PLEASE REFER TO S1316 PROTOCOL FOR CURRENT FORMS AND PROCEDURES

Contact S1316@swog.org

if you have questions.

S1316 – Malignant Bowel Obstruction

Handouts of S1316 Study Forms and Procedures as of October 24, 2014 for

Investigator and Staff Training Session

Handouts for S1316 Study Forms and Procedures Presentation

Time point	Activities	Related Forms and Documents
Patient hospitalized with MBO	Establish eligibility	Protocol Section 5.0
	Establish equipoise with regard to surgical treatment of patient's MBO	S1316 Surgical Equipoise Document
	Obtain informed consent	S1316 Consent
	Patient decides to be randomized or not	S1316 Registration Worksheet
Registration	Register patient via OPEN	
	Obtain treatment assignment (if randomized)	
	Patient receives MBO treatment within 2 days of registration	
	Complete patient contact info for site	S1316 Participant Contact Form
	Complete patient contact info for dietary recalls (Arizona Diet, Behavior and QOL Assessment Lab)	S1316 Dietary Recall Contact Form
	Email patient contact info to the Arizona Diet, Behavior and QOL Assessment Lab	
	Obtain baseline documentation	S1316 Onstudy Form
		Pathology Report
		Radiology Report(s)
	Administer PRO forms	Cover Sheet for Patient-Completed Questionnaires
		S1316 M.D. Anderson Symptom Inventory (MDASI-GI)
		S1316 EQ-5D-5L Health Questionnaire
Patient discharged from hospital	Collect MBO treatment data	S1316 Malignant Bowel Obstruction Treatment Form
		S1316 Malignant Bowel Obstruction Treatment Complications Form
		S1316 Somatostatin Analogue Treatment Form
	Collect hospitalization documentation	*Discharge Summary*
		Death Summary

Time point	Activities	Related Forms and Documents
Weekly, Weeks 1-13	Contact patient to determine any hospitalizations in the past week and to administer the PRO forms	S1316 Malignant Bowel Obstruction Assessment Form
		Cover Sheet for Patient-Completed Questionnaires
		S1316 M.D. Anderson Symptom Inventory (MDASI-GI)
		S1316 EQ-5D-5L Health Questionnaire
Report of hospitalization, Weeks 1-13	Obtain hospitalization documentation	*Discharge Summary*
		Death Summary
	Obtain MBO treatment data from this hospitalization	S1316 Malignant Bowel Obstruction Treatment Form
		S1316 Malignant Bowel Obstruction Treatment Complications Form
		S1316 Somatostatin Analogue Treatment Form
Every 4 weeks, Weeks 1-13	Arizona Diet, Behavior and QOL Assessment Lab will call the patient to administer the dietary recall	
Week 13	Report days hospitalized, based on discharge and/or death summaries	S1316 Hospitalization Days Record
		Discharge Summaries
		Death Summary
Every 4 weeks, Weeks 17-53	Contact patient to determine any hospitalizations in the past week and to administer the PRO forms	S1316 Malignant Bowel Obstruction Follow-Up Form
		Cover Sheet for Patient-Completed Questionnaires
		S1316 M.D. Anderson Symptom Inventory (MDASI-GI)
	Arizona Diet, Behavior and QOL Assessment Lab will call the patient to administer the dietary recall	

Time point	Activities	Related Forms and Documents
Patient completes 53 weeks of follow-up	Remove patient from follow-up	S1316 Off Protocol Notice
Patient refuses further phone calls from site or Arizona Diet, Behavior and QOL Assessment Lab	Remove patient from active follow-up. Vital status and hospitalizations should still be reported.	S1316 Off Protocol Notice
Patient dies	Report patient death and remove patient from follow-up	S1316 Off Protocol Notice
		Notice of Death
		S1316 Malignant Bowel Obstruction Treatment Complications Form

