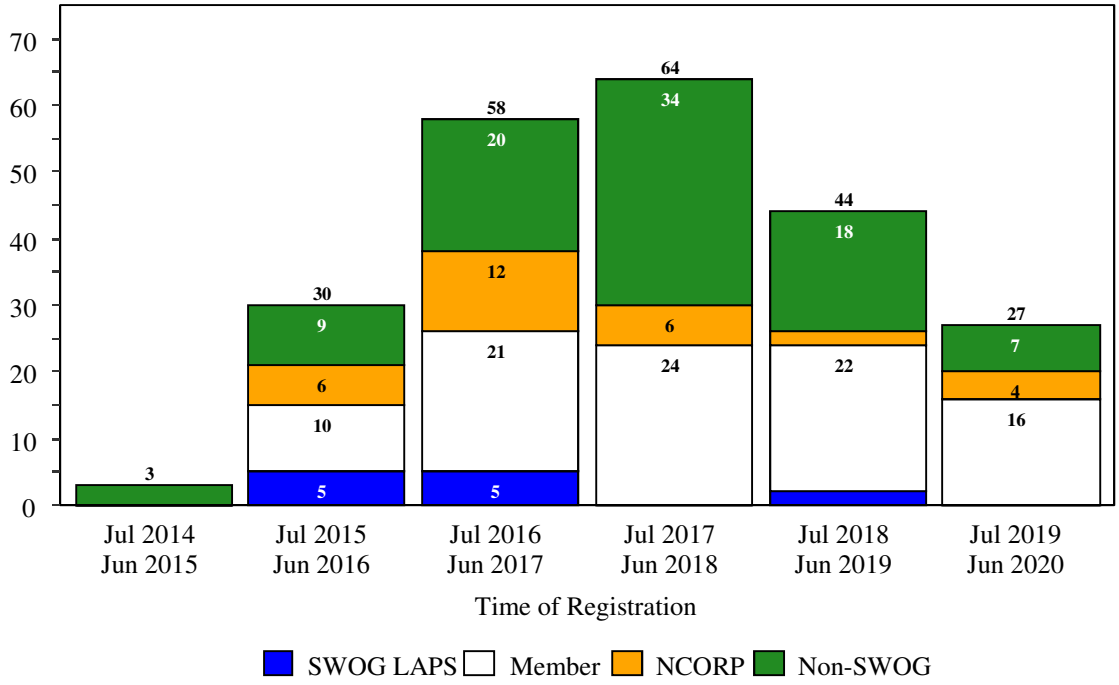
PALLIATIVE AND END OF LIFE CARE COMMITTEE

CONTENTS

Patient Registrations to Studies

by 12 Month Intervals
PALLIATIVE AND EOL CARE COMMITTEE
As Primary Committee



Screening registrations and registrations to Biologic only studies are excluded.

Patient Registrations by Study and Arm

PALLIATIVE AND EOL CARE COMMITTEE

As Primary Committee

	Jan 2020 Jun 2020	Jul 2019 Dec 2019	Jan 2019 Jun 2019	All Patients
S1316 Compar. Effectiv. Trial for MBO				
Registration				
Randomization Surgery	3	7	12	29
Randomization Non-surgical M	2	10	7	27
Patient Choice Surgery	0	0	11	65
Patient Choice Non-surgical M	0	0	0	100
	5	17	30	221
S1820 Rectal, Diet modification to manage GI sx				
Run-In				
Run-In	17	0	0	17
Randomization				
Diet Modification Coaching	1	0	0	1
Healthy Living Education	4	0	0	4
	5	0	0	5

S1316 Pilot

Coordinating Group: SWOG

Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction

---

Participants:
SWOG, CTSU (Supported by Alliance)

Study Chairs:
R Krouse, J Deneve, A Secord (Alliance)

