

North Central Cancer Treatment Group

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

Update 1 – June 19, 2009

Summary

- Administrative/Editorial changes have been made on the title page, the protocol resource page, Section 4.0, and the consent form.

An updated version of the protocol is included.

Title Page

Page 1:

Under the Study Chair's contact information, "QCS" has been removed from the line with the fax number, moved up to follow the phone number, and updated to "QAS."

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Jacksonville, FL 32224
Phone: 507/284-4918 (QAS)
Fax: 507/284-5280 (~~QCS~~)

The NCI version date has been updated.

The activation date has been entered in the Document History and for Study Participants Date Activated.

Update 1 has been added to the title page with an effective date of June 19, 2009.

Protocol Resources Page

Page 2:

The contact information in the first row has been updated.

Deb Papenfus
NCCTG *Research Base* Quality ~~Control~~ Assurance Specialist (QCS QAS)...

Protocol Resources Page

Page 2 (cont'd) The contact information for Non-paraffin biospecimens has been updated.

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Section 3.0

Page 16:

Patient Eligibility

Section 3.11 has been corrected. Central review is not required prior to registration. Tissue for central review is due within 30 days after registration as noted in Section 17.1.

~~Histologically or cytology confirmedby central review prior to registration....~~

Section 4.0

Pages 20-21:

Test Schedule

A correction has been made in the row labeled "QOL Form...." The "X" in the second row ("Weekly during RT and chemotherapy") has been deleted as the QOL information is not being collected at this timepoint.

Footnote 9 has been deleted and the reader referred to Section 6.9c. Subsequent footnotes have been renumbered.

Section 6.0

Page 23:

Registration/Randomization Procedures

Section 6.9c has been revised to incorporate new standardized language.

An NCCTG-approved radiation oncologist....

Section 7.0

Page 27:

Protocol Treatment

Section 7.175 has been revised to incorporate new standardized language.

~~Quality control will be done utilizing the guidelines in Appendix II.~~ **Quality Control and Definitions of Deviations will be done according to the guidelines in Appendix II. All plans and associated materials as per NCCTG standard will be reviewed by 2 radiation oncologists and the RPC.**

Section 18.0**Records and Data Collection Procedures**

Page 86:

The row for the Concurrent Treatment Form has been deleted as this form is not needed for this trial.

Page 88:

The first “Note” in footnote 4 has been reworded to incorporate standardized language.

~~When images are submitted on CD(s), must include a viewing tool.~~

Images submitted on CD(s), must include a viewing tool.

The RT Coordinator’s name, ~~Kathryn Scherger~~ has been removed to minimize the need for updates in the event of personnel changes.

Appendix I**Consent Form**

Page 6 of 24:

A new paragraph has been added to the end of the section labeled (During the study: Tests and procedures” (which begins on page 5 of 24). After “During Step 3 (panitumumab only),” the new paragraph has been inserted to describe the Quality of Life (QOL) questionnaire to be completed by the patient.

Throughout the study, you will also be asked to fill out a questionnaire which asks one question about your overall quality of life. You will fill out this questionnaire when you start the study, after you finish radiation, every 2 cycles during treatment, and at the end of treatment.

Appendix IV

On page 1 of 2, item #1 has been corrected to include the booklet that is to be completed after radiation.

1. The booklet contains one quality of life question for you to answer at the following times during the study:
 - a. Within 2 weeks before registration
 - b. After radiation**
 - c. Every 2 cycles during treatment (i.e., every 8 weeks)
 - d. At the end of treatment