

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 7 – January 21, 2011

Summary

- Contact information for Research Base Data Management Specialist has been removed
- Per NCI, the Secondary AML/MDS Report Form will no longer be used. Therefore, Sections 10.0 and 18.0 have been revised accordingly.
- Revised reporting for AdEERS if internet connectivity is disrupted is included in Section 10.21
- Administrative/Editorial Changes have been made to the consent form for correction/clarification.

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

Title page Addendum 7 has been added and the NCI Version date has been updated.

Protocol Resources

Page 2: The Research Base Data Management Specialist contact has been removed (Linda Berge). Please contact the NCCTG Research Base Quality Assurance Specialist (QAS) for technical questions regarding electronic form entry.

Section 10.0 Adverse Event (AE) Reporting and Monitoring

Page 26: Bullet point 2 in Section 10.21 has been revised with current information regarding the AdEERS forms and contact information. Changes are 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. 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.** ~~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.~~

With the removal of the Secondary AML/MDS Report Form, new Section 10.22 has been added for clarification and the remaining section (now 10.23) has been revised in the second column of the first row, as follows:

10.22 Additional Instructions or Exceptions

- **SECONDARY MALIGNANCIES** (defined as “cancer caused by treatment for a previous malignancy”, e.g., treatment with radiation or chemotherapy) are to be reported through AdEERS.
- **Secondary malignancies are not considered metastasis of the initial neoplasm. Secondary malignancy is unrelated to the first cancer that was treated, and may occur months or even years after initial treatment.**
- **Second Primary malignancy (malignancy not due to prior treatment) should not be reported through AdEERS.**

10.23 Other Required Expedited Reporting

EVENT TYPE	REPORTING PROCEDURE
Secondary AML/MDS	<p>Reporting for this event required during and after completion of study treatment, via AdEERS.</p> <p>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:</p> <ul style="list-style-type: none"> - Leukemia secondary to oncology chemotherapy OR - Myelodysplastic syndrome OR - Treatment related secondary malignancy. <p>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.</p>

Section 18.0 **Records and Data Collection Procedures**

Pages 56/57:

With the removal of the Secondary AML/MDS Report form, the row “NCI/CTEP Secondary AML/MDS Report Form” and corresponding Footnote 4 have been deleted. With the deletion of Footnote 4 the remaining footnotes have been renumbered.

Appendix I **Consent Form**

Page 1 of 12:

The title has been corrected with the word “**Metastatic**” added before the word “Adenocarcinoma”.

Page 2 of 12:

Text has been revised for correction and clarification to the section “What will happen if I take part in this research study” as follows:

Before you begin the study

You will need to have the following exams, tests or procedures to find out...

- Physical examination and history **including your weight, height, blood pressure, and tests to rate how well you perform activities of daily living**
- Blood tests
- Pregnancy test (for females of childbearing potential only)
- CT scan, MRI or x-ray of the chest **for tumor measurement**
- **Electrocardiogram (ECG) of your heart (a test that checks for problems with the electrical activity of your heart)**
- **Echocardiogram/MUGA (optional)**

At the discretion of your physician an echocardiogram/MUGA may also be submitted, but this is not required to join the study. An echocardiogram is an ultrasound of your heart that looks at how your heart is working by measuring how much blood is moved out of the left side of the heart with each heartbeat (called “ejection fraction”). A MUGA scan is done by injecting a radioactive dye into your bloodstream and watching your heart on an x-ray screen to see how well it is working.

During the study

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures.

They are part of regular cancer care.

- **Physical examination and history**
- **Blood tests**
- **Tumor tissue sample (see details below)**

You will also be asked to fill out a single page compliance questionnaire which is for research purposes only and you will not have to pay for it:

Tumor tissue sample ~~If the exams, tests and procedures show that you can be in the study, and you choose to take part,~~ **You will provide tumor tissue samples...**

Page 3 of 12:

Located in the “Tumor tissue sample” section of the “What will happen if I take part in this research study” the second paragraph of the “For both groups” has been modified for clarification, as follows:

Each 21 days is called a “cycle”. You can continue taking cycles of study treatment unless your disease gets worse or you stop for another reason. **You will have a doctor exam including blood pressure measurement before each cycle of treatment.**