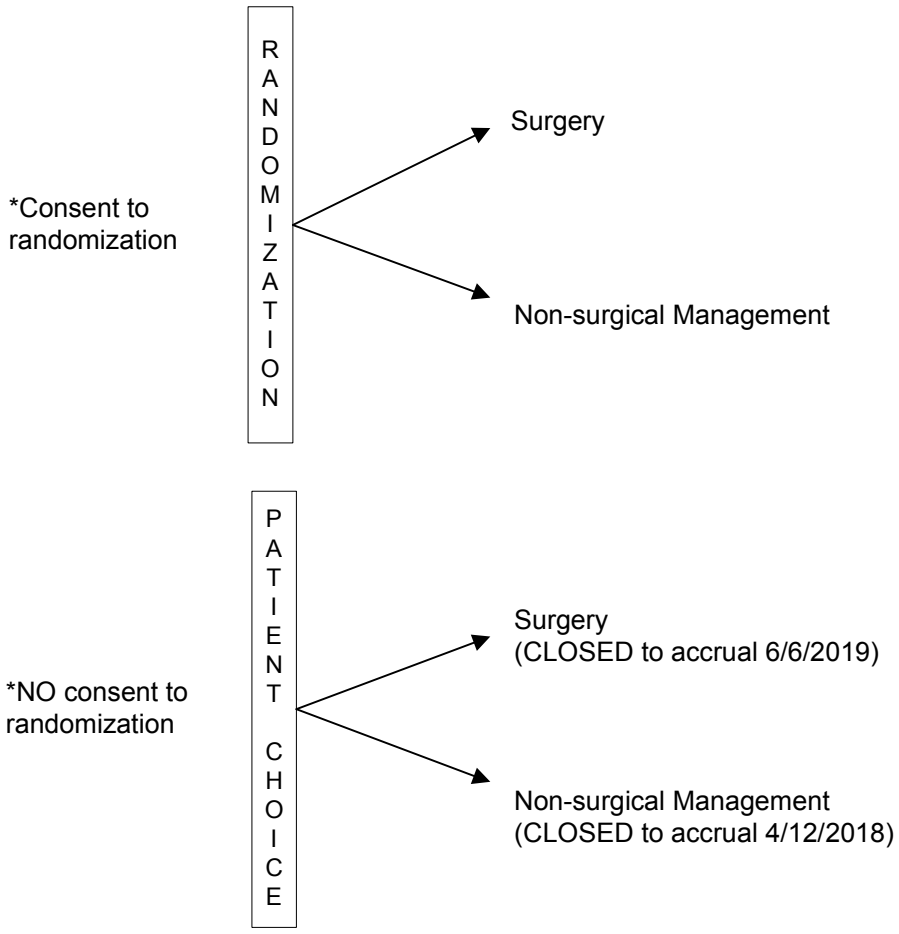
Statisticians:
G Anderson, K Arnold

Data Coordinator:
R Topacio

Date Activated:
03/09/2015

Date Closed:
05/15/2020

SCHEMA



*Patients will be enrolled into either the randomized or patient choice portion, not both

Objectives

To compare quality of life, as assessed by the number of days alive and residing outside of the hospital within the first 91 days (13 weeks) after registration, among patients with malignant bowel obstruction (MBO) who receive surgical intervention and similar patients treated non-surgically.

To explore whether there are differences in other health related quality of life (HRQOL) factors of particular interest in this population, including ability to eat, days with nasogastric tube, development of nausea, days of intravenous hydration, days eating solid foods and days drinking that are different for patients with MBO who receive surgical intervention as compared to non-surgical intervention.

To explore whether overall survival is different for patients with MBO who receive surgical intervention as compared to non-surgical intervention. To estimate the effects of surgical versus non-surgical management on quality of life after adjustment for non-adherence to initially assigned/chosen treatment.

To explore whether there are clinical factors (e.g., ascites, albumin, carcinomatosis) that predict better quality of life outcomes for patients with MBO who receive surgical intervention as compared to non-surgical intervention.

Patient Population

Patients must have clinical evidence of a small bowel obstruction (via history, physical, and radiographic examination) distal to ligament of Treitz, with radiographic confirmation prior to registration. Patients must have intra-abdominal primary cancer with incurable disease. Patients may still have primary tumor as long as it is not a primary large bowel obstruction from colorectal cancer. Patients must not have signs of bowel perforation necessitating surgery or "acute" abdomen as evidenced by peritonitis on physical exam within two days prior to registration.

Patients must be registered to the study within three days after being seen by a surgical team for MBO or within three days after completion of indicated treatment (e.g. TPN, anticoagulation reversal) to make them eligible for surgical intervention, whichever is later, and prior to any treatment (surgical or non-surgical) for MBO. Somatostatin analogues may be used prior to registration if that use is limited to not more than the two days just prior to registration.

