

FORMS PACKET

N0735 Phase II Trial of Albumin-Bound Paclitaxel in Combination with Gemcitabine and Bevacizumab in Patients with Metastatic Breast Cancer

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✓ designates revised/new forms

*Generic forms completion instructions are available on the NCCTG web site under “the CRA link in the Remote Registration and Data Entry section and are titled “Remote Data Entry Screen Instructions (Forms Completion).”

The specific forms instructions take precedence over the generic forms instructions, so it is very important to review them in addition to the generic forms instructions.

NORTH CENTRAL CANCER TREATMENT GROUP
Eligibility Checklist

10/30/2009

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N0735: Phase II Trial of Albumin-Bound Paclitaxel in Combination with Gemcitabine and Bevacizumab in Patients with Metastatic Breast Cancer

First 6 patients: To register a patient, call (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.

After the first 6 patients, to register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application

Has the patient ever been on a prior study entered through this Registration Office? Yes No

If yes: Prior study number _____; prior patient study ID number _____

Registration date (date on) (mm/dd/yyyy) ___/___/_____

Patient study ID number (provided at time of Reg/Random) _____

NCCTG member (participant sponsor) _____

NCCTG treating location _____

NCCTG treating physician _____

Institution patient number (local subject number) _____

IRB approval date (mm/dd/yyyy) ___/___/_____

Person Completing Form:

Last Name: **(print)** _____ First Name: **(print)** _____

Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____

Gender (check one) Male Female Unknown

Date of birth (mm/dd/yyyy) ___/___/_____

Zip code _____

Country of Residence _____

Race (check all that apply)

White

Black or African American

Native Hawaiian or Other Pacific Islander

Asian

American Indian or Alaska Native

Not reported: Patient refused or not available

Unknown: Patient unsure

Method of payment (check one)

PI (Private Insurance)

MR (Medicare)

MRP (Medicare and Private Insurance)

MD (Medicaid)

MM (Medicaid and Medicare)

MVA (Military or Veterans Sponsored,

Not Otherwise Specified (NOS))

MS (Military Sponsored [including CHAMPUS & TRCARE])

MV (Veterans Sponsored)

SP (Self pay [no insurance])

NP (No means of payment [no insurance])

OTH (Other)

UNK (Unknown)

Ethnicity (check one)

Not Hispanic or Latino

Hispanic or Latino

Not reported: Refused or data not available

Unknown: Unsure of their ethnicity

Patient study ID number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Required Characteristics

Yes No NA

| | | | |
|--|-----|-----|-----|
| Women or men \geq 18 years of age. Age _____. | ___ | ___ | ___ |
| Histologically or cytologically diagnosed infiltrating breast cancer with clinical evidence of metastatic disease. | ___ | ___ | ___ |
| Measurable disease (defined by the presence of at least one measurable lesion per RECIST criteria; see Section 11.0). | ___ | ___ | ___ |
| May have received one prior adjuvant chemotherapy regimen, and no chemotherapy for metastatic disease. Neoadjuvant chemotherapy is also allowed. Taxane therapy is allowed as adjuvant or neoadjuvant treatment if completed \geq 6 months before study entry. | ___ | ___ | ___ |
| If patient is HER2+ must have received prior treatment with trastuzumab or have contraindication for trastuzumab. If not HER2+ (<i>check NA</i>). | ___ | ___ | ___ |
| May have received prior hormonal treatment in either adjuvant or metastatic setting. Unlimited prior hormonal therapy is allowed. | ___ | ___ | ___ |
| The following laboratory values obtained \leq 15 days prior to registration. Earliest laboratory test date ___/___/_____; latest laboratory test date ___/___/_____. NOTE: These dates pertain to the following labs only. | ___ | ___ | ___ |
| • ANC \geq 1500/mm ³ . ANC = _____. | ___ | ___ | ___ |
| • PLT \geq 100,000/mm ³ . PLT = _____. | ___ | ___ | ___ |
| • HgB \geq 9.0 g/dL. HgB = _____. | ___ | ___ | ___ |
| • AST (SGOT) \leq 2.5 x upper limit of normal (ULN). AST (SGOT) = _____ ; ULN _____. | ___ | ___ | ___ |
| • ALT (SGPT) \leq 2.5 x upper limit of normal (ULN). ALT (SGPT) = _____ ; ULN _____. | ___ | ___ | ___ |
| • Alkaline phosphatase \leq 2.5 x ULN. Alkaline phosphatase = _____ ; ULN _____. | ___ | ___ | ___ |
| • Total bilirubin \leq 1.5 x ULN. Total bilirubin = _____ ; ULN _____. | ___ | ___ | ___ |
| • Creatinine \leq 1.5 mg/dL. Creatinine = _____. | ___ | ___ | ___ |
| • Urine Protein/Creatinine Ration (UPCR) < 1 or Urinalysis <1+ protein. Urine protein = _____. Patients discovered to have \geq 1+ proteinuria at baseline must undergo a 24-hour urine collection. This collection must be adequate, and must demonstrate <1g of protein/24hr to allow participation in the study. | ___ | ___ | ___ |
| Negative pregnancy test done \leq 7 days prior to registration, for women of childbearing potential only. | ___ | ___ | ___ |
| Not a woman of childbearing potential or male (<i>check NA</i>) vs. negative pregnancy test date ___/___/_____. | ___ | ___ | ___ |
| Life expectancy \geq 12 weeks. | ___ | ___ | ___ |
| ECOG performance status (PS) 0 or 1. PS = _____. | ___ | ___ | ___ |
| Ability to complete questionnaire(s) alone or with assistance. | ___ | ___ | ___ |

All responses in above section must be “Yes” unless specified as “NA.”

