



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: October 8, 2010

To: Primary Clinical Research Associates

From: Linda S. Long
Research Protocol Specialist III

Re: N064A, Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation in Patients with Locally Advanced Pancreatic Cancer

Attached are updated form(s) for this protocol. Edits are as follows:

CRF Title	Brief Description of Edit
Nadir/Adverse Event Form	<ul style="list-style-type: none">Added "CTCAE v3.0" to CTC Adverse Events Term on all 4 pages.
Baseline Adverse Events Form	<ul style="list-style-type: none">Added "CTCAE v3.0" to CTC Adverse Events Term

If you have any questions, please feel free to contact me at long.linda@mayo.edu or by phone at (507) 266-3853.

Enclosure

North Central Cancer Treatment Group

N064A, Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation in Patients with
Locally Advanced Pancreatic Cancer

Addendum 5 – October 8, 2010

Summary

- In compliance with the NCI/CTEP mandate (dated May 28, 2010), expedited adverse event reporting requirements were converted from CTCAE v3.0 to CTCAE v4.0 (affected sections 10.1 and 10.11) while routine data collection via Case Report Forms (which includes the Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form) will remain using CTCAE v3.0 (clarifications added to sections 10.21, 10.22, 10.3, 10.31, and 16.352). Effective January 1, 2011, expedited reporting via AdEERS must use CTCAE v4.0 while the remainder of the data collection for legacy trials will continue to use CTCAE v3.0.
- Per NCI, the Secondary AML/MDS Report Form will no longer be used. Therefore, Sections 10 and 18 have been revised accordingly

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

Title Page The Addendum 5 has been added and the NCI version date has been updated.

Section 10.0 Adverse Event (AE) Reporting and Monitoring

Page 42: Section 10.1 and Section 10.11 have been revised as follows to update the required AE reporting from CTCAE v3.0 to CTCAE v4.0.

- 10.1 ~~This study will utilize the Common Terminology Criteria for Adverse Events (CTCAE) v3.0 for adverse event monitoring and reporting. The CTCAE v3.0 can be accessed from the CTEP home page <http://ctep.cancer.gov>.~~ **CTCAE term (AE description) and grade: The descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 will be utilized until December 31, 2010 for AE reporting. CTCAE v4.0 will be utilized for expedited adverse event reporting only, beginning January 1, 2011. All appropriate treatment areas should have access to a copy of the CTCAE v3.0. A copy of the CTCAE version 4.0 can be downloaded from the CTEP web site (<http://ctep.cancer.gov>).**

10.11 Adverse event monitoring and reporting is a routine part of every ...

Expedited adverse event reporting requires submission of an electronic Adverse Event Expedited Reporting System (AdEERS)...

Effective with Addendum 5, and beginning January 1, 2011, expedited AdEERS reporting for this protocol has been updated by the NCI/CTEP to use CTCAE v4.0. Therefore;

- 1) Events requiring expedited reporting through AdEERS must be reported through the AdEERS system in CTCAE v4.0.**
- 2) The events reported via AdEERS must ALSO be reported through routine reporting (i.e., Case Report Forms) using CTCAE v3.0.**
- 3) Routine data collection via Case Report Forms, including the "Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form", will remain using CTCAE v3.0 for this study.**

Pages 43: The second bullet under Section 10.21 table has been revised for clarification as follows:
Any medical event equivalent to CTCAE v4.0 grade 3, 4, or 5...

Pages 43-44: A new fourth bullet has been added under Section 10.21 due to the removal of the Secondary AML/MDS Report form. The following text has been added:

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

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

Page 45: Text has been revised in the second column of the “Secondary AML/MDS” row of Section 10.22 due to the removal of the Secondary AML/MDS Report Form. Changes are as follows:
Reporting for this event required during and after completion of study treatment, via AdEERS.

