

North Central Cancer Treatment Group

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

Update 1 – January 10, 2003

Summary

1. Editorial/administrative changes.

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

Title page: Reflects Update 1.

Page 3: Index: The heading for Section 5.0 has been revised to read “~~Stratification~~ **Grouping Factors**”

Page 15: Section 4.0, first column (Tests and Procedures), the fourth to the last item has been revised to read “Anticonvulsant and ~~concurrent~~ **steroid** treatment log”

Page 16: The heading for Section 5.0 has been revised to read “~~Stratification~~ **Grouping Factors**”

Page 20: Section 7.41, the second sentence has been revised to read “At the completion of phase ~~± I~~ for each study cohort, the protocol will be amended to stipulate the phase ~~± II~~ doses...”

The fifth sentence has been revised to read “Patients not on EIACs....escalated to the stipulated phase ~~± II~~ dose once they have...”

Page 29: The third column in Section 10.22 has been revised to read “Grades 1 ~~and~~ **through 3**”

Page 31: The last item in the second column of the table in Section 10.3 has been revised to read “~~Any Brain – Late RT~~”

A Footnote has been identified with an asterisk by the X in the last column of the last item and reads “**Following RT**”

Page 39: Section 15.11, the fourth sentence has been revised to read “The ~~yellow~~ **white** 25 mg tablets....are supplied 30 tablets/bottle.”

Page 49: The fifth item from the bottom in the first column (Forms) of the table in Section 18.2 has been revised to read “~~Concurrent~~ **Anticonvulsant and Steroid Treatment Log**”