

## FORMS PACKET

N0321: Phase I/II Study of PS-341 in Combination with Paclitaxel, Carboplatin, and Concurrent Thoracic Radiation Therapy for Non-small Cell Lung Cancer (NSCLC)

- Contents:
- ✓ Eligibility checklist (10/9/09)
  - \* Forms completion instructions (9/10/04)
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  - Grade 4 or 5 non-AER reportable events/hospitalization form (6/1/06)

✓ designates revised/new forms

\* Forms completion instructions are available on the NCCTG web site under “Generic Instructions for Forms Completion (MS Word).”

NORTH CENTRAL CANCER TREATMENT GROUP  
Eligibility Checklist

08/28/2009  
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N0321: **Phase I/II Study of PS-341 in Combination with Paclitaxel, Carboplatin, and Concurrent Thoracic Radiation Therapy for Non-small Cell Lung Cancer (NSCLC)**

***Phase I component only: Prior to discussing protocol entry with the patient, call the Registration Office (507/284-4130) to ensure that a place on the protocol is open to the patient. If an opening is available, a slot may be reserved for no longer than 5 working days.***

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 Registration) \_\_\_\_\_

NCCTG member (participant sponsor) \_\_\_\_\_

NCCTG treating location (chemo) \_\_\_\_\_  
(RT) \_\_\_\_\_

NCCTG treating physician (chemo) \_\_\_\_\_  
(RT) \_\_\_\_\_

Institution patient number (local subject number) \_\_\_\_\_

IRB approval date (chemo) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_ IRB approval date (RT) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

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

NCCTG Eligibility Checklist N0321

08/28/2009

Patient study ID number (provided at time of Registration) \_\_\_\_\_

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**Eligibility Check** - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

**Required Characteristics:**

- \_\_\_\_ \_\_\_\_ ≥18 years of age. Age = \_\_\_\_\_.
- \_\_\_\_ \_\_\_\_ Histologic or cytologic confirmation of non-small cell lung carcinoma.
- \_\_\_\_ \_\_\_\_ Non-metastatic NSCLC requiring definitive radiation therapy.
- \_\_\_\_ \_\_\_\_ ECOG performance score (PS) 0 or 1. PS = \_\_\_\_\_.
- \_\_\_\_ \_\_\_\_ Life expectancy ≥12 weeks.
- \_\_\_\_ \_\_\_\_ Weight loss <10% in past 3 months.
- \_\_\_\_ \_\_\_\_ Forced expiratory volume in 1 second (FEV1) ≥1 L or ≥35% of predicted.
- \_\_\_\_ \_\_\_\_ Locally advanced NSCLC stages IIIA/IIIB not considered resectable. Patients with stage IV disease are not eligible.
- \_\_\_\_ \_\_\_\_ The following laboratory values obtained ≤21 days prior to registration. Earliest laboratory test date \_\_\_\_-\_\_\_\_-\_\_\_\_; latest laboratory test date \_\_\_\_-\_\_\_\_-\_\_\_\_. NOTE: These dates pertain to the following labs only.
  - \_\_\_\_ \_\_\_\_ • ANC ≥1500/mL. ANC = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • PLT ≥100,000/mL. PLT = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • Total bilirubin ≤1.5 x UNL or direct bilirubin ≤1.5 x UNL.
    - \_\_\_\_ \_\_\_\_ **Which was done?**
    - \_\_\_\_ \_\_\_\_ Both Total and Direct bilirubin → Complete both total and direct bilirubin values below.
    - \_\_\_\_ \_\_\_\_ Total bilirubin → Total bilirubin = \_\_\_\_\_; UNL = \_\_\_\_\_.
    - \_\_\_\_ \_\_\_\_ Direct bilirubin → Direct bilirubin = \_\_\_\_\_; UNL = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • AST ≤3 x UNL. AST = \_\_\_\_\_; UNL = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • Creatinine ≤1.5 x UNL. Creatinine = \_\_\_\_\_; UNL = \_\_\_\_\_.
- \_\_\_\_ \_\_\_\_ **Is this patient a woman of childbearing potential?** (This question may be answered yes or no.)
- \_\_\_\_ \_\_\_\_ Yes → Complete; Negative serum pregnancy test ... question
- \_\_\_\_ \_\_\_\_ No → Skip; Negative serum pregnancy test ... question
- \_\_\_\_ \_\_\_\_ Negative serum pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Negative serum pregnancy test date \_\_\_\_-\_\_\_\_-\_\_\_\_.

