

North Central Cancer Treatment Group

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

Addendum 6 – January 19, 2007

Summary

- Timepoints for the submission of the Specimen Submission Form has been corrected in Section 18 of the protocol.
- Editorial/administrative changes.

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

Title page: Updated to reflect Addendum 6 and revised NCI version date.

Protocol Resource Page

Page 2: The “Questions” column for the “NCCTG Research Base Pathology Coordinators” has now been identified as “**Paraffin-embedded Tissue Pathology.**”

A new category has been added for “Non-paraffin Biospecimens” with Jacqueline M. Lafky being added as the NCCTG Biospecimen Resource Manager.

Section 14.0 Translational Research and Pharmacologic Studies...

Page 34: The contact information in Section 14.121 has been updated as follows:

NCCTG Operations Office
ATTN: NCCTG Research Coordinator
RO_FF_03_24-CC/NW Clinic 3-24
200 First Street, SW
Rochester, MN 55905
~~ATTN: NCCTG Pathology Coordinator~~

The shipping address for the TACMA lab in Section 14.122 has been updated as follows:
The NCCTG Pathology Coordinator will forward the material to TACMA/NCCTG Biospecimens Resource lab, **Stabile 13-10, Mayo Clinic Rochester.**

Page 35: Specimens will be sent to the BAP lab for accessioning, then BAP will forward to the TACMA lab. Therefore, Sections 14.24 and 14.25 will be reversed along with additional revisions as follows:

~~14.25~~ **14.24** Acquisition and Shipping Instructions:

Tissue should be plunge frozen in liquid nitrogen and kept frozen at temperatures between -20°C and -80° C until mailed. Samples should be shipped on enough dry ice to ensure safe transport while frozen. Samples may be sent Monday through ~~Friday~~ **Thursday** and should be sent in batches whenever possible. Send samples to ~~TACMA~~ **Biospecimens Accessioning and Processing (BAP) Laboratory/NCCTG Biospecimens Resource** at the Mayo Clinic at the following address:

~~TACMA~~**BAP/NCCTG Biospecimens Resource**
ATTN: BAP Supervisor
~~Guggenheim 1036~~ **Stabile 13-10A**
~~200 First Street, SW~~ **221 4th Avenue SW**
 Rochester, MN 55905
~~ATTN: Biospecimens Coordinator~~
Phone: 507-538-7062

~~14.24~~ **14.25** Methods: **The BAP Laboratory will accession the specimens and the tissues will be sent to and distributed by to the TACMA/NCCTG Biospecimens Resource, Stabile 13-10, Mayo Clinic Rochester.** Assays will be performed in the appropriate Mayo laboratories responsible for conducting these analyses. Controls will include unstimulated or growth factor-stimulated glioma cell lines and in non-malignant brain tissues (resected from patients without brain tumors to control seizures). As this is a pilot study of a limited number of tumors to characterize the status of the selected proteins by immunoblot, a descriptive analysis of the results is not planned.

Pages 37,39,40: Additional contact information has been revised as follows:

- The fourth sentence in Section 14.41 now reads “Blood should be mailed per kit instructions **provided in the kit (see Section 14.42)** to ~~the TACMA/NCCTG Biospecimens Resource~~ **Mayo Central Laboratory for Clinical Trials (MCLCT)** ~~in the provided kit~~ as soon as is practical following procurement of the sample.”
- The first sentence in Section 14.42 now reads “Kits for shipment of the blood samples will be supplied through ~~Mayo Central Laboratory for Clinical Trials (MCLCT).~~”

- The last sentence of the first paragraph in Section 14.44 now reads “Samples may be sent Monday through ~~Friday~~ **Thursday**.”
- The second paragraph and mailing information in Section 14.44 now reads:
Samples should be shipped after the blood draw per kit instructions to ~~TACMA/NCCTG Biospecimens Resource~~ at the following address ~~MCLCT~~:

~~TACMA/NCCTG Biospecimens Resource
Guggenheim 1036
200 First Street, SW
Rochester, MN 55905
ATTN: Biospecimens Coordinator~~

