**95% CI**	**Rate**	**95% CI**	**Rate**	**95% CI**	**Rate**	**95% CI**
All patients	0.6% (19/3050)	0.4%-1.0%	6.5% (197/3050)	5.6%-7.4%	2.4% (71/2990)	1.9%-3.0%	1.1% (34/3045)	0.8%-1.6%
Newly diagnosed	0.3% (8/3050)	0.1%-0.5%	5.7% (172/3050)	4.9%-6.5%	0.7% (22/2990)	0.5%-1.1%	0.1% (2/3045)	0.0%-0.2%
Proportion newly diagnosed	42.1% (8/19)	20.3%-66.5%	87.3% (172/197)	81.8%-91.6%	31.0% (22/71)	20.5%-43.1%	5.9% (2/34)	0.7%-19.7%
Previously diagnosed	0.4% (11/3050)	0.2%-0.6%	0.8% (25/3050)	0.5%-1.2%	1.6% (49/2990)	1.2%-2.2%	1.1% (32/3045)	0.7%-1.5%
By Cancer Type								
Blood/Marrow	0.5% (2/369)	0.1%-1.9%	4.3% (16/369)	2.5%-7.0%	2.5% (9/364)	1.1%-4.6%	1.9% (7/369)	0.8%-3.9%
Breast	0.4% (4/1058)	0.1%-1.0%	6.2% (66/1058)	4.9%-7.9%	0.9% (9/1046)	0.4%-1.6%	0.2% (2/1056)	0.0%-0.7%
Colorectal	0.6% (2/362)	0.1%-2.0%	5.0% (18/362)	3.0%-7.7%	2.0% (7/356)	0.8%-4.0%	1.4% (5/362)	0.4%-3.2%
Liver	6.5% (4/62)	1.8%-15.7%	8.1% (5/62)	2.7%-17.8%	17.3% (9/52)	8.2%-30.3%	0.0% (0/61)	0.0%-5.9%
GI, Other	1.3% (3/235)	0.3%-3.7%	9.4% (22/235)	6.0%-13.8%	1.3% (3/228)	0.3%-3.8%	2.1% (5/235)	0.7%-4.9%
Head & Neck	0.9% (1/111)	0.0%-4.9%	8.1% (9/111)	3.8%-14.8%	4.7% (5/106)	1.6%-10.7%	0.9% (1/111)	0.0%-4.9%
Lung	0.6% (2/356)	0.1%-2.0%	8.7% (31/356)	6.0%-12.1%	4.9% (17/347)	2.9%-7.7%	1.1% (4/356)	0.3%-2.8%
Prostate	0% (0/100)	0.0%-3.6%	12.0% (12/100)	6.4%-20.0%	3.1% (3/98)	0.6%-8.7%	1.0% (1/100)	0.0%-5.5%
Other	0.3% (1/392)	0.0%-1.4%	4.6% (18/392)	2.7%-7.2%	2.3% (9/388)	1.1%-4.4%	2.3% (9/390)	1.1%-4.3%
Missing	5		5		5		5	

* Denominator is the numer of patients with viral status established.

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)

