CANCER CARE DELIVERY COMMITTEE

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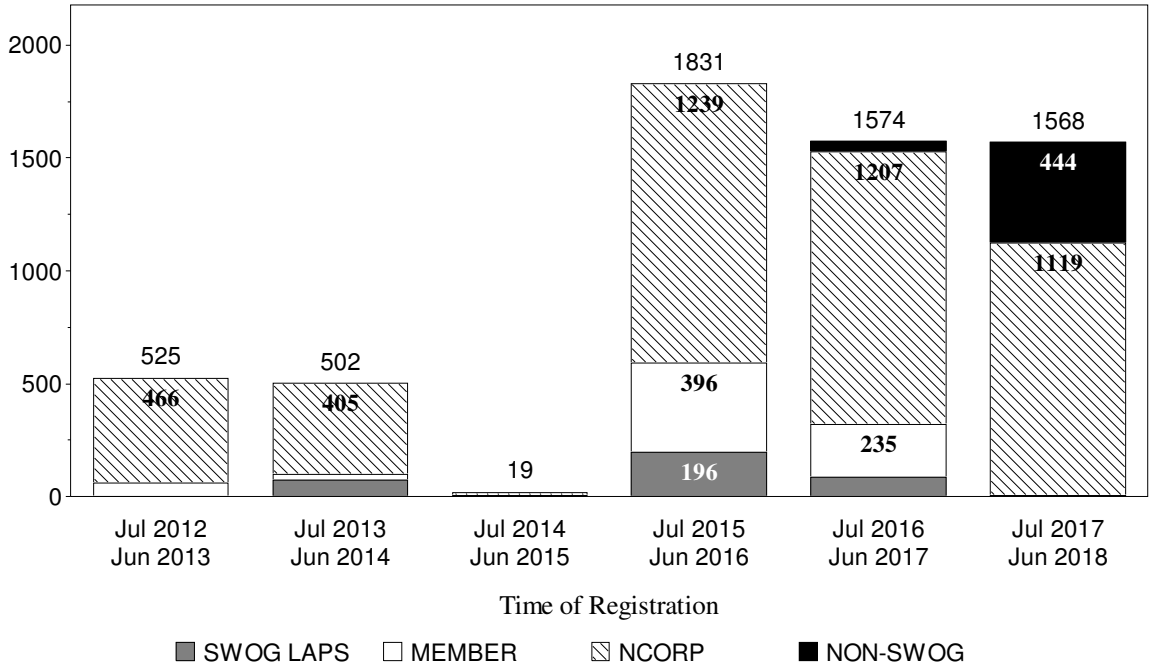
Patient Registrations to Studies

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

	Jan 2018 Jun 2018	Jul 2017 Dec 2017	Jan 2017 Jun 2017	All Patients
S1007 Breast,Adj,N1,Endocrine+/-Chemo*				
Randomization				
Chemo and Endocrine Therapy	0	67	134	2,547
Endocrine Therapy Alone	0	68	142	2,536
	0	135	276	5,083
S1204 Prevalence HIV,HBV,HCV+Cost Eff				
Registration				
HIV, HBV, HCV Prevalence	0	0	229	3,092
S1415CD TrACER CSF Standing Order Intervention for FN				
Registration				
Site assigned to Cohort	144	131	190	513
Site randomized: Control	104	140	101	348
SiteRand Int Risk: CSF	250	218	127	603
SiteRand Int Risk: No CSF	181	182	85	452
	679	671	503	1,916
S1417CD Colorectal, Cost Cohort Study				
Registration				
Observation	122	81	53	272

* Studies with Cancer Care Delivery as a secondary committee

Non-SWOG Studies with SWOG-Credited Registrations

CANCER CARE DELIVERY COMMITTEE

Studies with Accrual from January 2017 - June 2018

	SWOG Champion	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*		2	4	14	233
A191402C PROS, Testing Decision Aids for Minority Men Date Activated: 07/14/17 *No Progress Report Available*		5	4	10	81

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 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

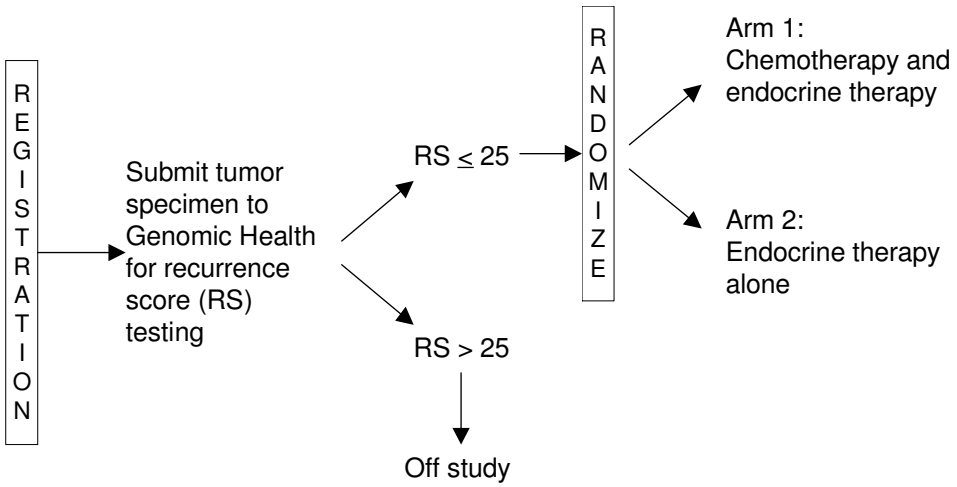
Data Coordinators:
L Kaye, J Scurlock

Date Activated:
01/15/2011

Date Closed*:
11/01/2017

* 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.

