



S1316- MBO STUDY

September 18, 2017

In this issue:

- Accrual Update
- Welcome New Sites
- Open Sites
- Tracking Log
- Site Reminders
- Study Training Materials on CTSU
- SWOG's Fall 2017 Group Meeting
- On-call Weekend Coordinator
- Coordinator's Teleconference
- Study Information



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.

Study Accrual through August 31, 2017

Accrual by Site				
Site Name	N Randomized	N Patient Choice	N Total	% Total
TOTAL ACCRUAL	2	104	106	100
University of Tennessee	0	17	17	16
Northwell Health	0	15	15	14
University of Kansas Cancer Center	0	12	12	11
University of Arizona Medical Center - Univ Campus	0	10	10	9
University of Oklahoma Health Sciences Center	0	10	10	9
Duke University Medical Center	0	8	8	8
University of Michigan Comprehensive Cancer Center	1	6	7	7
City of Hope National Medical Center	0	7	7	7
Medical Univ of South Carolina MU-NCORP	0	5	5	5
University of Arkansas for Medical Sciences	0	5	5	5
Baylor University Medical Center	0	2	2	2
Froedtert and the Medical College of Wisconsin	0	2	2	2
Rhode Island Hospital	0	2	2	2
Baylor College of Medicine	1	0	1	1
Columbia University Minority Underserved NCORP	0	1	1	1
MD Anderson Cancer Center	0	1	1	1
Rush University Medical Center	0	1	1	1

★ Congratulations to the sites that have accrued 5 or more participants

Welcome New Sites

Loma Linda Cancer Center

24 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 C C 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 |

F Y I

Tracking Log

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.

Investigator									
Participant Site									
Row	Month	Patient initials (redact for submission to S1316 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 pa- tient eligible for study participation? (If not, list the reason why not eligible)	Was the pa- tient willing to participate (if not, list reason why not willing)	Was the patient registered? (if not, list reason why not regis- tered)

Monthly Patient Logs: how are these really used?

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!



SITE REMINDERS



When a patient is registered to **S1316**, sites should make a calendar for the patient with dates the patient should expect to receive the phone calls for the study assessments. See the Study Calendar in **Section 9.0** of the protocol.

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. Follow-up assessments of patients are based from the date of registration. The time window for each assessment is +/- 2 days to allow for scheduling. **The first assessment (Week 1) should happen 7 days after registration.**

Note: The Confirmation of Registration page from OPEN (Oncology Patient Enrollment Network) should not be used as a calendar for this purpose. The "Expectations for this registration" dates listed on the Confirmation of Registration page after a successful registration does not provide target dates for scheduling patient assessments. It shows the due dates for each form, which are well after the assessment target dates.

Study Training Materials on CTSU

Many sites participating in S1316 access the study materials using CTSU

While there are multiple ways to find documents for S1316 on CTSU, we encourage sites to utilize the *Protocols* tab next to the *Home* button at the top left rather than the *Document Search* tab on the CTSU Home page. The *Protocols* tab links to all **S1316 study materials**, including providing Web Links back to SWOG for study specific training materials while the *Document Search* button only links to pdfs for the protocol, including forms, memoranda, revisions and editable Word documents.

To find the site training materials, open the *Protocols* tab. You may either type *S1316* in the search box or drill down to NCORP, SWOG, S1316, LPO Documents, and then *Education* and *Promotion Materials*. In the main window you will find the link to the *S1316 Training and Site Materials*, which is a Web Link to the SWOG Study S1316 Page on www.swog.org

SWOG's Fall 2017 Group Meeting

SWOG'S Fall 2017 Group Meeting will take place **October 11-14, 2017** at the **Hyatt Regency in Chicago, Illinois**. The **S1316 study meeting** will be on **October 12, 2017 from 5:30 pm-6:30pm**, in the **Gold Coast room** (located on the Concourse level of the west tower). If you are not able to attend, you can join by dialing **1 (855) 295-4424** conference code **7586712**

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 \$80/day; \$160/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.



Coordinator's 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 September 20, 2017 at 1:00 P.M. ET, 12:00 P.M. CT, and 10:00 A.M. PT. The number to call is 1-855-295-4424. Conference code is 6221480#.



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.

Have a question for the Study Coordinator 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 for S1316 questions related to study forms or data submission.