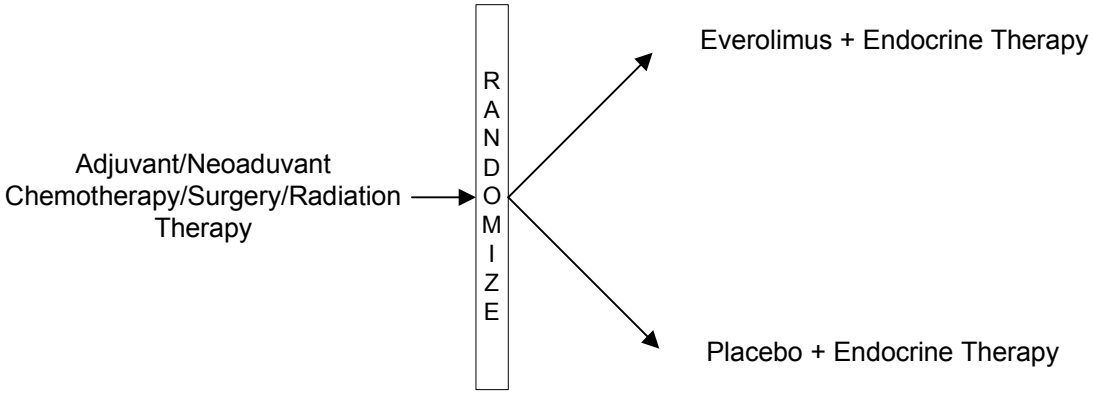
Date Activated:
09/03/2013

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

Statisticians:
W Barlow, J Miao, D Lew

Data Coordinator:
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.

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 Coordinator:
K Carvalho

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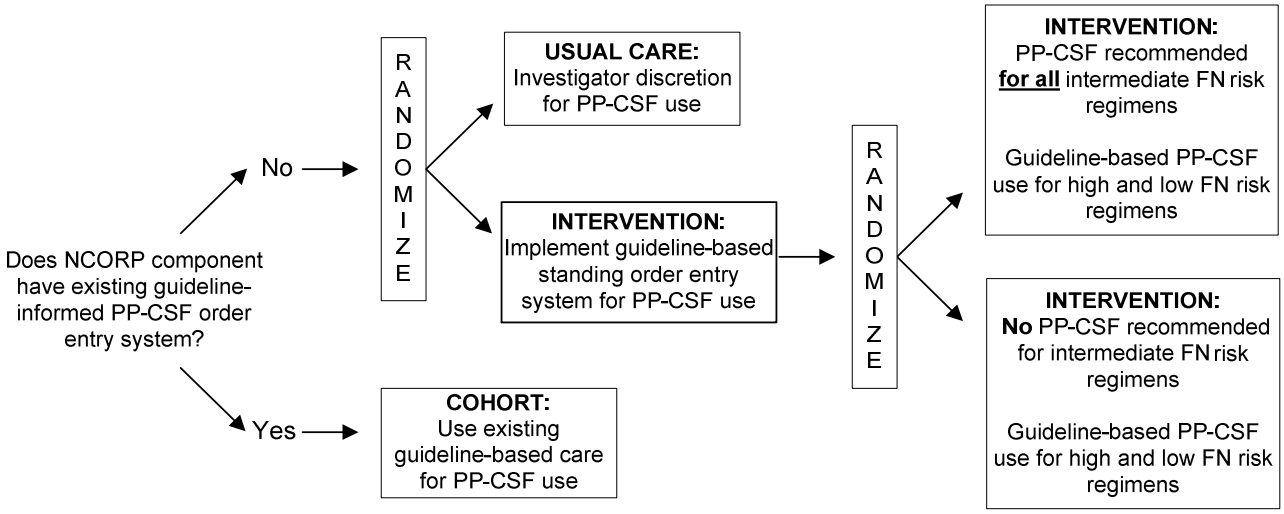


Randomization is at the NCORP component level. All patients at participating components will be subject to the PP-CSF use care as determined by component assignment (Usual Care, Intervention, or Cohort). Only consented patients registered to the study will participate in the data collection.

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 cancer diagnosis. Patients must be registered prior to or on the same day as their first cycle of chemotherapy. Patient must not have had any systemic therapy (chemotherapy or combination regimens) in the 180 days just prior to registration. Prior biologic therapy, immunotherapy, and hormonal therapy are allowed. 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 *E. 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 during their first six months after registration.

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. Complete outcome is defined as an assessment of FN after six months of follow-up after treatment commences.

Summary Statement

This study was activated on September 1, 2016, at limited institutions. As of December 31, 2018, 2,480 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 the two Intervention arms. Six of the 13 Cohort components have completed accrual.

Forty-five patients are ineligible. Of these, 15 patients planned to have concurrent radiation therapy, 13 patients had systemic therapy within 180 days of registration, seven patients were planning to have regimens not listed in Appendix 18.1, six patients began treatment prior to registration, two patients did not have lung, breast or colon cancer, and two patients had regimens listed in Section 18.1 with planned dose reductions that were non-standard regimen dosing. Six patients are not analyzable, five because they never started systemic therapy and one because they withdrew consent on the day of registration.

