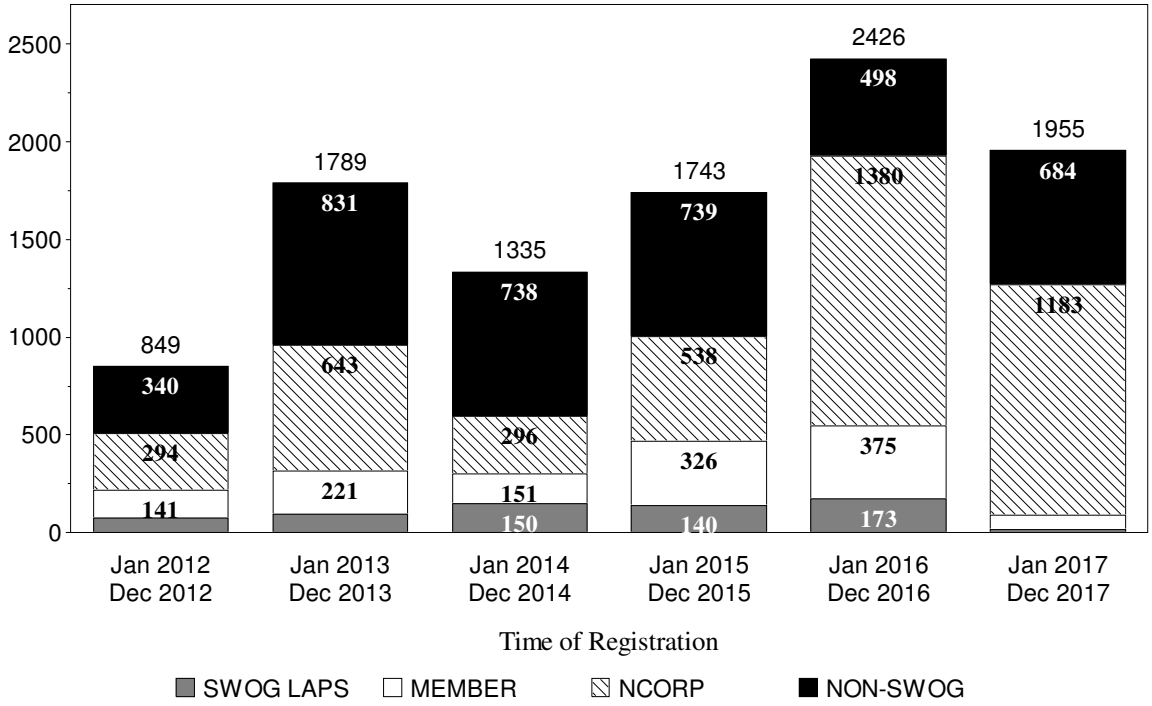
CANCER CARE DELIVERY COMMITTEE

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

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	Jul 2017 Dec 2017	Jan 2017 Jun 2017	Jul 2016 Dec 2016	All Patients
S1007 Breast,Adj,N1,Endocrine+/-Chemo				
Randomization				
Chemo and Endocrine Therapy	67	134	137	2,547
Endocrine Therapy Alone	68	142	137	2,536
	135	276	274	5,083
S1204 Prevalence HIV,HBV,HCV+Cost Eff				
Registration				
HIV, HBV, HCV Prevalence	0	229	706	3,092
S1415CD TrACER CSF Standing Order Intervention for FN				
Registration				
Site assigned to Cohort	131	190	48	369
Site randomized: Control	140	101	3	244
SiteRand Int Risk: CSF	218	127	8	353
SiteRand Int Risk: No CSF	182	85	4	271
	671	503	63	1,237
S1417CD Colorectal, Cost Cohort Study				
Registration				
Observation	81	53	15	150
A011104 Preoperative Breast MRI*				
Total Registrations	4	3	2	12

* 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 July 2016 - December 2017

	SWOG Champion	Date Activated	Date Closed	Total Accrued
A011104 Preoperative Breast MRI		02/21/14		200
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, CSTU (Supported by NRG, Alliance, ECOG-ACRIN, CCTG, GEICAM and 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