NCCTG Eligibility Checklist N0735

10/30/2009
Page 3 of 5

Patient study ID number _____

Contraindications

Yes No NA

| | | | |
|--|------|------|--|
| Any of the following because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential, who are unwilling to employ adequate contraception as determined by the treating physician, while on this study and for 30 days after end of treatment with the study drugs. | ____ | ____ | |
| Prior chemotherapy for metastatic disease. | ____ | ____ | |
| Major surgery, chemotherapy, or immunologic therapy ≤ 6 weeks prior to registration. | ____ | ____ | |
| Minor surgery (e.g. core biopsy) ≤ 7 days prior to registration. Note: Placement of vascular access device does not require 7 day wait. | ____ | ____ | |
| Neurosurgery ≤ 3 months prior to registration. | ____ | ____ | |
| Evidence of active brain metastasis per MRI or CT, including leptomeningeal involvement. CNS metastasis controlled by prior surgery and/or radiotherapy are allowed. (To be considered controlled, there must be at least 2 months of no symptoms or no evidence of progression prior to study entry.) | ____ | ____ | |
| Only non-measurable disease is defined as all other lesions, including small lesions (longest diameter < 2 cm) and truly non-measurable lesions, which include the following per RECIST criteria dated June 1999 (see Section 11.0 for RECIST criteria): <ul style="list-style-type: none"> • Bone lesions • Leptomeningeal disease • Ascites • Pleural/pericardial effusion • Inflammatory breast disease • Lymphangitis cutis/pulmonis • Abdominal masses that are not confirmed and followed by imaging techniques • Cystic lesions | ____ | ____ | |
| Pre-existing peripheral neuropathy $> \text{Grade } 1$ (using CTCAE v3.0 criteria). | ____ | ____ | |
| Radiotherapy ≤ 4 weeks prior to registration, except if to a non-target lesion only, or single dose radiation for palliation. Prior radiation to a target lesion(s) is permitted only if there has been clear progression of the lesion since radiation was completed. If patient receives single dose radiation for palliation or radiation to non-target lesion, they may immediately proceed to registration without waiting 4 weeks. | ____ | ____ | |
| Received treatment with any other cytotoxic chemotherapeutic agent or investigational drug ≤ 4 weeks prior to registration. | ____ | ____ | |
| Received treatment with any taxane (docetaxel or paclitaxel) ≤ 6 months prior to registration. | ____ | ____ | |
| Current or recent use (≤ 2 weeks prior to registration) of aspirin, anticoagulants or thrombolytic agents. Exception allowed for one-daily 81 mg aspirin. | ____ | ____ | |
| History of allergy or hypersensitivity to albumin-bound paclitaxel, paclitaxel, gemcitabine, bevacizumab, albumin, drug product excipients, or chemically similar agents. | ____ | ____ | |
| Any Stage III or IV invasive, non-breast malignancy in ≤ 5 years prior to registration. | ____ | ____ | |
| Active other malignancy, excepting non-melanotic skin cancer or carcinoma-in-situ of the cervix. If there is a history of prior malignancy, patient must not be receiving other specific treatment for their cancer. | ____ | ____ | |
| Uncontrolled hypertension (blood pressure [BP] $> 160/90$ mmHg on ≥ 2 occasions at least 5 minutes apart). (Patients who have recently started or adjusted antihypertensive medications are eligible providing that BP is $< 140/90$ mmHg on any new regimen for ≥ 3 different observations in ≥ 14 days.) | ____ | ____ | |
| History of hypertensive crisis (CTCAE Grade 4 Hypertension) or hypertensive encephalopathy. | ____ | ____ | |
| Presence of bleeding diathesis or uncontrolled coagulopathy. | ____ | ____ | |
| Hemoptysis ≤ 6 months prior to registration. | ____ | ____ | |

NCCTG Eligibility Checklist N0735

10/30/2009
Page 4 of 5

Patient study ID number _____

Contraindications continued

| | Yes | No |
|--|-----|-----|
| History of abdominal fistula or gastrointestinal perforation ≤6 months prior to registration. | ___ | ___ |
| Serious non-healing wound, ulcer or fracture. | ___ | ___ |
| Arterial or venous thrombosis ≤12 months prior to registration. | ___ | ___ |
| History of cerebrovascular accident. | ___ | ___ |
| Clinically significant cardiac disease (define as congestive heart failure, symptomatic coronary artery disease, unstable angina or cardiac arrhythmias not well controlled with medication) or myocardial infarction ≤12 months prior to registration. | ___ | ___ |
| Currently receiving treatment in a different clinical study in which investigational procedures are performed or investigational therapies are administered. Note: Patient may not enroll in such clinical trials while participating in this study. Exception may be granted for trials related to symptom management (Cancer Control) which do not employ hormonal treatments or treatments that may block the path of the targeted agents used in this trial. | ___ | ___ |
| Co-morbid systemic illnesses or other severe concurrent disease which, in the judgment of the investigator, would make the patient inappropriate for entry into this study or interfere significantly with the proper assessment of safety and toxicity of the prescribed regimens. | ___ | ___ |

All responses in above section must be “No” unless specified as “NA.”