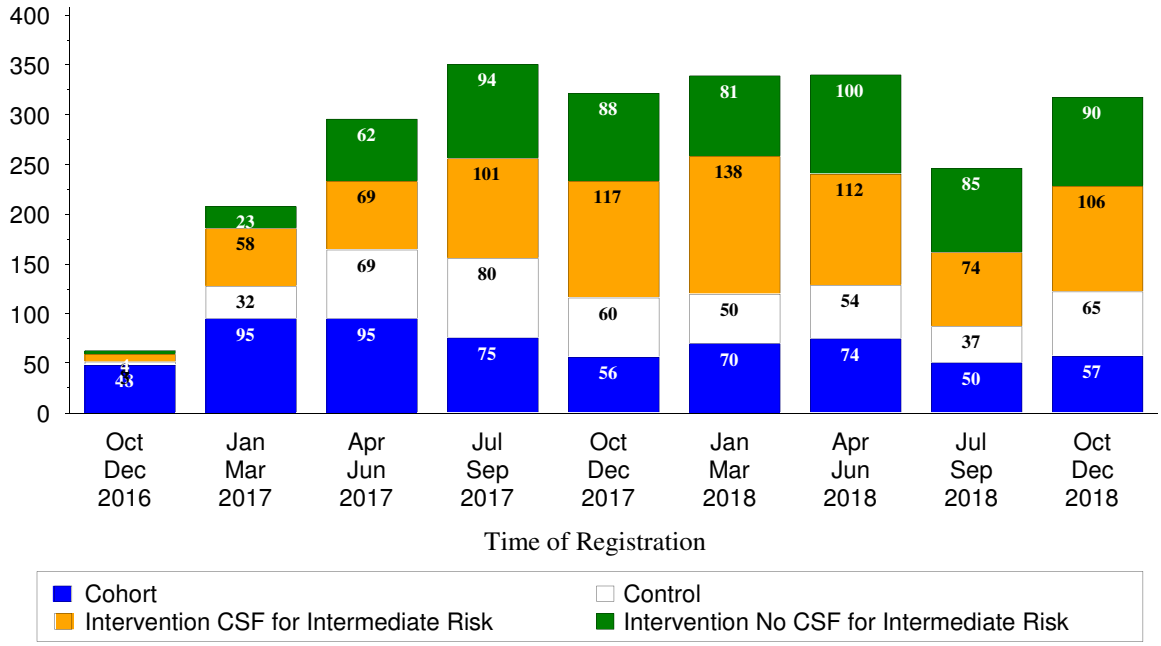
Two patients have had a major deviation, one due to not receiving treatment at the registering component and one due to changing planned treatment to one not listed in Appendix 18.1. Patients are observed and followed for 12 months, regardless of cancer therapy or PP-CSF received. A total of 1,349 patients are off treatment, most of whom completed the full 12 months of study follow up. Eleven patients who are off treatment due to refusal unrelated to adverse events have all withdrawn consent for any further follow-up.

Adverse events shown are those attributable to PP-CSF (first cycle only). A total of 1,308 patients have been assessed for adverse events across all study arms. Thirty-seven patients have had Grade 3 events across all arms with almost all related to pain (34) such as bone pain, arthralgia, myalgia, back pain, chest wall pain, and/or headache. One Cohort patient had a Grade 4 platelet count decrease and one randomized patient had a Grade 4 white blood cell decrease.

The first interim analysis will be presented to the DSMC at the Spring 2019 meeting.

