

North Central Cancer Treatment Group

N0747: A Randomized Phase II Trial of Sunitinib Plus Capecitabine Versus Capecitabine Alone (with the potential for crossover) for Elderly and/or Poor Performance Status Patients with Metastatic Adenocarcinoma of the Esophagus or Gastroesophageal Junction

Addendum 5 – July 30, 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, 10.11, and 10.22) 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 8.2, 10.22, 10.3, 10.31, and 16.52). 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.

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

Title page Addendum 5 has been added and the NCI Version date has been updated.

Section 8.0 **Dosage Modification Based on Adverse Events**
Page 23: The first column header in the Section 8.2 table has been revised for clarification as follows:

CTCAE V3.0 CATEGORY

Section 10.0 **Adverse Event (AE) Reporting and Monitoring**
Page 25: 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 September 30, 2010 for AE reporting. 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 5, 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 26: 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.

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

Submit the Grade 4 or 5 Non-AER form electronically via the NCCTG Remote Data Entry System within 5 working days, **using CTCAE v3.0**, of the date the CRA is aware of the event(s) necessitating the form.

Pages 27/29: 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...

Section 16.0 **Statistical Considerations and Methodology**

Page 46: A new last sentence of the first paragraph in Section 16.52 has been added for clarification as follows:

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