SWOG
Leading cancer research. Together.

GROUP CHAIR'S OFFICE
Charles D. Blanke, MD
CHAIR
3181 SW Sam Jackson Pk Rd
MC: L586
Portland, OR 97239
503-494-5586
503-346-8038 FAX

OPERATIONS OFFICE
4201 Medical Dr
Suite 250
San Antonio, TX 78229
210-614-8808
210-614-0006 FAX

STATISTICAL CENTER
1730 Minor Ave
Suite 1900
Seattle, WA 98101
206-652-2267
206-342-1616 FAX

1100 Fairview Ave North
M3-C102
PO Box 19024
Seattle, WA 98109
206-667-4623
206-667-4408 FAX

swog.org

November 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 October 9, 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.
Nathan Erickson
Elaine Armstrong, M.S.
Dana B. Sparks, M.A.T.
Amber Roberts

Statistical Center
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North, M3-C102
Seattle, Washington 98109-1024
Phone: 206/667-4623
FAX 206/667-4408

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: October 11, 2015
RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 9, 2015

1. Prevention S0820 – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES). The DSMC is encouraged that the Step 0 administrative registration is being used, and we understand that the competing trial from the Alliance will complete accrual and close very soon. The DSMC remains concerned that there has not been a modest increase in accrual despite rectal cancer patients becoming eligible. The DSMC expects that accrual will improve over the next six months. The Committee will review this trial 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 fourth planned interim analysis comparing event-free survival between the IA and 7+3 arms, the DSMC recommends the trial should continue as planned.

3. Lung S1300 - A Randomized Phase II Trial of Crizotinib Plus Premetrexed versus Premetrexed Monotherapy in Alk-Positive Non-Squamous NSCLC Patients Who Have Progressed Systematically after Previous Clinical Benefit from Crizotinib. The DSMC recognizes that the changing treatment landscape in this disease setting makes the originally designed trial infeasible to accrue to. We encourage the study team and CTEP to activate the new design amendment quickly so the study may answer the new primary objective. The DSMC will continue to monitor the accrual to this trial after the amendment.

4. Cancer Control S1105: Randomized Trial of Text-Messaging Intervention to Reduce Early Discontinuation of Adjuvant Aromatase Inhibitor Therapy in Women with Early Stage Breast Cancer. The DSMC gives approval for the study team to conduct a correlative analysis of baseline urinary AI levels with other trial demographics and baseline PRO measures while they wait for the endpoint data to mature on this trial.

Statistical Center
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North, M3-C102
Seattle, Washington 98109-1024
Phone: 206/667-4623
FAX 206/667-4408

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

Breast
S1007, S1207

Cancer Control
S1200, S1202, S1316

Gastrointestinal
S1201, S1313, S1406

Genitourinary
S0931, S1011, S1216, S1314

Lung
S0905, S1300, S1400, S1400A – S1400D, S1403

Melanoma
S1320

Myeloma
S1211, S1304

The next DSMC meeting is tentatively expected to be held by conference call on Friday, April 29, 2016, coinciding with the SWOG Group Meeting in San Francisco. Details will be confirmed later.