

North Central Cancer Treatment Group

N0272: Phase I/II Trial of Imatinib Mesylate; (Gleevec; STI571) in Treatment of Recurrent Oligodendroglioma and Mixed Oligoastrocytoma

Addendum 14 – April 15, 2011

Summary

- Per NCI, the Secondary AML/MDS Report Form will no longer be used. Therefore, Sections 10 and 18 have been revised accordingly.
- Administrative/editorial changes.

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

Title page Revised to reflect Addendum 14 and updated NCI version date.

Protocol Resources

Page 2: The e-mail for Carlene Dillavou has been updated as follows:
cdillavou@uswest.net cdillavou@iora.org

John M. (Jack) Beranek replaces ~~Sara Braun~~ as the NCCTG *Research Base* Protocol Specialist.

The Research Base Data Management Specialist contact information has been removed (Vicki Bryhn). Please contact the NCCTG *Research Base* Quality Assurance Specialist (QAS) for technical questions regarding electronic form entry.

Section 10.0 Adverse Event (AE) Reporting and Monitoring

Pages 27-28: Due to the removal of the Secondary AML/MDS Report Form, a new fourth bullet has been added under the table in Section 10.21 and Section 10.22 as follows:

- **SECONDARY MALIGNANCIES (defined as “cancer caused by treatment for a previous malignancy,” e.g., treatment with radiation or chemotherapy) are to be reported through AdEERS, as noted in Section 10.22. Secondary malignancies are not considered metastasis of the initial neoplasm. Secondary malignancy is unrelated to the first cancer that was treated, and may occur months or even years after initial treatment.**

Note: Second Primary malignancy (malignancy not due to prior treatment) should not be reported through AdEERS.

The first bullet under the Additional Instructions sections in Section 10.21 and 10.22 have been updated to reflect current submission procedures as follows:

- In the rare event when Internet connectivity is disrupted, a report may be prepared using the Adverse Event Expedited Report—Single Agent or Multiple Agents paper template (available on the CTEP Home Page at <http://ctep.cancer.gov>). Refer to CTEP, NCI Guidelines: Adverse Event Reporting Requirements for back up submission instructions. When internet connectivity is interrupted, a 24-hour notification is made to CTEP by telephone at 301-897-7497. Once internet connectivity is restored, an AE report submitted on a paper template or a 24-hour notification that is called in, must be entered into electronic AdEERS by the original submitter of the report at the site **24-hour notification is to be made to NCI by**

telephone at: 301-897-7497. An electronic report MUST be submitted immediately upon re-establishment of internet connection. Please note that all paper AdEERS forms have been removed from the CTEP web site and will NO LONGER be accepted.

Page 29: With the removal of the Secondary AML/MDS Report Form, the second column for the “Secondary AML/MDS” row has been revised as follows:
Reporting for this event required during and after completion of study treatment **via AdEERS.**

AdEERS will only accept CTCAE v4.0 for this study. Report these events using “Neoplasms benign, malignant and unspecified (incl. cysts and polyps)” and including all appropriate adverse event:
- Leukemia secondary to oncology chemotherapy OR
- Myelodysplastic syndrome OR
- Treatment related secondary malignancy

~~Submit the NCI/CTEP Secondary AML/MDS Report form within 15 days via fax or mail to the NCCTG SAE Coordinator, NCCTG Operations Office, 200 First Street SW, Rochester, MN 55905, Fax (507)284-9628. The Operations Office will submit to NCI.~~

Section 18.0 **Records and Data Collection Procedures**

Page 59: With the removal of the Secondary AML/MDS Report Form, the row for the “NCI/CTP Secondary AML/MDS Report Form has been deleted.