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

Yes No NA

| | | | |
|--|-----|-----|-----|
| Consent form signed and dated. Date of consent ___ / ___ / ____ . | ___ | ___ | ___ |
| Authorization for use and disclosure of protected health information signed and dated. Non-USA institution only (check NA) vs. Date of authorization ___ / ___ / ____ . | ___ | ___ | ___ |
| Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician. | ___ | ___ | ___ |
| Treatment cannot begin prior to registration and must begin ≤8 days after registration. | ___ | ___ | ___ |
| Pretreatment tests/procedures must be completed ≤22 days prior to registration (see Section 4.0). Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____. NOTE: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date and the latest pretreatment test date must be greater than or equal to the latest laboratory test date. | ___ | ___ | ___ |
| All required baseline symptoms must be documented and graded. | ___ | ___ | ___ |
| Study drug availability checked. (Study drug must be in site pharmacy for this patient prior to registration.) | ___ | ___ | ___ |
| Blood kit availability check. (Kits are required for this study.) (Site must have a kit on hand for this patient prior to registration.) | ___ | ___ | ___ |
| Patient QOL booklet availability checked (copies are not acceptable.) (Site must have booklets on hand for this patient prior to registration.) | ___ | ___ | ___ |

All responses in above section must be “Yes” unless specified as “NA.”

NCCTG Eligibility Checklist N0735

10/30/2009
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Patient study ID number _____

Registration Check continued

Yes No

| | |
|---|------|
| Patients should also be enrolled on N0392. (Was It Worth It – QOL study). (NCCTG Protocol N0392 must be open at site and offered to patient.) Patient was offered N0392 and agreed to participation. | |
| An optional translational research component is available for your patient. | |
| • Patient has given permission to give blood sample(s) for research testing. | ____ |
| • Patient has given permission to give tissue sample(s) for research testing. | ____ |
| At the time of registration, the following will also be recorded: | |
| • Patient has given permission to store and use blood sample(s) for future research of cancer. | ____ |
| • Patient has given permission to store and use blood sample(s) for future research to learn about, prevent, or treat other health problems. | ____ |
| • Patient has given NCCTG permission to give her/his blood sample(s) to outside researchers. | ____ |
| • Patient has given permission to store and use tissue sample(s) for future research of cancer. | ____ |
| • Patient has given permission to store and use tissue sample(s) for future research to learn about, prevent, or treat other health problems. | ____ |
| • Patient has given NCCTG permission to give her/his tissue sample(s) to outside researchers. | ____ |

All responses in above section may be “Yes” or “No”.

Assigned Treatment

_____ A) ABRAXANE + GEMZAR + AVASTN

Person registering _____ Signature Registration Office specialist _____ initials

Physician _____ Signature M - D - Y

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

ON-STUDY FORM

Patient ID Number: Patient Initials: L F M

Institution Number:

Institution:

ALL ITEMS MUST BE COMPLETED pg 1 of 3

Are data amended? (check one) Yes No (if data are amended, please circle in red when using paper form)

Description of Primary Disease

MedDRA code: 10006190 [Invasive breast carcinoma]

Primary Tumor Site: Breast

Cell Type: (check one)

- 1 Infiltrating ductal 6 Mucinous (colloid)
2 Infiltrating lobular 7 Papillary
3 Comedo 8 Scirrhus
4 Inflammatory 9 Tubular
5 Medullary with lymphocytic infiltrate 10 Other, specify

Nottingham Grade: (check one)

- 1 Well 3 Poor
2 Moderate 9 Unknown

Tumor Laterality: (check one)

- 1 Left 2 Right 3 Bilateral

Chronology of Diagnoses

Table with 2 columns: Method of Diagnosis* and Date (mm/dd/yyyy). Rows include Primary, First local recurrence, and First regional/distant recurrence.

* (1=None 2=Yes, biopsy 3=Yes, cytology 4=Yes, clinical)

Regional/Distant Metastases (Method of Diagnosis*)

- 1 Nodal (excludes axillary) 1 Skin 1 Bone 1 Lung
1 Nodal-axillary 1 Abdominal 1 Brain 1 Chestwall
1 Liver
1 Other, specify

* (1=None 2=Yes, biopsy 3=Yes, cytology 4=Yes, clinical)

Previous Breast Surgery Related to Tumors: (check one) 1 Yes 2 No

Operative Procedure (check all that apply)

Date (mm/dd/yyyy)

- 1 Lumpectomy
1 Mastectomy
1 Sentinel node dissection (1 Positive 2 Negative)
1 Axillary lymph node dissection (ALND)
Number of positive nodes (include both sentinel node biopsy and ALND results)
Number of nodes examined (include both sentinel node biopsy and ALND results)
1 Other, specify

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

ON-STUDY FORM

Patient ID Number: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED pg 2 of 3

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Previous Radiotherapy: (check one) 1 Yes 2 No

If Yes, complete table.

| Site | Date (mm/dd/yyyy) | |
|------|-------------------|---------------|
| | From | To |
| | ___/___/_____ | ___/___/_____ |
| | ___/___/_____ | ___/___/_____ |
| | ___/___/_____ | ___/___/_____ |

Previous Systemic Therapy (e.g. chemo, hormonal, antibody, biologic, etc.) for Breast Cancer: (check one) 1 Yes 2 No