9.0 STUDY CALENDAR

REQUIRED STUDIES	Hospital Admission/ Baseline	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	F/U every 4 Weeks through Wk 53
PHYSICAL															
History and Physical Exam	X														
Weight and Performance Status	X														
Patient Assessment α		X	X	X	X	X	X	X	X	X	X	X	X	X	
LABORATORY															
Serum Albumin	X														
CBC †	X														
Electrolyte Panel (sodium, potassium, bicarbonate, chloride, BUN, creatinine) †	X														
SCANS															
CT or MRI for disease assessment	X														
PATIENT QUESTIONNAIRES & FOLLOW-UP															
S1316 Cover Sheet for Patient-Completed Questionnaires	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
S1316 MDASI-GI	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
S1316 EQ-D5	X		X		X				X				X		
S1316 MBO Assessment		X	X	X	X	X	X	X	X	X	X	X	X	X	
S1316 MBO Follow-Up															X
S1316 Hospitalization Days Record β														X	
Dietary Recall δ		X				X				X				X	X
TREATMENT															
Surgery (Arms 1 and 3)		X													
Non-surgical management (Arms 2 and 4)		X													

Footnotes:

α Weekly follow-up during Weeks 2-13 will take place by phone or in person if patient is in the hospital (see Section 7.5b).

β Assessment done weekly; data reported at Week 13.

† Recommended laboratory values to be collected on the **S1316** On Study Form if testing is performed.

δ To be administered monthly by phone by the Arizona Diet, Behavior and Quality of Life Assessment Lab (see Section 7.4).

SWOG
S1316 PARTICIPANT CONTACT FORM

SWOG Patient ID:_____ Patient Initials _____ (L, F M) Date of Birth_____

Institution / Affiliate _____ Physician _____

Instructions: Page 1 is used to track the weekly phone calls. Pages 2 & 3 are to obtain information on other caregivers or family who you may need to contact if the participant is unavailable. At each contact, ask if there are any changes to this information as the study participant's friends and family become more or less involved with the participant's care. Do NOT fax to the SWOG Data Operations Center.

Participant Name _____

☐ **Do not call participant, contact authorized alternate:** _____

Ethnicity (choose one): ☐ Asian ☐ Black ☐ Hispanic ☐ Native American ☐ White/Caucasian

Address: ☐ Home ☐ Nursing Home ☐ Care Facility ☐ Other: _____

_____

_____

_____

		Preferred phone for calls (choose one)
Home phone number	**( )** _____	☐
Cell phone number	**( )** _____	☐
Other phone number	**( )** _____	☐

Email address _____

Week of _____ **Study Week #**_____

Preferred time to call (place "X" in all that apply and a "C" to indicate when the call was completed):

Time	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Morning - Anytime							
7 - 9 AM							
9 - 11 AM							
11 - noon							
Afternoon - Anytime							
Noon - 2 PM							
2 - 4 pm							
4 – 6 pm							
Evening							
6 – 8 pm							
8 – 9 pm							
Other							

Complete as much information as possible to be able to remain in contact with the study participant. Indicate relationship of the contact to the study participant (e.g.., spouse, caregiver, daughter, friend)

Name, Address and Phone Numbers for other contacts in order of preferred contact:

Name: _____

Relationship to Pt: _____

Home Address: _____

_____

_____

Preferred phone for calls
(choose one)

Home phone number: ( ) _____ ☐

Cell phone number: ( ) _____ ☐

Other phone number: ( ) _____ ☐

Email address: _____

Notes: _____

☐ **Authorized to represent patient** ☐ **Only authorized to know contact info for patient**

Name: _____

Relationship to Pt: _____

Home Address: _____

_____

_____

Preferred phone for calls
(choose one)

Home phone number: ( ) _____ ☐

Cell phone number: ( ) _____ ☐

Other phone number: ( ) _____ ☐

Email address: _____

Notes: _____

☐ **Authorized to represent patient** ☐ **Only authorized to know contact info for patient**

Name: _____

Relationship to Pt: _____

Home Address: _____

_____

_____

Preferred phone for calls
(choose one)