S1105 Phase III

Randomized Trial of Text-Messaging Intervention to Reduce Early Discontinuation of Adjuvant Aromatase Inhibitor Therapy in Women with Early Stage Breast Cancer

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Study Chairs:
A Neugut, D Hershman

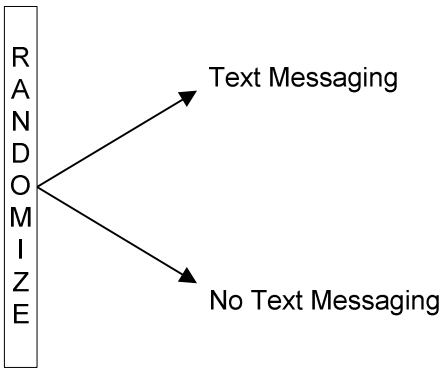
Statisticians:
J Unger, K Arnold

Data Coordinator:
M Yee

Date Activated:
03/27/2012

Date Closed:
09/15/2013

SCHEMA



Objectives

To determine the efficacy of a reminder message, sent by text message to mobile phones twice weekly, to improve adherence to adjuvant aromatase inhibitor (AI) therapy as determined by urinary AI levels in women with early stage hormone-sensitive breast cancer versus usual care.

To compare the effect of a reminder message sent twice weekly to mobile phones as compared to usual care to improve adherence to adjuvant AI therapy according to self-report.

To explore the efficacy of the text message intervention for reducing early discontinuation as compared to usual care at 12, 24 and 36 months of adjuvant AI therapy in subgroups of breast cancer patients as defined by age group, stage, year of therapy, education, race/ethnicity, teaching hospital versus community hospital, AI-related side effects (as determined by serial questionnaires), insurance status, and prescription co-pay status.

To explore the reasons for early discontinuation of AI therapy in those who do discontinue in the intervention and control group by querying quality of life as assessed by the Functional Assessment of Cancer Therapy-Endocrine Subscales (FACT-ES) and symptoms and other issues related to hormonal therapy at each follow-up visit, using the Brief Pain Inventory (BPI-SF), and at annual visits the Beliefs about Medicine Questionnaire (BQM) and the Treatment Satisfaction Questionnaire for Medication (TSQM).

To conduct a sensitivity analysis assessing time to last evidence of adherence.

Patient Population

Patients must be women with a diagnosis of histologically confirmed, primary invasive, hormone-sensitive (either ER or PR positive or both) adenocarcinoma of the breast (Stage I, II or III) with no evidence of recurrent or metastatic disease (M0).

Patients must be post adjuvant chemotherapy (if to be utilized) and primary curative surgery and must have recovered from all side-effects of the surgery. Patients who received hormonal therapy for prior breast cancer are not eligible. Patients must be currently taking an aromatase inhibitor (AI) and meet ALL of the following conditions at the time of registration: completed at least 30 days of AI therapy; be within the first 730 days (two years) of planned AI therapy; if prior tamoxifen was received, total hormonal therapy, including tamoxifen and AI therapy, must have started within 730 days (two years; have at least three years of AI therapy remaining; total planned AI therapy must be at least five years duration. Patients must be willing to provide urine specimen to test for the presence of aromatase inhibitor within 28 days of randomization and at each three month clinic visit for three years.

Patients must be postmenopausal as defined in the protocol and have a Zubrod performance status of 0-2. Patients must have a mobile phone from one of the approved carriers that can receive text messages and must currently use or be willing to learn to use text messaging. Patients must be able to complete study questionnaires in English or Spanish.

Stratification/Descriptive Factors

Randomization will be dynamically balanced according to the following stratification factors: (1) length of time on AI therapy prior to registration < 12 months vs 12-24 months; (2) type of AI therapy: anastrozole vs letrozole vs exemestane.

Accrual Goals

A total of 692 patients will be accrued to achieve 636 eligible patients.