Through December 31, 2010, continue using CTCAE v3.0: Report Myelodysplasia as “Blood/Bone Marrow - Myelodysplasia” and Leukemias as “Blood/Bone Marrow - Other (Specify, ___)”.

Beginning January 1, 2011, AdEERS will only accept CTCAE v4.0 for this study: Report these events using “Neoplasms benign, malignant and unspecified (including cysts and polyps) - Other, specify”..

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

~~Office will submit to NCI.~~

Page 45: Text has been added to the “Other Grade 4 or 5 Events...” in the first paragraph of the right hand column in Section 10.22 for clarification as follows:

Complete a Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form within 5 working days of the date the clinical research associate (CRA) is aware of the event(s) necessitating the form, **using CTCAE v3.0.**

Text has been added at the bottom of the table (right hand column) in Section 10.22 for clarification, as follows:

You must use CTCAE v3.0 for data submission with this form. The events reported on this form must also appear on the Case Report Forms (i.e., routine data) for this study.

Pages 46-48: Section 10.3 and Section 10.31 have been revised for clarification. In Section 10.3 the first column headers in the charts have added **v3.0** and Section 10.31 has been revised as follows:

10.31 Submit to the NCCTG Research Base via the Nadir/AE Log the following AEs **using CTCAE v3.0** experienced by a patient and not...

Section 16.0 **Statistical Considerations and Methodology**

Page 78: The last sentence in Section 16.352 has been added for clarification as follows:

CTCAE v3.0 will be used to determine grading for these stopping rules.

Section 18.0 **Records and Data Collection Procedures**

Page 87: With the removal of the Secondary AML/MDS Report Form, the row for the “NCI/CTEP Secondary AML/MDS Report Form” has been deleted. Secondary AML/MDS is now reported through AdeERS, see Section 10.22.

North Central Cancer Treatment Group

**Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation
in Patients with Locally Advanced Pancreatic Cancer**

*For any communications regarding this protocol,
please call the protocol resource person on the following page.*

Study Chairs: George P. Kim, M.D. (Research Base)*
Mayo Clinic
4500 San Pablo Road
Jacksonville, FL 32224
Phone: 507/284-4918 (QAS)
Fax: 507/284-5280

John W. Bollinger, M.D. (Radiation Oncology NCCTG)

Study Co-Chair: Michael G. Haddock, M.D. (Research Base, Radiology)
Thomas C. Smyrk, M.D. (Research Base, Pathology) ✓
Steven P. Olson, M.D. (NCCTG, Pathology) ✓
Robert B. Jenkins, M.D. (Research Base, Laboratory) ✓
Matthew M. Ames, Ph.D. (Research Base, Laboratory) ✓
Stephen N. Thibodeau, Ph.D. (Research Base, Laboratory) ✓
Monica Reinholz, Ph.D. (Research Base, Laboratory) ✓
Bradley J. Erickson, M.D. (Research Base, Radiology) ✓
Donald G. Nordstrom, M.D. (NCCTG, Radiology) ✓

Statistician: Nathan R. Foster, M.S. ✓
507/284-8803

Drug Availability

DCTD Supplied Investigational Agents: None

Commercial Agents: Gemcitabine, 5-fluorouracil, capecitabine

Drug Company Supplied: Panitumumab –IND # 103808

*Investigator having NCI responsibility for this protocol.

✓Study contributor(s) not responsible for patient care.

Document History	(Effective Date)
Activation	June 19, 2009
Update 1	June 19, 2009
Addendum 1	August 28, 2009
Addendum 2	March 19, 2010
Addendum 3	March 19, 2010
Addendum 4	July 9, 2010
Addendum 5	October 8, 2010

<u>Study Participants</u>	<u>Date Activated</u>
Entire NCCTG	June 19, 2009

NCI Version Date: September 30, 2010

10.0 Adverse Event (AE) Reporting and Monitoring

Add 5 10.1 CTCAE term (AE description) and grade: The descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 will be utilized until December 31, 2010 for AE reporting. CTCAE v4.0 will be utilized for expedited adverse event reporting only, beginning January 1, 2011. All appropriate treatment areas should have access to a copy of the CTCAE v4.0. A copy of the CTCAE version 4.0 can be downloaded from the CTEP web site (<http://ctep.cancer.gov>).