**All responses in above section must be “Yes.”**

**Contraindications:**

- \_\_\_\_ \_\_\_\_ Any of the following:
  - Pregnant women
  - Nursing women
  - Men or women of childbearing potential or their sexual partners who are unwilling to employ adequate contraception (condoms, diaphragm, birth control pills, injections, intrauterine device [IUD], or abstinence, etc.) as this regimen may be harmful to a developing fetus or nursing child

*NOTE: This study involves an investigational agent whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown.*
- \_\_\_\_ \_\_\_\_ Any of the following prior therapies:
  - Prior radiation therapy to the chest
  - Prior systemic chemotherapy for NSCLC (phase II portion)
- \_\_\_\_ \_\_\_\_ New York Heart Association classification III or IV (see Appendix II).
- \_\_\_\_ \_\_\_\_ Any other severe underlying diseases which are, in the judgment of the investigator, inappropriate for entry into this study.
- \_\_\_\_ \_\_\_\_ Uncontrolled infection.
- \_\_\_\_ \_\_\_\_ Major surgery or unhealed wound ≤2 weeks prior to registration.
- \_\_\_\_ \_\_\_\_ Major surgery date \_\_\_\_-\_\_\_\_-\_\_\_\_ vs. not applicable \_\_\_\_.

Patient study ID number (provided at time of Registration) \_\_\_\_\_

Eligibility Check – (Contraindications continued)

Yes No

- \_\_\_\_ \_\_\_\_ Prior history of malignancy ≤5 years, except for adequately treated basal cell or squamous cell skin cancer, adequately treated noninvasive carcinomas (carcinoma in situ), or localized prostate cancer.
- \_\_\_\_ \_\_\_\_ Peripheral neuropathy ≥grade 2.

**All responses in above section must be “No.”**

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

- \_\_\_\_ \_\_\_\_ Consent form signed and dated. Date of consent \_\_\_\_-\_\_\_\_-\_\_\_\_.
- Is this an USA institution?** (This question may be answered yes or no.)
- \_\_\_\_ Yes → Complete authorization question below.
- \_\_\_\_ No → Check “not applicable (**Non-USA institution only**)” and go to next question.
- \_\_\_\_ \_\_\_\_ Authorization for use and disclosure of protected health information signed and dated.
- \_\_\_\_ \_\_\_\_ Date of authorization \_\_\_\_-\_\_\_\_-\_\_\_\_ vs. not applicable (**Non-U.S.A. institution only**) \_\_\_\_.
- \_\_\_\_ \_\_\_\_ Treatment on this protocol must commence at the accruing membership under the supervision of a NCCTG member physician.
- \_\_\_\_ \_\_\_\_ Treatment cannot begin prior to registration and must begin ≤21 days after registration.
- \_\_\_\_ \_\_\_\_ Treatment start date \_\_\_\_-\_\_\_\_-\_\_\_\_.
- \_\_\_\_ \_\_\_\_ Pretreatment tests/procedures must be completed ≤21 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 measurement ≤30 days prior to registration (see Section 4.0). A CT chest to include the liver and adrenals are required for baseline evaluation, 4 wks following RT, 3 months following RT, and every 3 months after that for a maximum of 2 years during the observation phase.
- \_\_\_\_ \_\_\_\_ Tumor measurement date \_\_\_\_-\_\_\_\_-\_\_\_\_.
- \_\_\_\_ \_\_\_\_ All required baseline symptoms must be documented and graded.
- \_\_\_\_ \_\_\_\_ A radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.

