SWOG
Leading cancer research. Together.

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August 1, 2015

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

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

RE: GUIDANCE ON REPORTING ADVERSE EVENTS TO INSTITUTIONAL REVIEW BOARDS FOR NIH-SUPPORTED MULTICENTER CLINICAL TRIALS (http://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 http://swog.org/Visitors/download/policies/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 (http://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 May 1, 2015 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 Statistical Center.

PC/dbs

Enclosure

cc: Cathy M. Tangen, Dr.P.H.
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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: May 4, 2015

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, May 1, 2015

1. Prevention S0820 – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES). The DSMC appreciated the helpful and thorough presentation from the study leadership. The DSMC remains concerned about the current accrual rate for this trial and the feasibility of addressing the primary objective. Based on amendments expanding the patient population and the upcoming closure of competing studies, there is an expectation of a modest increase in the study's accrual rate by the October 2015 DSMC meeting. However, the DSMC expects a substantial increase in the accrual rate after January 2016. For that reason, the DSMC will review again in the fall to ensure the accrual rate is going in the correct direction and then review very critically at the April 2016 meeting.

2. Leuk S1203 – A Randomized Phase III Study of Standard Cytarabine Plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) Versus IA with Vorinostat (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia. After reviewing the second and third planned interim analysis, the DSMC recommends the following: In terms of the response assessment among the first 100 patients on each induction arm (second interim analysis), the recommendation is that the IA+V be closed to further enrollment due to futility defined as a CR rate on that arm that is less than the CR rate on the 7+3 or IA arm. In terms of the third interim analysis which compares event-free survival between the IA and 7+3 arms, the recommendation is that the two arms should continue as planned.

3. GU S1011 - A Phase III Surgical Trial to Evaluate the Benefit of a Standard versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer. The DSMC reviewed the first planned interim analysis for this trial, and recommends the trial should continue as planned.

4. GU S0931 - EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy: A Phase III Study. The DSMC reviewed the first planned interim analysis for this trial, and recommends the study should continue as planned.

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

Breast
S1007, S1207, S1222

Cancer Control
S0812, S1105, S1200, S1202, S1204, S1316

Gastrointestinal
S1201, S1310, S1406

Genitourinary
S1216, S1314

Lung
S0819, S0905, S1300, S1400, S1400A – S1400E, S1403

Melanoma
S1320

Myeloma
S1211, S1304

The next DSMC meeting is tentatively expected to be held by conference call on Friday, October October 9, 2015, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.

"Premature disclosure of confidential Data and Safety Monitoring Committee interim therapeutic results on SWOG by members of the Data Monitoring Committee will result in censure of that member by the Board of Governors. Censure options will include immediate loss of authorship in the study presentation and publication, decertification of status as a current and future Study Coordinator, and/or removal from leadership in the disease committee of record."