Initial Registrations by 3 Month Intervals

Divisions by ARM



Time of Registration

Cohort
Control
Intervention CSF for Intermediate Risk
Intervention No CSF for Intermediate Risk

Registrations by Study Component and Study Arm

Registrations ending December 31, 2018

	Total (n=2480)	
COHORT		
Adena Regional Medical Center	19	1%
Cancer Center of Kansas	60	2%
Carle Cancer Center	60	2%
CHI Health Saint Francis	52	2%
Cox Health South	46	2%
Dayton Physicians LLC	35	1%
Greenville Memorial Hospital	61	2%
Intermountain Healthcare	22	1%
Mercy Hospital Springfield	60	2%
MultiCare Tacoma General Hosp.	48	2%
Novant Health Forsythe Med Ctr	60	2%
Spartanburg Medical Center	60	2%
West Michigan Cancer Center	37	1%
USUAL CARE		
Baptist MU-NCORP	79	3%
Christus St. Vincent Reg. CC	32	1%
LSU HSC-Shreveport	49	2%
Oncology Associates at Mercy	62	2%
Research Medical Center	3	0%
Saint Luke's Tumor Inst.	88	4%
St. John Hospital and Med Ctr	72	3%
Swedish Cancer Institute	65	3%
INTERVENTION CSF FOR INTERMEDIATE RISK		
Beaumont NCORP	5	0%
CC Specialists of C. Illinois	108	4%
Contra Costa Regional Med Ctr	20	1%
Doctors Cancer Center Manati	67	3%
Essentia Health Cancer Center	82	3%
Geisinger Medical Center	94	4%
Illinois Cancer Care-Peoria	105	4%
John H Stroger Jr Hospital	109	4%
Marshfield Clinic	105	4%
Meharry Medical College	11	0%
Presbyterian Kaseman Hospital	47	2%
Tripler Medical Center	30	1%
INTERVENTION NO CSF FOR INTERMEDIATE RISK		
Augusta University Med Ctr	52	2%
Billings Clinic Cancer Center	40	2%
Bozeman Deaconess Cancer Ctr	36	1%
Columbia U/Herbert Irving CC	77	3%
Lewis Cancer & Research	49	2%
LSU HSC-New Orleans	17	1%
Med Onc and Hematology Assoc.	69	3%
Michigan NCORP	82	3%
Queen's Medical Center	20	1%
Sanford Medical Center-Fargo	102	4%
St. Alphonsus Regional Med Ctr	19	1%
University of New Mexico CC	64	3%

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2018; Data as of February 12, 2019

	TOTAL	Cohort	Usual Care	Intervention CSF for Intermediate Risk	Intervention No CSF for Intermediate Risk
NUMBER REGISTERED	2480	620	450	783	627
INELIGIBLE	45	8	9	13	15
ELIGIBLE	2435	612	441	770	612
Analyzable, Pend. Elig.	2	0	0	2	0
Not Analyzable	6	3	1	1	1
ADVERSE EVENT ASSESSMENT					
Evaluable	1308	385	234	417	272
Not Evaluable	892	191	164	286	251
Too Early	229	33	42	66	88

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending December 31, 2018; Data as of February 12, 2019

	Cohort (n=609)		Usual Care (n=440)		Intervention CSF for Intermediate Risk (n=769)		Intervention No CSF for Intermediate Risk (n=611)	
AGE								
Median	58.8		58.6		59.2		58.7	
Minimum	25.8		29.4		18.8		27.2	
Maximum	94.8		86.1		91.5		89.7	
SEX								
Males	102	17%	89	20%	192	25%	117	19%
Females	507	83%	351	80%	577	75%	494	81%
HISPANIC								
Yes	11	2%	19	4%	138	18%	74	12%
No	597	98%	410	93%	619	80%	523	86%
Unknown	1	0%	11	2%	12	2%	14	2%
RACE								
White	537	88%	341	77%	626	81%	455	74%
Black	53	9%	74	17%	82	11%	69	11%
Asian	7	1%	11	2%	26	3%	19	3%
Pacific Islander	0	0%	1	0%	6	1%	3	0%
Native American	0	0%	0	0%	15	2%	12	2%
Multi-Racial	6	1%	0	0%	1	0%	4	1%
Unknown	6	1%	13	3%	13	2%	49	8%
FEBRILE NEUTROPENIA RISK								
Low	100	16%	90	20%	149	19%	122	20%
Intermediate	192	32%	149	34%	351	46%	212	35%
High	317	52%	201	46%	269	35%	277	45%