If Yes, complete table

| Therapy | Date (mm/dd/yyyy) | | Was Therapy: (check one) |
|---------|-------------------|---------------|--|
| | From | To | |
| | ___/___/_____ | ___/___/_____ | 1 <input type="checkbox"/> Adjuvant 2 <input type="checkbox"/> Metastatic 3 <input type="checkbox"/> Neoadjuvant |
| | ___/___/_____ | ___/___/_____ | 1 <input type="checkbox"/> Adjuvant 2 <input type="checkbox"/> Metastatic 3 <input type="checkbox"/> Neoadjuvant |
| | ___/___/_____ | ___/___/_____ | 1 <input type="checkbox"/> Adjuvant 2 <input type="checkbox"/> Metastatic 3 <input type="checkbox"/> Neoadjuvant |
| | ___/___/_____ | ___/___/_____ | 1 <input type="checkbox"/> Adjuvant 2 <input type="checkbox"/> Metastatic 3 <input type="checkbox"/> Neoadjuvant |
| | ___/___/_____ | ___/___/_____ | 1 <input type="checkbox"/> Adjuvant 2 <input type="checkbox"/> Metastatic 3 <input type="checkbox"/> Neoadjuvant |

Current Diabetes (check one) 1 Yes 2 No

If Yes: How long? _____ months.

Describe: _____

Any Previous Cancer: (check one) 1 Yes 2 No

If Yes: Site _____

Date of Diagnosis: (mm/dd/yyyy) ___/___/_____

Treatment: _____

Other Current Diseases: (check one) 1 Yes 2 No

If Yes, specify _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

ON-STUDY FORM

Patient ID Number: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED pg 3 of 3

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Estrogen/Progesterone HER2 Data

Most recent estrogen receptor (ER) status: (check one) 1 Positive 2 Negative 3 Unknown/no data

Date: (mm/dd/yyyy) ___/___/_____

ER: % cells stained positive: ___ %

Most recent progesterone receptor (PgR) status: (check one) 1 Positive 2 Negative 3 Unknown/no data

Date: (mm/dd/yyyy) ___/___/_____

PgR: % cells stained positive: ___ %

HER2 results/IHC: (check one) 0 0 3 3+ / strongly positive
1 1+ / weakly positive 4 HER2/IHC testing not done
2 2+ / moderately positive

HER2 results/FISH: R/G ratio: ___ : ___ 3 Not done

Descriptive Factors

Neoadjuvant and/or adjuvant chemotherapy: (check one) 1 Yes 2 No

Prior hormonal therapy in the metastatic setting: (check one) 1 Yes 2 No

Height: (cm) _____ .

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**BASELINE
ADVERSE EVENTS FORM**

ALL ITEMS MUST BE COMPLETED

Are data amended? (*check one*) Yes No
(if data are amended, please circle in red when using paper form)

| Required Baseline Adverse Events from Section 10.0 of Protocol | | |
|---|----------------------------------|--|
| CTC Adverse Events Term (CTCAE v3.0) | MedDRA Code (v. 10.0) | CTC Adverse Event Grade |
| Baseline number of stools per day: _____ | | |
| Hemoglobin | 10019483 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Neutrophils/granulocytes (ANC/AGC) | 10029366 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Platelets | 10035528 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Fatigue (asthenia, lethargy, malaise) | 10016256 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Hair loss/alopecia (scalp or body) | 10001760 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 |
| Mucositis/stomatitis (functional/symptomatic) - <i>Selects</i> | | |
| - Oral cavity | 10028130 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| - Pharynx | 10065881 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Nausea | 10028813 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Vomiting | 10047700 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Proteinuria | 10037020 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Neuropathy: sensory | 10034620 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Pain - <i>Selects</i> | | |
| - Joint | 10023222 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| - Muscle | 10028411 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |
| Dyspnea (shortness of breath) | 10013963 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 |

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 4

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number (adverse events associated with this cycle): _____

Evaluation Date: (mm/dd/yyyy) ____/____/____

| CTC Adverse Event Term (CTCAE v3.0) | MedDRA Code (v. 10.0) (must be completed) | CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's | CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite | Has an adverse event expedited report been submitted?* (Enter 1 for Yes or 2 for No) |
|--|---|---|--|--|
| Required Adverse Events from Section 10.0 of Protocol | | | | |
| Allergic reaction/hypersensitivity (including drug fever) | 10020751 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Hemoglobin | 10019483 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Neutrophils/granulocytes (ANC/AGC) | 10029366 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Platelets | 10035528 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Cardiac Ischemia/infarction | 10028601 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Fatigue (asthenia, lethargy, malaise) | 10016256 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Fever (in the absence of neutropenia, where neutropenia is defined as ANC <1.0 x 10 ⁹ /L) | 10016558 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Hair loss/alopecia (scalp or body) | 10001760 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Rash: hand-foot skin reaction | 10019126 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Diarrhea | 10012727 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Mucositis/stomatitis (functional/symptomatic) - Selects | | | | |
| - Oral cavity | 10028130 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| - Pharynx | 10065881 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |
| Nausea | 10028813 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | ____ |

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 4

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number (adverse events associated with this cycle): _____

| CTC Adverse Event Term (CTCAE v3.0) | MedDRA Code (v. 10.0) (must be completed) | CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's | CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite | Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No) |
|-------------------------------------|---|--|---|---|
|-------------------------------------|---|--|---|---|