Summary Statement

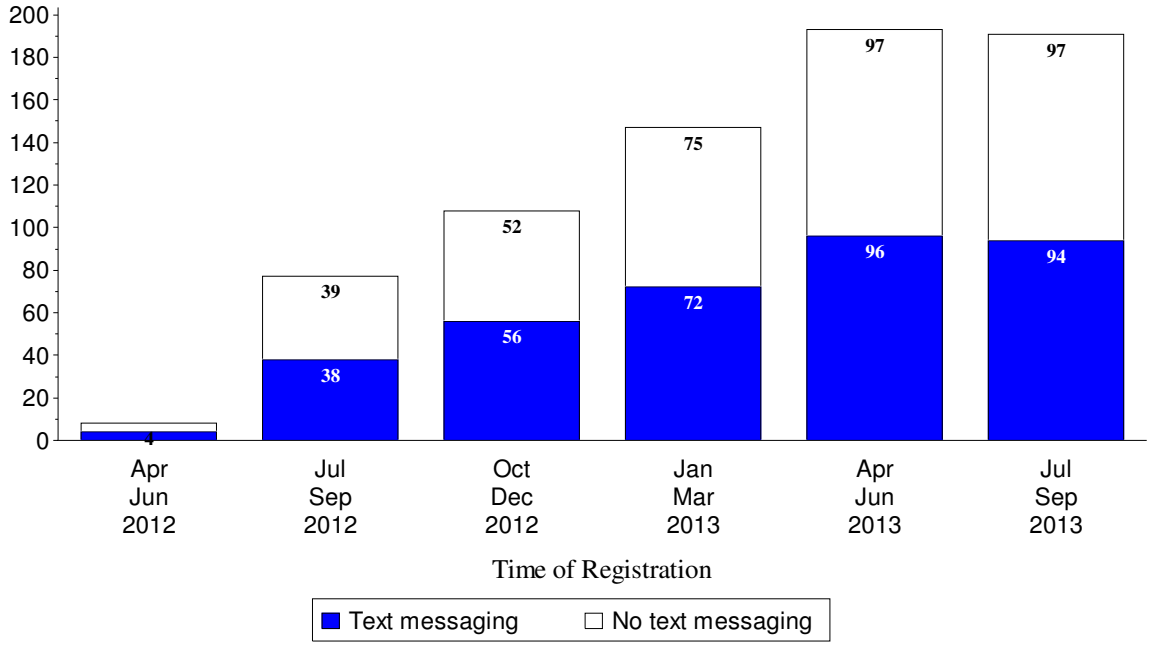
This study closed to accrual on September 15, 2013, with 724 participants registered. The study has completed follow-up, and the final analysis is underway.

Twenty-two patients are ineligible. Seven patients received more than two years of AI treatment prior to registration, seven patients were premenopausal, five patients received more than the allowable duration of tamoxifen use prior to randomization, two patients did not take any aromatase inhibitors prior to registration, and one patient did not have hormone-sensitive breast cancer.

Twelve major protocol deviations were recorded for patients on the text messaging arm: three patients refused study participation prior to initiating text messaging; three patients had a delay in receipt of initial texts; two patients did not have approved cell phone plans; two patients did not respond to the CareSpeak opt-in message to initial text messages; one patient did not have her own phone; and one patient was erroneously removed from follow-up by the site. The no text messaging arm had one major deviation: one patient received text messages.

Initial Registrations By 3 Month Intervals

Divisions by ARM



Registration by Institution

Institutions	Total Reg	Institutions	Total Reg
Wichita NCORP	99	Eisenhower Army MC/Brooke Army Med Ctr	7
Heartland NCORP	97	McKay-Dee Hospital/Intermountain MC	6
Kaiser Perm NCORP	71	Schumpert St Mary/San Antonio, U of TX	6
Southeast COR NCORP	42	Akron Gen Med Ctr/Cleveland Clinic OH	4
Northwest NCORP	41	Henry Ford Hospital	4
Greenville NCORP	37	Kansas City NCORP	4
New Mexico MU-NCORP	37	Columbus NCORP	3
CRC West MI NCORP	35	Cotton O'Neil CC/Kansas, U of	3
Dayton NCORP	34	Quad Cities/Genesis/Loyola University	3
Columbia MU-NCORP	28	Utah, U of	3
Upstate Carolina	27	Brooke Army Med Ctr	2
Michigan CRC NCORP	24	St Elizabeth's MC/Davis, U of CA	2
Providence Hosp	19	Baylor Univ Med Ctr	1
Ozarks NCORP	14	Good Samaritan Hosp/CORA NCORP	1
Prov Portland MC/PCRC NCORP	14	Harrington CC	1
Beaumont NCORP	9	Highline Medical Ctr/Franciscan Res Ctr	1
Boston MC MBCCOP	9	Loyola University	1
Hawaii MU-NCORP	9	PIH Health Hosp/Irvine, U of CA	1
Rochester, Univ of	9	UCH Mem Hosp Central/Colorado, U of	1
Mercy Hosp Ft Smith/Arkansas, U of	8	**Total (40 Institutions)**	**724**
Baptist Health/Cincinnati MC, U of	7		

Registration, Eligibility, and Evaluability

Data as of July 10, 2018

	TOTAL	Text messaging	No text messaging
NUMBER REGISTERED	724	360	364
INELIGIBLE	22	12	10
ELIGIBLE	702	348	354

Patient Characteristics

All eligible and selected ineligible patients included

Data as of July 10, 2018

	Text messaging (n=348)		No text messaging (n=354)	
AGE				
Median	61.3		60.3	
Minimum	30.7		32.1	
Maximum	77.9		82.4	
HISPANIC				
Yes	12	3%	18	5%
No	335	96%	333	94%
Unknown	1	0%	3	1%
RACE				
White	318	91%	307	87%
Black	17	5%	29	8%
Asian	3	1%	13	4%
Pacific Islander	1	0%	1	0%
Native American	3	1%	0	0%
Multi-Racial	4	1%	1	0%
Unknown	2	1%	3	1%
AI DURATION				
< 12 months	223	64%	230	65%
12-24 months	125	36%	124	35%
AI TYPE				
Anastrozole	249	72%	253	71%
Letrozole	85	24%	84	24%
Exemestane	14	4%	17	5%

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 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

