

North Central Cancer Treatment Group

N0821: A Phase II First-Line Study of a Combination of Pemetrexed, Carboplatin and Bevacizumab in Advanced Nonsquamous NSCLC Evaluating Efficacy and Tolerability in Elderly Patients (Age ≥ 70 yrs) with Good Performance Status (PS < 2)

Addendum 2 – June 26, 2009

Summary

- Sections 3.12 and 17.21 have been revised for clarification.
- Administrative/editorial changes.

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

- Title page** Updated to reflect Addendum 2 and current NCI version date.
- Section 3.0** **Patient Eligibility**
Page 12: The bullet in Section 3.12 has been revised for clarification as follows:
 - ~~Mixed histology allowed if all components consistent with NSCLC. Patients whose tumors have predominately squamous cell component are NOT eligible.~~ **Although patients with squamous cell carcinomas are not eligible, adenosquamous histology is allowed.**
- Section 4.0** **Test Schedule**
Page 16: The heading of the third column has been revised for clarification as follows:
 ≤ 7 days prior to first dose of pemetrexed disodium
- Section 7.0** **Protocol Treatment**
Page 20: The first sentence of Section 7.11 has been revised for clarification as follows:
Pemetrexed pretreatment – Patient must take folic acid for at least ~~5~~ ~~of the 7~~ **3** days immediately preceding the first dose of study therapy.
- The “Day” column for both Folic Acid and Vitamin B₁₂ has been revised for clarification as follows:
Folic Acid – May be started ~~5-7~~ **at least 3** days before cycle 1...
Vitamin B₁₂ – May be started between ~~7-14~~ **1-28** days before cycle 1...
- Section 8.0** **Dosage Modification Based on Adverse Events**
Page 24: Reference to Footnote #7 has been deleted in the last column for the Grade 2 Other non-hematologic section as this was incorrectly listed.

Section 16.0 **Statistical Considerations and Methodology**

Page 56: Radiation is not part of this study. Therefore, the last sentence in the “Primary Endpoint” of Section 16.2 has been correct as follows:

All patients meeting the eligibility criteria who have signed a consent form and have begun treatment with ~~radiation and~~ chemotherapy will be considered evaluable for both endpoints.

Section 17.0 **Pathology Considerations/Tissue Biospecimens**

Page 62: The second paragraph in Section 17.21 has been revised for clarification as follows:

Note: ~~Mixed histology allowed if all components consistent with NSCLC.~~
~~Patients whose tumors have squamous cell histology/feature are NOT eligible.~~
Adenosquamous histology allowed.