Required Adverse Events from Section 10.0 of Protocol

| | | | | |
|---|----------|---------------------|-----------|-----|
| Vomiting | 10047700 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| Hemorrhage, CNS | 10022763 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| Hemorrhage, GI - <i>Selects</i> | | | | |
| - Lower GI NOS | 10051746 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| - Upper GI NOS | 10055356 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| Hemorrhage, pulmonary/upper respiratory - <i>Selects</i> | | | | |
| - Lung | 10037397 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| - Nose | 10019561 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| - Respiratory Tract NOS | 10038730 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC <1.0 x 10 ⁹ /L, fever ≥ 38.5° C) | 10016288 | 0 3 4 5 (death) | 1 2 3 4 5 | ___ |
| Proteinuria | 10037020 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| CNS cerebrovascular ischemia | 10023030 | 0 2 3 4 5 (death) | 1 2 3 4 5 | ___ |
| Leukoencephalopathy (radiographic findings) | 10024382 | 0 1 2 3 | 1 2 3 4 5 | ___ |
| Neuropathy: sensory | 10034620 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | ___ |

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 3 of 4

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number *(adverse events associated with this cycle)*: _____

| CTC Adverse Event Term (CTCAE v3.0) | MedDRA Code (v. 10.0) <i>(must be completed)</i> | CTC Adverse Event Grade <i>(highest grade this cycle)</i> INCLUDE GRADE 0's | CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite | Has an adverse event expedited report been submitted?* <i>(Enter 1 for Yes or 2 for No)</i> |
|-------------------------------------|--|--|--|--|
|-------------------------------------|--|--|--|--|

Required Adverse Events from Section 10.0 of Protocol

Pain - *Selects*

| | | | | |
|-------------------------------|----------|---------------------|-----------|-------|
| - Joint | 10023222 | 0 1 2 3 4 | 1 2 3 4 5 | _____ |
| - Muscle | 10028411 | 0 1 2 3 4 | 1 2 3 4 5 | _____ |
| Dyspnea (shortness of breath) | 10013963 | 0 1 2 3 4 5 (death) | 1 2 3 4 5 | _____ |
| Thrombosis/thrombus/embolism | 10043607 | 0 2 3 4 5 (death) | 1 2 3 4 5 | _____ |

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 4 of 4

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number (*adverse events associated with this cycle*): _____

Were (*other*) adverse events assessed during this report period?

1 Yes, and reportable adverse events occurred

3 Yes, but no reportable adverse events occurred (*Stop here*)

2 No (*Stop here*)



Adverse Events beyond those required in Section 10.0 of the protocol. Record grade 2 with attribution of possible, probable or definite and all grade 3, 4 and 5 regardless of attribution.**

| Other CTC Adverse Event Terms not listed (CTCAE v3.0) | MedDRA Code (v. 10.0) (must be completed) | CTC Adverse Event Grade (highest grade this cycle) | CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite | Has an adverse event expedited report been submitted?* (Enter 1 for Yes or 2 for No) |
|---|---|---|--|--|
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |
| | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death) | <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 | — |

* See Section 10.0 of the protocol.

** Both hematologic and nonhematologic Adverse Events must be graded on this form as applicable.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**PRETREATMENT
RECIST MEASUREMENT FORM**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

INSTRUCTIONS

1. Record target lesions (per Section 11 of the protocol).
2. Measure target lesions in cm. using longest diameter (one dimension only).
- 3 Record measurements at pretreatment.
4. Maintain same type of assessment throughout study.
- 5 Record presence or absence of non-target lesions at baseline, thereafter record the status of non-target lesions at each required evaluation.

| | |
|---|---|
| Assessment Date (mm/dd/yyyy) <u> </u> / <u> </u> / <u> </u> <u> </u> <u> </u> <u> </u> <i>(Assessment date is the date reflecting type of assessment, not the physician interpretation date.)</i> | |
| Did patient have measurable disease per Section 11.0 of the protocol? | 1 <input checked="" type="checkbox"/> Yes. If Yes, complete Target and Non-Target Lesions |

| Target Lesion Site(s) | Type of Assessment | | | | | Measurement (cm) |
|---------------------------|----------------------------|----------------------------|-----------------------------|----------------------------|----------------------------|---------------------|
| | PE | CT | Spiral CT | MRI | CXR | |
| 1 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 2 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 3 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 4 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 5 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 6 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 7 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 8 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 9 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| 10 | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 13 <input type="checkbox"/> | 3 <input type="checkbox"/> | 5 <input type="checkbox"/> | |
| Sum of all Lesions | | | | | | |

| | | |
|---|------------------------------------|-----------------------------------|
| Non-Target Lesions <i>(check one)</i> | 1 <input type="checkbox"/> Present | 2 <input type="checkbox"/> Absent |
|---|------------------------------------|-----------------------------------|

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**ACTIVE MONITORING
RECIST MEASUREMENT FORM**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number: _____

INSTRUCTIONS

1. Record the target lesions in the same order as recorded at pretreatment (refer to Section 11 of the protocol).
2. Measure target lesions in cm. using longest diameter (one dimension only).
3. Record measurements at scheduled evaluations and progression (refer to protocol Section 4).
4. Maintain same type of assessment throughout study.
5. Record presence or absence of non-target lesions at baseline, thereafter record the status of non-target lesions at each required evaluation.
6. Overall objective status is determined by combining status of target lesions, non-target lesions and new lesions (refer to protocol Section 11).