Treatment Summary

Classified by Cohort vs Randomized Arms
All eligible and selected ineligible patients included
Registrations ending December 31, 2018; Data as of February 12, 2019

	TOTAL	Cohort	Randomized Arms
NUMBER ON PROTOCOL TREATMENT	1080	217	863
NUMBER OFF PROTOCOL TREATMENT	1349	392	957
REASON OFF TREATMENT			
Treatment completed as planned	1211	362	849
Adverse Event or side effects	0	0	0
Refusal unrelated to adverse event	11	2	9
Progression/relapse	0	0	0
Death	120	27	93
Other - not protocol specified	0	0	0
Reason under review	7	1	6
MAJOR PROTOCOL DEVIATIONS	2	0	2
LOST TO FOLLOW-UP	0	0	0
CONSENT WITHDRAWAL AFTER TREATMENT INITIATION	11	2	9

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

Classified by Cohort vs Randomized Arms
Adverse Events Unlikely or Not Related to Treatment Excluded
All Eligible and Selected Ineligible Patients Included
Registrations ending December 31, 2018; Data as of February 12, 2019

	Cohort (n=385) Grade						Randomized Arms (n=923) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
ALT increased	385	0	0	0	0	0	922	1	0	0	0	0
AST increased	385	0	0	0	0	0	922	1	0	0	0	0
Anorexia	385	0	0	0	0	0	922	0	1	0	0	0
Arthralgia	341	33	9	2	0	0	796	81	39	7	0	0
Back pain	380	2	2	1	0	0	914	7	2	0	0	0
Blood/lymph disorder-Other	385	0	0	0	0	0	922	1	0	0	0	0
Bone pain	295	51	34	5	0	0	647	148	105	23	0	0
Chest wall pain	383	1	0	1	0	0	923	0	0	0	0	0
Constipation	384	1	0	0	0	0	922	0	1	0	0	0
Diarrhea	385	0	0	0	0	0	915	6	2	0	0	0
Dizziness	384	1	0	0	0	0	923	0	0	0	0	0
Dry skin	385	0	0	0	0	0	922	1	0	0	0	0
Edema trunk	384	1	0	0	0	0	923	0	0	0	0	0
Fatigue	381	2	2	0	0	0	915	7	1	0	0	0
Febrile neutropenia	385	0	0	0	0	0	922	0	0	1	0	0
Fever	384	1	0	0	0	0	922	1	0	0	0	0
Flu like symptoms	385	0	0	0	0	0	919	2	2	0	0	0
Flushing	383	2	0	0	0	0	923	0	0	0	0	0
Headache	382	2	0	1	0	0	914	4	4	1	0	0
Hot flashes	384	0	1	0	0	0	923	0	0	0	0	0
Insomnia	384	0	0	1	0	0	921	2	0	0	0	0
Leukocytosis	385	0	0	0	0	0	922	0	0	1	0	0
Mucosal infection	385	0	0	0	0	0	922	0	1	0	0	0
Mucositis oral	378	5	2	0	0	0	882	29	11	1	0	0
Myalgia	378	6	0	1	0	0	907	13	3	0	0	0
Myositis	380	2	3	0	0	0	897	14	11	1	0	0
Nausea	384	1	0	0	0	0	919	0	4	0	0	0
Neutrophil count decreased	385	0	0	0	0	0	921	1	0	1	0	0
Non-cardiac chest pain	385	0	0	0	0	0	922	0	1	0	0	0
Pain	384	1	0	0	0	0	922	0	1	0	0	0
Pain in extremity	384	0	1	0	0	0	922	1	0	0	0	0
Peripheral sensory neuropathy	385	0	0	0	0	0	922	0	1	0	0	0
Platelet count decreased	384	0	0	0	1	0	923	0	0	0	0	0
Pruritus	383	1	1	0	0	0	922	1	0	0	0	0
Rash maculo-papular	383	2	0	0	0	0	923	0	0	0	0	0
Skin induration	385	0	0	0	0	0	922	1	0	0	0	0
Skin/subq tissue ds-Other	384	1	0	0	0	0	923	0	0	0	0	0
Sore throat	385	0	0	0	0	0	922	0	1	0	0	0
Vomiting	384	1	0	0	0	0	923	0	0	0	0	0
White blood cell decreased	385	0	0	0	0	0	922	0	0	0	1	0
MAX. GRADE ANY ADVERSE EVENT	254	76	47	7	1	0	545	211	136	30	1	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