**All responses in above section must be “Yes.”**

- \_\_\_\_ \_\_\_\_ Registration Office will register patients separately to the optional translational research component of this study (see Section 14.0).
- Patient has given permission to give their tissue sample for research testing.
- \_\_\_\_ \_\_\_\_ At the time of registration, the following will also be recorded:
- \_\_\_\_ \_\_\_\_ Patient has given permission to store sample(s) for future research of cancer.
- \_\_\_\_ \_\_\_\_ Patient has given permission to store sample(s) for future research to learn, prevent, or treat other health problems.
- \_\_\_\_ \_\_\_\_ Patient has given NCCTG permission to give their sample(s) to outside researchers.

**Responses in above section may be “Yes” or “No.”**

NCCTG Eligibility Checklist N0321

08/28/2009  
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Patient study ID number (provided at time of Registration) \_\_\_\_\_

Grouping Factor

Component

- \_\_\_ Phase I patients not receiving MTD
- \_\_\_ Phase I patients receiving MTD + Phase II patients

Descriptive Factors

Pretreatment supraclavicular involvement

- \_\_\_ Yes
- \_\_\_ No

Maximum pre-treatment tumor size (cm)

- \_\_\_ <3
- \_\_\_ 3-6
- \_\_\_ >6

Weight loss in past 3 months

- \_\_\_ <5%
- \_\_\_ 5 - <10%

Diabetes

- \_\_\_ No
- \_\_\_ Type I
- \_\_\_ Type II

Dose Level (to be assigned by Registration Office)

- \_\_\_ -1      \_\_\_ 3
- \_\_\_ 0        \_\_\_ 4
- \_\_\_ 1        \_\_\_ 5
- \_\_\_ 2        \_\_\_ 6

Assigned Treatment

\_\_\_ A) PS-341\* + TAXOL\*\* + CBDCA\*\*\* + RT

- \*PS-341: Dose = \_\_\_\_\_ (mg/m<sup>2</sup>); Level = \_\_\_\_\_
- \*\*TAXOL: Dose = \_\_\_\_\_ (mg/ m<sup>2</sup>); Level = \_\_\_\_\_
- \*\*\*CBDCA: Dose = \_\_\_\_\_ (AUC); Level = \_\_\_\_\_

Person registering Signature \_\_\_\_\_ Registration Office specialist initials \_\_\_\_\_

Physician Signature \_\_\_\_\_ Date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_

## **Specific Forms Completion Instructions for N0321**

### **General Notes**

- A **cycle** is defined as the time treatment starts until the patient receives another round of treatment. A cycle for this protocol is defined as 21 days with PS-341 treatment administered IV on days 1, 4, 8, 11; Taxol/CBDCA treatment administered IV on day 2; RT daily, beginning on day 1 cycle 1.

### **Dose-Limiting Toxicity Reporting Form**

- This form should be submitted if any of the following are recorded on the Nadir/Adverse Event Log:
  - Hematologic, grade  $\geq 4$
  - Esophagitis, grade  $\geq 3$
  - Other nonhematologic, grade  $\geq 4$  other than radiation dermatitis, esophagitis, pneumonitis, or dyspnea
- This form will provide additional data to the operations office and will help to determine if an event should be considered a DLT.

PLACE LABEL HERE

NCCTG  
ON-STUDY FORM

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**DESCRIPTION OF PRIMARY DISEASE**

- Primary Tumor Site: (check one)
- 1  Right upper lobe
  - 2  Left upper lobe
  - 3  Right mid lobe
  - 4  Left mid lobe
  - 5  Right lower lobe
  - 6  Left lower lobe
- Histology: (check one)
- 1  Adenocarcinoma
  - 2  Squamous cell carcinoma
  - 3  Non-small cell, unspecified
  - 4  Other, specify \_\_\_\_\_
- Stage: 5  IIIA      T stage =       N stage =       M stage =
- 6  IIIB
- 9  IIIB with pleural effusion

- Status of Primary Tumor
- 1 - Resected with no residual
  - 2 - Resected with known residual
  - 3 - Unresected
  - 4 - Recurrent