| | |
|--|--|
| Assessment Date(mm/dd/yyyy) <u> </u> / <u> </u> / <u> </u> <i>(Assessment date is the date reflecting type of assessment, not the physician interpretation date. If tumor measurements are not required this cycle per Section 4.0, Assessment Date is the date the patient was evaluated.)</i> | |
| <p style="text-align: center;">Overall Response Status <i>(check one)</i></p> <p>Note: If PD is selected for overall response status, and Yes is selected for "Was the appearance of any new lesions documented," go to Non-Target Lesions.</p> | <p>19 <input type="checkbox"/> N/A <i>(not applicable this cycle)</i> → End Form</p> <p>1 <input type="checkbox"/> CR*</p> <p>2 <input type="checkbox"/> PR*</p> <p>5 <input type="checkbox"/> SD</p> <p>6 <input type="checkbox"/> PD* <i>(Complete End of Active Treatment and Event Monitoring Forms.)</i></p> <p>• Was the appearance of any new lesions documented? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>• Symptomatic Deterioration? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> |
| Did patient have measurable disease at study entry? | 1 <input checked="" type="checkbox"/> Yes → Complete Target and Non-Target Lesions |
| Target Lesion Site(s) Measurement (cm) | |
| 1. | |
| 2. | |
| 3. | |
| 4. | |
| 5. | |
| 6. | |
| 7. | |
| 8. | |
| 9. | |
| 10. | |
| Sum of all Lesions: | |
| Non-Target Lesions | Change: (check one) 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> NonCR/NonPD 3 <input type="checkbox"/> PD 5 <input type="checkbox"/> Not Done 9 <input type="checkbox"/> Not Applicable |

*Submit documentation to verify CR,PR, PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**ACTIVE MONITORING
BLOOD SPECIMEN SUBMISSION FORM**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number: _____

INSTRUCTIONS:

Complete this form for all patients and enter into the remote data entry system within 7 days of specimen collection. See Section 14 of the protocol for specimen requirements and shipment.

Did this patient provide written consent to give blood specimen(s) for research? (check one)

1 Yes. If Yes, complete rest of form

2 No. If No, end form

Was a research blood specimen collected? (check one)

1 Yes. If Yes: Date of collection: (mm/dd/yyyy) ___/___/____

Date Specimen Shipped: (mm/dd/yyyy) ___/___/____

2 No. If No, reason: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**CONCURRENT TREATMENT FORM
(BASELINE)**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Evaluation Date: (mm/dd/yyyy) ___/___/_____

Concomitant medications? (check one)

1 Yes 2 No (Stop here)

If Yes, enter all medications (including prescription, over-the-counter, and alternative medications).

| Concomitant Treatment |
|-----------------------|
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**CONCURRENT TREATMENT FORM
(ACTIVE MONITORING PHASE)**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number: _____

Evaluation Date: (mm/dd/yyyy) ___/___/_____

Has there been any change in medications since the previous visit?

1 Yes 2 No (*Stop here*)

If Yes, enter medications (*including prescription, over-the-counter, and alternative medications*) that have **not** been previously reported, no longer being taken or have a dose and/or schedule change.

| Concomitant Treatment | Reason for entry: 1= New medication 2= Medication no longer being taken 3= Dose and/or schedule change |
|-----------------------|---|
| | _____ |
| | _____ |
| | _____ |
| | _____ |
| | _____ |
| | _____ |
| | _____ |
| | _____ |
| | _____ |
| | _____ |

PLACE LABEL HERE

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

PATIENT QUESTIONNAIRE BOOKLET COMPLIANCE FORM

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Complete this form only if the entire Patient Questionnaire booklet contains absolutely NO patient provided assessment information.

Baseline: _____ or Current Cycle Number: _____

Date this form completed: (mm/dd/yyyy) ____/____/____

Reason Patient Questionnaire booklet was not completed. (check one)

- 1 Patient refusal
- 2 Unable to accommodate disability or language needs
- 3 Staff unavailable
- 4 Patient not given form by staff
- 5 Patient did not like content of questions
- 6 Site did not like content of questions
- 7 Other reason, specify _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM

page 1 of 3

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) [] Yes [] No
(if data are amended, please circle in red when using paper form)

Protocol Number: N0735

Patient ID: Patient Initials: L F M

Institution Number:

Institution:

Use one form per cycle, one column per agent.

Current Cycle Number:

Weight (kg):
(used for this cycle, round to the nearest tenth)

ECOG Performance Status: (check one) [0] [1] [2] [3] [4]
(used for this cycle)

BSA(m^2): (used for this cycle)

Was this cycle of treatment held (Day 1)? (check one)

1 [] Yes, planned 2 [] No 3 [] Yes, unplanned

If Yes, planned or unplanned; Primary reason treatment held: (check one)

- 70 [] Neurologic 137 [] Bilirubin 99 [] Other (not per protocol), specify
95 [] ANC 48 [] Proteinuria 177 [] Leukoencephalopathy syndrome
87 [] Platelets

Table with 2 columns: Agent, Albumin-bound paclitaxel (ABRAXANE). Rows include Agent Start Date, Initial Dose, Total Dose of Agents/Drugs, and Dose Adjustment reasons.

Agent: Albumin-bound Paclitaxel
Was dose omitted (day 1)? (check one) 1 [] Yes 2 [] No
If Yes, primary reason dose omitted: (check one)
95 [] ANC
87 [] Platelets
38 [] Non-hematologic adverse event
Was dose omitted (day 8)? (check one) 1 [] Yes 2 [] No
If Yes, primary reason dose omitted: (check one)
70 [] Neurologic 137 [] Bilirubin
95 [] ANC 38 [] Non-hematologic adverse event
87 [] Platelets 99 [] Other (not per protocol), specify

