



# S1316- MBO STUDY

June 8, 2018

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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 May 31, 2018

| Accrual by Site                                    |              |                  |            |            |   |
|--|--------------|------------------|------------|------------|---|
| Site Name  | N Randomized | N Patient Choice | N Total    | % Total    |   |
| <b>TOTAL ACCRUAL</b>                               | <b>10</b>    | <b>145</b>       | <b>155</b> | <b>100</b> |   |
| University of Tennessee                            | 6            | 23               | 29         | 19         | ★ |
| Northwell Health                                   | 2            | 24               | 26         | 17         | ★ |
| University of Arizona Medical Center - Univ Campus | 0            | 16               | 16         | 10         | ★ |
| University of Kansas Cancer Center                 | 0            | 16               | 16         | 10         | ★ |
| University of Oklahoma Health Sciences Center      | 0            | 13               | 13         | 8          | ★ |
| Duke University Medical Center                     | 0            | 11               | 11         | 7          | ★ |
| University of Michigan Comprehensive Cancer Center | 1            | 6                | 7          | 5          |   |
| City of Hope National Medical Center               | 0            | 7                | 7          | 5          |   |
| University of Arkansas for Medical Sciences        | 0            | 6                | 6          | 4          |   |
| Medical Univ of South Carolina MU-NCORP            | 0            | 5                | 5          | 3          |   |
| Froedtert and the Medical College of Wisconsin     | 0            | 4                | 4          | 3          |   |
| Valley Health / Winchester Medical Center          | 0            | 3                | 3          | 2          |   |
| Baylor University Medical Center                   | 0            | 2                | 2          | 1          |   |
| H. Lee Moffitt Cancer Center                       | 0            | 2                | 2          | 1          |   |
| Rhode Island Hospital                              | 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          |   |

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

# Welcome New Sites



## Princess Margaret Cancer Center and Toronto General Hospital



**Instituto Nacional de  
Cancerología (México)**

**Instituto Nacional de  
Enfermedades  
Neoplásicas (Perú)**

### 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 |                                    |                             | Valley Health                               | Hackensack Meridian   |



### Tracking Log

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



## 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.



## Study is Now Open

Enrollment to S1316 was re-opened on June 1, 2018. Sites may resume accrual once IRB approval of the protocol and model consent form Revision #12, version date 4/4/2018, has been obtained. In the interim, sites may not use any prior consent forms to register patients.

### **Oops! Please modify the Consent prior to IRB submission**

We missed an edit to the recently revised Model Consent Form, Version Date 04/04/2018. Please make the following correction prior to IRB submission (see Page 10 on the Model Consent):

**(If no) I agree to participate and be a part of the non-randomized study and select my own treatment. The treatment option I have selected is:**

**Surgery**    ~~**Non-Surgical Treatment**~~ *(remove this option)*



This is in accordance with the change in Revision #12 of the protocol and model consent form to close the non-randomized, non-surgical arm of the study. We will update the consent to reflect this in the next revision.

## Coordinator's Teleconference

**Remember!**

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 June 13, 2018 at 1:00 P.M. ET, 12:00 P.M. CT, 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 [obojoqrqu@email.arizona.edu](mailto:obojoqrqu@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.