Home phone number: ( ) _____ ☐

Cell phone number: ( ) _____ ☐

Other phone number: ( ) _____ ☐

Email address: _____

Notes: _____

☐ **Authorized to represent patient** ☐ **Only authorized to know contact info for patient**

Name: _____

Relationship to Pt: _____

Home Address: _____

_____

_____

Preferred phone for calls
(choose one)

Home phone number: ( ) _____ ☐

Cell phone number: ( ) _____ ☐

Other phone number: ( ) _____ ☐

Email address: _____

Notes: _____

☐ **Authorized to represent patient** ☐ **Only authorized to know contact info for patient**

S1316 Dietary Recall Contact Form

Instructions: This form will be used by the Arizona Diet, Behavior, and Quality of Life Assessment Lab to contact the patient 4 weeks after the baseline visit to conduct a 24-hour dietary recall. Email this form to [TBD] at the Arizona Diet, Behavior, and Quality of Life Assessment Lab within 24 hours after registration to S1316.

Patient First Name and Last Name Initial: _____

Site Name _____ Site PR# _____

SWOG ID: _ _ _ _ _ _ _ _ _ _ Registration Date:_____

Phone # (best): (_ _ _) _ _ _ - _ _ _ _ Time Zone (Please circle): ET CT MT PT Cell or Land

Phone Number (alt): (_ _ _) _ _ _ - _ _ _ _ Time Zone (Please circle): ET CT MT PT Cell or Land

Full name of an authorized alternate contact who could respond to dietary questions (always provide):

_____

Alternate's contact phone number (best): (_ _ _) _ _ _ - _ _ _ _ Type: Cell or Land

Alternate's Email address:_____

NOTES re Alternate Contact: _____

☐ **DO NOT CALL THE PATIENT if this box is marked**; use the authorized alternate contact for the information.

Preferred time to call (place "yes" in available times):

Time	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Morning - Anytime							
7 - 9 AM							
9 - 11 AM							
11 - noon							
Afternoon - Anytime							
Noon - 2 PM							
2 - 4 pm							
4 – 6 pm							
Evening							
6 – 8 pm							
8 – 9 pm							
Other							

SWOG
S1316 MALIGNANT BOWEL OBSTRUCTION ASSESSMENT FORM (DRAFT)

Patient Identifier | | | | | | | **Study Identifier** | S | 1 | 3 | 1 | 6 | **Registration Step** | 1 |

Patient Initials _____ (L, F M)

Institution/Affiliate _____ Physician _____

☐ Week 1 ☐ Week 2 ☐ Week 3 ☐ Week 4 ☐ Week 5 ☐ Week 6 ☐ Week 7

☐ Week 8 ☐ Week 9 ☐ Week 10 ☐ Week 11 ☐ Week 12 ☐ Week 13

Instructions: Submit at each follow-up contact listed above. If an assessment is missed, obtain information covering the missed period at the next assessment.

VITAL STATUS

Vital status: ☐ Alive ☐ Dead

(If vital status is Dead, complete and submit Notice of Death form)

Date of last contact: __ __ / __ __ / __ __ __ __

If dead, date of death: __ __ / __ __ / __ __ __ __

Was the patient (or the patient's representative) contacted for this assessment? ☐ Yes ☐ No

If no, reason for missed assessment *(select one):*

☐ Illness/deteriorating health

☐ Unable to contact, patient refusal (not illness related)

☐ Institutional error (e.g., forgot to administer)

☐ Patient off protocol follow-up

☐ Other

If assessment was not done, form is complete.