Study Chairs:
V Shankaran, S Ramsey

Statisticians:
J Unger, A Darke

Data Coordinator:
D Liggett

Date Activated:
05/13/2016

Date Closed:
02/01/2019

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.

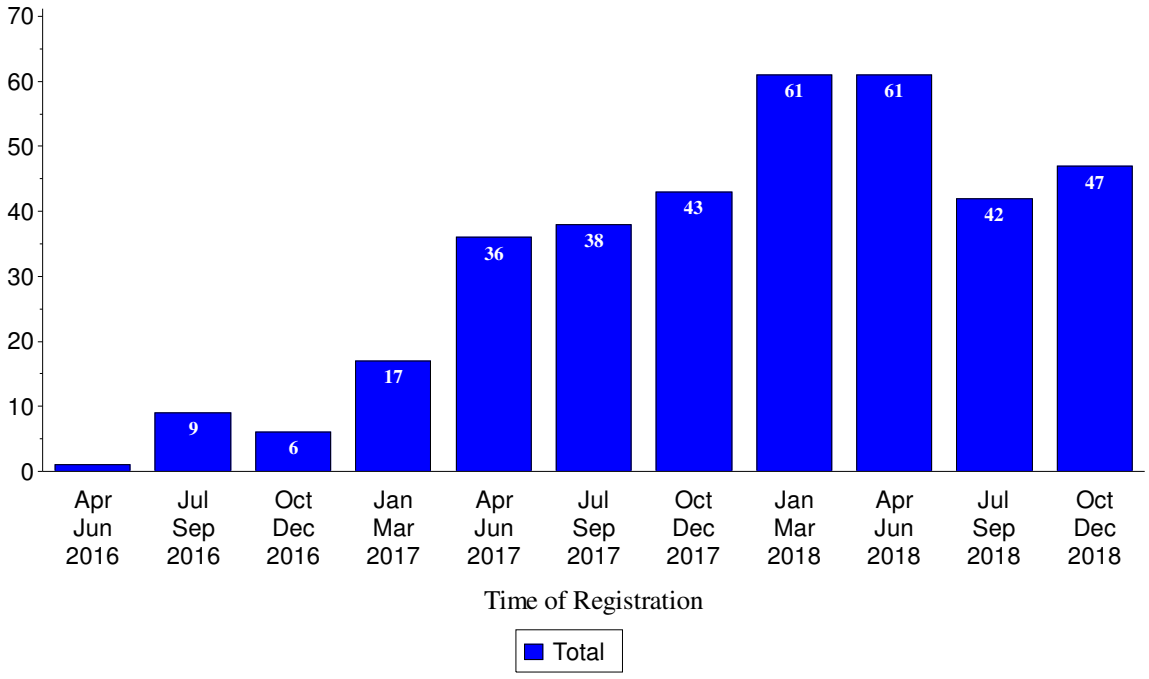
Accrual Goals
A total of 374 patients will be enrolled to achieve 320 eligible patients.

Summary Statement
S1417CD is restricted to NCORP components and subcomponents and does not use the Central IRB (CIRB). This study was activated on May 13, 2016. As of December 31, 2018, 361 patients have been accrued.

Three patients are ineligible due to: initiating treatment for metastatic colorectal cancer more than 60 days prior to registration (2 patients) and diagnosis with metastatic colorectal cancer more than 120 days prior to registration (1). Five additional patients are not analyzable due to withdrawal of consent prior to completing the baseline questionnaire.