10.11 Adverse event monitoring and reporting is a routine part of every clinical trial. First, identify and grade the severity of the event using the CTCAE. Next, determine whether the event is expected or unexpected (see Section 10.12) and if the adverse event is related to the medical treatment or procedure (see Section 10.13). With this information, determine whether the event must be reported as an expedited report (see Section 10.2). Important: All AEs reported via expedited mechanisms must also be reported via the routine data reporting mechanisms defined by the protocol (see Sections 10.3 and 18.0).

Expedited adverse event reporting requires submission of an Adverse Event Expedited Reporting System (AdEERS) report. Other expedited reporting requirements and systems may also apply. Expedited and routine reports are to be completed within the timeframes and via the mechanisms specified in Sections 10.2 and 10.3. All expedited AE reports must also be sent to the local Institutional Review Board (IRB) according to local IRB's policies and procedures.

Add 5 Effective with Addendum 5, and beginning January 1, 2011, expedited AdEERS reporting for this protocol has been updated by the NCI/CTEP to use CTCAE v4.0. Therefore;

- 1) Events requiring expedited reporting through AdEERS must be reported through the AdEERS system in CTCAE v4.0.
- 2) The events reported via AdEERS must ALSO be reported through routine reporting (i.e., Case Report Forms) using CTCAE v3.0.
- 3) Routine data collection via Case Report Forms, including the "Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form", will remain using CTCAE v3.0 for this study.

10.12 Expected vs. Unexpected Events

- The determination of whether an AE is expected is based on the agent-specific information provided in Section 15.0 of this protocol.
- Unexpected AEs are those not listed in the agent-specific information provided in Section 15.0 of this protocol.

10.13 Assessment of Attribution

When assessing whether an adverse event is related to a medical treatment or procedure, the following attribution categories are utilized:

Definite - The adverse event *is clearly related* to the agent(s).

Probable - The adverse event *is likely related* to the agent(s).

Possible - The adverse event *may be related* to the agent(s).

Unlikely - The adverse event *is doubtfully related* to the agent(s).

Unrelated - The adverse event *is clearly NOT related* to the agent(s).

- 10.14 Additional instructions for trials that include both investigational agent(s) (those under an IND) and a commercial agent(s):
- When an investigational agent (an agent under an IND) is used in combination with a commercial agent(s) on the same treatment arm, the combination is considered investigational. Expedited reporting will follow the requirements for investigational agents. However, if the event occurs prior to the participant having received any investigational agent, expedited reporting may follow the requirements for commercial agents.

10.2 Expedited Reporting Requirements

10.21 Requirements for Expedited **Investigational** Reporting via AdEERS for Adverse Events That Occur Within 30 Days¹ of the Last Dose of the Investigational Agent

	Grade 1	Grade 2	Grade 2	Grade 3		Grade 3		Grades 4 & 5 ²	Grades 4 & 5 ²
	Unexpected and Expected	Unexpected	Expected	Unexpected with Hospitalization	without Hospitalization	Expected with Hospitalization	without Hospitalization	Unexpected	Expected
Unrelated Unlikely	Not Required	Not Required	Not Required	7 Calendar Days	Not Required	7 Calendar Days	Not Required	7 Calendar Days	7 Calendar Days
Possible Probable Definite	Not Required	7 Calendar Days	Not Required	7 Calendar Days	7 Calendar Days	7 Calendar Days	Not Required	24-Hour; 3 Calendar Days	7 Calendar Days

¹ Adverse events with attribution of possible, probable, or definite that occur greater than 30 days after the last dose of treatment with an agent under an IND require reporting as follows:
 AdEERS 24-hour notification followed by complete report within 3 calendar days for:

- Grade 4 and Grade 5 unexpected events

AdEERS 7 calendar day report:

- Grade 3 unexpected events with hospitalization or prolongation of hospitalization
- Grade 5 expected events

² Although an AdEERS 24-hour notification is not required for death clearly related to progressive disease, a full report is required as outlined in the table.