Has the patient been admitted to the hospital since the last assessment? ☐ Yes ☐ No

(If Yes, submit the S1316 Malignant Bowel Obstruction Treatment form)

Has the patient had any MBO treatment related problems outside the hospital? ☐ Yes ☐ No

If Yes, select all that apply:

☐ Fluid in the abdomen (ascites) → **Date of drainage of fluid from the abdomen (paracentesis):** __ __ / __ __ / __ __ __ __

☐ Wound problems

☐ Other, specify: _____

Has the patient received additional chemotherapy for his/her cancer treatment? ☐ Yes ☐ No

Comments:

5.0 ELIGIBILITY CRITERIA

NOTE: Patients must be eligible and evaluable for all eligibility criteria, regardless of study group (randomized vs non-randomized) and treatment (surgery vs non-surgical management)

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration. Use the spaces provided to confirm a patient's eligibility. For each criterion requiring test results and dates, please record this information on the Onstudy Form and submit via Medidata Rave® (see Section 14.0). Any potential eligibility issues should be addressed to the Data Operations Center in Seattle at 206/652-2267 prior to registration.

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday 4 weeks later would be considered Day 28. This allows for efficient patient scheduling without exceeding the guidelines. **If Day 3 or 7 falls on a weekend or holiday, the limit may be extended to the next working day.**

SWOG Patient No. _____

Patient's Initials (L, F, M) _____

5.1 Disease Related Criteria

_____ a. Patient must have malignant bowel obstruction (MBO) as evidenced by all of the following *(24)*:

- Clinical evidence of a bowel obstruction (via history, physical, and radiographic examination)
- Bowel obstruction below (distal to) ligament of Treitz
- Intra-abdominal primary cancer with incurable disease

_____ b. Patients must have malignant bowel obstruction due to an intra-abdominal primary cancer (i.e. stomach, small bowel [including duodenum], pancreas, colon, rectum, appendiceal, ovarian, uterine, cervical, kidney, bladder, prostate, GIST [all sites], and sarcoma).

_____ c. Patient must be able to tolerate a major surgical procedure based on clinical evaluation, status of their cancer, and any other underlying medical problems.

_____ d. A member of the patient's surgical team must indicate equipoise for the benefit of the surgical treatment for MBO. The surgeon must respond "Yes" to each of the following questions and sign the **S1316** Surgical Equipoise Documentation form for the patient to be eligible:

1. Is surgery for treatment of malignant bowel obstruction (MBO) being considered for this patient?

2. Do you have equipoise (If the treating team finds that an operation is required [e.g., for acute abdomen], or they would not offer the patient an operation [e.g., patient is too weak to tolerate surgery], then there is no equipoise)?

_____ e. Patients must not have signs of bowel perforation or "acute" abdomen as evidenced by free air on radiologic imaging or peritonitis on physical exam within 2 days prior to registration.

SWOG Patient No. _____

Patient's Initials (L, F, M) _____

5.2 Clinical/Laboratory Criteria

_____ a. Patients must be registered to the study within 48 hours after admission, within 3 days after surgical consult for MBO and prior to any treatment (surgical or non-surgical) for MBO. Treatment is defined as any medication or invasive interventions beyond nasogastric decompression, hydration, pain medications or antiemetic medications.

_____ b. Patients must have Zubrod Performance Status of 0-2 within 7 days prior to registration (see Section 10.4).

_____ c. Serum albumin must be planned to be collected after admission, but prior to treatment.

_____ d. Patients must be able to complete the study questionnaires in English.

_____ e. Patients must be ≥ 18 years of age.

5.3 Regulatory Criteria

_____ a. Patients or their legally authorized representative must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.

_____ b. As a part of the OPEN registration process (see Section 13.4 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.

_____ c. Patients must consent and provide both their contact information and that of their representative for a monthly 24-hour dietary recall phone call to be conducted by the Arizona Diet, Behavior and Quality of Life Assessment Lab.

SWOG
S1316 SURGICAL EQUIPOISE DOCUMENTATION (DRAFT)

Patient Identifier | | | | | | | **Study Identifier** | S | 1 | 3 | 1 | 6 | **Registration Step** | 1 |

Patient Initials _____ (L, F M)

Institution/Affiliate _____ Physician _____

Instructions: A member of the patient's consulting surgical team must respond to both of these questions prior to registration. Communication may be verbal or written. The patient is potentially eligible for S1316 only if the response to both questions is "Yes". Do not submit this form.