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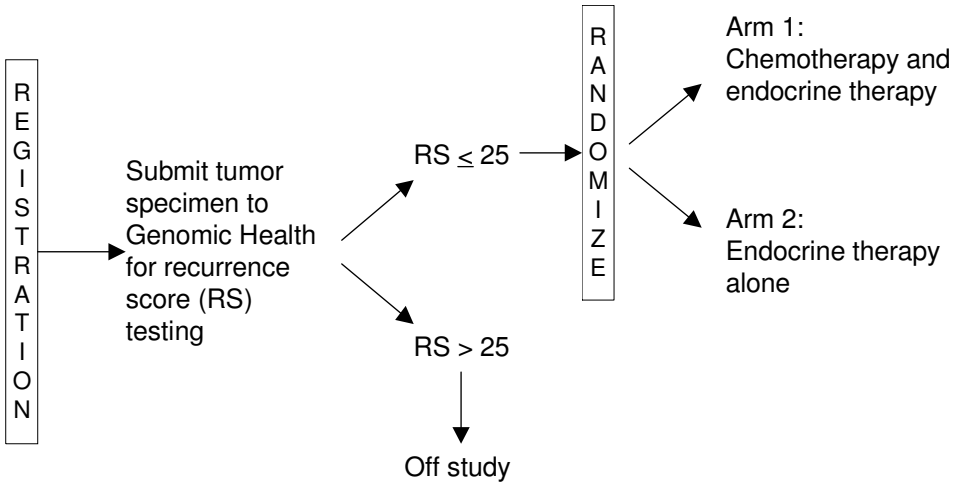

Objectives

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.

S1207 Phase III

Coordinating Groups: SWOG and NRG

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

e3 Breast Cancer Study - evaluating everolimus with endocrine therapy

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Participants:
SWOG, NRG, CTSU (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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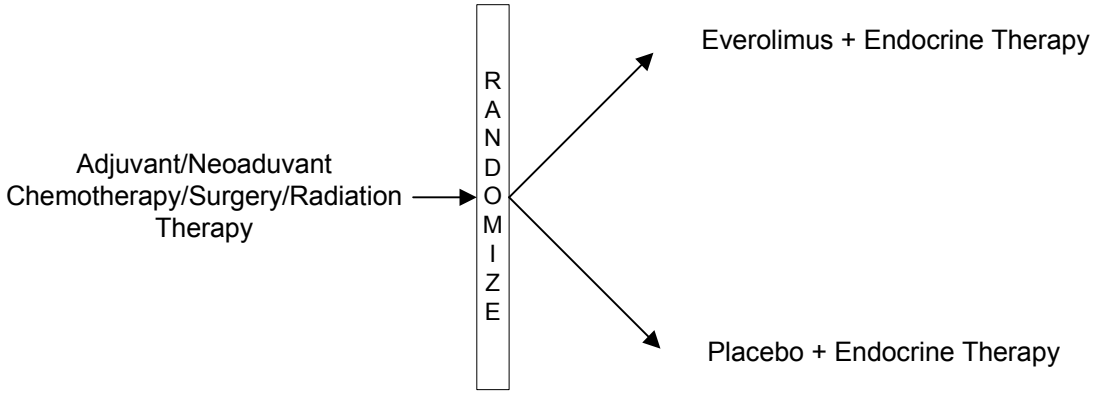

Objectives

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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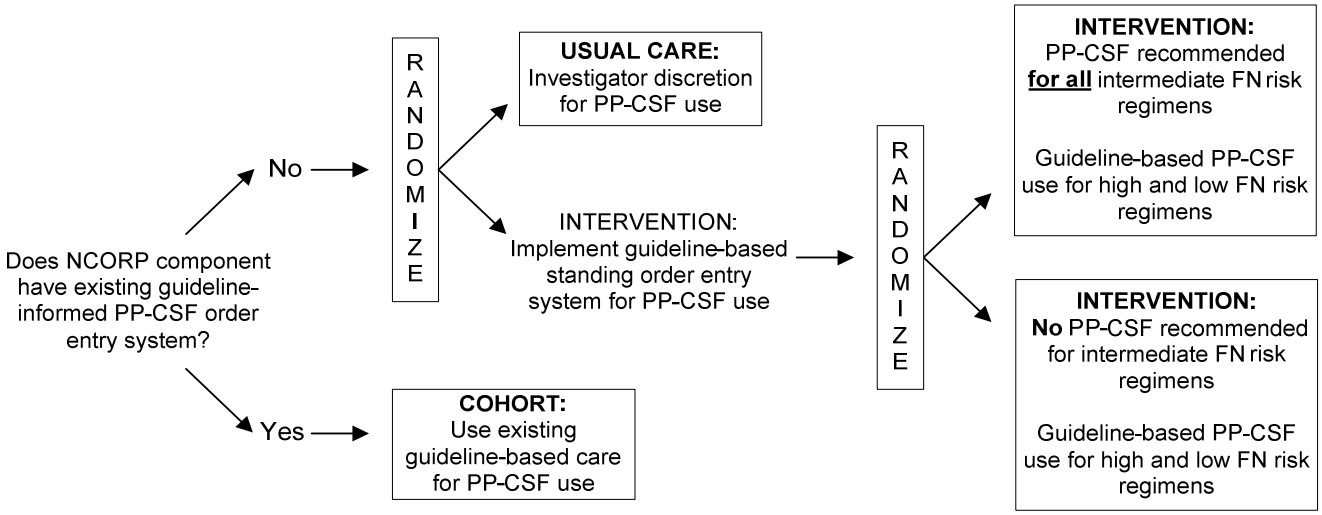