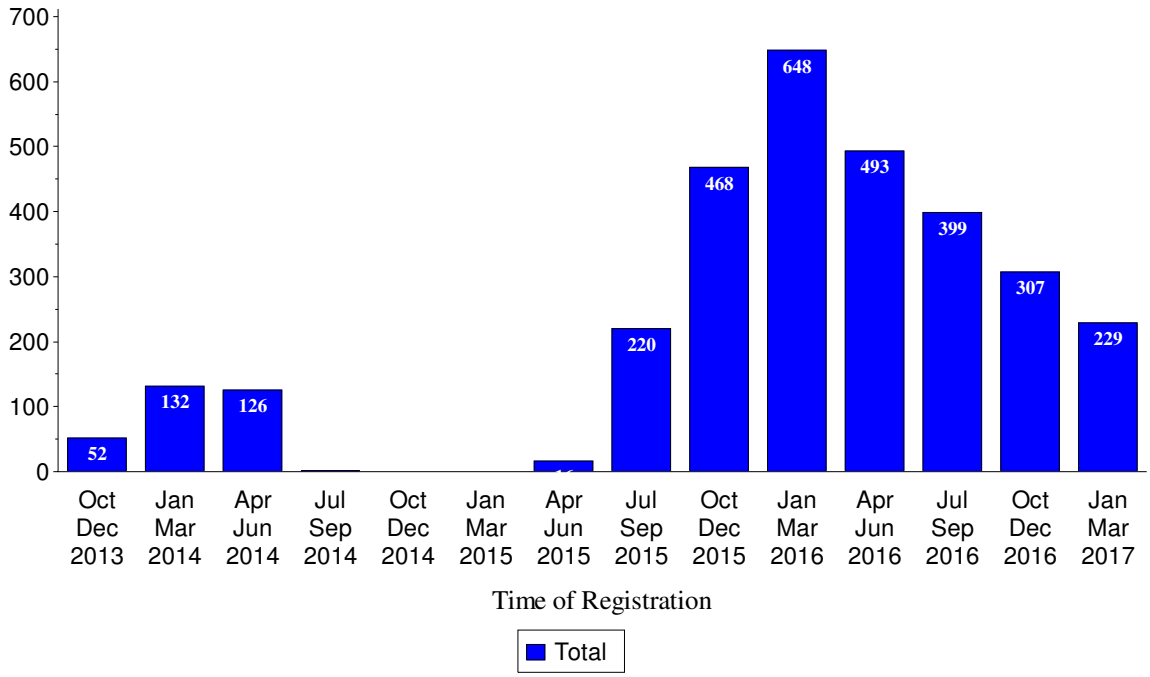
A total of 3,061 patients will be accrued to achieve 3,000 eligible patients.

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. The primary analysis is underway.

Thirty-four patients are 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 are not analyzable due to withdrawal of consent prior to data submission.

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 July 13, 2018

	Total
NUMBER REGISTERED	3092
INELIGIBLE	34
ELIGIBLE	3058
Not Analyzable	3

Patient Characteristics

Data as of July 13, 2018

	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%

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)

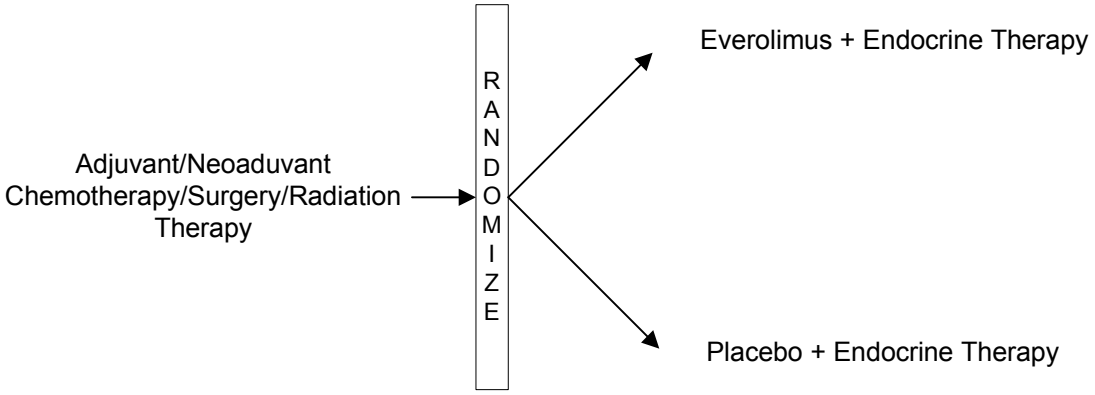
Date Activated:
09/03/2013

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

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.

