

North Central Cancer Treatment Group

N0321: Phase I/II Study of PS-341 in Combination with Paclitaxel, Carboplatin, and Concurrent Thoracic Radiation Therapy for Non-small Cell Lung Cancer (NSCLC)

Update 2 – February 11, 2011

Summary

- Correction to the Cockcroft and Gault formula has been made in Section 7.42.
- Administrative changes.

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

Title Page Updated to reflect Update 2 and revised NCI version date.

Protocol Resources

Page 2: **Linda S. Long** replaces ~~Alicia L. Elsing~~ as the NCCTG *Research Base* Research Protocol Specialist.

Section 7.0 **Protocol Treatment**

Page 21: Section 7.42, footnote 3, has been corrected as follows:

Dosed using Calvert Formula with Cockcroft & Gault Equation Calvert Formula: CBDCA dose (mg) = target AUC x (GFR + 25). Note: The glomerular filtration rate (GFR) used in the Calvert formula to calculate AUC-based dosing should not exceed 125 mL/min. Therefore, for newly enrolled patients, the maximum carboplatin dose for this study is 900 mg. For the purposes of this protocol, the GFR is considered to be equivalent to the creatinine clearance (CrCl) and can be measured or calculated (Note: When concerned about patient safety in a given patient, measure GFR. The CrCl is calculated by the method of Cockcroft & Gault (CrCl[mL/min] = (140 – age) x actual body weight [kg] / ~~divided by~~ [plasma Cr [mg/dL] x 72] x [0.85 if female ~~or 1.0 if male~~]). **You can also access the carboplatin dosing (Cockcroft and Gault) calculator via the NCCTG web site at <https://ncctg.mayo.edu/ncctg/group/cra/worksheet.html#CDC>.** Note: A correction factor is NOT to be used to calculate carboplatin doses based on the IDMS serum creatinine.