PLACE LABEL HERE

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM

page 2 of 3

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number: _____

| | |
|--|---|
| Agent | Gemcitabine (GEMZAR) |
| Agent Start Date (<i>this cycle</i>) (mm/dd/yyyy) | ___/___/____ |
| Initial Dose (<i>dose level day one this cycle</i>) (<i>If agent was not given this cycle, enter the dose level received on last day of treatment.</i>) | _____ mg/m ² |
| Total Dose of Agents/Drugs this cycle (<i>If agent was not given this cycle, enter 0 for total dose.</i>) | _____ mg |
| Was DOSE LEVEL adjusted (<i>Day 1 or 8</i>)? (mg/m ²) | 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No |
| If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. (<i>Check one</i>) | 36 <input type="checkbox"/> Hematologic Nadirs 95 <input type="checkbox"/> ANC 87 <input type="checkbox"/> Platelets 99 <input type="checkbox"/> Other (not per protocol), specify _____ |

Agent: Gemcitabine

Was dose omitted (*day 1*)? (*check one*) 1 Yes 2 No

If Yes, primary reason dose omitted: (*check one*)

95 ANC
87 Platelets
38 Non-hematologic adverse event
99 Other (not per protocol), specify _____

Was dose omitted (*day 8*)? (*check one*) 1 Yes 2 No

If Yes, primary reason dose omitted: (*check one*)

95 ANC
87 Platelets
38 Non-hematologic adverse event
99 Other (not per protocol), specify _____

PLACE LABEL HERE

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM

page 3 of 3

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

| | |
|--|---|
| Agent | Bevacizumab (AVASTIN) |
| Agent Start Date (this cycle) (mm/dd/yyyy) | ___/___/___ |
| Initial Dose (dose level day one this cycle) (If agent was not given this cycle, enter the dose level received on last day of treatment.) | mg/Kg |
| Total Dose of Agents/Drugs this cycle (If agent was not given this cycle, enter 0 for total dose.) | mg |
| Was DOSE LEVEL adjusted (Day 1)? (mg/m ²) | 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No |
| If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. (Check one) | 99 <input type="checkbox"/> Other (not per protocol), specify _____ |

Agent: Bevacizumab

| |
|---|
| <p>Was dose omitted (day 1)? (check one) 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>If Yes, primary reason dose omitted: (check one)</p> <p>177 <input type="checkbox"/> Leukoencephalopathy syndrome 148 <input type="checkbox"/> Proteinuria 146 <input type="checkbox"/> Hypertension 38 <input type="checkbox"/> Non-hematologic adverse event 137 <input type="checkbox"/> Bilirubin 99 <input type="checkbox"/> Other (not per protocol), specify _____</p> |
|---|

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM

Patient ID: _____ Patient Initials: _____

Submit Once Per Patient

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Institution: _____

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Last Date (any modality of) protocol therapy was given: (mm/dd/yyyy) ___/___/_____
(date of last treatment dose on this study or date decision made not to initiate protocol treatment)

Off Treatment Date: (mm/dd/yyyy) ___/___/_____
(date decision was made to end active treatment or not to initiate protocol treatment)

This patient will now go to: (check one)
(See Schema and Section 13.0 of the protocol)

- 2 Event Monitoring (follow Event Monitoring schedule)
- 9 Off Study (cancels only)

| Reason Treatment Ended <i>(check one)</i> | COMMENTS |
|--|--------------------------------|
| 1 <input type="checkbox"/> Treatment Completed Per Protocol Criteria | |
| 2 <input type="checkbox"/> Patient Withdrawal/Refusal After Beginning Protocol Therapy | Specify: |
| 24 <input type="checkbox"/> Patient Withdrawal/Refusal Prior To Beginning Protocol Therapy <i>(cancel)</i> | Specify: |
| 3 <input type="checkbox"/> Adverse Event/Side Effects/Complications | Specify: |
| 4 <input type="checkbox"/> Disease Progression, Relapse During Active Treatment* | Complete Event Monitoring Form |
| 10 <input type="checkbox"/> Disease Progression Before Active Treatment | |
| 5 <input type="checkbox"/> Alternative Therapy | Specify: |
| 6 <input type="checkbox"/> Patient Off-Treatment For Other Complicating Disease | Specify: |
| 7 <input type="checkbox"/> Death On Study | Complete Event Monitoring Form |
| 8 <input type="checkbox"/> Other | Specify: |

* Submit documentation to verify progression. See Section 11.0 and Section 18.0 of protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

EVENT MONITORING FORM

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 2

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Were you able to obtain any information about the patient since the last report?*

- 1 Yes. If Yes, complete rest of form.
- 2 No. If No, date of last attempt to contact patient: (mm/dd/yyyy) ___/___/_____ (End form)

Vital Status

- 1 Alive Date of last contact or date of death: (mm/dd/yyyy) ___/___/_____
- 2 Dead
 - Primary Cause of Death: (check one) 1 Due to this disease 2 Due to other cause, specify _____
 - 4 Due to protocol treatment
(adverse event related to treatment)

Disease Follow-up Status

- Has the patient had a documented clinical assessment for this cancer *(since submission of the last event monitoring form)?**
- 2 No. If No, Go to Notice of New Primary.
- 1 Yes. If Yes, Cancer Follow-up Status Date: (mm/dd/yyyy) ___/___/_____

Notice of First Relapse/Progression in the Event Monitoring Phase

- Has the patient developed a first relapse or progression **that has not been previously reported (in the event monitoring phase)?**
- 2 No 1 Yes. If Yes, Date of Relapse/Progression:** (mm/dd/yyyy) ___/___/_____
- Site(s) of Relapse/Progression: Bone Lung Brain Chestwall
(check all that apply) Liver Nodes Skin Other, specify _____
- Method (s) of Diagnosis: Physical Exam MRI Chest x-ray
(check all that apply) CT ULT Patient correspondence
 Other, specify _____