Please see additional instructions and/or exceptions below under section entitled “Additional Instructions or Exceptions.”
 March 2005

Note: All deaths on study require both routine and expedited reporting regardless of causality. Attribution to treatment or other cause should be provided.

- Expedited AE reporting timelines defined:
 - “24 hours; 3 calendar days” – The investigator must initially report the AE via AdEERS within 24 hours of learning of the event followed by a complete AdEERS report within 3 calendar days of the initial 24-hour report.
 - “7 calendar days” - A complete AdEERS report on the AE must be submitted within 7 calendar days of the investigator learning of the event.
- Any medical event equivalent to CTCAE v4.0 grade 3, 4, or 5 that precipitates hospitalization (or prolongation of existing hospitalization) must be reported regardless of attribution and designation as expected or unexpected with the exception of any events identified as protocol-specific expedited adverse event reporting exclusions.
- Any event that results in persistent or significant disability/incapacity, congenital anomaly, or birth defect must be reported via AdEERS if the event occurs following treatment with an agent under a CTEP IND.
- **SECONDARY MALIGNANCIES** (defined as “cancer caused by treatment for a previous malignancy”, e.g., treatment with radiation or chemotherapy) are to be reported through AdEERS, as noted in Section 10.22. Secondary malignancies are not considered metastasis of the initial neoplasm. Secondary malignancy is unrelated to the first cancer that was treated, and may occur months or even years after initial treatment.

Add 5

Add 5

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

- Use the NCI protocol number and the protocol-specific patient ID provided during trial registration on all reports.

Additional Instructions or Exceptions to AdEERS Expedited Reporting Requirements

Within 1 working day of notification of an SAE, an e-mail notification of all AdEERS reports to will go to:

- ✓ The NCCTG IND Coordinator who will notify the FDA as warranted by the event and stipulated in the U.S. Code of Federal Regulations.
- ✓ Amgen Global Safety (FAX: 888/814-8653).
- In the rare event when Internet connectivity is disrupted, a report may be prepared using the Adverse Event Expedited Report – Single Agent or Multiple Agents paper template (available on the CTEP Home Page at <http://ctep.cancer.gov>). Contact the NCCTG SAE Coordinator (as identified on the NCCTG Protocol Resources page) for back-up submission instructions.
- Refer to Section 10.22 of this protocol for additional expedited reporting requirements.

10.22 Other Required Expedited Reporting

EVENT TYPE	REPORTING PROCEDURE
<p>Add 5</p> <p>Secondary AML/MDS</p>	<p>Reporting for this event required during and after completion of study treatment, via AdEERS.</p> <p>Through December 31, 2010, continue using CTCAE v3.0: Report Myelodysplasia as “Blood/Bone Marrow - Myelodysplasia” and Leukemias as “Blood/Bone Marrow - Other (Specify, ___)”.</p> <p>Beginning January 1, 2011, AdEERS will only accept CTCAE v4.0 for this study: Report these events using “Neoplasms benign, malignant and unspecified (including cysts and polyps) - Other, specify”.</p>
<p>Add 5</p> <p>Other Grade 4 or 5 Events and/or Any Hospitalizations During Treatment Not Otherwise Warranting an Expedited Report</p>	<p>Complete a Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form within 5 working days of the date the clinical research associate (CRA) is aware of the event(s) necessitating the form, using CTCAE v3.0.</p> <p>If an AdEERS report has been submitted, this form does not need to be submitted.</p> <p>Submit the Non-AER form electronically via the NCCTG Remote Data Entry System within 5 working days of the date the CRA is aware of the event(s) necessitating the form.</p> <p>The NCCTG SAE Coordinator will notify the NCCTG IND Coordinator who will submit to the FDA IND as warranted by the event and stipulated in the U.S. Code of Federal Regulations.</p> <p>You must use CTCAE v3.0 for data submission with this form. The events reported on this form must also appear on the Case Report Forms (i.e., routine data) for this study.</p>