One hundred and ninety-seven patients are off protocol treatment. One patient had a major protocol deviation due to not beginning treatment within 90 days after registration. Six patients withdrew consent to participate after completing the baseline questionnaire. Credit reports have been obtained on 290 of the 361 patients registered as of December 31, 2018. This study closed to accrual on February 1, 2019, after enrolling 380 patients and reaching its accrual goal. Only data for patients accrued through December 31, 2018 are shown in the tables below.

Registration by 3 Month Intervals



Registration by Institution

Institutions	Total Reg	Institutions	Total Reg
Kaiser Perm NCORP	40	New Mexico MU-NCORP	5
Heartland NCORP	37	Dayton NCORP	4
Columbus NCORP	25	Northwest NCORP	3
CRC West MI NCORP	20	Ozarks NCORP	3
Greenville NCORP	20	Bay Area NCORP	2
CORA NCORP	18	Wisconsin NCORP	2
Southeast COR NCORP	14	Carle CC NCORP	1
Gulf South MU-NCORP	12	Kansas City NCORP	1
Michigan CRC NCORP	11	Montana NCORP	1
Columbia MU-NCORP	10	Nevada CRF NCORP	1
Georgia NCORP	9	ECOG-ACRIN	59
PCRC NCORP	8	ALLIANCE	21
Wichita NCORP	8	NRG	19
Hawaii MU-NCORP	7	**Total (27 Institutions)**	**361**

Registration, Eligibility, and Evaluability

Data as of February 25, 2019

	Observation
NUMBER REGISTERED	361
INELIGIBLE	3
ELIGIBLE	358
Not Analyzable	5

Patient Characteristics

All eligible and selected ineligible patients included
Data as of February 25, 2019

	Observation (n=353)	
AGE		
Median	60.1	
Minimum	21.1	
Maximum	89.3	
SEX		
Males	214	61%
Females	139	39%
HISPANIC		
Yes	19	5%
No	323	92%
Unknown	11	3%
RACE		
White	276	78%
Black	47	13%
Asian	12	3%
Pacific Islander	2	1%
Native American	1	0%
Unknown	15	4%

Treatment Summary

All eligible and selected ineligible patients included
Data as of February 25, 2019

	Total
NUMBER ON PROTOCOL TREATMENT	156
NUMBER OFF PROTOCOL TREATMENT	197
REASON OFF TREATMENT	
Treatment completed as planned	79
Adverse Event or side effects	0
Refusal unrelated to adverse event	8
Progression/relapse	0
Death	47
Other - not protocol specified	3
Reason under review	60
MAJOR PROTOCOL DEVIATIONS	1
LOST TO FOLLOW-UP	0
CONSENT WITHDRAWAL AFTER TREATMENT INITIATION	6

S1703 Phase III

Coordinating Group: SWOG

Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) Versus Usual Care in Patients with Metastatic Hormone Receptor Positive Breast Cancer