Notice of First Subsequent Treatment

- Has the patient received subsequent treatment for this cancer **that has not been previously reported?**
- 2 No 3 Unknown 1 Yes. If Yes, Start date of subsequent treatment: (mm/dd/yyyy) ___/___/_____
- Specify subsequent treatment: _____

Notice of New Primary

- Has a new primary cancer been diagnosed **that has not been previously reported?**
- 2 No 3 Unknown 1 Yes. If Yes, New Primary Cancer Date: (mm/dd/yyyy) ___/___/_____
- Site of New Primary: _____

Late Adverse Event (post completion of active monitoring)

- Has the patient experienced (prior to treatment for progression or relapse or a second primary, and prior to non-protocol treatment) any severe (grade ≥ 3) long term toxicity that has not been previously reported:
 - Adverse events at least possibly attributed to treatment on this study.
 - Death within 30 days of treatment.
 - Death any time at least **possibly** treatment related.
- 2 No 3 Unknown/Not evaluated 1 Yes. If Yes, Submit page 2 of the Event Monitoring Form for Late Adverse Event Reporting.

*If this is the first event monitoring form check yes, enter cancer follow-up status date and complete the rest of the form.

**Submit documentation to verify PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**EVENT MONITORING FORM
(LATE ADVERSE EVENT REPORTING)**

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

The CTC AE v.3.0 will be used to evaluate the following adverse events:

| CTC Adverse Event Term | MedDRA Code (v. 10.0) (must be completed) | CTC Adverse Event Grade (Highest Grade) | CTC AE Attribution Code 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite | Late Adverse Event Onset Date (mm/dd/yyyy) |
|------------------------|---|--|--|---|
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
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| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |
| | <input type="text"/> | <input type="text"/> <input type="text"/> <input type="text"/> (death) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ___/___/_____ |

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0735

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**NOTIFICATION FORM
Grade 4 or 5 Non-AER Reportable Events/Hospitalization
ALL ITEMS MUST BE COMPLETED**

INSTRUCTIONS:

- Use this form to report all known information on non-AER reportable grade 4 or 5 adverse events or any hospitalization during active treatment.
- Verify reporting requirements listed within the study protocol, prior to entering into the remote data entry system.
- If AER has been submitted for this event do not enter this form.
- Fill out all information known.
- Enter into the remote data entry system within 5 working days of notification.
- These events must also be reported on the Nadir/Adverse Event Form.

Date membership CRA aware of event(s): (mm/dd/yyyy) ___/___/_____

Name of Person Completing Form: _____ Phone: (_____) _____ - _____

Current Cycle Number: _____ Assigned Treatment Arm: _____

Event ≥ Grade 4: (check one) 1 Yes 2 No

| Date of First Occurrence of Adverse Event (mm/dd/yyyy) | CTC Adverse Event Term (only one event per line) | CTC Adverse Event Grade | In your opinion, is this related to the study medication?* |
|--|--|---|--|
| ___/___/_____ | | <input type="checkbox"/> 4 <input type="checkbox"/> 5 | 4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown |
| ___/___/_____ | | <input type="checkbox"/> 4 <input type="checkbox"/> 5 | 4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown |
| ___/___/_____ | | <input type="checkbox"/> 4 <input type="checkbox"/> 5 | 4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown |
| ___/___/_____ | | <input type="checkbox"/> 4 <input type="checkbox"/> 5 | 4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown |
| ___/___/_____ | | <input type="checkbox"/> 4 <input type="checkbox"/> 5 | 4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown |

*Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure. Verify if expedited reporting (e.g. ADEERS) is required (see protocol), based on relationship to study treatment.

Hospitalization: (check one) 1 Yes 2 No

If Yes: Hospital Admission Date: (mm/dd/yyyy) ___/___/_____

Reason(s) for Hospitalization:

- 1 Adverse Event, specify type and grade: _____
- 2 Prophylactic, specify: _____
- 3 Other reason, specify _____

Biospecimen Accessioning Processing
Fax Supply Order Form – No Cover Sheet Necessary
Fax to Research Kit Building @ 507-538-4103

NOTE: Form must be either typed or printed legibly and filled out completely.

Study ID: N0735 _____

Investigator: _____

Order Placed By: _____ Phone #: () _____

Email: _____ Fax #: () _____

Address (kits sent to):

ALLOW AT LEAST TWO WEEKS TO RECEIVE THE KITS.

NOTE: Kits will be sent via FedEx® Ground at no additional cost to the participating institutions. Kits will not be sent via rush delivery service unless the participating institution provides their own FedEx® account number or alternate billing number for express service. **The study will not cover the cost for rush delivery of kits.**

Date Needed: _____
(Please be specific)

Fed Ex account number (Rush deliveries only) _____

Type of Kits

of Kits Needed

N0735 Research Blood Specimens Kit _____

Total Kits _____

Questions? Contact the Biospecimen Resource Manager listed on the Protocol Resource page of the protocol.



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Version Date: October 29, 2008

Order Form

Quality-of-Life Booklets

N0735, Phase II Trial of Albumin-Bound Paclitaxel in Combination with Gemcitabine and Bevacizumab in Patients with Metastatic Breast Cancer

Patient Questionnaire

Number of booklets needed: _____

Fax form to: 507-284-1902

Attention: NCCTG Operational Support Clerk

Requestor: _____ Phone: _____

Affiliate/Membership: _____/_____

Shipping address: _____

Date requested: _____