

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

Addendum 4 – December 10, 2010

Summary

- In compliance with the NCI/CTEP mandate (dated May 28, 2010), expedited adverse event reporting requirements were converted from CTCAE v3.0 to CTCAE v4.0 (affected sections 10.1 and 10.11) while routine data collection via Case Report Forms (which includes the Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form) will remain using CTCAE v3.0 (clarifications added to sections 10.22, 10.3, 10.31, and 16.13). Effective October 1, 2010, expedited reporting via AdEERS must use CTCAE v4.0 while the remainder of the data collection for legacy trials will continue to use CTCAE v3.0.
- Per NCI, the Secondary AML/MDS Report Form will no longer be used. Therefore, Section 10 has been revised accordingly.
- Clarification to eligibility criterion 3.29f regarding when combination treatment regimens are allowed.
- Administrative/Editorial Changes.

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

Title page The title page has been updated with the current version date.

Protocol Resources

Page 2: Contact information for the NCCTG Research Base Data Management Specialist (Barb Warren) has been deleted. Please contact the QAS for technical questions regarding electronic forms entry.

Section 3.0

Page 15:

Patient Eligibility

3.29f revised for clarification, as follows:

3.29f. Planning to start or complete any type of cancer therapy during the 8 week, double blind, course of the study, once randomized on the study. Note: If not currently getting treatment, no chemotherapy agents ≤ 21 days prior to randomization. **Combination treatment regimens that have components ending at different times are allowed, as long as any part of the initially started treatment continues through the double blind portion of the study.**

Section 10.0
Pages 22-23:

Adverse Event (AE) Reporting and Monitoring

Section 10.1 and Section 10.11 have been revised as follows to update the required AE reporting from CTCAE v3.0 to CTCAE v4.0.

10.1 ~~This study will utilize the Common Terminology Criteria for Adverse Events (CTCAE) v3.0 for adverse event monitoring and reporting. The CTCAE v3.0 can be accessed from the CTEP home page <http://ctep.cancer.gov>. CTCAE term (AE description) and grade: The descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 will be utilized for reporting via the AE Log throughout the course of the study. CTCAE version 3.0 will be used for expedited adverse event reporting until September 30, 2010. CTCAE v4.0 will be utilized for expedited adverse event reporting only, beginning October 1, 2010. All appropriate treatment areas should have access to a copy of the CTCAE v3.0. A copy of the CTCAE version 4.0 can be downloaded from the CTEP web site (<http://ctep.cancer.gov>).~~

10.11 Adverse event monitoring and reporting is a routine part of every ...

Expedited adverse event reporting requires submission of an electronic Adverse Event Expedited Reporting System (AdEERS)...

Effective with Addendum 4, and beginning October 1, 2010, expedited AdEERS reporting for this protocol has been updated by the NCI/CTEP to use CTCAE v4.0. Therefore;

- 1) Events requiring expedited reporting through AdEERS must be reported through the AdEERS system in CTCAE v4.0.**
- 2) The events reported via AdEERS must ALSO be reported through routine reporting (i.e., Case Report Forms) using CTCAE v3.0.**
- 3) Routine data collection via Case Report Forms, including the "Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form", will remain using CTCAE v3.0 for this study.**

Page 24:

With the removal of the Secondary AML/MDS Report Form, the second column for the "Secondary AML/MDS" row has been revised 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 ____."

~~Submit the NCI/CTEP Secondary AML/MDS Report form within 15 days via fax or mail to the NCCTG SAE Coordinator, NCCTG Operations Office, 200 First Street SW, Rochester, MN 55905, Fax (507)284-9628. The Operations Office will submit to NCI.~~

Page 24: The second paragraph in the last section (right hand column) in Section 10.22 has been revised for clarification as follows:

NCCTG Institutions Only: Complete a Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form within 5 working days **using CTCAE v3.0**, of the date the clinical research associate (CRA) is aware of the event(s) necessitating the form.

Text has been added at the bottom of the table (right hand column) in Section 10.22 for clarification, as follows:

You must use CTCAE v3.0 for data submission with this form. The events reported on this form must also appear on the Case Report Forms (i.e., routine data) for this study.

Section 10.3 and Section 10.31 have been revised for clarification. In Section 10.3 the first column header in the chart has added (**CTCAE v3.0**) after the word “Category” and Section 10.31 has been revised as follows:

10.31 Submit to the NCCTG Research Base via the Nadir/AE Log the following AEs **using CTCAE v3.0** experienced by a patient and not...

Page 41: A new sentence has been added to the first paragraph in Section 16.13 for clarification as follows:

CTCAE v3.0 will be used to determine grading for these stopping rules.