

North Central Cancer Treatment Group

N07C2, The Use of Wisconsin Ginseng (panax quinquefolius) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study

Update 3 – December 10, 2010

**Summary**

Administrative/Editorial Changes.

**Replacement pages are included. Please incorporate into the protocol and keep this addendum with your protocol.**

**Title page**

Updated to reflect Update 3 and the current version date.

**Section 10.0**

Page 23:

**Adverse Event (AE) Reporting and Monitoring**

Footnote 2 has been updated in Section 10.21 to reflect current submission procedures as follows:

In the rare event when Internet connectivity is disrupted, a ~~report may be prepared using the Adverse Event Expedited Report—Single Agent or Multiple Agents paper template (accessible from the CTEP Home Page at <http://ctep.cancer.gov>).~~ Contact the NCCTG SAE Coordinator (as identified on the NCCTG Protocol Resources page) for back-up submission instructions **24-hour notification is to be made to NCI by telephone at: 301-897-7497. An electronic report MUST be submitted immediately upon re-establishment of internet connection. Please note that all paper AdeERS forms have been removed from the CTEP website and will NO LONGER be accepted.**

Page 24:

With the removal of the Secondary AML/MDS Report Form, the second column for the “Secondary AML/MDS” row has been updated for clarification as follows:  
Reporting for this event required during and after completion of study treatment via AdeERS.

Beginning October 1, 2010, AdeERS will only accept CTCAE v4.0 for this study: Report these events using “Neoplasms benign, malignant and unspecified (including cysts and polyps) —~~Other, Specify \_\_\_\_\_.~~” ***And including the appropriate adverse event:***

- **Leukemia secondary to oncology chemotherapy OR**
- **Myelodysplastic syndrome OR**
- **Treatment related secondary malignancy**