**CHRONOLOGY OF DIAGNOSES**

DATES      METHOD OF DX†  
    Primary

† (2 - biopsy, 3 - cytology)

**PREVIOUS SURGERY RELATED TO THIS TUMOR**

PROCEDURE	RESULTS			DATE (mm/dd/yyyy)
Mediastinoscopy	1 <input type="checkbox"/> Pos	2 <input type="checkbox"/> Neg	3 <input type="checkbox"/> ND	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Bronchoscopy	1 <input type="checkbox"/> Pos	2 <input type="checkbox"/> Neg	3 <input type="checkbox"/> ND	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Supraclavicular biopsy	1 <input type="checkbox"/> Pos	2 <input type="checkbox"/> Neg	3 <input type="checkbox"/> ND	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Thoracoscopy	1 <input type="checkbox"/> Pos	2 <input type="checkbox"/> Neg	3 <input type="checkbox"/> ND	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Fine Needle Aspirate	1 <input type="checkbox"/> Pos	2 <input type="checkbox"/> Neg	3 <input type="checkbox"/> ND	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other _____ (specify)	1 <input type="checkbox"/> Pos	2 <input type="checkbox"/> Neg	3 <input type="checkbox"/> ND	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

**PREVIOUS RADIOTHERAPY**  (2-No, 1-Yes, describe below)

Site	From	Date (mm/dd/yyyy)	To
	<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"/> <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"/>
	<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"/> <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"/>
	<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"/> <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"/>

Other Cardiac Diseases \_\_\_\_\_

Cardiac Medications \_\_\_\_\_

Height (cm):  .

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

BASELINE

ADVERSE EVENTS/SYMPTOMS FORM

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**BASELINE ADVERSE EVENTS/SYMPTOMS**

Baseline # of Stools Per Day:

Required Baseline Adverse Events from Section 10.0 of Protocol		
Adverse Event/Symptom	MedDRA Code v. 6.0	Grade (CTCAE v. 3.0)
<b>Fatigue (lethargy, malaise, asthenia)</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 6 <input type="text"/> 2 <input type="text"/> 5 <input type="text"/> 6	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Dysphagia (difficulty swallowing)</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 3 <input type="text"/> 9 <input type="text"/> 5 <input type="text"/> 0	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Nausea</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 2 <input type="text"/> 8 <input type="text"/> 8 <input type="text"/> 1 <input type="text"/> 3	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Vomiting</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 4 <input type="text"/> 7 <input type="text"/> 7 <input type="text"/> 0 <input type="text"/> 6	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Neuropathy: motor</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 <input type="text"/> 8 <input type="text"/> 0	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Neuropathy: sensory</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 6 <input type="text"/> 2 <input type="text"/> 0	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Somnolence/depressed level of consciousness</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 7 <input type="text"/> 3	<input type="text"/> 0 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Musculoskeletal - Muscle</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 2 <input type="text"/> 8 <input type="text"/> 4 <input type="text"/> 1 <input type="text"/> 1	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Dyspnea (shortness of breath)</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 3 <input type="text"/> 9 <input type="text"/> 6 <input type="text"/> 8	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4
<b>Pneumonitis/ pulmonary infiltrates</b>	<input type="text"/> 1 <input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 3 <input type="text"/> 5 <input type="text"/> 7 <input type="text"/> 5 <input type="text"/> 5	<input type="text"/> 0 <input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_ L F M

**SPECIMEN SUBMISSION FORM**

**INSTRUCTIONS**

Complete this form for all patients who have given consent to provide specimen/s for research and submit to the Operations Office. See Section 14 of the protocol for specimen requirements and shipment.

1. Was a tumor tissue block/slide obtained?

1  Yes Date of biopsy:  /  /   
m m d d y y y y

2  No Reason: \_\_\_\_\_

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**Please indicate all prior cancer treatment the patient has received. More than one therapy may be included. Multi-modality treatment should be listed separately (e.g. mastectomy followed by tamoxifen-code as surgery and hormonal therapy).**

Check all that apply.