Patients must be able to tolerate a major surgical procedure based on clinical evaluation, status of their cancer, and any other underlying medical problems. A member of the patient's surgical team must indicate equipoise for the benefit of the surgical treatment for MBO. Patients must be 18 years or older and have Zubrod performance status of 0-2 within seven days prior to hospitalization. Serum albumin must be planned to be collected after hospital admission, but prior to treatment. History and physical must be obtained within three days prior to registration. Patients must be able to complete the study questionnaires in English or Spanish.

Stratification/Descriptive Factors

Patient randomization will be stratified by primary tumor type: colorectal cancer vs ovarian cancer vs other cancer.

Accrual Goals

A total of 220 patients will be accrued to achieve 200 eligible patients, with a target of 50 eligible patients in the randomized component.

Summary Statement

This study was activated on March 9, 2015, at limited institutions. The study closed to accrual on May 15, 2020 with 221 patients registered at 30 institutions, including 56 patients to the randomized portion. The Latin American sites in Mexico, Peru, and Colombia randomized 16 patients.

Four randomized patients are ineligible due to the bowel obstruction not being located in the small bowel. Five patients registered to the Patient Choice Surgery arm are ineligible due to: the bowel obstruction not being located in the small bowel (2 patients); surgery prior to registration (2); and bowel obstruction not confirmed via CT scan (1). Six patients registered to the Patient Choice Non-surgical Management arm are ineligible due to: the bowel obstruction not being located in the small bowel (3); treatment prior to registration (1); bowel obstruction not confirmed via CT scan (1); and not having intra-abdominal cancer (1). Among 154 eligible patients in the Patient Choice group, 60 (39%) chose surgery at time of consent.

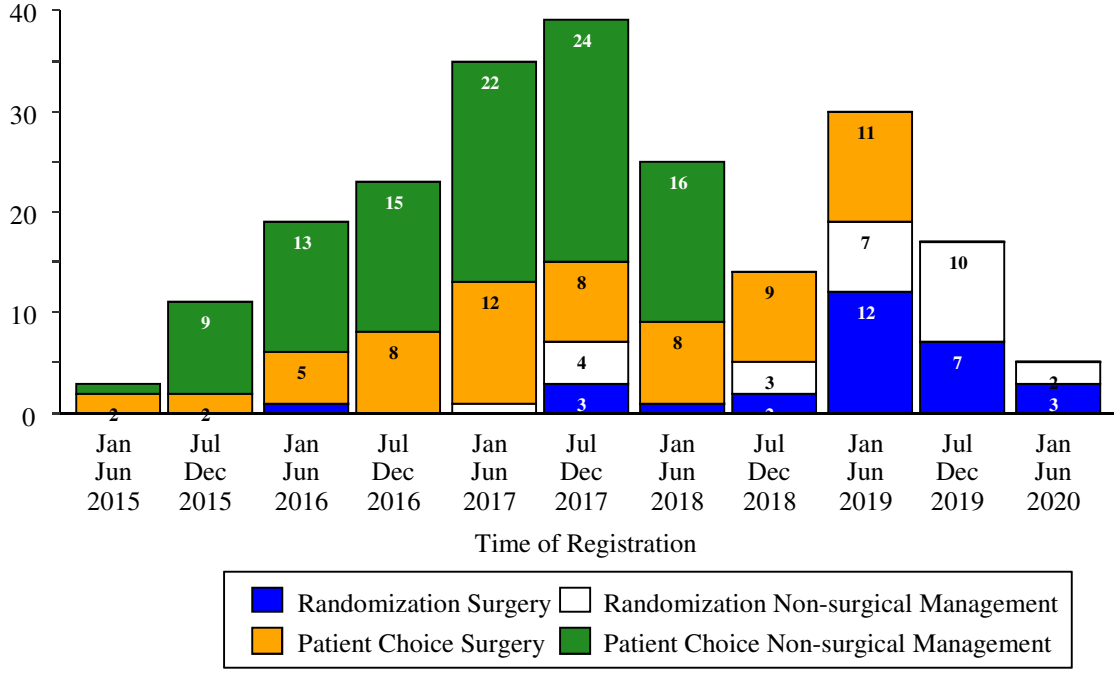
Twenty four patients had a major protocol deviation due to not receiving assigned treatment, including eleven randomized patients, one patient on the Patient Choice Surgery arm who did not have surgery and twelve patients on the Patient Choice Non-surgical Management arm who received surgery.

Nine patients are actively being followed and completing study questionnaires and dietary recalls.