Randomization is at the NCORP component level. All patients at participating components will be subject to the PP-CSF use care as determined by component assignment (Usual Care, Intervention, or Cohort). Only consented patients registered to the study will participate in the data collection.

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 chemotherapy. Prior systemic therapy (chemotherapy, immunotherapy, biologic therapy, or combination regimens) must have been completed at least 180 days 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 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 during their first 6 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, 2017, 1237 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. All Intervention sites have completed updating their standing order systems and are open to accrual, though one site opened only recently and has not accrued patients yet. All of the Usual Care and Cohort components are open.

Twenty-five patients are ineligible. Of these, eight patients planned to have concurrent radiation therapy, six patients were to have regimens not listed in Appendix 18.1, five patients had systemic therapy within 180 days of registration, two 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. Four patients are not analyzable, three because they never started systemic therapy and one because they withdrew consent on the day of registration.

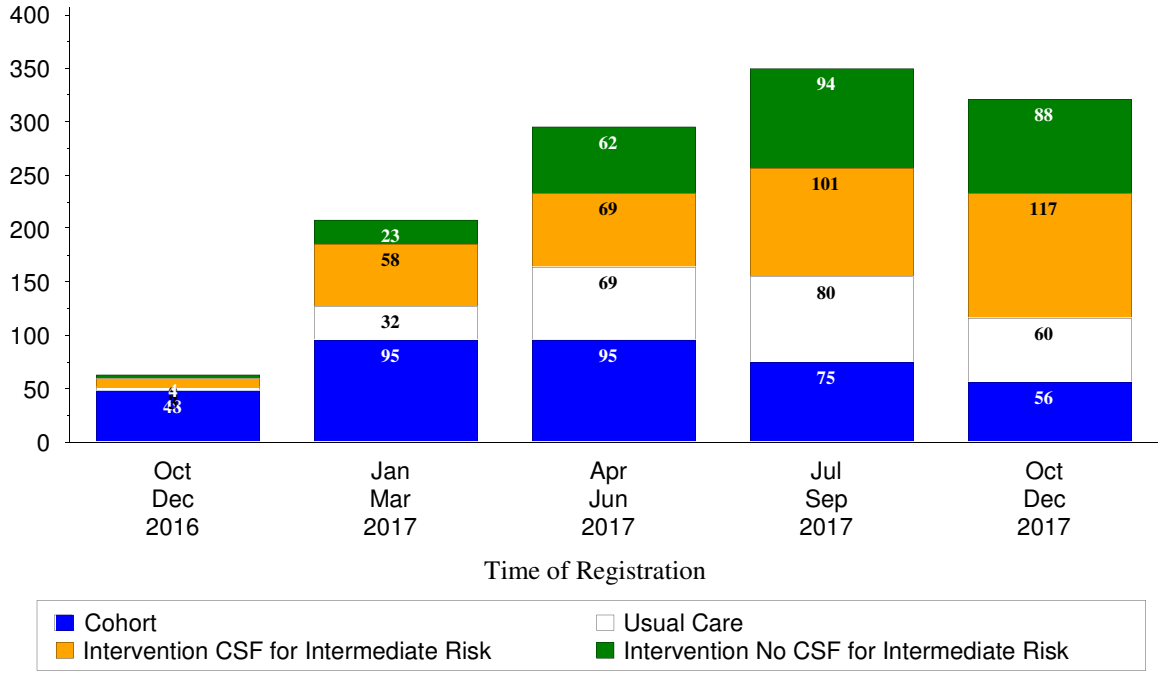
One patient has had a major deviation due to not receiving treatment at the registering component. One hundred and twenty-three patients are off treatment.