- No prior therapy [10052052]
- Chemotherapy single agent systemic [10008456]
- Chemotherapy multi-agent systemic [10008452]
- Chemotherapy Not Otherwise Specified (NOS) [10050693]
- Chemotherapy non-cytotoxic [90003014]
- Immunotherapy (e.g. interleukin-2, interferon) [90003006]
- Hormonal Therapy (e.g. tamoxifen, androgen deprivation) [10042027]
- Surgery [10030858]
- Radiotherapy (NOS) [10037794]
- Bone Marrow Transplant [10005990]
- Prior therapy (NOS) [90003010]
- Gene transfer [90003004]
- Anti-retroviral Therapy [90003000]
- Antisense [90003002]
- Oncolytic Virotherapy [90003008]
- Vaccine [10036903]
- Therapy NOS [90003012]

# of prior chemotherapy regimens

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**PATHOLOGY SUBMISSION FORM**

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

Protocol Number: N0321

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**\*\* 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) \_\_\_/\_\_\_/\_\_\_\_

Reviewer: Dr. Marie-Christine Aubry, Mayo Clinic Rochester - Rochester, MN

Number of slides sent: \_\_\_

Accession numbers on the slides sent:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Number of blocks sent: \_\_\_

Accession numbers on the blocks sent:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Comments:

<b>Institution Contact Information: (Please Print)</b>
CRA/Nurse Contact: _____
Institution Name: _____
Street Address: _____
City: _____
State: _____ Zip: _____
Phone Number: _____
Fax Number: _____
E-mail Address: _____

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP  
PATHOLOGY REPORTING FORM  
LUNG CARCINOMA**

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_  
L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Primary Pathologist: \_\_\_\_\_ No. of slides sent: \_\_\_\_\_

Clinic/Hospital: \_\_\_\_\_ Date sent: \_\_\_\_\_

Reviewer: \_\_\_\_\_ Slide No. \_\_\_\_\_ Sequence No. \_\_\_\_\_

I. CRA/RN

1. DATE OF OPERATIVE PROCEDURE (MO-DAY-YEAR)

/

\_\_\_\_\_ to \_\_\_\_\_  
\_\_\_\_\_ to \_\_\_\_\_

2. OPERATIVE PROCEDURE

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

II. Completed by central 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
  - 3. Metastatic tumor with clinical evidence of primary tumor in lung
- Specify metastatic site(s): \_\_\_\_\_

COMMENTS: \_\_\_\_\_

III. Signatures

\_\_\_\_\_  
Reviewer  
  /   /      
Date

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

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Research Base Advisor  
  /   /      
Date

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

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Committee Chairman  
  /   /      
Date

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

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N0321

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

Did patient have measurable disease per Section 11.0 of the protocol?   
 1  Yes. If Yes, complete Target and Non-Target Lesions  
 2  No. If No, go to Non-Target Lesions

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

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

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N0321

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) \_\_\_/\_\_\_/\_\_\_

(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><b>Overall Response Status</b> (check one)</p> <p><b>Note: If PD is selected for objective status, and Yes is selected for "Was the appearance of any new lesions documented," go to Non-Target Lesions.</b></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>
<p>Did patient have measurable disease at study entry?</p>	<p>1 <input type="checkbox"/> Yes → Complete Target and Non-Target Lesions</p> <p>2 <input type="checkbox"/> No → Go to Non-Target Lesions</p>

Target Lesion Site(s) Measurement (cm)	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
<b>Sum of all Lesions:</b>	

<b>Non-Target Lesions</b>	<p><b>Change: (check one)</b></p> <p>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</p>
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\*Submit documentation to verify CR,PR, PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP  
RADIATION THERAPY REPORTING FORM

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Treating Institution: \_\_\_\_\_

Local ID # \_\_\_\_\_ Member \_\_\_\_\_ L F M

Radiation Oncologist: \_\_\_\_\_

LUNG

Lung

RT Start Date          
m m d d y y y y

RT End Date          
m m d d y y y y

**TECHNIQUE**

Definition of prescription point (check one):