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

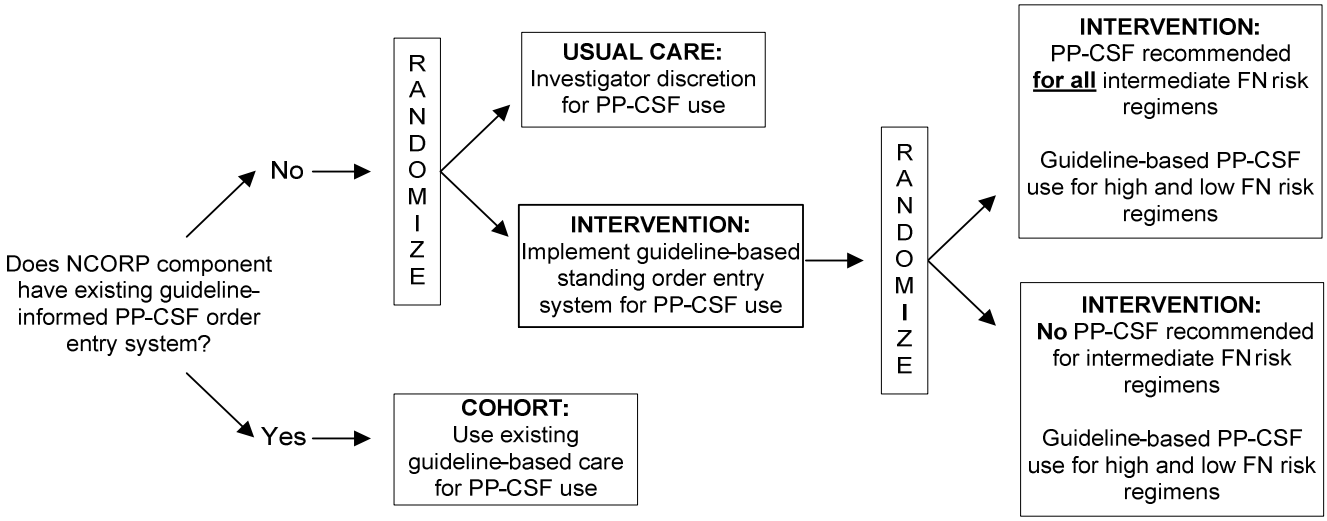
Study Chairs:
S Ramsey, D Hershman

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

Project Manager:
K Watabayashi (HICOR)

Data Coordinator:
K Carvalho

SCHEMA



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

Objectives

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

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

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

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

To compare the FN-related health-related quality of life (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 June 30, 2018, 1,916 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. All Intervention sites have completed updating their standing order systems and are open to patient accrual. All of the 13 Usual Care and eight Cohort components are open to patient accrual.

Thirty-nine patients are ineligible. Of these, 15 patients planned to have concurrent radiation therapy, eleven patients had systemic therapy within 180 days of registration, six patients were planning to have regimens not listed in Appendix 18.1, three 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. Five hundred fifty-three patients are off treatment.

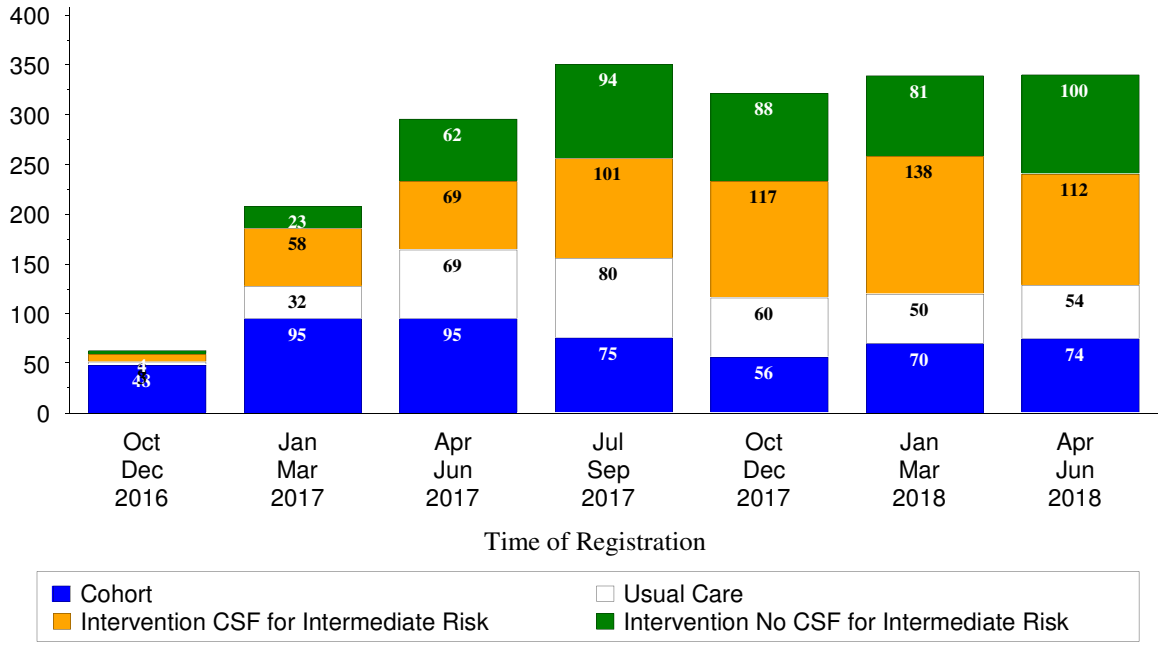
Adverse events shown are those attributable to PP-CSF (first cycle only). Nine hundred and eighty-one patients have been assessed for adverse events across all study arms. Thirty-two patients have had Grade 3 events across all arms with almost all related to pain (30) such as bone pain, arthralgia, myalgia, back pain and/or chest wall pain. One patient in the Cohort component had a Grade 4 platelet count decrease.

As of June 30, 2018, 447 patients in the intermediate risk group have been accrued at intervention clinics. The first interim analysis requires 360 intermediate patients at intervention clinics with six months of follow-up to assess the primary outcome. Therefore, the first interim analysis is planned to be presented to the DSMC at the Spring 2019 meeting.

Revision #5 (version date April 8, 2018) clarified eligibility and includes updated regimen lists in Section 18.1. Revision #6 (version date June 13, 2018) clarified eligibility and the timing of data submission requirements, and updated forms.