Toxicities are reported in groups according to treatment specified at registration, regardless of randomization status: surgery vs non-surgical management. Among 84 eligible patients registered to the Surgery arms who have had adverse events assessed, one patient experienced Grade 4 anemia and one patient experienced Grade 4 myocardial infarction. Among 119 eligible patients who have had adverse events assessed on the Non-surgical Management arms, one patient had Grade 5 sepsis, pneumonitis and cardiac arrest, and one patient experienced Grade 4 anemia and post-operative hemorrhage after surgery during a second hospitalization.

Initial Registrations by 6 Month Intervals

Divisions by ARM



Registration by Network Groups

Institutions	Total Reg
SWOG	130
NRG	62
ALLIANCE	27
ECOG-ACRIN	2
Total (4 Network Groups)	**221**

Registration by Institution

Institutions	Total Reg
The West Clinic - Wolf River (TN089)	45
Long Island Jewish Medical Center (NY065)	21
North Shore University Hospital (NY064)	19
Banner University Medical Center - Tucson (AZ017)	18
University of Kansas Cancer Center (KS004)	18
University of Oklahoma Health Sciences Center (OK003)	13
Duke University Medical Center (NC010)	11
City of Hope Comprehensive Cancer Center (CA043)	9
Instituto Nacional De Cancerologia de Mexico (48007)	8
University of Michigan Comprehensive Cancer Cen (MI014)	8
Instituto Nacional de Enfermedades Neoplasicas (55004)	7
University of Arkansas for Medical Sciences (AR006)	6
Medical University of South Carolina (SC008)	5
Medical College of Wisconsin (WI013)	4
Rhode Island Hospital (RI005)	4
Valley Health / Winchester Medical Center (VA008)	4
Moffitt Cancer Center (FL065)	3
University Hospital (TX182)	3
Baylor University Medical Center (TX012)	2
M D Anderson Cancer Center (TX035)	2
UMass Memorial Medical Center - University Camp (MA011)	2
Baylor College of Medicine/Dan L Duncan Compreh (TX041)	1
Essentia Health Cancer Center (MN024)	1
Instituto Nacional De Cancerologia (15002)	1
Loma Linda University Medical Center (CA078)	1
NYP/Columbia University Medical Center/Herbert (NY024)	1
Rush University Medical Center (IL043)	1
Southside Hospital (NY394)	1
University of New Mexico Cancer Center (NM004)	1
University of Tennessee Health Science Center (TN030)	1
Total (30 Institutions)	**221**

Registration, Eligibility, and Evaluability

Data as of July 15, 2020

	TOTAL	Randomization Surgery	Randomization Non-surgical Management	Patient Choice Surgery	Patient Choice Non-surgical Management
NUMBER REGISTERED	221	29	27	65	100
INELIGIBLE	15	3	1	5	6
ELIGIBLE	206	26	26	60	94
Analyzable, Pend. Elig.	7	4	2	0	1
ADVERSE EVENT ASSESSMENT					
Evaluable	203	25	26	59	93
Too Early	3	1	0	1	1

Patient Characteristics

All Eligible and Selected Ineligible Patients Included
Data as of July 15, 2020

	Randomization Surgery (n=26)		Randomization Non-surgical Management (n=26)		Patient Choice Surgery (n=60)		Patient Choice Non-surgical Management (n=94)	
AGE								
Median	63.4		61.8		61.1		58.3	
Minimum	43.2		45.7		23.0		32.7	
Maximum	84.7		82.3		90.8		85.6	
SEX								
Males	8	31%	10	38%	24	40%	29	31%
Females	18	69%	16	62%	36	60%	65	69%
HISPANIC								
Yes	9	35%	6	23%	6	10%	14	15%
No	14	54%	18	69%	53	88%	78	83%
Unknown	3	12%	2	8%	1	2%	2	2%
RACE								
White	10	38%	12	46%	40	67%	69	73%
Black	6	23%	7	27%	14	23%	15	16%
Asian	1	4%	1	4%	1	2%	2	2%
Pacific Islander	0	0%	0	0%	0	0%	2	2%
Native American	1	4%	1	4%	0	0%	1	1%
Unknown	8	31%	5	19%	5	8%	5	5%
PRIMARY TUMOR TYPE								
Colorectal cancer	7	27%	8	31%	20	33%	25	27%
Ovarian cancer	9	35%	8	31%	11	18%	34	36%
Other cancer	10	38%	10	38%	29	48%	35	37%