Add 5

10.3 Adverse events to be graded at each evaluation and pretreatment symptoms/conditions to be evaluated at baseline per Common Terminology Criteria for Adverse Events (CTCAE) v3.0 grading unless otherwise stated:

Add 5

	Adverse event/Symptoms	Baseline	Each Evaluation¹
CTCAE v3.0 Category			
Blood/Bone Marrow	Hemoglobin	X	X
	Neutrophils/Granulocytes (ANC/AGC)	X	X
	Platelets	X	X
Constitutional Symptoms	Fatigue (lethargy, malaise, asthenia)	X	X
	Fever (in the absence of neutropenia, where neutropenia is defined as ANC <1.0 X 10 ⁹ /L)	X	X
Syndromes	Cytokine release syndrome/infusion reaction		X
Dermatology/skin	Nail changes	X	X
	Pruritis/itching	X	X
	Rash: Acne/acneiform	X	X
	Rash: Erythema multiforme	X	X
	Rash/desquamation	X	X
	Ulceration	X	X
Gastrointestinal	Anorexia	X	X
	# of stools per day	X	
	Diarrhea		X
	Nausea	X	X
	Mucositis/Stomatitis (clinical exam)		
	-oral cavity		X
	-pharynx		X
	Mucositis/Stomatitis (functional/symptomatic)		
	-oral cavity		X
	-pharynx		X
Vomiting	X	X	

Continued on next page

	Adverse event/Symptoms	Baseline	Each Evaluation¹
CTCAE v3.0 Category			
Infection	Febrile neutropenia (fever of unknown origin without clinical or microbiologically documented infections) (ANC <1.0 x 10 ⁹ /L, fever ≤38.5°C)	X	X
	Infection (documented clinically or microbiologically) with grade 3 or 4 neutrophils (ANC < 1.0 X 10 ⁹ /L) -Skin (cellulitis) -Abdomen NOS -Catheter-related -Wound -Biliary tree		X X X X X
	Infection with unknown ANC -Skin (cellulitis) -Abdomen NOS -Catheter-related -Wound -Biliary tree		X X X X X
Pulmonary/Upper Respiratory	Cough	X	X
	Dyspnea (shortness of breath)	X	X
	Hypoxia	X	X
	Pneumonitis/pulmonary infiltrates	X	X
Metabolic/Laboratory	Creatinine	X	X
	Magnesium serum-low (hypomagnesemia)	X	X

1. See Section 4.0 for schedule of adverse event assessments.

Add 5

- 10.31 Submit to the NCCTG Research Base via the Nadir/AE Log the following AEs using CTCAE v3.0 experienced by a patient and not specified in Section 10.3:
- 10.311 Grade 2 AEs deemed *possibly, probably, or definitely* related to the study treatment or procedure.
 - 10.312 Grade 3 and 4 AEs regardless of attribution to the study treatment or procedure
 - 10.313 Grade 5 AEs (Deaths)
 - 10.3131 Any death within 30 days of the patient's last study treatment or procedure regardless of attribution to the study treatment or procedure
 - 10.3132 Any death more than 30 days after the patient's last study treatment or procedure that is felt to be at least possibly treatment related must also be submitted as a Grade 5 AE, with a CTCAE type and attribution assigned.
- 10.32 Refer to the instructions in the Forms Packet (or electronic data entry screens, as applicable) regarding the submission of late occurring AEs following completion of the Active Monitoring Phase (i.e., compliance with Test Schedule in Section 4.0).

events (SAEs) to the NCCTG study sites. When an SAE report is received, all studies using the drug(s) listed are identified. SAEs are scanned and copies posted in protocol-specific folders on the NCCTG members' web site. A protocol-specific memo is then distributed electronically to NCCTG member sites on a weekly basis. Contact information for the NCCTG protocol specialist for that study is included in the memo.

