



# S1316- MBO STUDY

July 10, 2019

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**Welcome** to the MBO Study quarterly newsletter.

Our research team has created this newsletter to provide you with the latest news about this study.

If you would like to contribute to the newsletter send your comments or questions to Octavio Bojorquez at [obojoqrqu@email.arizona.edu](mailto:obojoqrqu@email.arizona.edu).

## Study Accrual through Tuesday July 2, 2019

Accrual by Site				
Site Name	N Randomized	N Patient Choice	N Total	% Total
<b>TOTAL ACCRUAL</b>	34	165	199	100
University of Tennessee	12	28	40	20
Northwell Health	8	28	36	18
University of Kansas Cancer Center	0	18	18	9
Banner University Medical Center –Tucson	0	17	17	9
University of Oklahoma Health Sciences Center	0	13	13	7
Duke University Medical Center	0	11	11	6
University of Michigan Comprehensive Cancer Center	1	7	8	4
City of Hope National Medical Center	0	8	8	4
University of Arkansas for Medical Sciences	0	6	6	3
Instituto Nacional de Cancerologia (INCan)	5	0	5	3
Instituto Nacional de Enfermedades Neoplasicas	5	0	5	3
Medical Univ of South Carolina MU-NCORP	0	5	5	3
Froedtert and the Medical College of Wisconsin	0	4	4	2
Valley Health / Winchester Medical Center	0	4	4	2
H. Lee Moffitt Cancer Center	1	2	3	2
Rhode Island Hospital	0	3	3	2
Baylor University Medical Center	0	2	2	1
MD Anderson Cancer Center	0	2	2	1
University of Massachusetts Medical School	0	2	2	1
Baylor College of Medicine	1	0	1	1
Loma Linda University Cancer Institute	1	0	1	1
Columbia University Minority Underserved NCORP	0	1	1	1
Essentia Health Cancer Center	0	1	1	1
New Mexico Minority Underserved NCORP	0	1	1	1
Rush University Medical Center	0	1	1	1
University Hospital	0	1	1	1

★ Congratulations to the sites that have accrued ten or more participants

# OPEN SITES

University of Arizona	City of Hope	Baylor UMC Dallas	Duke University	Columbia University	Northwell Health
Medical University of South Carolina	University of Oklahoma	University of Michigan	University of Massachusetts	Rhode Island (Brown)	MD Anderson
Rush University Medical Center	Essentia Health CC Minnesota	Medical College of Wisconsin	University of Arkansas	Instituto Nacional de Cancerología Colombia	University of Kansas
University of Tennessee	University of Pennsylvania	Baylor College of Medicine Houston	University of New Mexico	University of Massachusetts	MOFFITT Cancer Center
Loma Linda Center	University of Texas Health San Antonio	Instituto Nacional de Cancerología México	Instituto Nacional de Enfermedades Neoplásicas Perú	Valley Health	Hackensack Meridian

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## Tracking Log

Investigator									
Participant Site									
Row	Month	Patient initials <i>(redact for submission to S1316 team)</i>	Confirmed MBO patient? <i>(Y/N)</i>	When was patient admitted? <i>(regular hours, after hours, week-end, holiday)</i>	Was patient ever considered for study participation? <i>(if not, list reason why not considered)</i>	Was the patient ever approached for study participation? <i>(If not, list reason why not approached)</i>	Was the patient eligible for study participation? <i>(if not, list the reason why not eligible)</i>	Was the patient willing to participate <i>(if not, list reason why not willing)</i>	Was the patient registered? <i>(if not, list reason why not registered)</i>

**S1316 Patient Accrual Tracking Log** to keep track of all potential patients. Please send the log to our team **once a month**. The log is available at the SWOG study webpage or you can request one from Octavio Bojorquez.

Thank you to everyone who has submitted a monthly patient log! These logs are used in the study's report to the DSMC to describe why it is so hard to register (and randomize) patients in this study population. Please continue to send them in!



