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January 15, 2014

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

FROM: SWOG Operations Office

RE: New AdEERS Reporting Requirements for Pregnancy, Fetal Death, and Death Neonatal


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**MEMORANDUM**

The purpose of this memorandum is to inform sites of new and updated requirements for reporting pregnancy, fetal death, and death neonatal via AdEERS. The new/updated reporting requirements are outlined below and became effective 1/1/14. This information will be added to individual protocols as regular revisions are made.

For questions regarding the new/updated requirements, please contact Kari Williams, the SAE Coordinator in the SWOG Operations Office, via e-mail at kwilliams@swog.org.

**Reporting Pregnancy, Fetal Death, and Death Neonatal**

- **Pregnancy** Study participants who become pregnant while on study; that pregnancy should be reported in an expedited manner via AdEERS as **Grade 3 "Pregnancy, puerperium and perinatal conditions – Other (pregnancy)"** under the **Pregnancy, puerperium and perinatal conditions** SOC.
  *Additionally, the pregnancy outcome for patients on study should be reported via AdEERS at the time the outcome becomes known, accompanied by the same Pregnancy Report Form used for the initial report.*

- **Fetal Death** Fetal Death defined in CTCAE as "A disorder characterized by death in utero; failure of the product of conception to show evidence of respiration, heartbeat, or definite movement of a voluntary muscle after expulsion from the uterus, without possibility of resuscitation" should be reported expeditiously as **Grade 4 "pregnancy, puerperium and perinatal conditions – Other (pregnancy loss)" under the Pregnancy, puerperium and perinatal conditions** SOC.

- **Death Neonatal** Neonatal death, defined in CTCAE as "A disorder characterized by cessation of life occurring during the first 28 days of life" that is felt by the investigator to be at least possibly due to the investigational agent/intervention should be reported expeditiously.
  A neonatal death should be reported expeditiously as **Grade 4 "General disorders and administration – Other (neonatal loss)"** under the **General disorders and administration** SOC.

*Fetal death and neonatal death should **NOT** be reported as a Grade 5 event. If reported as such, the AdEERS interprets this as a death of the patient being treated.*

**NOTE:** When submitting AdEERS reports for “Pregnancy, “Pregnancy loss”, or “Neonatal loss”, the Pregnancy Information Form should also be completed and faxed with any additional medical information to 301-230-0159. The potential risk of exposure of the fetus to the investigational agent(s) or chemotherapy agent(s) should be documented in the “Description of Event” section of the AdEERS report.

The Pregnancy Information Form is available in the NCI Guidelines for Investigators: Adverse Event Reporting Requirements (see Appendix 7) http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf.

This memorandum serves to notify the NCI and SWOG Statistical Center.

PC/sjf

cc: Charles Blanke, M.D.
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