Adverse events shown are those attributable to PP-CSF (first cycle only). Among 215 patients who have had adverse events assessed in the Cohort group, two patients had Grade 3 bone pain, one of whom also had Grade 3 arthralgia, and one patient had Grade 3 back pain and chest wall pain. Among 115 patients who have had adverse events assessed in the Usual Care group, two patients had Grade 3 bone pain, one patient had Grade 3 bone pain and arthralgia, and one patient had Grade 3 non-cardiac chest pain. Among 168 patients who have had adverse events assessed in the Intervention CSF for Intermediate Risk group, four patients had Grade 3 bone pain, one patient had Grade 3 rash acneiform, one patient had Grade 3 myalgia, and one patient had Grade 3 neutrophil count decrease. Among 125 patients who have had adverse events assessed in the Intervention No CSF for Intermediate Risk group, five patients had Grade 3 bone pain, one of whom also had Grade 3 arthralgia, and two patients had Grade 3arthralgia.

A total of 266 patients in the intermediate group have been accrued at intervention clinics. The first interim analysis requires 360 intermediate patients at intervention clinics with 6 months of follow-up to assess the primary outcome. Therefore, the first interim analysis is not likely to be presented until the Spring 2019 DSMC meeting.

Revision #4, distributed on December 15, 2017, clarified eligibility and form submission requirements and includes updated regimen lists in Section 18.1.

Initial Registrations By 3 Month Intervals



Registrations by Study Component and Study Arm

Registrations ending December 31, 2017; Data as of February 2, 2018

	Total (n=1237)	
COHORT		
Adena Regional Medical Center	7	1%
Cancer Center of Kansas	59	5%
Carle Cancer Center	36	3%
CHI Health Saint Francis	13	1%
Cox Health South	27	2%
Dayton Physicians LLC	7	1%
Greenville Memorial Hospital	54	4%
Mercy Hospital Springfield	60	5%
MultiCare Tacoma General Hosp.	27	2%
Novant Health Forsythe Med Ctr	60	5%
Spartanburg Medical Center	17	1%
West Michigan Cancer Center	2	0%
USUAL CARE		
Baptist MU-NCORP	33	3%
Christus St. Vincent Reg. CC	16	1%
LSU HSC-Shreveport	24	2%
Oncology Associates at Mercy	42	3%
Saint Luke's Tumor Inst.	80	6%
St. John Hospital and Med Ctr	23	2%
Swedish Cancer Institute	26	2%
INTERVENTION CSF FOR INTERMEDIATE RISK		
Beaumont NCORP	1	0%
CC Specialists of C. Illinois	71	6%
Contra Costa Regional Med Ctr	11	1%
Doctors Cancer Center Manati	4	0%
Essentia Health Cancer Center	27	2%
Geisinger Medical Center	46	4%
Illinois Cancer Care-Peoria	88	7%
John H Stroger Jr Hospital	49	4%
Marshfield Clinic	24	2%
Presbyterian Kaseman Hospital	19	2%
Tripler Medical Center	13	1%
INTERVENTION NO CSF FOR INTERMEDIATE RISK		
Augusta University Med Ctr	1	0%
Billings Clinic Cancer Center	14	1%
Bozeman Deaconess Cancer Ctr	20	2%
Columbia U/Herbert Irving CC	61	5%
Lewis Cancer & Research	14	1%
LSU HSC-New Orleans	8	1%
Med Onc and Hematology Assoc.	25	2%
Michigan NCORP	18	1%
Queen's Medical Center	12	1%
Sanford Medical Center-Fargo	71	6%
St. Alphonsus Regional Med Ctr	3	0%
University of New Mexico CC	24	2%

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2017; Data as of February 2, 2018

	TOTAL	Cohort	Usual Care	Intervention CSF for Intermediate Risk	Intervention No CSF for Intermediate Risk
NUMBER REGISTERED	1237	369	244	353	271
INELIGIBLE	25	7	5	10	3
ELIGIBLE	1212	362	239	343	268
Analyzable, Pend. Elig.	1	1	0	0	0
Not Analyzable	4	3	1	0	0