- The second paragraph in Section 14.59b now reads “Samples should be sent per kit instructions **provided in the kit** to ~~TACMA/NCCTG Biospecimens Resource~~ **MCLCT** in the provided kit as they are obtained, e.g., as soon as is practical following procurement of the sample.”
- The first sentence of the third paragraph in Section 14.59b now reads “Kits for shipment of the blood samples will be supplied through ~~Mayo Clinical Laboratories Clinical Trials Facility (MCLCT)~~.”
- The fourth paragraph and mailing information in Section 14.59b now reads:
Copies of the complete pharmacokinetic sample acquisition sheet should accompany each sample. Samples are to be packed in dry ice in styrofoam containers with enough dry ice to ensure that samples will not thaw within a 48-hour period. Samples may be sent Monday through ~~Friday~~ **Thursday**. Samples should be shipped per kit instructions to ~~TACMA/NCCTG Biospecimens Resource~~ **MCLCT** at the following address:

~~TACMA/NCCTG Biospecimens Resource
Guggenheim 1036
200 First Street, SW
Rochester, MN 55905
ATTN: Biospecimens Coordinator~~

- The last paragraph in Section 14.59b now reads “Samples will **be forwarded to the BAP Laboratory/NCCTG Biospecimens Resource for storage and** later be distributed from ~~TACMA~~**BAP/NCCTG Biospecimens Resource** to Dr. Merrill Egorin at the University of Pittsburgh for pharmacokinetic analysis.”

- The contact information throughout the table in Section 14.6 has been revised as follows:

TISSUE OBTAINED	TRANSLATIONAL STUDY	DETAILS IN SECTION	WHEN TO OBTAIN/DRAW:	MAILING INSTRUCTIONS
Paraffin Tissues	Imatinib inhibition targets; downstream signaling pathway studies; FISH 1p/19q and PTEN analyses	14.1; 14.3	Evaluate availability of prior surgical specimens at study entry; obtain and mail within 1 month of on study date	To: NCCTG Operations Office ATTN: NCCTG Research Coordinator NW Clinic 3-24 RO_FF_03_24-CC/NW Clinic 200 First Street, SW Rochester, MN 55905 ATTN: NCCTG Pathology Coordinator (507-266-0724)
Frozen Tissues	Activation target molecules and downstream signaling activation	14.2	Evaluate availability of prior surgical specimens at study entry; obtain and mail within 1 month of on study date	On dry ice, per section 14.2 instructions to: BAP Laboratory/NCCTG Biospecimens Resource ATTN: BAP Supervisor Guggenheim 1036 Stabile 13-10A 221 4th Avenue SW 200 First Street, SW Rochester, MN 55905 (800-826-5561) 507-538-7062)
Peripheral Blood Lymphocytes	Correlative Gene Studies	14.4	Before first treatment of Imatinib	Use kits, per instructions in Section 14.4; send to: NCCTG Biospecimens Resource Guggenheim 1036 200 First Street, SW Rochester, MN (800-826-5561) Samples should be shipped after the blood draw per kit instructions to MCLCT
Blood for Pharmacokinetic analyses	Imatinib steady state pharmacokinetics	14.5	According to schedule in Section 14.56	Use kits per section 14.59b and send on dry ice to: NCCTG Biospecimens Resource Guggenheim 1036 200 First Street, SW Rochester, MN (800-826-5561) Samples may be sent Monday through Thursday. Samples should be shipped per kit instructions to MCLCT

Section 17

Page 57:

Pathology Considerations

The bolded statement in Section 17.1 has been updated to reflect an alternate telephone number as follows:

A call needs to be made to the NCCTG pathology coordinator (507/266-0724 or 507/266-8919) prior to forwarding the following material:

The shipping address in Section 17.2 has updated as follows:

NCCTG Operations Office

ATTN: NCCTG Research Coordinator

RO_FF_03_24-CC/NW Clinic, 3-24

200 First Street, SW

Rochester, MN 55905

~~ATTN: NCCTG Pathology Coordinator~~

Section 18.0

Page 59:

Records and Data Collection Procedures

According to the protocol, the only submission prior to study entry is the pathology material. Therefore, the timing of the specimen submissions have been clarified as follows:

- The “X” in the row for “Specimen Submission...Blood for PK” has been deleted from the “Prior to Study Entry” column and has been placed under both the “ ≤ 2 weeks after registration” and “At each evaluation” columns.