

S1316- MBO STUDY

February 3, 2016

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Welcome to our second edition of our monthly newsletter. Our research team has created this newsletter to provide you with the latest news, and questions that arise with the study.

If you would like to contribute with your comments or questions for this newsletter send them to Octavio Bojorquez at objorqu@email.arizona.edu

Coordinators Call Summary

Thanks to the 13 staff representing 9 study sites who attended this call.

There was all around congratulations for everyone's hard work at all sites who either added to accrual in the last month or now has IRB approval. Protocol cards have been mailed to study sites; please remember to add a label to the card with your contact information before distributing the cards. The following question was discussed:

- What are the radiology requirements for bowel obstruction?
Any indication of possible bowel obstruction is eligible for the study.



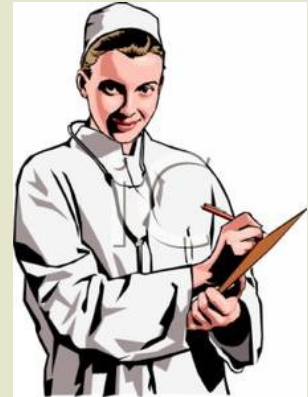
The following reminders were discussed by SWOG personnel:

- Management of different levels of patient follow-up :
 - ◇ Active follow-up is when the patient consents to receive the study-related phone calls; all patients are in active follow-up when they register to the study.
 - ◇ Passive follow-up is when the patient no longer wants to receive the study-related phone calls, but agrees to allow their data to be collected.
 - ◇ Sites must submit the S1316 Off Protocol Notice within 3 days when a patient no longer wants to be called, so that the Arizona Diet, Behavior, and Quality of Life Assessment Lab, which makes the monthly dietary recall calls, is notified.
 - ◇ Patients who have declined further phone calls and are under passive follow-up should still have their data reported, using medical records. If the patient is going to be followed at another Institution, study staff should obtain a Release of Information so you can request the patient's medical records.
 - ◇ Patients that refuse all further follow-up and no longer wish to participate in the study in any capacity must be removed from follow-up using the Consent Withdrawal form; no further data will be collected from these patients.
- Equipose eligibility criteria: It is equipose if it is reasonable to go either way on treatment options (surgical versus non-surgical).

Finally, we reminded sites that we have the optional Patient Accrual Tracking Log available at the SWOG website or you can request it from S1316@swog.org.

Study Accrual through January 31, 2015

Accrual by Site		
Site Name	N	%
TOTAL ACCRUAL	17	100
City of Hope Comprehensive Cancer Center	1	6
Duke University Medical Center	3	18
Medical University of South Carolina	3	18
The University of Arizona Medical Center-University Campus	4	24
University of Arkansas for Medical Sciences	2	12
University of Michigan Comprehensive Cancer Center	4	24



Accruing patients after-hours

Patients participating in the non-randomized portion of the study may be registered under SWOG Policy #12. This policy specifies that registrations to the non-randomized portion of a study (1) after regular business hours (e.g., on holidays or weekends), or (2) while the site is unable to access the online registration program, may be completed by calling the Data Operations Center rather than using OPEN. To implement SWOG Policy #12 correctly, the institution must call the Data Operations Center leaving a voice mail message on the day treatment is to begin. Please review the full SWOG Policy #12 <https://swog.org/Visitors/Policies.asp> before registering a patient in this manner.

Coordinators call

We have a monthly 30-60 minute teleconference call for coordinators from open and planning to open study sites to discuss any study issues with the research team. Join us Wednesday, February 10th, 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#.



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Spring 2016 SWOG Meeting

The next SWOG group meeting will take place on April 27-30, 2016 at the Hyatt Regency San Francisco in San Francisco, California.

Join us at the SWOG Meeting In April

Staff from all participating sites are invited to attend an informal one hour meeting at the SWOG meeting in San Francisco, Friday, April 29, 8:00 – 9:00 A.M. PT, at the Hyatt Regency San Francisco. This will be a great opportunity to meet other staff and get updates from the study leadership. Look for more information about this meeting in future newsletters. For more information about the group meeting visit <https://swog.org/Visitors/>

STUDY INFORMATION

Study information is available swog.org and CTSU @<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 PI Dr. Robert S. Krouse? Feel free to call his cell phone at (520) 631-5642