Patient Characteristics

All Eligible and Analyzable Patients

Registrations ending December 31, 2017; Data as of February 2, 2018

	Cohort (n=359)		Usual Care (n=238)		Intervention CSF for Intermediate Risk (n=343)		Intervention No CSF for Intermediate Risk (n=268)	
AGE								
Median	59.2		58.9		59.3		57.8	
Minimum	25.8		29.9		22.5		27.2	
Maximum	91.2		86.2		88.4		83.8	
SEX								
Males	65	18%	47	20%	85	25%	35	13%
Females	294	82%	191	80%	258	75%	233	87%
HISPANIC								
Yes	7	2%	11	5%	36	10%	41	15%
No	352	98%	222	93%	298	87%	220	82%
Unknown	0	0%	5	2%	9	3%	7	3%
RACE								
White	318	89%	192	81%	272	79%	192	72%
Black	31	9%	31	13%	41	12%	23	9%
Asian	5	1%	6	3%	16	5%	12	4%
Pacific Islander	0	0%	1	0%	4	1%	2	1%
Native American	0	0%	0	0%	5	1%	7	3%
Multi-Racial	3	1%	0	0%	0	0%	2	1%
Unknown	2	1%	8	3%	5	1%	30	11%
FEBRILE NEUTROPENIA RISK								
Low	56	16%	50	21%	81	24%	56	21%
Intermediate	147	41%	94	39%	175	51%	91	34%
High	156	43%	94	39%	87	25%	121	45%

Treatment Summary

All Eligible and Analyzable Patients

Registrations ending December 31, 2017; Data as of February 2, 2018

	TOTAL	Cohort	Usual Care	Intervention CSF for Intermediate Risk	Intervention No CSF for Intermediate Risk
NUMBER ON PROTOCOL TREATMENT	1085	289	230	309	257
NUMBER OFF PROTOCOL TREATMENT	123	70	8	34	11
REASON OFF TREATMENT					
Treatment completed as planned	85	57	5	17	6
Adverse Event or side effects	0	0	0	0	0
Refusal unrelated to adverse event	4	0	1	2	1
Progression/relapse	0	0	0	0	0
Death	32	12	2	14	4
Other - not protocol specified	0	0	0	0	0
Reason under review	2	1	0	1	0
MAJOR PROTOCOL DEVIATIONS	1	0	0	0	1

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

Adverse Events Unlikely or Not Related to Treatment Excluded
All Eligible and Analyzable Patients with Toxicity Assessment
Registrations ending December 31, 2017; Data as of February 2, 2018

	Cohort (n=215) Grade						Usual Care (n=115) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Alkaline phosphatase increased	214	1	0	0	0	0	115	0	0	0	0	0
Anorexia	215	0	0	0	0	0	114	0	1	0	0	0
Arthralgia	180	28	6	1	0	0	100	6	8	1	0	0
Back pain	212	0	2	1	0	0	112	2	1	0	0	0
Bone pain	168	34	11	2	0	0	80	12	20	3	0	0
Chest wall pain	213	1	0	1	0	0	115	0	0	0	0	0
Chills	215	0	0	0	0	0	115	0	0	0	0	0
Constipation	215	0	0	0	0	0	115	0	0	0	0	0
Diarrhea	215	0	0	0	0	0	115	0	0	0	0	0
Edema trunk	214	1	0	0	0	0	115	0	0	0	0	0
Fatigue	213	2	0	0	0	0	112	2	1	0	0	0
Flu like symptoms	215	0	0	0	0	0	115	0	0	0	0	0
Flushing	214	1	0	0	0	0	115	0	0	0	0	0
Headache	214	1	0	0	0	0	114	1	0	0	0	0
Laryngeal inflammation	215	0	0	0	0	0	114	0	1	0	0	0
Mucositis oral	209	5	1	0	0	0	109	3	3	0	0	0
Myalgia	211	4	0	0	0	0	114	0	1	0	0	0
Myositis	213	0	2	0	0	0	114	0	1	0	0	0
Nausea	215	0	0	0	0	0	114	0	1	0	0	0
Neutrophil count decreased	215	0	0	0	0	0	115	0	0	0	0	0
Non-cardiac chest pain	215	0	0	0	0	0	113	1	0	1	0	0
Pain	215	0	0	0	0	0	115	0	0	0	0	0
Pain in extremity	215	0	0	0	0	0	115	0	0	0	0	0
Rash acneiform	215	0	0	0	0	0	115	0	0	0	0	0
Skin/subq tissue ds-Other	214	1	0	0	0	0	115	0	0	0	0	0
Upper respiratory infection	214	0	1	0	0	0	115	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	142	50	20	3	0	0	66	20	25	4	0	0

