

February 15, 2013

TO: ALL SWOG MEMBER, CCOP, UCOP AND AFFILIATE MEDICAL ONCOLOGISTS, SURGEONS, RADIATION ONCOLOGISTS, PATHOLOGISTS AND CLINICAL RESEARCH ASSOCIATES; ACRIN, ECOG, CALGB, NCIC-CTG, NCCTG, RTOG, COG, ACOSOG, NSABP, EORTC, IBCSG, BMT-CTN, AND CTSU

GROUP CHAIR'S OFFICE

Laurence H. Baker, DO
CHAIR

FROM: Laurence H. Baker, D.O. - Chairman

24 Frank Lloyd Wright Dr
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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>)

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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 19, 2012 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.
Kati M. Stoermer, M.S.B.A.

Reviewed by Charles Blanke, M.D. _____



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M E M O R A N D U M

TO: Dr. Baker, Dr. LeBlanc and Data and Safety Monitoring Committee
FROM: Cathy Tangen, DrPH
DATE: October 25, 2012
RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 19, 2012

Interim Analysis

1. **Breast S0221** – *A Phase III Trial of Continuous Schedule AC + G Vs. Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node-Positive or High-Risk Node-Negative Breast Cancer.*
The DSMC reviewed the planned interim analysis. As a statistical boundary has been crossed, the Committee recommends early reporting of the results. All patients are off protocol treatment.
2. **Breast S0307** – *A phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer.*
The DSMC reviewed the planned interim analysis. No statistical boundary has been crossed, and so the recommendation is that the study should continue as planned.
3. **Breast S0500** - *A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining Therapy for Metastatic Breast Cancer Who Have Elevated Circulating Tumor Cell Levels at First Follow-up Assessment.*
The DSMC reviewed the planned interim analysis. As no statistical boundaries were crossed, the recommendation is that the study should continue as planned.
4. **Lung S0819** – *A Randomized Phase III Study Comparing Carboplatin, Paclitaxel, Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer.*
The DSMC reviewed the safety data, the tissue submission rate and EGFR positivity rate in addition to a planned interim analysis. The recommendation is that the study should continue as planned.

"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."

Slow Accrual

- 5. **Lung S0905** – *A Phase I/Randomized Phase II Study of Cediranib (NSC #732208) versus Placebo in Combination with Cisplatin and Pemetrexed in Chemo-naïve Patients with Malignant Pleural Mesothelioma.*

The trial leadership provided some suggestions for how accrual might be increased. The DSMC looks forward to seeing some improvement at the spring 2013 review.

Additional Issues

- 6. **Breast S0800** – *A Randomized Phase II Trial of Weekly Nanoparticle Albumin Bound Paclitaxel (Nab-Paclitaxel) (NSC-736631) With or Without Bevacizumab, Either Preceded by or Followed by Q 2 Week Doxorubicin (A) and Cyclophosphamide (C) Plus Pegfilgrastim (Peg-G) as Neoadjuvant Therapy for Inflammatory and Locally Advanced Her-2/Neu Negative Breast Cancer*

The DSMC appreciates the explanation for the incorrect treatment allocation weighting that took place for a period of time in the spring of 2012, and they are supportive of the additional safe guards that have been put in place. No additional action is requested.

- 7. **Gastrointestinal S0518** – *A phase III prospective randomized comparison of depot octreotide plus interferon alpha versus depot octreotide plus bevacizumab in advanced, poor prognosis carcinoid patients.*

The DSMC is concerned about the missing scan review data from ACRIN as these data are critical for the interpretation of the S0518 trial primary endpoint. The Committee expects that SWOG leadership is doing everything it can to get the complete data in a timely fashion. The DSMC would be happy to assist with this task if that would be useful to SWOG.

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

Breast	Genitourinary
S1007	S0337
Cancer Control	S0925
S0812	S0931
S0927	S1011
S1105	Leukemia
S1200	S1117
Gastrointestinal	Myeloma
S1201	S0777

The next DSMC meeting is expected to be held via conference call in early May 2013. Details still to be arranged.

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