1  Isocenter    2  Isodose line, specify \_\_\_\_\_    3  Volume, specify \_\_\_\_\_

Inhomogeneity corrections?    1  Yes    2  No

	Total Dose to Prescription Point	Energy (Photon)	Number of Treatment Fields	Gantry Angle 0° - 360°
Lung fields:				
Initial	_____	_____ MV	<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"/> <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"/> , <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> , <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Boost #1	_____	_____ MV	<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"/> <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"/> , <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> , <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Boost #2 (if applicable)	_____	_____ MV	<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"/> <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"/> , <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> , <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

**TREATMENT AREAS, DOSE, and TIME**

	Daily Dose (Gy)	Total Tumor Dose (Gy)	Daily #FX	Total # Fractions	Elapsed Days
Lung (isocenter)					
Volume	_____	_____	_____	_____	_____

Lung: V<sub>20</sub>: \_\_\_\_\_ %    V<sub>13</sub>: \_\_\_\_\_ %    Mean lung dose: \_\_\_\_\_  
Heart: V<sub>60</sub>: \_\_\_\_\_ %    V<sub>50</sub>: \_\_\_\_\_ %    V<sub>40</sub>: \_\_\_\_\_ %  
Esophagus: V<sub>55</sub>: \_\_\_\_\_ %    Mean esophagus dose: \_\_\_\_\_    Max esophagus dose: \_\_\_\_\_  
Spinal cord: Max spinal cord dose: \_\_\_\_\_



NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM

ALL ITEMS MUST BE COMPLETED

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution     L    F    M    

Amended Data:  if yes, check box and **highlight** amended areas

**Use one form per cycle, one column per agent.**

Cycle:

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)

Check One:  Treatment  Observation → Day 1 of this observation cycle //  
(complete rest of form) ↓  
1  End of observation? (check if yes)  
↓  
Stop here

BSA(m<sup>2</sup>): .  
(used for this cycle)

Was this cycle of treatment held? 1  Yes 2  No

Primary Reason

- 95  ANC
- 87  PLT
- 58  Febrile neutropenia
- 99  Other (not per protocol) \_\_\_\_\_
- 44  Dysphagia
- 38  Other non-hematologic

Agent Start Date day one this cycle (mm/dd/yyyy)	<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"/> <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"/> <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"/> <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"/> <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"/> <input type="checkbox"/>	Was DXM given this cycle? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Agent	PS-341	TAXOL	CBDCA	Was BEN given this cycle? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Dose Level day one this cycle (i.e. mg/m <sup>2</sup> )			AUC _____ . _____	Was RANIT or CIMET given this cycle? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Total Dose (mg) this cycle				Was FAMOT given this cycle? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
Was DOSE LEVEL adjusted from day 1 of the previous cycle (i.e. mg/m <sup>2</sup> )	1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no ↓	1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no ↓	1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no ↓	Was Bactrim given this cycle? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes.  (Check one)	95 <input type="checkbox"/> ANC 87 <input type="checkbox"/> PLT 58 <input type="checkbox"/> Febrile neutropenia 44 <input type="checkbox"/> Dysphagia 38 <input type="checkbox"/> Other non-hematologic 120 <input type="checkbox"/> Neuropathy: motor 99 <input type="checkbox"/> Other (not per protocol) _____	95 <input type="checkbox"/> ANC 87 <input type="checkbox"/> PLT 58 <input type="checkbox"/> Febrile neutropenia 44 <input type="checkbox"/> Dysphagia 38 <input type="checkbox"/> Other non-hematologic 120 <input type="checkbox"/> Neuropathy: motor 99 <input type="checkbox"/> Other (not per protocol) _____	95 <input type="checkbox"/> ANC 87 <input type="checkbox"/> PLT 58 <input type="checkbox"/> Febrile neutropenia 44 <input type="checkbox"/> Dysphagia 38 <input type="checkbox"/> Other non-hematologic 120 <input type="checkbox"/> Neuropathy: motor 99 <input type="checkbox"/> Other (not per protocol) _____	