	Intervention CSF for Intermediate Risk (n=168) Grade						Intervention No CSF for Intermediate Risk (n=125) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Alkaline phosphatase increased	168	0	0	0	0	0	125	0	0	0	0	0
Anorexia	168	0	0	0	0	0	124	1	0	0	0	0
Arthralgia	154	10	4	0	0	0	102	12	8	3	0	0
Back pain	166	1	1	0	0	0	125	0	0	0	0	0
Bone pain	117	30	17	4	0	0	90	18	12	5	0	0
Chest wall pain	168	0	0	0	0	0	125	0	0	0	0	0
Chills	168	0	0	0	0	0	124	1	0	0	0	0
Constipation	167	0	1	0	0	0	125	0	0	0	0	0
Diarrhea	165	3	0	0	0	0	125	0	0	0	0	0
Edema trunk	168	0	0	0	0	0	125	0	0	0	0	0
Fatigue	166	2	0	0	0	0	123	2	0	0	0	0
Flu like symptoms	167	0	1	0	0	0	125	0	0	0	0	0
Flushing	168	0	0	0	0	0	125	0	0	0	0	0
Headache	167	1	0	0	0	0	124	0	1	0	0	0
Laryngeal inflammation	168	0	0	0	0	0	125	0	0	0	0	0
Mucositis oral	161	6	1	0	0	0	122	1	2	0	0	0
Myalgia	166	1	0	1	0	0	124	1	0	0	0	0
Myositis	162	5	1	0	0	0	115	4	6	0	0	0
Nausea	167	0	1	0	0	0	122	3	0	0	0	0
Neutrophil count decreased	167	0	0	1	0	0	125	0	0	0	0	0
Non-cardiac chest pain	167	0	1	0	0	0	125	0	0	0	0	0
Pain	167	0	1	0	0	0	125	0	0	0	0	0
Pain in extremity	168	0	0	0	0	0	124	1	0	0	0	0
Rash acneiform	167	0	0	1	0	0	125	0	0	0	0	0
Skin/subq tissue ds-Other	168	0	0	0	0	0	125	0	0	0	0	0
Upper respiratory infection	168	0	0	0	0	0	125	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	101	36	24	7	0	0	71	32	15	7	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.

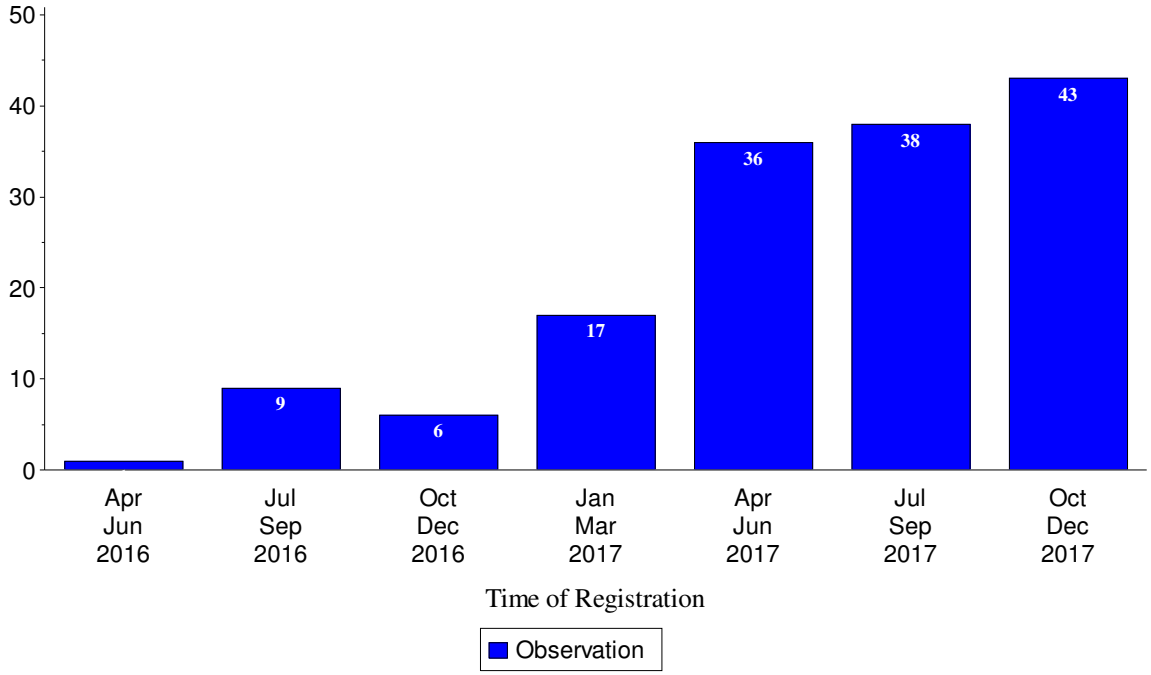
Patients may have received prior chemotherapy, biologic therapy, radiation therapy, or surgery for non-metastatic colorectal cancer.