Add 3

16.352 Adverse Event Stopping Rules: The stopping rules specified below are based on the knowledge available at study development. We note that the Adverse Event Stopping Rule may be adjusted in the event of either (1) the study re-opening to accrual or (2) at any time during the conduct of the trial and in consideration of newly acquired information regarding the adverse event profile of the treatment(s) under investigation. The study team may choose to suspend accrual because of unexpected adverse event profiles that have not crossed the specified rule below. CTCAE v3.0 will be used to determine grading for these stopping rules.

Add 5

Based on data from previous studies (i.e., N0349 – 49%, N9942 – 38%), we expect about 45% of patients to experience Grade 3 or 4 non-hematologic adverse events, probably or definitely related to the study treatment across all cycles of treatment. In addition, we expect about 2% of patients to experience a Grade 5 adverse event, at least possibly related to the study treatment. Accrual will be temporarily suspended to this study if at any time we observe adverse events that satisfy any of the following criteria:

- If at any time 12 or more patients in the first 20 treated patients experience a Grade 3 or 4 non-hematologic adverse event (probably or definitely related to the study treatment).
- If at any time 2 or more Grade 5 events occur in the first 20 treated patients (possibly, probably, or definitely related to the study treatment).
- If after the first 20 patients have been treated:
 - 60% or more of all patients experience a Grade 3 or 4 non-hematologic adverse event (probably or definitely related to the study treatment).
 - 2 or more of all patients experience a Grade 5 adverse event (possibly, probably, or definitely related to the study treatment).

We note that we will review all Grade 5 adverse events on a case-by-case basis as well (regardless of attribution), and may suspend accrual after just one Grade 5 event, if we feel it is necessary for patient safety.

FORMS PACKET

N064A, Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation
in Patients with Locally Advanced Pancreatic Cancer

- Contents:
- * Eligibility checklist *(03/19/2010)*
 - * Forms completion instructions
 - On-study form *(11/2/2009)*
 - Pre-treatment RECIST measurement form *(6/8/2009)*
 - Active monitoring RECIST measurement form *(6/8/2009)*
 - Baseline tissue specimen submission form *(6/8/2009)*
 - Baseline blood specimen submission form *(6/8/2009)*
 - Active monitoring blood specimen submission form *(6/28/2010)*
 - Pathology submission form *(3/17/2010)*
 - Pathology reporting form *(5/9/2008)*
 - ✓ Baseline adverse events form *(10/4/2010)*
 - ✓ Nadir/adverse event form *(10/4/2010)*
 - Evaluation/treatment form - chemotherapy concurrent with radiation cycle 1 (days 1-28) *(1/7/2010)*
 - Evaluation/treatment form - chemotherapy concurrent with radiation cycle 2 (days 29-end of RT) *(1/7/2010)*
 - Evaluation/treatment form – 4-6 weeks after completion of radiation therapy cycles 3, 4, 5 *(1/7/2010)*
 - Evaluation/treatment form – maintenance therapy cycles 6-11 *(6/8/2009)*
 - Radiation therapy reporting form *(6/10/2009)*
 - End of active treatment/cancel notification form *(5/9/2008)*
 - Evaluation/observation form *(6/19/2006)*
 - Event monitoring form *(5/9/2008)*
 - Notification form Grade 4 or 5 non-AER reportable events/hospitalization form *(5/9/2008)*
 - Patient Questionnaire Booklet Compliance Form *(12/5/08)*
 - Booklet order form *(6/10/09)*
 - Biospecimen accessioning processing fax supply order form