Initial Registrations By 3 Month Intervals

Divisions by ARM



Registrations by Study Component and Study Arm

Registrations ending June 30, 2018

	Total (n=1916)	
COHORT		
Adena Regional Medical Center	16	1%
Cancer Center of Kansas	60	3%
Carle Cancer Center	59	3%
CHI Health Saint Francis	34	2%
Cox Health South	38	2%
Dayton Physicians LLC	26	1%
Greenville Memorial Hospital	61	3%
Intermountain Healthcare	7	0%
Mercy Hospital Springfield	60	3%
MultiCare Tacoma General Hosp.	37	2%
Novant Health Forsythe Med Ctr	60	3%
Spartanburg Medical Center	41	2%
West Michigan Cancer Center	14	1%
USUAL CARE		
Baptist MU-NCORP	53	3%
Christus St. Vincent Reg. CC	22	1%
LSU HSC-Shreveport	35	2%
Oncology Associates at Mercy	50	3%
Research Medical Center	1	0%
Saint Luke's Tumor Inst.	85	4%
St. John Hospital and Med Ctr	51	3%
Swedish Cancer Institute	51	3%
INTERVENTION CSF FOR INTERMEDIATE RISK		
Beaumont NCORP	3	0%
CC Specialists of C. Illinois	94	5%
Contra Costa Regional Med Ctr	17	1%
Doctors Cancer Center Manati	41	2%
Essentia Health Cancer Center	57	3%
Geisinger Medical Center	81	4%
Illinois Cancer Care-Peoria	99	5%
John H Stroger Jr Hospital	93	5%
Marshfield Clinic	65	3%
Meharry Medical College	8	0%
Presbyterian Kaseman Hospital	25	1%
Tripler Medical Center	20	1%
INTERVENTION NO CSF FOR INTERMEDIATE RISK		
Augusta University Med Ctr	23	1%
Billings Clinic Cancer Center	22	1%
Bozeman Deaconess Cancer Ctr	25	1%
Columbia U/Herbert Irving CC	65	3%
Lewis Cancer & Research	31	2%
LSU HSC-New Orleans	9	0%
Med Onc and Hematology Assoc.	45	2%
Michigan NCORP	66	3%
Queen's Medical Center	14	1%
Sanford Medical Center-Fargo	87	5%
St. Alphonsus Regional Med Ctr	19	1%
University of New Mexico CC	46	2%

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2018; Data as of July 24, 2018

	TOTAL	Cohort	Usual Care	Intervention CSF for Intermediate Risk	Intervention No CSF for Intermediate Risk
NUMBER REGISTERED	1916	513	348	603	452
INELIGIBLE	39	8	7	13	11
ELIGIBLE	1877	505	341	590	441
Analyzable, Pend. Elig.	1	0	0	0	1
Not Analyzable	4	3	1	0	0

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending June 30, 2018; Data as of July 24, 2018

	Cohort (n=502)		Usual Care (n=340)		Intervention CSF for Intermediate Risk (n=590)		Intervention No CSF for Intermediate Risk (n=441)	
AGE								
Median	58.8		58.3		58.8		58.3	
Minimum	25.8		29.9		18.8		27.2	
Maximum	94.8		86.1		91.5		89.7	
SEX								
Males	89	18%	68	20%	155	26%	77	17%
Females	413	82%	272	80%	435	74%	364	83%
HISPANIC								
Yes	8	2%	13	4%	95	16%	53	12%
No	493	98%	317	93%	484	82%	376	85%
Unknown	1	0%	10	3%	11	2%	12	3%
RACE								
White	440	88%	267	79%	470	80%	329	75%
Black	47	9%	51	15%	72	12%	47	11%
Asian	7	1%	10	3%	22	4%	14	3%
Pacific Islander	0	0%	1	0%	5	1%	3	1%
Native American	0	0%	0	0%	11	2%	9	2%
Multi-Racial	5	1%	0	0%	0	0%	3	1%
Unknown	3	1%	11	3%	10	2%	36	8%
FEBRILE NEUTROPENIA RISK								
Low	87	17%	68	20%	120	20%	89	20%
Intermediate	174	35%	124	36%	290	49%	156	35%
High	241	48%	148	44%	180	31%	196	44%

Treatment Summary

All eligible and selected ineligible patients included

Registrations ending June 30, 2018; Data as of July 24, 2018

	TOTAL	Cohort	Usual Care	Intervention CSF for Intermediate Risk	Intervention No CSF for Intermediate Risk
NUMBER ON PROTOCOL TREATMENT	1320	274	241	448	357
NUMBER OFF PROTOCOL TREATMENT	553	228	99	142	84
REASON OFF TREATMENT					
Treatment completed as planned	476	206	82	112	76
Adverse Event or side effects	0	0	0	0	0
Refusal unrelated to adverse event	10	2	3	3	2
Progression/relapse	0	0	0	0	0
Death	62	20	11	25	6
Other - not protocol specified	0	0	0	0	0
Reason under review	5	0	3	2	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 Selected Ineligible Patients Included

