





S1316- MBO STUDY

March 12, 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 obojorqu@email.arizona.edu.

Study Accrual through February 28, 2019

Accrual by Site							
Site Name	N Randomized	N Patient Choice	N Total	% Total			
TOTAL ACCRUAL	20	156	176	100			
University of Tennessee	9	27	36	20			
Northwell Health	5	26	31	18			
University of Arizona Medical Center - Univ Campus	0	16	16	9			
University of Kansas Cancer Center	0	16	16	9			
University of Oklahoma Health Sciences Center	0	13	13	7			
Duke University Medical Center	0	11	11	6			
City of Hope National Medical Center	0	8	8	5			
University of Michigan Comprehensive Cancer Center	1	6	7	3			
University of Arkansas for Medical Sciences	0	6	6	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			
Rhode Island Hospital	0	3	3	2			
Instituto Nacional de Cancerologia (INCan)	2	0	2	1			
Instituto Nacional de Enfermedades Neoplasicas	2	0	2	1			
Baylor University Medical Center	0	2	2	1			
H. Lee Moffitt Cancer Center	0	2	2	1			
Baylor College of Medicine	1	0	1	1			
Columbia University Minority Underserved NCORP	0	1	1	1			
Essentia Health Cancer Center	0	1	1	1			
MD Anderson 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			
University of Massachusetts Medical School	0	1	1	1			

Welcome New Site





University of Utah





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		Instituto Nacional de Cancerología México	FNTOTMONANCE	Valley Health	Hackensack Meridian	

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Tracking Log

Investigator Participant Sit	to								
Participant 3n	te								
Row	Month	Patient initials (redact for submission to \$1316 team)	Confirmed MBO patient? (Y/N)	When was patient admitted? (regular hours, after hours, week- end, holiday)	Was patient ever considered for study partici- pation? (if not, list reason why not consid- ered)	Was the patient ever approached for study participation? (If not, list reason why not approached)	Was the patient eligible for study participation? (If not, list the reason why not eligible)	Was the patient willing to participate (if not, list reason why not willing)	Was the patient registered? (if not, list reason why not registered)

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!



Patient Retention Options

For patients who no longer want to participate on the study, make sure they understand their options for reducing their own burden while continuing to contribute to the study:

- Weekly calls may be limited to hospitalization information (no questionnaires).
- Patients may designate a representative or alternate contact to respond to the calls on their behalf.
- Patients and/or their representative may refuse to complete a dietary recall.
- Patients may refuse all future calls and still allow the site to collect hospitalization data from their medical records (submit the S1316 Off Protocol to trigger this passive follow-up).
- Consent withdrawal should be the final option, and then only if requested by the patient. Patients who
 withdraw consent no longer contribute any data to the study, including survival and hospitalization data, the study's
 primary outcome.



SWOG's Spring 2019 Group Meeting

SWOG'S Spring 2019 Group Meeting will take place **April 24-27** at the **Hyatt Regency in San Francisco**. The **S1316 study meeting** will be on **Thursday April 25**, **from 1:00 pm-2:00pm Pacific Time**. Details about the location and phone line to connect to the meeting if you are not attending in person will be sent at a later time.

April's site coordinator meeting will be cancelled. Instead, we ask the coordinators to join the group call.



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 March 13, 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 #





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 obojorqu@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.