



S1316- MBO STUDY

December 8, 2017

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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.

Study Accrual through December 5, 2017

| Accrual by Site | | | | |
|----------------------------------------------------|--------------|------------------|---------|---------|
| Site Name | N Randomized | N Patient Choice | N Total | % Total |
| TOTAL ACCRUAL | 8 | 120 | 128 | 100 |
| University of Tennessee | 4 | 20 | 24 | 19★ |
| Northwell Health | 2 | 20 | 22 | 17★ |
| University of Kansas Cancer Center | 0 | 14 | 14 | 11★ |
| University of Arizona Medical Center - Univ Campus | 0 | 12 | 12 | 9★ |
| University of Oklahoma Health Sciences Center | 0 | 12 | 12 | 9★ |
| Duke University Medical Center | 0 | 8 | 8 | 6 |
| University of Michigan Comprehensive Cancer Center | 1 | 6 | 7 | 5 |
| City of Hope National Medical Center | 0 | 7 | 7 | 5 |
| Medical Univ of South Carolina MU-NCORP | 0 | 5 | 5 | 4 |
| University of Arkansas for Medical Sciences | 0 | 5 | 5 | 4 |
| Froedtert and the Medical College of Wisconsin | 0 | 3 | 3 | 2 |
| Baylor University Medical Center | 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 |
| Essentia Health Cancer Center | 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 ten or more participants

Welcome New Sites University of Texas Health San Antonio



Valley Health

Hackensack Meridian



25 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 | | | | | |



Tracking Log

| 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 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!



Revisions

Revision #9 was distributed to the sites on November 1st, 2017. We have added, removed and updated information about some of the study sites. HIPAA policies, registration procedures and data submission language has been revised or updated as recommended by CTEP and CTSU. Sections of the model consent form have been modified to clarify options available to subjects participating in the study.

Revision # 10 has been recently approved. New sites have been added and verbiage has been added to clarify that it is optional for patients to receive a somatostatin analogue.

For more information about the changes in these revisions, please visit the protocol document available on [CTSU](#) or [SWOG](#).

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.



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 December 13, 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#.



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 oboiorqu@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.

Thanks to all site staff for your work on the S1316-MBO study