1. **Is surgery for treatment of malignant bowel obstruction (MBO) being considered for this patient?**
   - ☐ Yes – Go to Question 2
   - ☐ No – patient not eligible

2. **Do you have equipoise (If the treating team finds that an operation is required [e.g., for acute abdomen], or they would not offer the patient an operation [e.g., patient is too weak to tolerate surgery], then there is no equipoise)?**
   - ☐ Yes
   - ☐ No – patient not eligible

Name of surgical team member who responded: _____

Role: ☐ S1316 site team member ☐ Attending physician

Date: ☐☐/☐☐/☐☐☐☐

Signature of person completing form (optional): _____

Comments:

SWOG
S1316 REGISTRATION WORKSHEET (DRAFT)

PROSPECTIVE COMPARATIVE EFFECTIVENESS TRIAL FOR MALIGNANT BOWEL OBSTRUCTION

Registration Step 1

INSTRUCTIONS: All of the information on this Registration Worksheet and the Protocol Eligibility Section must be answered appropriately for a patient to be considered eligible for registration. This Registration Worksheet must be entirely filled out and referred to during the registration. **Do NOT submit this worksheet as part of the patient data.**

SWOG PATIENT ID

If the patient has a SWOG Patient ID assigned by a prior registration or Specimen Tracking, choose "Previous Patient" and use that number.

SWOG Patient ID Status: ☐ New Patient ☐ Previous Patient: **SWOG Patient ID:** ☐☐☐☐☐☐

DEMOGRAPHY

Full names preferred, initials OK

Patient First Name: _____

Patient Middle Name: _____

Patient Last Name: _____

FOR SWOG INSTITUTIONS

Registrar's SWOG Roster ID Number: ☐☐☐☐☐

SWOG Investigator Number: ☐☐☐☐☐

SWOG Treating Institution Number: ☐☐☐☐☐

PATIENT INFORMATION

Date Informed Consent Signed: ☐☐ / ☐☐ / ☐☐☐☐

Date HIPAA Authorization Signed: ☐☐ / ☐☐ / ☐☐☐☐ *(Not required if Country of Residence is not USA)*

Projected Start Date of Treatment: ☐☐ / ☐☐ / ☐☐☐☐

Stratification Questions

Primary tumor type: ☐ (1) colorectal cancer ☐ (2) ovarian cancer ☐ (3) other cancer

Patient's decision regarding treatment assignment:

☐ (1) Randomize patient: patient agrees to allow the study to randomly select his/her treatment
☐ (2) Patient has chosen to receive surgery
☐ (3) Patient has chosen to receive non-surgical treatment

Indicate how the patient answered the following question on the consent form

I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study. ☐ Yes ☐ No

Patient Eligibility

Has the SWOG Registration Worksheet been completed entirely and is the patient eligible according to the current version of protocol section 5.0? ☐ Yes ☐ No

I affirm that the eligibility criteria outlined in Section 5.0 of this study have been met.

Registering Investigator **Date**

SWOG
S1316 HOSPITALIZATION DAYS RECORD (DRAFT)

Patient Identifier | | | | | | |

Study Identifier S 1 3 1 6

Registration Step 1

Patient Initials ________________ (L, F M)

Institution/Affiliate ________________________________ Physician ________________________

Instructions: Submit this form within 14 days after the Week 13 assessment. Indicate "Yes" if the patient was in the hospital for all or part of a day for each date below. Mark "No" if the patient was alive and not in the hospital that day. Mark "N/A" if the date is prior to registration or after the date of death. Mark a response for all dates. Include days or parts of days the patient was admitted to the hospital or in the emergency room (ER).