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT LOG

ALL ITEMS MUST BE COMPLETED

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Amended Data:  if yes, check box and **highlight** amended areas

Complete a Dose-Limiting Toxicity Reporting Form if there was one of the following adverse events:

- Hematologic, grade  $\geq 4$
- Esophagitis, grade  $\geq 3$
- Pneumonitis, grade  $\geq 3$
- Other nonhematologic, grade  $\geq 4$  other than radiation dermatitis, esophagitis, pneumonitis, or dyspnea

Nadirs/Adverse Events associated with treatment cycle :

Evaluation Date :  /  /   
m m d d y y y y

Test	Date of Nadir	Nadir Value <sup>1</sup>	Is this nadir below the LLN? Check if Yes	Relationship to Study Medication 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if submitted
PLT K/uL or $10^9/L$	<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"/> <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"/> <input type="checkbox"/>	1 <input type="checkbox"/>
WBC K/uL or $10^9/L$	<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"/> <input type="checkbox"/> . <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>
Hgb g/dL	<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"/> <input type="checkbox"/> . <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>
ANC K/uL or $10^9/L$	<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"/> <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"/>	1 <input type="checkbox"/>

1. Note: 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.

Adverse Event CTCAE v. 3.0 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No Adverse Events (stop here) GRADE ALL ADVERSE EVENTS BELOW	MedDRA Code v. 6.0 (must be completed)	Grade (highest grade this cycle) INCLUDE GRADE 0's	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if submitted
---	--	---	---	----------------------------

Required Adverse Events from Section 10.0 of Protocol

Allergic reaction/hypersensitivity (including drug fever)	<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"/> <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"/> <input type="checkbox"/> (death)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>
Fatigue (lethargy, malaise, asthenia)	<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"/>	<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"/> <input type="checkbox"/>	1 <input type="checkbox"/>

\* See Section 10.0 of the protocol.  
 CONTINUED ON PAGE 2

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT LOG (continuation)

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

ALL ITEMS MUST BE COMPLETED

page 2 of 3

Amended Data:  if yes, check box and **highlight** amended areas

Nadirs/Adverse Events associated with treatment cycle :

Adverse Event CTCAE v. 3.0	MedDRA Code v. 6.0 (must be completed)	Grade (highest grade this cycle)  INCLUDE GRADE 0's	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if sub- mitted
Fever (in the absence of neutropenia, where neutropenia is defined as AGC <1.0 x 10 <sup>9</sup> /L)	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 6 <input type="checkbox"/> 6 <input type="checkbox"/> 0	<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	1 <input type="checkbox"/>
Rash: dermatitis associated with radiation - Chemoradiation	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 7 <input type="checkbox"/> 6 <input type="checkbox"/> 8	<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	1 <input type="checkbox"/>
Diarrhea	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 7 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<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	1 <input type="checkbox"/>
Dysphagia (difficulty swallowing)	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 3 <input type="checkbox"/> 9 <input type="checkbox"/> 5 <input type="checkbox"/> 0	<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	1 <input type="checkbox"/>
Mucositis/stomatitis (clinical exam) - Oral cavity	<input type="checkbox"/> 9 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<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	1 <input type="checkbox"/>
Mucositis/stomatitis (clinical exam) - Pharynx	<input type="checkbox"/> 9 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 4 <input type="checkbox"/> 6	<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	1 <input type="checkbox"/>
Mucositis/stomatitis (functional/ symptomatic) - Esophagus	<input type="checkbox"/> 9 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 5 <input type="checkbox"/> 8	<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	1 <input type="checkbox"/>
Mucositis/stomatitis (functional/ symptomatic) - Oral cavity	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 4 <input type="checkbox"/> 2 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 8	<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	1 <input type="checkbox"/>
Nausea	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 8 <input type="checkbox"/> 8 <input type="checkbox"/> 1 <input type="checkbox"/> 3	<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	1 <input type="checkbox"/>
Vomiting	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 4 <input type="checkbox"/> 7 <input type="checkbox"/> 7 <input type="checkbox"/> 0 <input type="checkbox"/> 6	<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	1 <input type="checkbox"/>
Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC <1.0 x 10 <sup>9</sup> /L, fever ≥38.5°C)	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 6 <input type="checkbox"/> 2 <input type="checkbox"/> 8 <input type="checkbox"/> 8	<input type="checkbox"/> 0 <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	1 <input type="checkbox"/>

\* See Section 10.0 of the protocol.

