SWOG
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June 15, 2018

TO: ALL SWOG MEMBER AND AFFILIATE MEDICAL ONCOLOGISTS, SURGEONS, RADIATION ONCOLOGISTS, PATHOLOGISTS AND CLINICAL RESEARCH ASSOCIATES; CTSU

FROM: Charles D. Blanke, M.D. - Chair

RE: GUIDANCE ON REPORTING ADVERSE EVENTS TO INSTITUTIONAL REVIEW BOARDS FOR NIH-SUPPORTED MULTICENTER CLINICAL TRIALS (https://grants.nih.gov/grants/guide/notice-files/not99-107.html)

MEMORANDUM

All SWOG Phase III studies are monitored by our Data and Safety Monitoring Committee (DSMC). The Group policy regarding the function and composition of the DSMC is Policy #21, which may be found on the public portion of the Group web site at https://www.swog.org/sites/default/files/docs/2017-10/Policy21.pdf.

Copies of this document must be made available to local Institutional Review Boards (IRBs).

As outlined in the "GUIDANCE ON REPORTING ADVERSE EVENTS TO INSTITUTIONAL REVIEW BOARDS FOR NIH-SUPPORTED MULTICENTER CLINICAL TRIALS" (https://grants.nih.gov/grants/guide/notice-files/not99-107.html), the NIH requires that summary reports of adverse events be communicated from the DSMC to the IRBs at participating institutions.

The interim reports for SWOG studies are posted in the Report of Studies area on the members side of the Group web site at https://swog.org/. This site also contains the deliberations of the DSMC from their most recent meetings. A copy of the deliberations from the April 13, 2018 meeting is attached. The information from this report must be made available to your IRB.

If the DSMC has decided to make recommendations resulting in substantial changes to a study, those changes will be circulated in the form of a protocol amendment or a special notification (e.g., "Dear Physician" letter).

This memorandum serves to notify the NCI and SWOG Statistics and Data Management Center.

PC/geg
Enclosure

cc: Cathy M. Tangen, Dr.P.H.
Nathan Eriksen
Elaine Armstrong, M.S.
Dana B. Sparks, M.A.T.

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M E M O R A N D U M

TO: Dr. Blanke, Dr. LeBlanc and Data and Safety Monitoring Committee

FROM: Cathy Tangen, DrPH

DATE: April 24, 2018

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, April 13, 2018

1. CC S1316: *Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction.* S1316 study leadership updated the DSMC on their plans to temporarily close the trial and reopen with the randomization portion and surgical choice arms still in place (closing the no-surgical management choice arm). The DSMC is supportive and recognizes that this design change will take a few months to get through DCP and site-level regulatory review, and so we do not expect significant accrual between now and the fall DSMC meeting. However, we will continue to keep an eye on this trial.

2. **LUNG S1403:** *A Randomized Phase II/III Trial of Afatinib Plus Cetuximab versus Afatinib Alone in Treatment-Naïve Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer.* The DSMC recommends that accrual should be stopped and trial results should be released to the study team for reporting as a futility analysis threshold has been crossed.

3. LUNG S1400I: *A Phase III Randomized Study of Nivolumab Plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (LUNG-MAO Sub-Study).* The DSMC recommends that accrual should be stopped and trial results released to the study team for reporting as a futility analysis threshold has been crossed.

4. BREAST S1416: *Phase II Randomized Placebo-Controlled Trial of Cisplatin With or Without ABT-888 (Veliparib) in Metastatic, Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer, With or Without Brain Metastases*. The DSMC appreciated the study update from Dr. Barlow, the study biostatistician. The DSMC is concerned about the poor accrual of the brain metastases cohort. We recognize that the study team is in discussion with CTEP about the accrual goal for the entire trial, and we are supportive of that effort.

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5. BREAST S1418: *A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) after Neoadjuvant Chemotherapy*. The DSMC gives permission for the study statistician to provide a small subset of data (n=50) that has been appropriately disguised to Merck in order to prepare their data systems for regulatory filing should the trial be positive. Any future data transfers to Merck prior to the release of outcome data to the study team must be cleared by the DSMC.

6. GU S1216: *A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer.* The DSMC gives permission for data from the TM studies involving testosterone, circulating tumor cells and bone markers to be reported both at baseline and longitudinally in the pooled treatment arms, but no correlation with PSA response is allowed at the current time.

The following trials were reviewed by mail, not discussed at the meeting, and should proceed with no change:

Breast: S1007, S1207

Cancer Control: S0820, S1415CD, S1501

Gastrointestinal: S1505, S1613

Genitourinary: S0931, S1011, S1314, S1500, S1602, S1605

Leukemia: S1318, S1612

Lung: S1206, S1400, S1400F, S1400G, S1400K

Lymphoma: S1608

Melanoma: S1320, S1404, S1616

Myeloma: S1211

The next DSMC meeting is expected to be held tentatively on Friday, October 5, 2018 at 7:30 am CT, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.