Date Range	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A

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SWOG
S1316 HOSPITALIZATION DAYS RECORD (DRAFT)

Patient Identifier ☐☐☐☐☐☐ **Study Identifier** S 1 3 1 6 **Registration Step** 1

Patient Initials ________________ (L, F M)

Date Range	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A

continued on next page

SWOG
S1316 HOSPITALIZATION DAYS RECORD (DRAFT)

Patient Identifier ☐☐☐☐☐☐ **Study Identifier** S 1 3 1 6 **Registration Step** 1

Patient Initials ________________ (L, F M)

Date Range	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A
________ to ________	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A	☐ Yes ☐ No ☐ Unknown ☐ N/A

Comments:

S1316 Protocol Section 7.5b

b. Follow-up

Study site staff will contact patients via phone for assessments weekly for the first 13 weeks after registration and every 4 weeks thereafter, up to one year after registration. The **S1316** Follow-Up Form collects information on vital status and hospitalization. Site staff (CRA) will administer all forms as outlined below. All patient-completed study forms will be administered via telephone or in person, if patient is in the hospital and allows an in-person visit. Forms are submitted according to the schedule in Section 14.4. Follow-up assessments of patients are based from the date of registration. The time window for each phone assessment is +/- 2 days to allow for scheduling. If a follow-up call or visit is missed, the information that was missed will be included during the next completed call or visit.

Every effort should be made to collect the follow-up data in identical fashion across all study arms (surgical vs. non-surgical management, randomized vs. non-randomized)

SWOG
S1316 MALIGNANT BOWEL OBSTRUCTION TREATMENT FORM

Patient Identifier ☐☐☐☐☐☐ **Study Identifier** S 1 3 1 6 **Registration Step** 1

Patient Initials _____ (L, F M)

Institution/Affiliate _____ Physician _____

Instructions: Complete this form each time the patient is admitted in a hospital setting (hospital or emergency room) for any reason. Submit within 14 days after hospital discharge. Complete this form even if the patient received no treatment for malignant bowel obstruction (MBO).

Hospitalization start date (admission): ☐☐/☐☐/☐☐☐☐

Hospitalization end date (discharge or death): ☐☐/☐☐/☐☐☐☐

Reason for hospitalization *(select all that apply)*:

- ☐ MBO
- ☐ Other, specify: _____

Did the patient have a blood transfusion? ☐ Yes ☐ No

If yes, number of RBC units: ☐☐ **OR** ☐ ≤5 units ☐ >5 units

SURGICAL TREATMENT

Did the patient receive any surgical treatment for his/her MBO? ☐ Yes ☐ No

If no, why did the patient not receive surgery? _____

If yes, complete the Surgical section below.

How was the procedure performed?

- ☐ Entire procedure laparoscopic
- ☐ Converted to open
- ☐ Entire procedure open
- ☐ Laparoscopic assisted
- ☐ Other, specify: _____

What MBO procedures were performed? *(select all that apply)*

- ☐ Lysis of adhesions
- ☐ Small bowel resection with primary anastomosis
- ☐ Large bowel resection with primary anastomosis
- ☐ Large bowel resection with end colostomy
- ☐ Intestinal bypass
  - ☐ Gastrojejunostomy
  - ☐ Jejunojejunostomy
  - ☐ Jejunoileostomy
  - ☐ Jejunocolostomy
  - ☐ Other
- ☐ Loop colostomy
- ☐ Gastrostomy
- ☐ Other
- ☐ None

continued on next page

S1316 MALIGNANT BOWEL OBSTRUCTION TREATMENT FORM

Patient Identifier | | | | | | | **Study Identifier** | S | 1 | 3 | 1 | 6 | **Registration Step** | 1 |

Patient Initials _____ (L, F M)

SURGICAL TREATMENT, *continued*

Other procedures performed *(mark all that apply)*

- ☐ Complete excision of tumor mass
- ☐ Incomplete excision of tumor mass (cytoreduction/debulking)
- ☐ Ureteral stent placement
- ☐ Other

Was re-operation required? ☐ Yes ☐ No

Was this an emergency operation?