Registrations ending June 30, 2018; Data as of July 24, 2018

	Cohort (n=304) Grade						Usual Care (n=172) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
ALT increased	304	0	0	0	0	0	172	0	0	0	0	0
Anorexia	304	0	0	0	0	0	171	0	1	0	0	0
Arthralgia	263	32	7	2	0	0	148	12	11	1	0	0
Back pain	300	1	2	1	0	0	169	3	0	0	0	0
Blood/lymph disorder-Other	304	0	0	0	0	0	171	1	0	0	0	0
Bone pain	236	43	20	5	0	0	115	18	34	5	0	0
Chest wall pain	302	1	0	1	0	0	172	0	0	0	0	0
Constipation	303	1	0	0	0	0	172	0	0	0	0	0
Diarrhea	304	0	0	0	0	0	172	0	0	0	0	0
Edema trunk	303	1	0	0	0	0	172	0	0	0	0	0
Fatigue	302	2	0	0	0	0	170	1	1	0	0	0
Fever	303	1	0	0	0	0	172	0	0	0	0	0
Flu like symptoms	304	0	0	0	0	0	172	0	0	0	0	0
Flushing	303	1	0	0	0	0	172	0	0	0	0	0
Headache	303	1	0	0	0	0	171	1	0	0	0	0
Insomnia	303	0	0	1	0	0	172	0	0	0	0	0
Mucosal infection	304	0	0	0	0	0	172	0	0	0	0	0
Mucositis oral	297	5	2	0	0	0	165	4	3	0	0	0
Myalgia	297	6	0	1	0	0	168	3	1	0	0	0
Myositis	301	1	2	0	0	0	171	0	1	0	0	0
Nausea	303	1	0	0	0	0	171	0	1	0	0	0
Neutrophil count decreased	304	0	0	0	0	0	172	0	0	0	0	0

	Cohort (n=304) Grade						Usual Care (n=172) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Non-cardiac chest pain	304	0	0	0	0	0	172	0	0	0	0	0
Pain	304	0	0	0	0	0	172	0	0	0	0	0
Pain in extremity	303	0	1	0	0	0	172	0	0	0	0	0
Platelet count decreased	303	0	0	0	1	0	172	0	0	0	0	0
Pruritus	303	1	0	0	0	0	172	0	0	0	0	0
Rash maculo-papular	303	1	0	0	0	0	172	0	0	0	0	0
Skin/subq tissue ds-Other	303	1	0	0	0	0	172	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	202	65	30	6	1	0	97	32	38	5	0	0

	Intervention CSF for Intermediate Risk (n=307) Grade						Intervention No CSF for Intermediate Risk (n=193) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
ALT increased	306	1	0	0	0	0	193	0	0	0	0	0
Anorexia	307	0	0	0	0	0	193	0	0	0	0	0
Arthralgia	273	24	10	0	0	0	152	26	11	4	0	0
Back pain	304	1	2	0	0	0	193	0	0	0	0	0
Blood/lymph disorder-Other	307	0	0	0	0	0	193	0	0	0	0	0
Bone pain	215	53	30	9	0	0	136	32	18	7	0	0
Chest wall pain	307	0	0	0	0	0	193	0	0	0	0	0
Constipation	306	0	1	0	0	0	193	0	0	0	0	0
Diarrhea	302	4	1	0	0	0	192	1	0	0	0	0
Edema trunk	307	0	0	0	0	0	193	0	0	0	0	0
Fatigue	305	2	0	0	0	0	192	1	0	0	0	0
Fever	306	1	0	0	0	0	193	0	0	0	0	0
Flu like symptoms	305	0	2	0	0	0	193	0	0	0	0	0
Flushing	307	0	0	0	0	0	193	0	0	0	0	0
Headache	304	2	1	0	0	0	192	0	1	0	0	0
Insomnia	307	0	0	0	0	0	193	0	0	0	0	0
Mucosal infection	307	0	0	0	0	0	192	0	1	0	0	0
Mucositis oral	292	12	3	0	0	0	187	1	4	1	0	0
Myalgia	304	1	1	1	0	0	189	4	0	0	0	0
Myositis	296	8	3	0	0	0	182	4	6	1	0	0
Nausea	306	0	1	0	0	0	192	1	0	0	0	0
Neutrophil count decreased	305	1	0	1	0	0	193	0	0	0	0	0
Non-cardiac chest pain	306	0	1	0	0	0	193	0	0	0	0	0
Pain	306	0	1	0	0	0	193	0	0	0	0	0
Pain in extremity	307	0	0	0	0	0	192	1	0	0	0	0
Platelet count decreased	307	0	0	0	0	0	193	0	0	0	0	0
Pruritus	307	0	0	0	0	0	193	0	0	0	0	0
Rash maculo-papular	307	0	0	0	0	0	193	0	0	0	0	0
Skin/subq tissue ds-Other	307	0	0	0	0	0	193	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	187	69	40	11	0	0	107	51	25	10	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 Coordinator:
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.