Treatment Summary

All Eligible and Selected Ineligible Patients Included
Data as of July 15, 2020

	TOTAL	Randomized	Patient Choice Surgery	Patient Choice Non-surgical Management
NUMBER ON PROTOCOL TREATMENT	9	5	4	0
NUMBER OFF PROTOCOL TREATMENT	197	47	56	94
REASON OFF TREATMENT				
Treatment completed as planned	27	2	15	10
Adverse Event or side effects	0	0	0	0
Refusal unrelated to adverse event	25	3	5	17
Progression/relapse	17	3	5	9
Death	128	39	31	58
Other - not protocol specified	0	0	0	0
Reason under review	0	0	0	0
MAJOR PROTOCOL DEVIATIONS	24	11	1	12

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

Classified by Study Arm
Adverse Events Unlikely or Not Related to Treatment Excluded
All Eligible and Selected Ineligible Patients Included
Data as of July 15, 2020

	Surgery Arms (n=84) Grade						Non-surgical Management Arms (n=119) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Abdominal infection	82	0	0	2	0	0	117	0	0	2	0	0
Abdominal pain	84	0	0	0	0	0	118	0	0	1	0	0
Anemia	75	1	1	6	1	0	113	1	2	2	1	0
Aspiration	83	0	1	0	0	0	118	0	1	0	0	0
Cardiac arrest	84	0	0	0	0	0	118	0	0	0	0	1
Diarrhea	84	0	0	0	0	0	118	0	1	0	0	0
Esophageal ulcer	84	0	0	0	0	0	118	1	0	0	0	0
Fever	83	1	0	0	0	0	118	0	1	0	0	0
Gastric ulcer	84	0	0	0	0	0	118	1	0	0	0	0
Gastrointestinal fistula	79	0	2	3	0	0	119	0	0	0	0	0
Gastrointestinal pain	83	0	0	1	0	0	117	1	0	1	0	0
GI disorders-Other, specify	83	0	1	0	0	0	119	0	0	0	0	0
Hypoalbuminemia	84	0	0	0	0	0	118	0	0	1	0	0
Hypokalemia	84	0	0	0	0	0	118	0	1	0	0	0
Hypomagnesemia	84	0	0	0	0	0	118	0	1	0	0	0
Ileus	83	0	0	1	0	0	118	0	0	1	0	0
Myocardial infarction	83	0	0	0	1	0	119	0	0	0	0	0
Nausea	84	0	0	0	0	0	118	0	1	0	0	0
Peritoneal infection	83	0	0	1	0	0	119	0	0	0	0	0
Pleural effusion	83	0	0	1	0	0	119	0	0	0	0	0
Pneumonitis	84	0	0	0	0	0	118	0	0	0	0	1
Postoperative hemorrhage	84	0	0	0	0	0	118	0	0	0	1	0
Seizure	84	0	0	0	0	0	118	0	1	0	0	0
Sepsis	84	0	0	0	0	0	118	0	0	0	0	1
Sinus bradycardia	84	0	0	0	0	0	117	2	0	0	0	0
Urinary tract infection	82	0	1	1	0	0	119	0	0	0	0	0
Urinary tract obstruction	84	0	0	0	0	0	118	0	0	1	0	0
Vomiting	84	0	0	0	0	0	118	0	0	1	0	0
Wound complication	81	0	3	0	0	0	119	0	0	0	0	0
Wound dehiscence	82	0	2	0	0	0	118	0	1	0	0	0
Wound infection	82	0	0	2	0	0	118	0	1	0	0	0
MAX. GRADE ANY ADVERSE EVENT	68	1	2	11	2	0	106	2	3	6	1	1

S1820 Pilot

Coordinating Group: SWOG

A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)

