

North Central Cancer Treatment Group

N064A, Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation in Patients with Locally Advanced Pancreatic Cancer

Addendum 6 – February 18, 2011

Summary

- The Research Protocol Specialist III has been updated.
- Contact information for the Data Management Specialist has been removed.
- Administrative/Editorial changes.

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

Title Page The Addendum 6 has been added and the NCI version date has been updated.

Protocol Resources

Page 2: Contact information has been revised for the Research Protocol Specialist III, as follows:

~~Linda S Long~~ **Sanna McKinzie**
NCCTG Research Base Research Protocol Specialist III
Phone: ~~507-266-3853~~ **538-6646**
Fax: 507-284-5280
E-mail: long.linda@mayo.edu mckinzie.sanna@mayo.edu

The Research Base Data Management Specialist contact has been removed (Brandon Messmer). Please contact the NCCTG Research Base Quality Assurance Specialist (QAS) for technical questions regarding electronic form entry.

Section 4.0 **Test Schedule**

Page 21: Footnote 12 has been revised for correction, as follows:

Kits are required. Blood is to be collected after registration but prior to first treatment...prior to cycle 9 day 1, and prior to cycle ~~4~~**10** day 15...

Section 10.0 Adverse Event (AE) Reporting and Monitoring

Page 44:

The following bullet point located under “Additional Instructions or Exceptions...” in Section 10.21 has been revised with current information regarding the AdEERS forms and contact information. Changes are as follow:

- 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.** ~~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>). Contact the NCCTG SAE Coordinator (as identified on the NCCTG Protocol Resources page) for back-up submission instructions.~~

Page 45:

In Section 10.22 the “Secondary AML/MDS” row has been revised as follows for correction:

<p>Secondary AML/MDS</p>	<p>Reporting for this event required during and after completion of study treatment, via AdEERS.</p> <p>Through December 31, 2010, continue using CTCAE v3.0: Report Myelodysplasia as “Blood/Bone Marrow—Myelodysplasia” and Leukemias as “Blood/Bone Marrow—Other (Specify, ___)”.</p> <p>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)” 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.
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