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Participants:
SWOG, CTSU

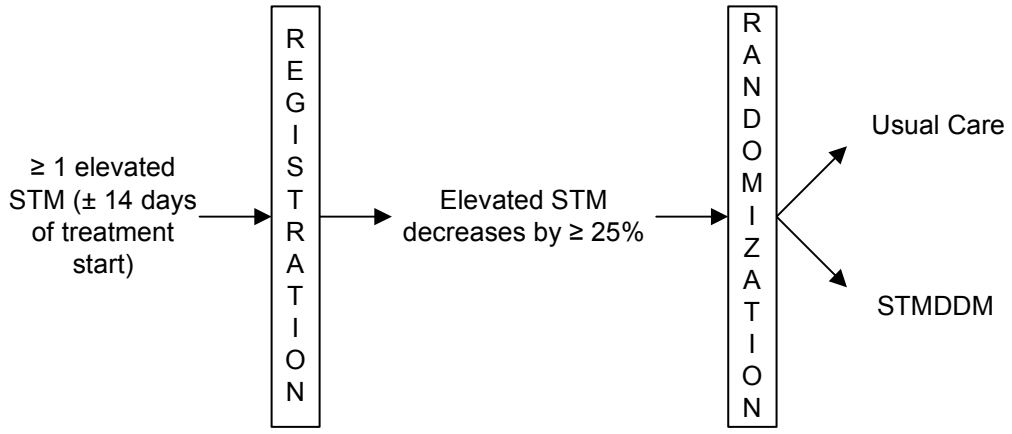
Date Activated:
07/16/2018

Study Chairs:
M Accordino, D Hershman

Statisticians:
J Unger, A Moseley

Data Coordinator:
D Liggett

SCHEMA



Objectives

To assess whether patients with HER-2 negative, hormone receptor positive, metastatic breast cancer who are monitored with serum tumor marker directed disease monitoring (STMDDM) have non-inferior overall survival compared to patients monitored with usual care.

To compare cumulative direct healthcare costs through 48 weeks among patients monitored with STMDDM versus those monitored with usual care in this patient population.

To assess whether the patient-reported outcomes (PROs) of anxiety and quality of life (QOL) are different among patients who are monitored with

STMDDM compared with patients who are monitored with usual care in this patient population.

To assess modality and frequency of disease monitoring testing in the usual care cohort.

To assess the association of PROs and patient preferences for disease monitoring testing.

To evaluate predictors of physician preferences for disease monitoring testing.

Patient Population

Patients must have a diagnosis of hormone receptor positive (ER+ and/or PR+), HER-2 negative, metastatic (M1) breast cancer and either be receiving or planning to receive first-line systemic treatment for metastatic disease. Patients must have been tested for the breast cancer specific serum tumor markers (STMs) CA 15-3, CA 27.29, and CEA, and at least one of these STMs must be elevated. To be randomized, these three markers must be retested within the timeframe specified in the protocol, and at least one of the previously elevated markers must have decreased by at least 25%. Patients must not have known brain metastases.

Patients must not have received prior systemic therapy for metastatic breast cancer except for their current regimen. Patients must have systemic radiographic imaging prior to initiation of systemic therapy and prior to registration. Patients must be willing to obtain disease monitoring (imaging and/or STM measurements) at their current center for the duration of the study. Patients must not be enrolled currently or plan to participate in a first-line treatment trial for metastatic breast cancer with a defined monitoring schedule.

Patients must not have known cirrhosis, untreated B12 deficiency, thalassemia, or sickle cell anemia.

Patients who are able to complete questionnaires in English or Spanish must participate in the PRO assessments.

Stratification/Descriptive Factors

Patient randomization will be stratified by disease type: bone only disease vs any visceral disease.

Accrual Goals

The accrual goal is 1,320 patients to achieve 1,056 randomized eligible patients (528 per arm).

Summary Statement

The study activated on July 16, 2018. As of December 31, 2018, nine patients have registered to Step 1 (Initial Registration), all of whom are eligible. Four of these patients will not register to Step 2 (Randomization) for the following reasons: progression of disease (2) and previously elevated STM(s) did not decrease by at least 25% (2). Three additional patients have not reached the end of the 56-112 day window after starting first line treatment for metastatic disease and therefore could still be randomized.

Two patients have been randomized: one to the STMDDM arm and one to the Usual Care arm. Both patients are eligible and remain on protocol-specified disease monitoring.

Registration by Institution

Initial Registration

Registrations ending December 31, 2018

Institutions	Total Reg
Heartland NCORP	2
Michigan CRC NCORP	2
Columbia MU-NCORP	1
Greenville NCORP	1
Lahey Hosp & Med Ctr	1
PCRC NCORP	1
ALLIANCE	1
Total (7 Institutions)	**9**

Patient Characteristics

Initial Registration

Registrations ending December 31, 2018; Data as of February 6, 2019

	Screening (n=9)	
AGE		
Median	68.5	
Minimum	38.9	
Maximum	90.7	
SEX		
Females	9	100%

Registration by Institution

Randomization

Registrations ending December 31, 2018

Institutions	Total Reg
Columbia MU-NCORP	1
Heartland NCORP	1
Total (2 Institutions)	**2**