

North Central Cancer Treatment Group

N0574: Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in the Management of Patients with One to Three Cerebral Metastases

Addendum 5 – October 21, 2011

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 10.23, 10.3, and 10.31). Effective October 1, 2011, 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.
- Administrative update.

A replacement protocol is provided. Please replace the current copy with the one attached. Please keep this addendum with your protocol. Note: for sites participating through NCCTG, replacement pages are provided. Please incorporate into the protocol and keep this addendum with your protocol.

Title page Updated to reflect the addition of Addendum 5 and a revised NCI version date.

NCCTG Address and Contact Information

Page 3: ~~Patricia A. Aggen~~ has been removed as the NCCTG Research Base Protocol Specialist.

Section 10.0 Adverse Event (AE) Reporting and Monitoring

Page 24: 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:

~~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 until September 30, 2011. CTCAE version 4.0 will be utilized for expedited adverse event reporting only, beginning October 1, 2011. (<http://ctep.cancer.gov>).** 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 clinical trial...

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

Effective with Addendum 8, and beginning July 1, 2011, expedited AdEERS reporting for this protocol has been updated by the NCI/CTEP to use CTCAE v4.0. Therefore:

- 1) **Events reporting 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:

The second column for Secondary AML/MDS in Section 10.23 has been revised for clarification as follows:

Reporting for this event required during and after completion of study treatment, via AdEERS ~~using CTCAE v3.0: Report Myelodysplasia as “Blood/Bone Marrow—Myelodysplasia” and Leukemias as “Blood/Bone Marrow—Other (Specify, —)”~~.

Beginning October 1, 2011, AdEERS will only accept CTCAE v4.0 for this study. Report these events using “Neoplasms benign, malignant and unspecified (incl. cysts and polyps)” and including the appropriate adverse event:

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

The second column for “Other Grade 4 or 5 Events...” section in Section 10.23 has been revised for clarification as follows:

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.**

Page 25:

Section 10.3 and Section 10.31 have been revised for clarification. In Section 10.3, the first column header in the table has added CTCAE v3.0 and Section 10.31 has been revised as follows:

Submit to the NCCTG Research Base via the Nadir/AE Log the following Aes **using CTCAE v3.0** experienced by a patient and not specified in Section 10.3: