

FORMS PACKET

N0626: Phase II Randomized Study Pemetrexed With Sorafenib versus Pemetrexed Alone as Second-line Therapy in Patients With Advanced Non-Small Cell Lung 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.

Eligibility Checklist

11/06/2009

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N0626: Phase II Randomized Study of Pemetrexed With Sorafenib Versus Pemetrexed Alone as Second-Line Therapy in Patients With Advanced Non-Small Cell Lung Cancer

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) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Date of birth (mm/dd/yyyy) __/__/____	<input type="checkbox"/> Black or African American
Zip code _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence _____	<input type="checkbox"/> Asian
	<input type="checkbox"/> American Indian or Alaska Native
	<input type="checkbox"/> Not reported: Patient refused or not available
	<input type="checkbox"/> Unknown: Patient unsure
Method of payment (check one)	Ethnicity (check one)
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MRP (Medicare and Private Insurance)	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MD (Medicaid)	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> MM (Medicaid and Medicare)	
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	
<input type="checkbox"/> MV (Veterans Sponsored)	
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

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

≥18 years of age. Age = _____.	___ ___
Histologic or cytologic confirmation of non-squamous NSCLC. Patient should have Stage IV or Stage IIIB disease (AJCC TNM sixth edition); symptomatic pleural effusions should be drained prior to registration. • Although patients with squamous cell carcinomas are not eligible, adenosquamous histology is allowed.	___ ___
Patients must have measurable disease as defined in Section 11.0 with at least one lesion whose longest diameter can be accurately measured as ≥2.0 cm with conventional techniques or as ≥1.0 cm with spiral CT. If spiral CT is used, it must be used for both pre- and post-treatment tumor assessments.	___ ___
Prior radiation therapy is permitted as long as: • Recovered from the toxic effects of radiation treatment before study entry, except for alopecia. • ≤25% of bone marrow radiated. • Presence of measurable disease whether in-field disease progression/recurrence or disease outside the treatment fields of radiation port.	___ ___
The following laboratory values obtained ≤14 days prior to registration. Earliest laboratory test date ___/___/_____; latest laboratory test date ___/___/_____. NOTE: These dates pertain to the following labs only.	___ ___
• ANC ≥1500/μL. ANC = _____.	___ ___
• PLT ≥100,000/μL. PLT = _____.	___ ___
• Hgb ≥9 g/dL. Hgb = _____.	___ ___
• Total bilirubin ≤1.5 x upper limit of normal (ULN) or direct bilirubin ≤ULN. Which was done? ___ Total bilirubin → Total bilirubin = _____; ULN = _____. ___ Direct bilirubin → Direct bilirubin = _____; ULN = _____. ___ Both total and direct bilirubin → Complete both total and direct bilirubin above.	___ ___
• AST and ALT ≤3 x ULN or AST and ALT ≤5 x ULN is acceptable if liver has tumor involvement. Does liver have tumor involvement? (This question may be answered yes or no.) ___ Yes (≤5 x ULN) → AST = _____; ULN = _____. ALT = _____; ULN = _____. ___ No (≤3 x ULN) → AST = _____; ULN = _____. ALT = _____; ULN = _____.	___ ___
• INR <1.5 or a PT/PTT within normal limits (WNL). Patients receiving anticoagulation treatment with an agent such as warfarin or prophylactic dose heparin are eligible if the parameters as outlined are met at the individual patient's stable dose of the anticoagulants. Which was done and within normal limits? ___ INR → INR (<1.5) = _____ ___ PT or PTT → PT or PTT (WNL) = _____; LLN = _____; ULN = _____.	___ ___
• Calculated creatinine clearance must be ≥45 ml/min using the Cockcroft-Gault formula (see Section 3.15). Creatinine clearance = _____.	___ ___
ECOG performance status (PS) 0 and 1.	___ ___
Negative pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential (check NA) vs. Negative pregnancy test date ___ / ___ / ___	___ ___ ___
Ability to provide informed consent.	___ ___
Life expectancy ≥12 weeks.	___ ___
Willingness to provide the biologic specimens as required by the protocol (see Sections 6.13, 14.0, 17.0). (Please note that the willingness to participate pertains only to the patient and does not factor in the institution's ability to participate in any part of the translational component.)	___ ___

Patient study ID number _____

Eligibility Check – (Required Characteristics continued)

Yes No

NA

Willingness to return to NCCTG enrolling institution for follow-up.	___ ___
Previously treated with 1 chemotherapy regimen. Prior treatment with adjuvant chemotherapy is allowed and not counted as a regimen.	___ ___
Able to take folic acid, vitamin B ₁₂ supplementation, and dexamethasone.	___ ___
Able to permanently discontinue aspirin dose of ≥ 1.3 grams/day ≥ 10 days before and after pemetrexed treatment.	___ ___
Stable brain metastasis that have been treated with either whole brain radiation therapy or gamma knife surgery and are off steroid treatment for >4 weeks.	___ ___

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

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. 	___ ___
Any clinically significant infection.	___ ___
Known HIV-positive patients. Those receiving anti-retroviral therapy are also excluded because of possible pharmacokinetic interactions with sorafenib and the possible unfavorable immunosuppressive effects of sorafenib.	___ ___
Evidence or history of bleeding diathesis or coagulopathy.	___ ___
Serious non-healing wound, ulcer, or bone fracture.	___ ___
Any of the following prior therapies:	
• Prior radiation to >25% of bone marrow.	___ ___
• Sorafenib.	___ ___
• Pemetrexed	___ ___
• Chemotherapy ≤ 3 weeks prior to registration. No prior chemotherapy (<i>check NA</i>) vs. Last day of chemotherapy ___ / ___ / ___.	___ ___ ___
• Mitomycin C/nitrosoureas ≤ 6 weeks prior to registration. No prior Mitomycin C/nitrosoureas therapy (<i>check NA</i>) vs Last day of mitomycin C/nitrosoureas therapy ___ / ___ / ___.	___ ___ ___
• Immunotherapy ≤ 2 weeks prior to registration. No prior immunotherapy (<i>check NA</i>) vs. Last day of immunotherapy ___ / ___ / ___.	___ ___ ___
• Biologic therapy ≤ 2 weeks prior to registration. No prior biologic therapy (<i>check NA</i>) vs. Last day of biologic therapy ___ / ___ / ___.	___ ___ ___
• Gene therapy ≤ 2 weeks prior to registration. No prior gene therapy (<i>check NA</i>) vs. Last day of gene therapy ___ / ___ / ___.	___ ___ ___
• Full field radiation therapy ≤ 4 weeks prior to registration. No prior full field radiation therapy (<i>check NA</i>) vs. Last day of full field radiation therapy ___ / ___ / ___.	___ ___ ___
• Limited field radiation therapy ≤ 2 weeks prior to registration. No prior limited field radiation therapy (<i>check NA</i>) vs. Last day of limited field radiation therapy ___ / ___ / ___.	___ ___ ___

Patient study ID number _____

Eligibility Check – (Contraindications continued)

Yes No NA

<ul style="list-style-type: none"> Major surgery (i.e., laparotomy), open biopsy, or significant traumatic injury ≤ 4 weeks prior to registration or anticipation of need for major surgical procedure during the course of the study. Minor surgery ≤ 2 weeks prior to registration. Insertion of a vascular access device is not considered major or minor surgery in this regard. 	<p>___ ___</p>
Other chemotherapy, immunotherapy, hormonal therapy, radiotherapy, or any ancillary therapy considered investigational (utilized for a non-FDA-approved indication and in the context of a research investigation) ≤ 4 weeks prior to registration.	<p>___ ___</p>
Patients with brain metastasis that require steroid therapy.	<p>___ ___</p>
Any bleeding \geq grade 2 ≤ 4 weeks prior to registration (EXCEPTION: Grade 2 petechiae).	<p>___ ___</p>
Second primary malignancy except carcinoma in situ of the cervix or non-melanomatous skin cancer, unless that prior malignancy was diagnosed and definitively treated ≥ 5 years previously with no subsequent evidence of recurrence. Patients with a history of low-grade (Gleason score ≤ 6) localized prostate cancer will be eligible even if diagnosed < 5 years prior to registration. Patients with a history of DCIS that has been definitively treated will be eligible even if diagnosed < 5 years prior to registration.	<p>___ ___</p>
Patients with only non-measurable disease, including small lesions whose longest diameter measures < 2 cm with conventional techniques or < 1.0 cm with spiral CT, and truly non-measurable lesions, which include the following: <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. 	<p>___ ___</p>
Any other severe underlying diseases which are, in the judgment of the investigator, inappropriate for entry into this study including uncontrolled hypertension.	<p>___ ___</p>
Inability to swallow pills.	<p>___ ___</p>
Any of the following concurrent severe and/or uncontrolled medical conditions: <ul style="list-style-type: none"> Uncontrolled blood pressure defined as systolic > 150 mmHg and/or diastolic > 100 mmHg, in spite of adequate anti-hypertensive therapy. Angina pectoris. History of congestive heart failure ≤ 3 months, unless ejection fraction $> 40\%$. Myocardial infarction ≤ 6 months prior to registration. Cardiac arrhythmia. Diabetes mellitus. Active hemoptysis. 	<p>___ ___</p>
Receiving therapeutic anticoagulation. Prophylactic anticoagulation (i.e. low dose warfarin) of venous or arterial access devices is allowed provided that the requirements for PT, INR, or PTT are met.	<p>___ ___</p>
Serious condition that, in the opinion of the investigator, would compromise the patient's ability to complete the study or increase the risk for serious adverse events.	<p>___ ___</p>
Symptomatic serosal effusion (\geq CTCAE v3.0 grade 2 dyspnea) that is not amenable to drainage prior to registration.	<p>___ ___</p>
Use of St. John's Wort that cannot be completely stopped for the duration of the study (because of the effects on hepatic drug metabolism).	<p>___ ___</p>
Prior therapy with agents that target VEGF, VEGF receptor or VEGF receptor tyrosine kinase inhibitors. Exception: Prior therapy with bevacizumab is allowed.	<p>___ ___</p>

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

Patient study ID number _____

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.(U.S.A. institutions only) Not a USA institution (check NA) vs. Date of authorization ____/____/____.	____	____	____
A mandatory translational research component is available for your patient, the subject will be automatically registered onto this component (Section 3.19b, 14.0, and 17.0).	____	____	____
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 ≤14 days after registration.	____	____	____
Pretreatment tests/procedures must be completed ≤14 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.	____	____	____
Exceptions to the above dates: Tumor assessment and chest x-ray (if not used for tumor assessment) performed ≤28 days prior to registration (see Section 4.0). Earliest exception test/procedure date ____/____/____; Latest exception test/procedure date ____/____/____.	____	____	____
All required baseline symptoms must be documented and graded.	____	____	____
Study drug availability checked.	____	____	____
Treatment assignment will be calculated using a dynamic allocation procedure which balances the marginal distributions of the stratification factors between the treatment groups. The factors defined in Section 5.0 will be used as stratification factors.	____	____	____

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

At the time of registration/randomization the following will also be recorded:

Yes No

• Patient has given permission for tissue sample(s) to be stored and used for future research to learn about, prevent, or treat cancer.	____	____
• Patient has given permission for tissue sample(s) to be stored and used for future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	____	____
• Patient has given permission for blood sample(s) to be stored and used for future research to learn about, prevent, or treat cancer.	____	____
• Patient has given permission for blood sample(s) to be stored and used for future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	____	____
• Patient has given NCCTG permission to contact them in the future to ask them to take part in more research.	____	____
Patient has agreed to take part in N0392.	____	____

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

Stratification Factors:

ECOG PS (check one):

____ 0
____ 1

Assigned Treatment

____ A) ALIMTA + BAY439006
____ B) ALIMTA

Person registering _____ Signature
Registration Office specialist _____ initials

Physician _____ Signature
M D Y

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

ON-STUDY FORM

Patient ID Number: Patient Initials: L F M

Institution Number:

Institution:

ALL ITEMS MUST BE COMPLETED

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: 10029514 [Non-small cell lung cancer, NOS]

Histologic Type: (check one)

- 2 Bronchoalveolar (BAC) 3 Adenocarcinoma 4 NSCLC, NOS 5 Large Cell undifferentiated 6 Other, specify

Status of Primary Tumor (check one)

- 1 Resected with no residual 2 Resected with known residual 3 Unresected 4 Recurrent

- Stage: (check one) 1 III B 2 IV

Chronology of Diagnoses

Table with 2 columns: Method of Diagnosis*, Date (mm/dd/yyyy). Rows: Primary, Recurrence of Primary, First Metastasis.

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

Metastatic Site(s) (check all that apply)

- Hilar nodes, Mediastinal nodes, Supraclavicular/scalene nodes, Ipsilateral lung, Contralateral lung, Pleura, Liver, Adrenal(s), Bone, Bone marrow, Brain, Skin, Other, specify

Previous Surgery Related To The Tumor

Table with 2 columns: Procedure, Results. Rows: Mediastinoscopy, Bronchoscopy, Supraclavicular biopsy, Thoracotomy, Fine Needle Aspirate, Other, specify.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

ON-STUDY FORM

Patient ID Number: Patient Initials:

Institution Number: L F M

Institution:

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)

Previous Radiotherapy: (check one) 1 Yes 2 No

Table with columns: Site, Dose (cGy), From, To, Date (mm/dd/yyyy)

Previous Systemic Cancer Therapy : (check one) 1 Yes 2 No

Table with columns: Therapy, Date (mm/dd/yyyy) From To, Response (NED, CR, PR, REGR, SD, PD)

Prior therapy with bevacizumab: (check one) 1 Yes 2 No

Current Symptoms & Disease:

Table with columns: Current Symptom/Disease, 1 Yes, 2 No

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

Site:

Date Dx: (mm/dd/yyyy)

Treatment:

Height (cm):

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**BASELINE
ADVERSE EVENTS FORM**

ALL ITEMS TEST 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	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Baseline number of stools per day: _____		
Hypertension	10020772	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Fatigue (lethargy, malaise, asthenia)	10016256	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Rash: acne/acneiform	10037847	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Rash/desquamation	10037853	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Rash: hand-foot skin reaction	10019126	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Anorexia	10002646	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Mucositis/stomatitis (clinical exam)		
- Oral cavity	10056848	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
- Pharynx	10065717	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Mucositis/stomatitis (functional/symptomatic)		
- 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
Hemorrhage, pulmonary/upper respiratory		
- Bronchus	10065757	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
- Lung	10037397	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Phosphate, serum low (hypophosphatemia)	10040370	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Lipase	10024574	<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
Somnolence/depressed level of consciousness	10012373	<input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Pain		
- Abdomen NOS	10000081	<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: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**HEMATOLOGY
INTERVAL LABORATORY FORM
ARM A, CYCLES 1 and 2
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: _____

	Tests	Test Result
Hematology	Week	_____
	Date of Collection (mm/dd/yyyy)	___/___/_____
	TESTS	UNITS
	HGB	g/dL
	Platelets	K/uL or 10 ⁹ /L
	WBC	K/uL or 10 ⁹ /L
	ANC	K/uL or 10 ⁹ /L
	Week	_____
	Date of Collection (mm/dd/yyyy)	___/___/_____
	TESTS	UNITS
	HGB	g/dL
	Platelets	K/uL or 10 ⁹ /L
	WBC	K/uL or 10 ⁹ /L
	ANC	K/uL or 10 ⁹ /L
	Week	_____
	Date of Collection (mm/dd/yyyy)	___/___/_____
	TESTS	UNITS
	HGB	g/dL
Platelets	K/uL or 10 ⁹ /L	
WBC	K/uL or 10 ⁹ /L	
ANC	K/uL or 10 ⁹ /L	

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**ARM A
EVALUATION/TREATMENT 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)

Use one form per cycle, one column per agent.

Current Cycle Number : ____

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

ECOG Perf. Status: (check one) 0 1 2 3 4
(used for this cycle)

BSA(m²): (used for this cycle) ____ . ____

Was this cycle of treatment held (delayed)? (check one)

1 Yes, planned 2 No

3 Yes, unplanned

99 Other (not per protocol) _____

Primary reason treatment held (delayed): (check one)

- | | |
|--|--|
| 146 <input type="checkbox"/> Hypertension | 60 <input type="checkbox"/> Gastrointestinal |
| 59 <input type="checkbox"/> Renal/Genitourinary | 38 <input type="checkbox"/> Other nonhematologic adverse event |
| 129 <input type="checkbox"/> Hemorrhage/bleeding | |
| 35 <input type="checkbox"/> Hematologic | 154 <input type="checkbox"/> Metabolic/Laboratory |

Agent	Pemetrexed (ALIMTA)	Sorafenib (BAY43_9006)
Agent Start Date this cycle (mm/dd/yyyy)	___/___/___	___/___/___
Dose Level day one this cycle	mg/m ²	mg
Total Dose this cycle	mg	mg
Was DOSE LEVEL adjusted this cycle? (i.e. mg/m ²)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. (If Yes, check one Primary Reason.)	35 <input type="checkbox"/> Hematologic 38 <input type="checkbox"/> Other nonhematologic adverse event 60 <input type="checkbox"/> Gastrointestinal 99 <input type="checkbox"/> Other (not per protocol) _____	146 <input type="checkbox"/> Hypertension 60 <input type="checkbox"/> Gastrointestinal 129 <input type="checkbox"/> Hemorrhage/Bleeding 154 <input type="checkbox"/> Metabolic/Laboratory 45 <input type="checkbox"/> Rash/desquamation 66 <input type="checkbox"/> Rash: Hand-foot skin reaction 51 <input type="checkbox"/> Neuropathy: sensory 35 <input type="checkbox"/> Hematologic 38 <input type="checkbox"/> Other nonhematologic adverse event 99 <input type="checkbox"/> Other (not per protocol) _____

Was folic acid taken this cycle? 1 Yes 2 No

Was vitamin B₁₂ administered this cycle? 1 Yes 2 No

Was dexamethasone taken this cycle? 1 Yes 2 No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ARM B
EVALUATION/TREATMENT 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)

Use one form per cycle, one column per agent.

Current Cycle Number : _____

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

ECOG Perf. Status: (check one) 0 1 2 3 4
(used for this cycle)

BSA(m²): (used for this cycle) _____

Was this cycle of treatment held (delayed)? (check one)
1 Yes, planned 2 No

3 Yes, unplanned

99 Other (not per protocol) _____

Primary reason treatment held (delayed): (check one)

- 146 Hypertension
- 59 Renal/Genitourinary
- 129 Hemorrhage/bleeding
- 35 Hematologic
- 60 Gastrointestinal
- 38 Other nonhematologic adverse event
- 154 Metabolic/Laboratory

Agent	Pemetrexed (ALIMTA)
Agent Start Date this cycle (mm/dd/yyyy)	____/____/____
Dose Level day one this cycle	_____ mg/m ²
Total Dose this cycle	_____ mg
Was DOSE LEVEL adjusted this cycle? (i.e. mg/m ²)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓
PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. (If Yes, check one Primary Reason.)	35 <input type="checkbox"/> Hematologic 38 <input type="checkbox"/> Other nonhematologic adverse event 60 <input type="checkbox"/> Gastrointestinal 99 <input type="checkbox"/> Other (not per protocol) _____

Was folic acid taken this cycle? 1 Yes 2 No

Was vitamin B₁₂ administered this cycle? 1 Yes 2 No

Was dexamethasone taken this cycle? 1 Yes 2 No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

EVALUATION/OBSERVATION FORM

Patient ID: _____ Patient Initials: _____

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)

Use one form per cycle.

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)

Observation

Day 1 of this observation cycle: (mm/dd/yyyy) ____/____/____

↓
End of observation? (check one) 1 Yes 2 No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/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)

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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

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

Test	Date of Nadir (Date of lab test) (mm/dd/yyyy)	Nadir Value <i>(The nadir is the lowest value of counts occurring between two treatments. If the only count available is taken the day of retreatment, use that value as the nadir.)</i>	Is this nadir below the LLN? (check one)	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)
PLT K/uL or 10 ⁹ /L	___/___/___	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to WBC)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
WBC K/uL or 10 ⁹ /L	___/___/___	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to Hgb)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Hgb g/dL	___/___/___	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to ANC)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
ANC K/uL or 10 ⁹ /L	___/___/___	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to Adverse Event)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___

CTC Adverse Event Term	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

Hypertension	10020772	<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 (lethargy, malaise, asthenia)	10016256	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<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	___
Weight loss	10047900	<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	___

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/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)

Protocol Number: N0626
 Patient ID: _____ Patient Initials: _____
 L F M
 Institution Number: _____
 Institution: _____

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

CTC Adverse Event Term	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				
Rash: acne/acneiform	10037847	0 1 2 3 5 (death)	1 2 3 4 5	—
Rash/desquamation	10037853	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Rash: hand-foot skin reaction	10019126	0 1 2 3	1 2 3 4 5	—
Anorexia	10002646	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Diarrhea	10012727	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Mucositis/stomatitis (clinical exam)				
- Oral cavity	10056848	0 1 2 3 4 5 (death)	1 2 3 4 5	—
- Pharynx	10065717	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Mucositis/stomatitis (functional/symptomatic)				
- Oral cavity	10028130	0 1 2 3 4 5 (death)	1 2 3 4 5	—
- Pharynx	10065881	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Nausea	10028813	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Vomiting	10047700	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Hemorrhage, pulmonary/upper respiratory				
- Bronchus	10065757	0 1 2 3 4 5 (death)	1 2 3 4 5	—
- Lung	10037397	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)	10016288	0 3 4 5 (death)	1 2 3 4 5	—

* See Section 10.0 of the protocol.

PLACE LABEL HERE

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/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 (nadir/adverse events associated with this cycle): _____

CTC Adverse Event Term	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

Infection with unknown ANC - Abdomen NOS	10056519	<input type="checkbox"/> 0 <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	_____
Phosphate, serum low (hypophosphatemia)	10040370	<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	_____
Lipase	10024574	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Neuropathy: sensory	10034620	<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	_____
Somnolence/depressed level of consciousness	10012373	<input type="checkbox"/> 0 <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	_____
Pain - Abdomen NOS	10000081	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<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

**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: N0626

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	Schedule

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

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

Patient ID: _____ Patient Initials: _____

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)

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 all medications (*including prescription, over-the-counter, and alternative medications*).

Concomitant Treatment	Schedule

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

Institution Number: _____ L F M

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 the 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) / /
(Assessment date is the date reflecting type of assessment, not the physician interpretation date.)

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 (check one)	1 <input type="checkbox"/> Present	2 <input type="checkbox"/> Absent
--	------------------------------------	-----------------------------------

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

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)

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) / /
 (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.)

<p>Overall Objective Status (check one)</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 (not applicable this cycle) → 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* (Complete End of Active Treatment and Event Monitoring Forms.)</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>
--	--

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

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

BASELINE

TISSUE 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)

INSTRUCTIONS:

Complete this form for all patients and enter into the remote data entry system within 60 days of study entry. See Section 17 of the protocol for specimen requirements and shipment.

Was a research tissue specimen obtained? (check one)

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

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

2 No. If No, reason: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**ACTIVE MONITORING - CYCLE 1
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)

Current Cycle Number: 1

INSTRUCTIONS:

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

Was a research blood specimen collected Cycle 1, Day 1 prior to treatment? (check one)

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

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

2 No. If No, reason: _____

Was a research blood specimen collected Cycle 1, 24 hours after Day 1 treatment? (check one)

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

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

2 No. If No, reason: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**ACTIVE MONITORING - ≥CYCLE 2
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)

Current Cycle Number: _____

INSTRUCTIONS:

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

Was a research blood specimen collected Day 1 prior to treatment? (check one)

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

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

2 No. If No, reason: _____

PLACE LABEL HERE

Protocol Number: N0626

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

(NOTE: This form is used to update the Outstanding Materials Report)

**** This form must be submitted to the NCCTG Operations Office at the time slides/blocks are sent to the NCCTG reviewer (see Pathology section of the protocol) ****

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

Number of slides sent: ___

Accession number(s) (on the slides sent):

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Number of blocks sent: ___

Accession number(s) (on the blocks sent):

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

COMMENTS:

Institution Contact Information: (Please Print)

Contact Person at Institution (CRA/Nurse): _____

Institution Name: _____

Street Address: _____

City: _____

State: _____

Zip Code: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY REPORTING FORM

LUNG CARCINOMA

Protocol Number: N0626

Patient ID Number: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Primary Pathologist: _____ No. of slides sent: _____

Clinic/Hospital: _____ Date sent: _____

Reviewer: _____ Slide No. _____ Sequence No. _____

I. CRA/RN

1. DATE OF OPERATIVE PROCEDURE

/ /
m m d d y y y y

_____ to _____
_____ to _____

2. OPERATIVE PROCEDURE

- 1. Biopsy
- 2. Resection (lung)
- 3. Resection (lobes)
- 4. Resection (segmental)

II. Completed by the NCCTG Pathology reviewer

3. LOCATION OF PRIMARY NEOPLASM

- LOBE
 - 1. Right upper
 - 2. Right middle
 - 3. Right lower
 - 4. Left upper
 - 5. Left lower
 - 6. Right mainstem
 - 7. Left mainstem
 - 8. Carina
 - 9. Multiple

- LOCATION WITHIN LUNG
 - 1. Central (perihilar)
 - 2. Peripheral
 - 3. Mid zone

4. SIZE OF PRIMARY NEOPLASM (Enter all 3 dimensions if possible OR the GREATEST dimension)

mm x mm x mm

5. HISTOLOGIC FEATURES OF PRIMARY NEOPLASM

HISTOLOGIC TYPE

- 1. Squamous cell
- 2. Large cell undifferentiated
- 3. Small cell undifferentiated
- 4. Adenocarcinoma
- 5. Alveolar carcinoma
- 6. Combined (mixed pattern) (specify): _____
- 7. Other (specify): _____

DEGREE OF DIFFERENTIATION

- 1. Grade 1
- 2. Grade 2
- 3. Grade 3
- 4. Grade 4

6. EXTENT OF LOCAL SPREAD

- 1. Confined to lung parenchyma
- 2. Involvement of bronchial margin of resection
- 3. Involvement of pleura

7. REGIONAL LYMPH NODE STATUS

Number of positive nodes (specify location): _____
(intrapulmonary peribronchial, hilar, mediastinal)

Number of negative nodes

8. SOURCE(S) OF SPECIMEN (specify location)

- 1. Primary tumor
- 2. Primary and metastatic tumor (specify metastatic site[s]): _____
- 3. Metastatic tumor with clinical evidence of primary tumor in lung

COMMENTS: _____

III. Signatures

NCCTG Pathology Reviewer

Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: _____

Research base Advisor

Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: _____

Committee Chairperson

Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: _____

Block/Slide number(s) to be used for research/banking: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

**END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM
Submit Once Per Patient**

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED

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)

- 1 Observation *(Observation required for all patients alive at end of treatment. Follow test schedule and enter cycle data)*
- 2 Event Monitoring *(follow Event Monitoring schedule)*
- 9 Off Study *(cancels only)*

Reason Treatment Ended <i>(check one)</i>	COMMENTS
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*	
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: N0626

EVENT MONITORING FORM

Patient ID Number: Patient Initials: L F M

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 2

Institution Number:

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

Institution:

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) Return form to Operations Office.

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 event monitoring phase)?
2 No 1 Yes. If Yes, Date of Relapse/Progression: (mm/dd/yyyy)
Site(s) of Relapse/Progression: Liver Adrenal Bone Lung Brain Other, specify
Method (s) of Diagnosis: Biopsy PET scan CT Other, specify MRI

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 or MDS (myelodysplastic syndrome) 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 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 assessment date and complete the rest of the form.

**Submit documentation to verify PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0626

**EVENT MONITORING FORM
(LATE ADVERSE EVENT REPORTING)
ALL ITEMS MUST BE COMPLETED**

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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

The CTC AE Version 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"/>	___/___/___
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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"/>	___/___/___
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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"/>	___/___/___
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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"/>	___/___/___

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NOTIFICATION FORM
Grade 4 or 5 Non-AER Reportable Events/Hospitalization

ALL ITEMS MUST BE COMPLETED

Protocol Number: N0626
Patient ID: Patient Initials: L F M
Institution Number:
Institution:

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.
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 1 [] Yes 2 [] No

Table with 4 columns: 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?^1

1. Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure.

Hospitalization: 1 [] Yes 2 [] No

Hospital Admission Date: (mm/dd/yyyy) ___/___/___

Reason(s) for Hospitalization:

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0626

BLOOD PRESSURE LOG

NCCTG Patient ID: _____ Patient Initials: _____

L F M

APPENDIX III

Institution Number: _____

Institution: _____

INSTRUCTIONS TO THE PATIENT:

1. Your blood pressure readings have two numbers. The first number is the pressure in your blood vessels during a heart beat (systolic), and the second number is the pressure in the vessels when the heart rests in between beats (diastolic). These numbers are usually written with a slash in between them (for example, normal blood pressure is 120/80).
2. Record the date, then record your blood pressure at least weekly:
 - blood pressure to be obtained after you have rested at least 30 minutes, either by a health care professional (e.g. physician, physician assistant, nurse, etc), at a senior center, pharmacy or at home.
3. If you take your blood pressure more often than once weekly, please record the numbers and date under "Other readings."
4. If your systolic pressure is greater than 140 (but less than or equal to 150) or your diastolic blood pressure is greater than 90 (but less than or equal to 100) twice in a row measured at least one hour apart, please contact your doctor's office at _____ for instructions. Any time your systolic pressure is greater than 150 or your diastolic blood pressure is greater than 100, please contact your study doctor's office immediately for instructions.
5. Please bring this form to every clinic visit or appointment.

