

North Central Cancer Treatment Group

N0177: A Phase I/II Study of OSI-774 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

Update 2 – September 24, 2004

Summary
Corrections were made in Section 7.0 of the protocol to conform with the protocol schema.
Correction was made to arm labeling.

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

Title page: Reflects addition of Update 2. The revised NCI version date has been added.

Page 20-23: The last sentence in paragraph 1, which appears in Sections 7.21 and 7.31 and the sixth sentence of the first paragraph in Section 7.41 have been corrected to reflect the schema as follows:

Four weeks after radiation is completed maintenance TMZ will be given daily (200 mg/m²/day) for 5 days, **week 1**, and repeated every 28 days for 6 cycles.

The tables in Sections 7.21, 7.31, and 7.41 (Protocol Treatment) have been corrected to reflect the schema as follows:

Agent	Dose	Route	Day(s)	Retreat
Radiation*	6000 cGy (200 cGy x 30 fractions)		5 days/week x 6 weeks	
OSI-774	Call Randomization Center for assigned dose level	Oral	Continues daily throughout study	Daily
TMZ*	75 mg/m ²	Oral	7 days/week for 6 weeks during RT	
After completion of daily TMZ and RT, patient <u>continues</u> OSI-774 alone daily x 4 weeks				
TMZ	200 mg/m ² daily	Oral	5 days/week Days 1-5, week 1	Every 28 days for 6 cycles
OSI-774	TBD	Oral	Daily continuously	Daily

Page 21 and 22: Sections 7.2 and 7.3 (Protocol Treatment), correction was made to arm labeling as follows:

Arm A is now labeled Arm D.
Arm B is now labeled Arm E.