## Study Update

### Patient Choice Arms Are Closed to Accrual

Both Patient Choice Arms (Surgery and Non-Surgical Management) are closed to accrual. The Patient Choice - Surgery arm closed on June 6, 2019, and the Patient Choice - Non-surgical Management arm closed on April, 2018. Patients must be followed per protocol Section 7.0.

### Randomization Arms are Open!

Patients may continue to be registered to the randomized component of the study. Because randomizations have been going so well, we received approval from the NCI to increase the number of randomizations, to 220 patients. Please continue to randomize patients!!

### Strategies to Increase Randomizations

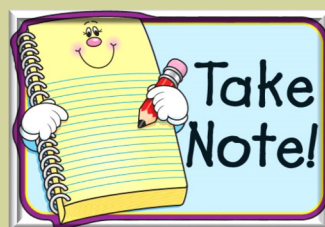
Looking for ideas on how to increase randomizations at your site? The S1316 investigators, including lead off author Dr. Gary Deutsch (American Journal of Hospice and Palliative Medicine, 2019), recently published an article based on the S1316 experience. Here are the suggestions:

1. Focus initial conversation on diagnosis and work-up of malignant bowel obstruction (bowel obstruction in setting of advanced cancer).
2. Discuss Treatment Options: Operative or Non-operative treatments.
3. After initial discussion of the diagnosis and management of their MBO, ask about the patient's thoughts on proceeding with operative or a non-operative treatment approach.
4. If the patient is leaning toward one option or the other, introduce the information regarding the Malignant Bowel Obstruction Study (S1316):
5. Discuss the S1316 study as a national collaboration among many well-known institutions (yours included) to try and answer this question – what treatment would be best for a particular patient with a malignant bowel obstruction?
6. It is very important to offer randomization to each eligible patient with MBO. While most surgeons will have biases about the most appropriate treatment option for patients with an MBO, randomization overcomes and negates these biases.

### Clarifications for Coordinators re: Consent and Addendum

A consent addendum was released to sites indicating the closure of the patient choice portion of the study on June 15, 2019. This addendum was released for site use if IRBs of record should require it when submitting closure of the patient choice portion to their IRBs of record. An updated consent form is now available on [swog.org](http://swog.org), reflecting the accrual increase as well as the patient choice arm closure.

If you have any other questions feel free to contact **Veronica Garcia** at (210) 614-8808 Ext 0944 or by email at [vgarcia@swog.org](mailto:vgarcia@swog.org)



## On-Call Weekend Coordinator

Funds are available for staff to be on-call on a weekend during normal working hours to assist with patient accrual. The study can provide a small stipend of \$40/day; \$80/weekend, and an additional \$200 if it is necessary to come in to register a patient. If you would like to use these funds or would like more information, please contact Octavio Bojorquez.



## Site Coordinators Teleconference

We have a monthly (30-60 minute) teleconference for coordinators from open and planning-to-open study sites to discuss study issues with the research team. Our next call will be July 10, 2019 at 1:00 P.M. ET, 12:00 P.M. CT, 10:00 AZ and 10:00 A.M. PT. The **TOLL-FREE DIAL-IN NUMBERS** for our next call are:

If you are in the **United States** dial **1-866-951-1151**

If you are in **México** dial **01-8000-925-0370**

If you are in **Colombia** dial **01-800-012-9050**

If you are in **Perú** dial **0-800-55463**

Enter Conference Room number **424 091 847** then press #



**Remember!**

## STUDY INFORMATION

Study information is available at <http://swog.org> and CTSU at <https://www.ctsu.org>. Have suggestions for our newsletter? Send your comments or suggestions to Octavio at [obojoqu@email.arizona.edu](mailto:obojoqu@email.arizona.edu).

Have a question for the Study Chair Dr. Robert S. Krouse? You can call his cell phone at (520) 631-5642 or Virginia Sun PhD., RN cell phone at (626) 257-4717.

Please use [cancercontrolquestion@crab.org](mailto:cancercontrolquestion@crab.org) for S1316 questions related to study forms or data submission.