

North Central Cancer Treatment Group

N0543: A Phase II Trial of Pharmacogenetic-Based Dosing of Irinotecan, Oxaliplatin, and Capecitabine as First-Line Therapy for Advanced Small Bowel Adenocarcinoma

Addendum 12 – January 21, 2011

Summary

- Contact information for Research Base Data Management Specialist has been removed
- Revised reporting for AdEERS if internet connectivity is disrupted included in Section 10.21 in addition to the added information concerning secondary malignancies.
- Editorial/administrative changes.

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

Title page Updated to reflect Addendum 12 and a new NCI version date.

Protocol Resources

Page 2: Due to the change in title Carol Leonard's job title has been updated, as follows:

NCCTG *Research Base* Quality Control Assurance Specialist

The Research Base Data Management Specialist contact has been removed (Kathleen Welch). 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 30: Bullet point 2 in Section 10.21 has been revised with current information regarding the AdEERS forms and contact information. Changes are as follows:

2. 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.~~

The third bullet point in Section 10.21 “Additional Instructions...” has been removed, as this is duplicate information of bullet point 2 above. New text has been added for clarification. Changes are 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>) and faxed to 301-230-0159. Contact the NCCTG SAE Coordinator (as identified on the NCCTG Protocol Resources page) for additional back-up submission instructions.~~
- **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, as noted in Section 10.22. 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.**

Note: Second Primary malignancy (malignancy not due to prior treatment) should not be reported through AdEERS.

Page 31:

Section 10.22 has been revised in the last column of the “Secondary AML/MDS” row, for clarification, as follows:

Reporting for this event required during and after completion of study treatment, via AdEERS

~~Through December 31, 2010, continue using CTCAE v3.0: Report Myelodysplasia as “Blood/Bone Marrow – Myelodysplasia” and Leukemias as “Blood/Bone Marrow – Other (Specify, ___)”.~~

Beginning January 1, 2011, 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~~. **and including the appropriate adverse event:**

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

Appendix I **Consent Form**

Page 10:

A correction in the “Rare, but serious” section for Oxaliplatin has occurred. The first bullet point has been revised to match the NCI risk template (Addendum 10 summary correctly identified, but the protocol was incorrect) as follows:

- Formation of blood clots in small blood vessels **around the body** that ~~causes damage to the blood vessels and can~~ leads to a low platelet count