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 December 31, 2017, 150 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 December 31, 2017

Institutions	Total Reg	Institutions	Total Reg
Kaiser Perm NCORP	19	Georgia NCORP	3
Heartland NCORP	15	New Mexico MU-NCORP	3
Columbus NCORP	13	Northwest NCORP	3
CRC West MI NCORP	11	Hawaii MU-NCORP	2
Columbia MU-NCORP	9	Montana NCORP	1
Greenville NCORP	9	Nevada CRF NCORP	1
CORA NCORP	7	PCRC NCORP	1
Southeast COR NCORP	6	ECOG-ACRIN	20
Michigan CRC NCORP	4	ALLIANCE	9
Wichita NCORP	4	NRG	7
Dayton NCORP	3	**Total (21 Institutions)**	**150**

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2017; Data as of February 6, 2018

	Observation
NUMBER REGISTERED	150
INELIGIBLE	1
ELIGIBLE	149
Analyzable, Pend. Elig.	44

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending December 31, 2017; Data as of February 6, 2018

	Observation (n=149)	
AGE		
Median	60.3	
Minimum	21.1	
Maximum	89.4	
SEX		
Males	90	60%
Females	59	40%
HISPANIC		
Yes	9	6%
No	135	91%
Unknown	5	3%
RACE		
White	110	74%
Black	21	14%
Asian	7	5%
Pacific Islander	1	1%
Native American	1	1%
Unknown	9	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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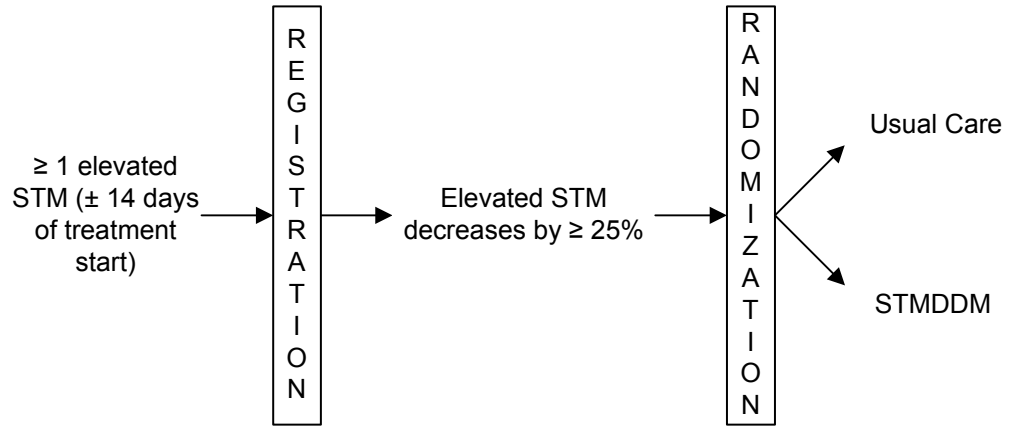
Participants:
SWOG, CTSU

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 received prior systemic therapy for metastatic breast cancer except for their current regimen. 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 who are able to complete questionnaires in English or Spanish must participate in the patient-reported outcome (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).