

North Central Cancer Treatment Group

N0321: Phase I/II Study of PS-341 in Combination with Paclitaxel, Carboplatin, and Concurrent Thoracic Radiation Therapy for Non-small Cell Lung Cancer (NSCLC)

Addendum 15 – November 26, 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 7.21, 8.0, 10.21, 10.22, 10.23, 10.3, 10.31, and 16.327). Effective January 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.

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

Title Page Updated to reflect Addendum 15 and revised NCI version date.

Section 7.0 **Protocol Treatment**
Page 19: Due to the CTCAE conversion, the heading of the first column in Section 7.21 has been updated for clarification as follows:
Toxicity (CTCAE v3.0)

Section 8.0 **Dosage Modification Based on Adverse Events**
Page 26: The first column header in the Section 8.0 table has been revised for clarification as follows:

CTCAE V3.0 CATEGORY

Section 10.0 Adverse Event (AE) Reporting and Monitoring

Pages 27-28:

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 until December 31, 2010 for AE reporting. CTCAE v4.0 will be utilized for expedited adverse event reporting only, beginning January 1, 2011. 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 14, and beginning January 1, 2011, 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.**

Pages 29/31:

The second bullet under Sections 10.21 and 10.22 tables have been revised for clarification as follows:

Any medical event equivalent to CTCAE **v4.0** grade 3, 4, or 5...

Text has been added at the bottom of the table (right hand column) in Section 10.23 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.

Page 30:

The first sentence in the first bullet under "Additional Instructions or Exceptions..." in Section 10.21 has been corrected as follows:

In the rare event when Internet connectivity is disrupted a 24-hour notification is to be made to NCI by telephone at: 301-897-7497, ~~or 301-897-7402 for CIP studies.~~

- Page 31: The first bullet under the “Additional Instructions...” section in Section 10.22 has been revised to reflect updated notification instructions 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 (available on the CTEP Home Page at <http://ctep.cancer.gov>). Refer to CTEP, NCI Guidelines: Adverse Event Reporting Requirements for back up submission instructions. When internet connectivity is interrupted, a 24-hour notification is made to CTEP by telephone at 301-897-7497. Once internet connectivity is restored, an AE report submitted on a paper template or a 24-hour notification that is called in, must be entered into electronic AdEERS by the original submitter of the report at the site. In the rare event when Internet connectivity is disrupted a 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.~~
- Pages 32-33: 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 **v3.0** 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...
- Section 16.0** **Statistical Considerations and Methodology**
- Page 49: The last sentence in Section 16.327 has been added for clarification as follows:
CTCAE v3.0 will be used to determine grading for these stopping rules.