- ☐ No
- ☐ Yes → Reason *(select only one)*
  - ☐ Bowel perforation
  - ☐ Acute (surgical) abdomen
  - ☐ Other, specify: _____

Site of obstruction *(mark all that apply)*

- ☐ Proximal jejunum
- ☐ Mid jejunum
- ☐ Ileum
- ☐ Colon

Ascites amount: ☐☐☐☐ cc

Total blood loss: ☐☐☐ cc

Other findings

- ☐ Carcinomatosis: trace/small amount
- ☐ Carcinomatosis: large/massive amount
- ☐ Other
- ☐ None

NON-SURGICAL TREATMENT

Did the patient receive any non-surgical treatment for his/her MBO? ☐ Yes ☐ No

If yes, complete the Non-Surgical Treatment section below.

Did the patient receive nasogastric (NG) decompression? ☐ Yes ☐ No

Did the patient receive a NG tube? ☐ Yes ☐ No

If yes, number of days with tube (total): ☐☐

If yes, number of days with tube (after medications started): ☐☐

Did the patient receive percutaneous endoscopic gastrostomy (PEG) tubes? ☐ Yes ☐ No

If yes, date: ☐☐ / ☐☐ / ☐☐☐☐

Did the patient develop aspiration pneumonia? ☐ Yes ☐ No

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S1316 MALIGNANT BOWEL OBSTRUCTION TREATMENT FORM

Patient Identifier | | | | | | | **Study Identifier** | S | 1 | 3 | 1 | 6 | **Registration Step** | 1 |

Patient Initials _____ (L, F M)

NON-SURGICAL TREATMENT, *continued*

Did the patient receive intravenous hydration? ☐ Yes ☐ No

If yes, number of days with IV hydration (total): | |

If yes, number of days with IV hydration (after medications started): | |

Did the patient receive TPN? ☐ Yes ☐ No

If yes, number of days with tube (total): | |

If yes, number of days with tube (after medications started): | |

What medications were used to treat the patient's MBO and related disorders? *(select all that apply)*

Anti-secretory agents

☐ Somatostatin analogue (lanreotide, octreotide, pasireotide, somatostatin) *(Submit S1316 Somatostatin Analogue Treatment Form)*

☐ Steroids → Start date: | | / | | / | | | |

☐ Scopolamine → Start date: | | / | | / | | | |

Pain medications

☐ Morphine
☐ Fentanyl
☐ Hydromorphone
☐ Methadone

Anti-emetic therapies

☐ Haloperidol
☐ Prochlorperazine

☐ Other medications

DISCHARGE MEDICATIONS AND HOME CARE

Was the patient discharged from the hospital? ☐ Yes ☐ No

If yes, complete the Discharge Medications and Home Care section below.

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S1316 MALIGNANT BOWEL OBSTRUCTION TREATMENT FORM

Patient Identifier | | | | | | | **Study Identifier** | S | 1 | 3 | 1 | 6 | **Registration Step** | 1 |

Patient Initials _____ (L, F M)

DISCHARGE MEDICATIONS AND HOME CARE, *continued*

Did the patient go home on any of the following? *(select all that apply)*

- ☐ Home TPN
- ☐ Tube feeding
- ☐ None of the above

What medications were prescribed for the patient for post-hospitalization use?

Anti-secretory agents

- ☐ Somatostatin analogue (lanreotide, octreotide, pasireotide, somatostatin)
  - ☐ Daily dose, specify dose:_____
  - ☐ Monthly shot (depot), specify dose: _____
- ☐ Steroids → Start date: ☐☐ / ☐☐ / ☐☐☐☐
- ☐ Scopolamine → Start date: ☐☐ / ☐☐ / ☐☐☐☐

Pain medications

- ☐ Morphine
- ☐ Fentanyl
- ☐ Hydromorphone
- ☐ Methadone

Anti-emetic therapies

- ☐ Haloperidol
- ☐ Prochlorperazine

- ☐ Other medications
- ☐ None

Comments:

