Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: ALL SWOG MEMBER, CCOP, UCOP AND AFFILIATE INVESTIGATORS AND CLINICAL RESEARCH ASSOCIATES

FROM: SWOG Operations Office

DATE: November 1, 2010

SUBJECT: Changes to SAE reporting guidelines for secondary AML/ALL/MDS

The purpose of this memorandum is to inform sites of a change to the SAE reporting guidelines for secondary AML/ALL/MDS.

Revisions to individual protocols are forthcoming, but in the meantime sites are instructed to use the updated guidelines for reporting instances of secondary AML/ALL/MDS**.**

If you have questions regarding these changes, please contact the SAE Coordinator at the Southwest Oncology Group Operations Office at 210/614-8808. Or for more information see:
http://ctep.cancer.gov/protocolDevelopment/default.htm#adverse_events_adeers

The new reporting guidelines are as follows:

1. All cases of acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), and myelodysplastic syndrome (MDS) that occur in patients on NCI-sponsored trials following chemotherapy for cancer must be reported in AdEERS.

   i. In protocols using CTCAE Version 4.0 for SAE reporting, three options are available to describe treatment-related events:

   - Leukemia secondary to oncology chemotherapy
   - Myelodysplastic syndrome. NOTE: The only grading option for "Myelodysplastic syndrome" is Grade 4, life-threatening. If reporting MDS that is other than Grade 4, use “Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, (specify,__)” and insert MDS as the specify term.
   - Treatment related secondary malignancy

   ii. In protocols using CTCAE Version 3.0 for SAE reporting, the event(s) can be reported as “Secondary malignancy-Other (specify, ___)”. Report MDS as “Myelodysplasia,” in the BLOOD/BONE MARROW category.

   iii. Secondary malignancies other than AML/ALL/MDS that are related to protocol treatment must also be reported in AdEERS.

   iv. Non-treatment related cases of AML/ALL/MDS must be reported as follows:

   In protocols using CTCAE Version 4.0 for SAE reporting, report as “Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify”

   In protocols using CTCAE Version 3.0 for SAE reporting, report MDS as “Myelodysplasia” and Leukemias as “Blood/Bone Marrow - Other (Specify, __)”

2. The following supporting documentation must also be submitted within 30 days:

- a copy of the pathology report confirming the AML/ALL/MDS diagnosis
- (if available) a copy of the cytogenetics report

Submit the Report and documentation to:

Investigational Drug Branch **and** by fax at 301-230-0159	Southwest Oncology Group ATTN: SAE Program 4201 Medical Drive, Suite 250 San Antonio, Texas 78229

NOTE: If a patient has been enrolled in more than one NCI-sponsored study, the report must be submitted for the most recent trial.

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