**NORTH CENTRAL CANCER TREATMENT GROUP**

**NADIR/ADVERSE EVENT LOG (continuation)**

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**ALL ITEMS MUST BE COMPLETED**

page 3 of 3

Amended Data:  if yes, check box and **highlight** amended areas

Nadirs/Adverse Events associated with treatment cycle :

Adverse Event CTCAE v. 3.0	MedDRA Code v. 6.0 (must be completed)	Grade (highest grade this cycle)  INCLUDE GRADE 0's	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER*  Check if sub- mitted
Neuropathy: motor	1 0 0 3 4 5 8 0	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Neuropathy: sensory	1 0 0 3 4 6 2 0	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Somnolence/depressed level of consciousness	1 0 0 1 2 3 7 3	0 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Musculoskeletal - Muscle	1 0 0 2 8 4 1 1	0 1 2 3 4	1 2 3 4 5	1 <input type="checkbox"/>
Dyspnea (shortness of breath)	1 0 0 1 3 9 6 8	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Pneumonitis/pulmonary infiltrates	1 0 0 3 5 7 5 5	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>

**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:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	<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 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>

\* See Section 10.0 of the protocol.

Place Label Here

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol # N0321

DOSE-LIMITING TOXICITY REPORTING FORM

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Treatment cycle:

Toxicity  
(check all that apply)

Date of Onset  
(mm/dd/yyyy)

Date Resolved to < Grade 4  
(mm/dd/yyyy)

Hematologic (ANC, Platelets), Grade ≥4 →

Date of Onset  
(mm/dd/yyyy)

Date Resolved to < Grade 3  
(mm/dd/yyyy)

Esophagitis, Grade ≥3 →

Was hospitalization required?

1  Yes 2  No

Other nonhematologic, Grade ≥4 →  
other than radiation dermatitis,  
esophagitis, pneumonitis, or dyspnea.

Was this event manageable with interventions (IV,  
narcotic)?

1  Yes 2  No

Specify: \_\_\_\_\_

Date of Onset  
(mm/dd/yyyy)

Date Resolved to < Grade 3  
(mm/dd/yyyy)

Pneumonitis, Grade ≥3 →

Was oxygen required?

1  Yes 2  No





**NORTH CENTRAL CANCER TREATMENT GROUP**

**EVENT MONITORING CONTINUATION FORM**

**(LATE ADVERSE EVENT REPORTING)**

**ALL ITEMS MUST BE COMPLETED**

**Amended Data:  if yes, check box and highlight amended areas**

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**LATE ADVERSE EVENTS**

The CTCAE Version 3.0 will be used to evaluate the following signs/symptoms:

Adverse Event CTCAE v. 3.0	MedDRA Code v. 6.0 (must be completed)	Highest Grade	Relationship to Study Medication 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Late Adverse Event Start Date (mm/dd/yyyy)
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>
<b>Other:</b>	<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"/>

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP  
NOTIFICATION FORM

Protocol # N0321

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_  
L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Grade 4 or 5 Non-AER Reportable Events/Hospitalization

**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 Number (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

Cycle Number: \_\_\_\_\_ Assigned Treatment Arm: \_\_\_\_\_

Event ≥ Grade 4    1  Yes    2  No



Date of First Occurrence of Adverse Event (mm/dd/yyyy)	Common Toxicity Criteria Adverse Event Term Type (only one event per line)	CTC Adverse Event Grade	Relationship to study medication. In your opinion, is this related to the study medication? <sup>1</sup>
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown

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 \_\_\_\_\_