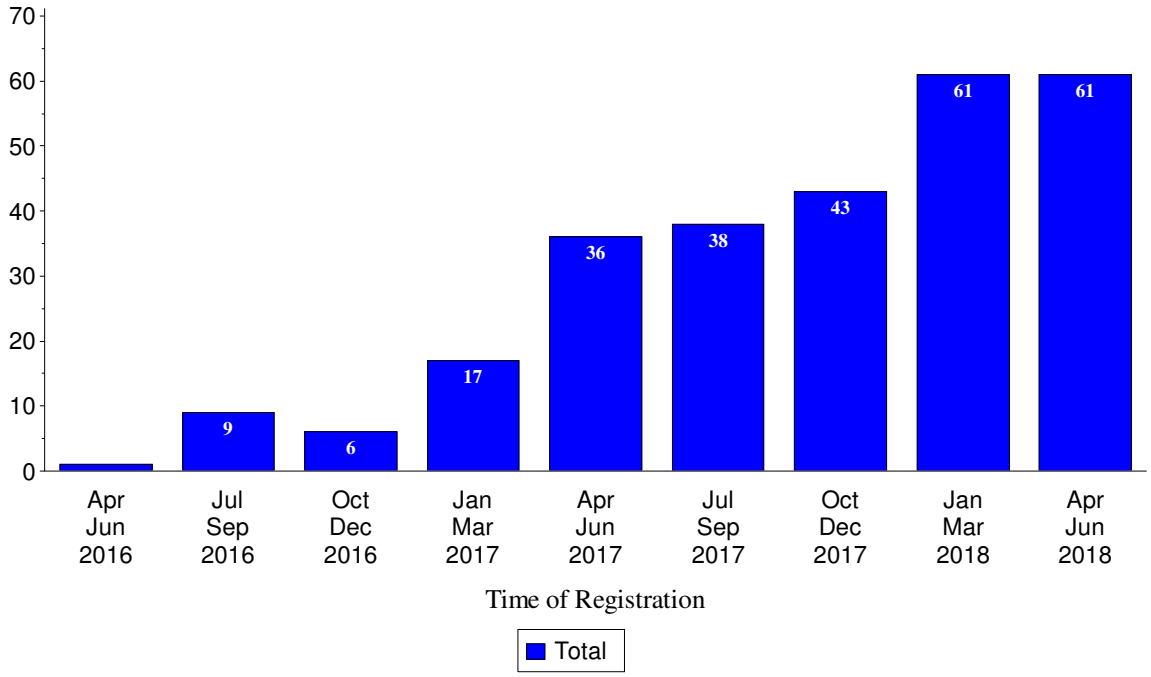
Patients may have received prior chemotherapy, biologic therapy, radiation therapy, or surgery for non-metastatic colorectal cancer.

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 on May 13, 2016. As of June 30, 2018, 272 patients have been accrued. Two patients are ineligible due to: diagnosis with metastatic colorectal cancer more than 120 days prior to registration (1 patient) and initiating treatment for metastatic colorectal cancer more than 60 days prior to registration (1). Two additional patients are not analyzable due to withdrawal of consent prior to completing the baseline questionnaire.

Initial Registrations By 3 Month Intervals



Registration by Institution

Registrations ending June 30, 2018

Institutions	Total Reg	Institutions	Total Reg
Kaiser Perm NCORP	33	New Mexico MU-NCORP	4
Heartland NCORP	23	Hawaii MU-NCORP	3
Columbus NCORP	22	Northwest NCORP	3
CORA NCORP	15	Ozarks NCORP	3
CRC West MI NCORP	15	Bay Area NCORP	2
Greenville NCORP	15	Carle CC NCORP	1
Columbia MU-NCORP	9	Montana NCORP	1
Georgia NCORP	9	Nevada CRF NCORP	1
Southeast COR NCORP	8	Wisconsin NCORP	1
Gulf South MU-NCORP	7	ECOG-ACRIN	42
Michigan CRC NCORP	7	ALLIANCE	19
PCRC NCORP	6	NRG	13
Wichita NCORP	6	**Total (26 Institutions)**	**272**
Dayton NCORP	4		

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2018; Data as of July 25, 2018

	Observation
NUMBER REGISTERED	272
INELIGIBLE	2
ELIGIBLE	270
Analyzable, Pend. Elig.	1
Not Analyzable	2

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending June 30, 2018; Data as of July 25, 2018

	Observation (n=268)	
AGE		
Median	60.9	
Minimum	21.1	
Maximum	89.3	
SEX		
Males	171	64%
Females	97	36%
HISPANIC		
Yes	15	6%
No	247	92%
Unknown	6	2%
RACE		
White	210	78%
Black	35	13%
Asian	8	3%
Pacific Islander	1	0%
Native American	1	0%
Unknown	13	5%

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

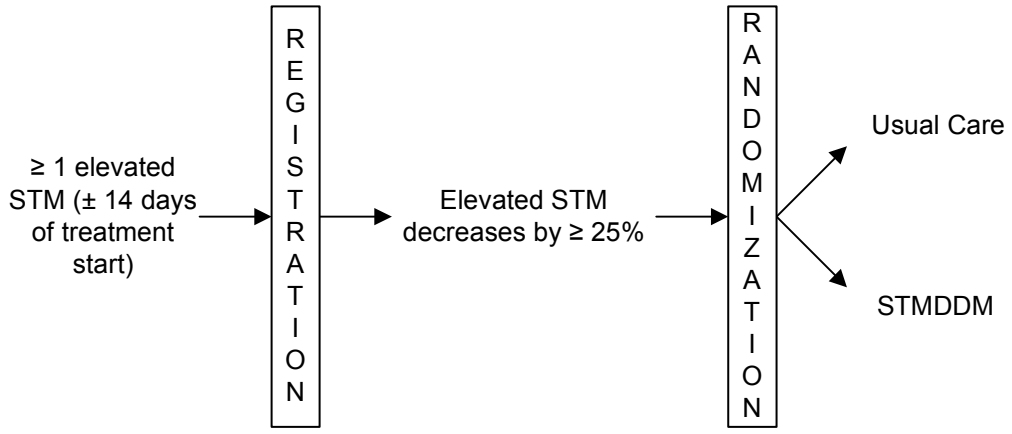
Date Activated:
07/16/2018

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.