Date of Blood Pressure (mm/dd/yyyy)	Blood Pressure Systolic / Diastolic	Other readings (include date)
_ _ / _ _ / _ _ _ _	_ _ _ / _ _ _	
_ _ / _ _ / _ _ _ _	_ _ _ / _ _ _	
_ _ / _ _ / _ _ _ _	_ _ _ / _ _ _	
_ _ / _ _ / _ _ _ _	_ _ _ / _ _ _	
_ _ / _ _ / _ _ _ _	_ _ _ / _ _ _	

Patient's Signature: _____ Date: _____

Physician's Office will complete this section:

Date of this clinic visit: _____

Physician/Nurse/Data Manager's Signature _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol # N0626

Patient ID # _____ Initials: _____

Local ID # _____ Institution L F M

PATIENT PILL DIARY
APPENDIX IV

Today's date _____

Patient's Name _____ Patient's Study ID _____
(Initials acceptable)

INSTRUCTIONS TO THE PATIENT:

1. Complete one form for each month.
2. You will take 2 pills two times a day (4 pills total each day). You may take the pill(s) one hour before or 2 hours after eating, as you prefer.
3. Record the date, the number of pills you took, and when you took them.
4. If you have any comments or notice any side effects, please record them in the Comments column.

Date	Day	# pills and when taken		Comments	Date	Day	# pills and when taken		Comments
		AM	PM				AM	PM	
	1					12			
	2					13			
	3					14			
	4					15			
	5					16			
	6					17			
	7					18			
	8					19			
	9					20			
	10					21			
	11								

Patient's Signature: _____

Date: _____



PREGNANCY MONITORING FORM

Local Drug Safety:	page 1 of 2
Local case ID:	Date received by Bayer: <input style="width: 150px;" type="text"/>
Global case ID:	

Part A

Drug exposure	via mother <input type="checkbox"/> (fill in 'Patient identification' for the mother) via father <input type="checkbox"/> (fill in 'Patient identification' for the father and 'Maternal identification')
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Patient Identification					
Initials	Date of birth [day/month/year]	Age at onset [years]	Height [cm] <input type="checkbox"/> [in] <input type="checkbox"/>	Weight* [kg] <input type="checkbox"/> [lb] <input type="checkbox"/>	Ethnic origin Asian <input type="checkbox"/> Black <input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Other <input type="checkbox"/>

If parent participates in a clinical study:

Study number	Centre number	Patient number	Random number
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Maternal Identification					
Initials	Date of birth [day/month/year]	Age at onset [years]	Height [cm] <input type="checkbox"/> [in] <input type="checkbox"/>	Weight* [kg] <input type="checkbox"/> [lb] <input type="checkbox"/>	Ethnic origin Asian <input type="checkbox"/> Black <input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Other <input type="checkbox"/>

Further Details of Pregnancy			
Date of last menstrual period [day/month/year]	Expected date of delivery [day/month/year]	Exposure to Bayer drug prior to onset of pregnancy Yes <input type="checkbox"/> No <input type="checkbox"/> (specify duration of pregnancy at onset of drug therapy) <input style="width: 50px;" type="text"/>	Gravida Para

Description of Drug Treatment							
Trade / Generic Name (INN)	Formulation	Total daily dose	Dose regimen	Route of application	Lot number (biologicals)	Date from-to or duration	Indication for use

Report Source			
Name		Specialist	
Address		Clinic	
Country		Phone/Fax/E-Mail	
Physician <input type="checkbox"/>	Pharmacist <input type="checkbox"/>	Other health professional <input type="checkbox"/>	specify: <input style="width: 50px;" type="text"/>
Lawyer <input type="checkbox"/>	Consumer <input type="checkbox"/>	Other non-health professional <input type="checkbox"/>	specify: <input style="width: 50px;" type="text"/>

