

North Central Cancer Treatment Group

N0177: Pilot and Phase II Trial of OSI-774 and Radiation in Glioblastoma Multiforme Patients

Addendum 5 – April 23, 2004

Summary

- Further clarification on the event monitoring processes have been made.
- Editorial/administrative changes.

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

Title page: Reflects addition of Addendum 5.

Page 2: Beverly L. Kowbel replaces Gwen Finck, R.N. as the NCCTG Nurse resource person.

Lori K. Kelly replaces Linda S. Long as the Administrative/document resource person.

Page 34: A new Section 13.14 (Treatment/Follow-up Decision at Evaluation of Patient) has been added as follows:

If off treatment for refusal/excessive toxicity, patients will go to observation phase.

A new Section 13.15 (Treatment/Follow-up Decision at Evaluation of Patient) has been added as follows:

Patients who PROG or complete the observation phase will begin event-monitoring. Event-monitoring information will be collected and entered every 3 months until 5 years from on study, yearly thereafter until 15 years from on study.

All remaining sections have been renumbered.

Page 35: A new Section 13.4 (Treatment/Follow-up Decision at Evaluation of Patient) has been added as follows:

If off treatment for refusal/excessive toxicity, patients will go to observation phase.

A new Section 13.5 (Treatment/Follow-up Decision at Evaluation of Patient) has been added as follows:

Patients who PROG or complete the observation phase will begin event-monitoring. Event-monitoring information will be collected and entered every 3 months until 5 years from on study, yearly thereafter until 15 years from on study.

All remaining sections have been renumbered.

- Page 49: Section 18.0 (Records and Data Collection Procedures) has been revised as follows:
- The second column under the “Event-Monitoring Phase” column has been revised as follows:
 - Q 3 months ~~if within~~ **until** 5 years from on study, yearly thereafter
 - Reference to footnote #6 in the heading entitled “Event-Monitoring Phase (Completion of Active-Monitoring Phase) has been deleted and reference to footnote #4 has been added.
 - Reference to footnote #4 in the heading entitled “End of RT” has now become footnote #5.
 - Reference to footnote #5 under the section entitled “End of RT” has now become footnote #6

- Page 50: New footnote #4 has been added as follows and all remaining footnotes have been renumbered:
- If a patient is still alive 15 years after registration, no further follow-up is required.**

Previous footnote #6 has been deleted as follows:
~~Only enter event monitoring phase if time from on study is less than 5 years.~~