Form or *Document* Name	Primary purpose	WHEN data are collected or form is administered	HOW data are collected or form is administered	WHEN form is submitted
S1316 Surgical Equipoise Documentation	Establish that the patient's MBO may reasonably be treated surgically or non-surgically.	Prior to registration	A member of the patient's surgical team must respond to the questions	Not submitted. Retain as source doc.
S1316 Registration Worksheet	Document basic patient data for registration and study arm (patient chose randomization or surgery or non-surgical treatment).	Prior to registration	Obtain from patient chart and patient interview	In OPEN at registration
S1316 Participant Contact Form	Obtain patient contact information to facilitate weekly study calls to the patient.	At registration	Patient interview	Not submitted. Retain as source doc.
S1316 Dietary Recall Contact Form	Obtain patient contact information for the Arizona Diet, Behavior and QOL Assessment Lab to condut the dietary recalls. Do not submit in Rave; email the form directly to the Lab.	At registration	Patient interview	Within 24 hours of registration (email to Lab)
S1316 Onstudy Form	Document cancer, prior cancer and MBO therapies, and other relevant baseline information.	At registration	Obtain from patient chart and patient interview	Within 7 days of registration
Pathology Report	Document primary intra-abdominal cancer.	At registration	Obtain from patient chart	Within 7 days of registration
Radiology Report(s)	Document all scans used to assess baseline MBO.	At registration	Obtain from patient chart	Within 7 days of registration
S1316 Malignant Bowel Obstruction Treatment Form	Document MBO treatment received during hospital stay (surgical and non-surgical) and any home care prescribed.	During each hospitalization	Obtain from patient chart	Within 14 days after discharge

Form or *Document* Name	**Primary purpose**	**WHEN data are collected or form is administered**	**HOW data are collected or form is administered**	**WHEN form is submitted**
S1316 Malignant Bowel Obstruction Treatment Complications Form	Document any complications related to MBO treatment patient experienced during hospital stay, as well as SAEs.	During each hospitalization	Obtain from patient chart	Within 14 days after discharge
S1316 Somatostatin Analogue Treatment Form	Document somatostatin analogue treatment received during hospital stay.	During each hospitalization	Obtain from patient chart	Within 14 days after discharge
Discharge Summary	Document hospitalization begin and end dates, for patients discharged from the hospital.	After each hospital visit ends	Obtain from patient chart	Within 14 days after discharge
Death Summary	Document hospitalization begin and end dates, for patients who dies while hospitalized.	After each hospital visit ends	Obtain from patient chart	Within 14 days after discharge
Cover Sheet for Patient-Completed Questionnaires	Document completion (or not) of PRO forms.	At registration and after each scheduled weekly (or monthly) call.	Patient interview	Within 7 days of assessment
S1316 M.D. Anderson Symptom Inventory (MDASI-GI)	Assess patient perception of cancer and GI symptoms.	At registration and after each scheduled weekly (or monthly) call.	Patient interview	Within 7 days of assessment
S1316 EQ-5D-5L Health Questionnaire	Assess patient perception of health.	At registration and Weeks 2, 4, 8 and 12 only.	Patient interview	Within 7 days of assessment
S1316 Hospitalization Days Record	Document days in and out of the hospital for first 91 days.	Weekly	Hospitalization documentation (discharge summaries)	Within 14 days after Week 13
S1316 Malignant Bowel Obstruction Assessment Form	Document whether patient was hospitalized in past week so appropriate forms can be submitted.	Weekly for Weeks 1-13	Patient interview	Within 7 days of assessment
S1316 Malignant Bowel Obstruction Follow-Up Form	Document whether patient was hospitalized in past four weeks.	Every 4 weeks for Weeks 17-53	Patient interview	Within 14 days of assessment

Form or *Document* Name	Primary purpose	WHEN data are collected or form is administered	HOW data are collected or form is administered	WHEN form is submitted
S1316 Off Protocol Notice	Remove patient from active follow-up (i.e., no more phone calls to patient).	At time of decision to remove patient from active follow-up, completion of 53 weeks of follow-up or death	Obtain from patient chart	Within 3 days of decision
Notice of Death	Document patient has died.		Obtain from patient chart and appropriate death source documents	Within 4 weeks of knowledge of death