Participants:
SWOG, CTSU

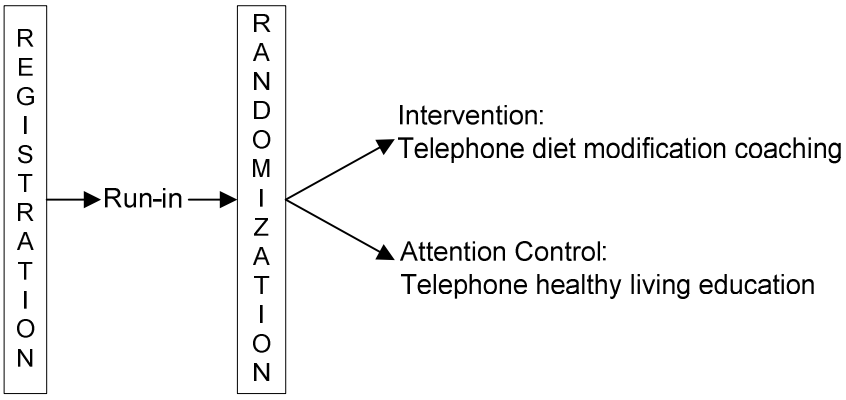
Date Activated:
12/09/2019

Study Chairs:
V Sun, C Thomson

Statisticians:
K Guthrie, K Arnold

Data Coordinator:
R Topacio

SCHEMA



Objectives

To compare total bowel function score, as measured by the Memorial Sloan-Kettering Cancer Center Bowel Function Index (BFI), at 18 weeks post-randomization between the intervention and attention control arms.

To compare total bowel function score at 26 weeks post-randomization between the intervention and attention control arms.

To compare bowel function subscale scores (dietary, urgency, frequency), as measured by the BFI at both 18 and 26 weeks post-randomization between the intervention and attention control arms.

To compare lower anterior resection syndrome (LARS) scores (for anastomosis participants only), quality of life, and dietary quality at both 18 and 26 weeks post-randomization between the intervention and attention control arms.

To compare motivation, self-efficacy, and positive/negative affect at both 18 and 26 weeks post-randomization between the intervention and attention control arms.

To assess study feasibility, adherence, retention, and acceptability at both 18 and 26 weeks post-randomization.

To explore variation in primary and secondary study outcomes according to sex, and to investigate whether intervention effects on the primary outcome differ across subgroups defined by sex.

Patient Population
Patients must have prior history of rectosigmoid colon cancer or rectal cancer. Patients must have a post-surgical permanent ostomy or anastomosis.

Patient's last date of treatment for rectal cancer (any surgery, chemotherapy, radiation therapy) must be at least 6 months prior to registration and not more than 24 months prior to registration.

Anastomosis patients must have LARS score of 21-42 (minor to major symptoms). Patients must be able to read, write and speak English. Patients must be at least 18 years of age. Patients must not be currently undergoing treatment for another cancer. Patients must not have been diagnosed with inflammatory bowel disease.

Stratification/Descriptive Factors
Patient randomization will be stratified according to the following factors: (1) sex: female vs male; and (2) ostomy status: permanent ostomy vs anastomosis.

Accrual Goals
The accrual goal is 94 randomized patients to achieve 88 eligible randomized patients, which is anticipated to require 126 patients registered to the run-in.

Summary Statement
This study was activated on December 9, 2019. As of June 30, 2020, 17 participants have been registered to the Run-in and 5 participants have been randomized.

One Run-in participant is ineligible due to receiving treatment less than 6 months prior to registration.

All randomized participants are eligible. One participant was randomized to receive Diet Modification Coaching and 4 participants were randomized to receive Healthy Living Education. One participant randomized to the Healthy Living Education arm is Off Treatment due to Refusal unrelated to adverse event.

Registration by Institution

Run-In
Registrations ending June 30, 2020

Institutions	Total Reg
Greenville NCORP	5
City of Hope Med Ctr	4
Irvine, U of CA	3
Michigan CRC NCORP	1
Northwestern Univ	1
NRG	3
Total (6 Institutions)	**17**

Registration, Eligibility, and Evaluability

Run-In
Registrations ending June 30, 2020; Data as of July 13, 2020

	Run-In
NUMBER REGISTERED	17
INELIGIBLE	1
ELIGIBLE	16

Patient Characteristics

Run-In
All Eligible and Selected Ineligible Patients Included
Registrations ending June 30, 2020; Data as of July 13, 2020

	Run-In (n=16)	
AGE		
Median	59.5	
Minimum	31.4	
Maximum	71.7	
SEX		
Males	9	56%
Females	7	44%
HISPANIC		
Yes	3	19%
No	13	81%
RACE		
White	11	69%
Asian	1	6%
Native American	2	13%
Unknown	2	13%

Registration by Institution

Randomization
Registrations ending June 30, 2020

Institutions	Total Reg
Greenville NCORP	3
City of Hope Med Ctr	1
Michigan CRC NCORP	1
Total (3 Institutions)	**5**