

North Central Cancer Treatment Group

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

Addendum 4 – April 23, 2004

Summary

- Event monitoring processes have been clarified in Section 4.0 (Test Schedule) and Section 18.0 (Records and Data Collection Procedures).
- 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 4.

Page 15: Section 4.0 (Test Schedule), a new column has been added entitled “End of RT” with Xs having been added to the following rows:

- Toxicity assessment
- Exam, wt, PS
- Anticonvulsant and steroid treatment log

Section 4.0 (Test Schedule), a new footnote #10 is newly added as follows:
Done last week of RT or within 10 days after RT completion.

Page 49: Section 18.0 (Records and Data Collection Procedures) has been revised as follows:

- A new column has been added to the “Initial Material” section entitled “End of RT” with Xs added to the following rows:
 - Neuro Measurement Form
 - Evaluation/Treatment Form
 - Nadir/Adverse Event Form
 - Anticonvulsant and Steroid Treatment Log
- The second column under the “Event-Monitoring Phase” column has been revised as follows:
 - **Every Q 3 months after PROG until if within 5 years from on study, yearly thereafter.**
- Reference to footnote #3 in the heading entitled “At PROG” under the “Event-Monitoring Phase” section has been deleted.
- Reference to footnote #4 in the heading entitled “Event-Monitoring Phase (Completion of Active-Monitoring Phase)” has been deleted.
- Reference to new footnote #4 in the heading entitled “End of RT” has been added.
- Reference to new footnote #5 under the section entitled “End of RT” has been added to the row for “Neuro Measurement Form.”
- Reference to new footnote #6 in the heading entitled “Event-Monitoring Phase (Completion of Active-Monitoring Phase)” has been added.
- A new row entitled “MMSE” has been added and will be collected ≤ 14 days after reg., end of RT, and at each evaluation.

Page 50:

Footnote #4 has been deleted as follows:

~~If a patient is still alive 15 years after registration, no further follow-up is required.~~

A new footnote #4 has been added as follows:

This data must be faxed to the Operations Office (507-266-7240) within 2 weeks of radiation therapy completion.

A new footnote #5 has been added as follows:

No scan required, form only.

A new footnote #6 has been added as follows:

Only enter event-monitoring phase if time from on-study is less than 5 years.