✓ 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.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064A

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**BASELINE
ADVERSE EVENTS FORM**

ALL ITEMS MUST BE COMPLETED

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

Required Baseline Adverse Events from Section 10.0 of Protocol		
CTC Adverse Events Term (CTCAE v3.0)	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Baseline number of stools per day: _____		
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
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
Nail changes	10028694	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Pruritis/itching	10037087	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Rash: acne/acneiform	10037847	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Rash: erythema multiforme (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis)	10015218	<input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Rash/desquamation	10037853	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Ulceration	10040947	<input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Anorexia	10002646	<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
Febrile neutropenia (fever of unknown origin without clinical or microbiologically documented infections) (ANC <1.0 x 10 ⁹ /L, fever ≤38.5° C)	10016288	<input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Cough	10011224	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Dyspnea (shortness of breath)	10013963	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Hypoxia	10021143	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Pneumonitis/pulmonary infiltrates	10035742	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Creatinine	10011368	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Magnesium serum-low (hypomagnesemia)	10040336	<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: N064A

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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)

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

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

Test	Nadir/Worst Date (Date of lab test) (mm/dd/yyyy)	Nadir/Worst Value (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.)	Is nadir below 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)
Platelets (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	_____
Leukocytes (total 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	_____
Hemoglobin (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	_____
Absolute Neutrophil Count (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 (CTCAE v3.0)	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's	CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)

Required Adverse Events from Section 10.0 of Protocol

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	_____
Cytokine release syndrome/infusion reaction	10052015	<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	_____
Nail changes	10028694	<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	_____
Pruritis/itching	10037087	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

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: N064A

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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

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

Required Adverse Events from Section 10.0 of Protocol

Rash: acne/acneiform	10037847	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <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	_____
Rash: erythema multiforme (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis)	10015218	<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	_____
Rash/desquamation	10037853	<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	_____
Ulceration	10040947	<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	_____
Anorexia	10002646	<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	_____
Diarrhea	10012727	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Nausea	10028813	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Mucositis/stomatitis (clinical exam) - Selects				
- Oral cavity	10056848	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
- Pharynx	10065717	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Mucositis/stomatitis (functional/symptomatic) - Selects				
- Oral cavity	10028130	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
- Pharynx	10065881	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Vomiting	10047700	<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	_____
Febrile neutropenia (fever of unknown origin without clinical or microbiologically documented infections) (ANC <1.0 x 10 ⁹ /L, fever ≤38.5° C)	10016288	<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	_____

* 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. 3 of 4

Are data amended? (check one) Yes No

(if data are amended, please circle in red when using paper form)

Protocol Number: N064A

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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

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

Required Adverse Events from Section 10.0 of Protocol

Infection (documented clinically or microbiologically) with grade 3 or 4 neutrophils (ANC < 1.0 x 10⁹/L) - *Selects*

- Skin (cellulitis)	90030270	<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	___
- Abdomen NOS	90030154	<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	___
- Catheter-related	90030174	<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	___
- Wound	90030304	<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	___
- Biliary tree	90030162	<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	___

Infection - *Selects*

- Skin (cellulitis)	10040872	<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	___
- 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	___
- Catheter-related	10007810	<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	___
- Wound	10048038	<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	___
- Biliary tree	10061695	<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	___
Cough	10011224	<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	___
Dyspnea (shortness of breath)	10013963	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <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	___
Hypoxia	10021143	<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	___
Pneumonitis/pulmonary infiltrates	10035742	<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	___
Creatinine	10011368	<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	___
Magnesium serum-low (hypomagnesemia)	10040336	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064A

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NADIR/ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 4 of 4

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

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

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

1 Yes, and reportable adverse events occurred

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

2 No (*Stop here*)



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

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

* See Section 10.0 of the protocol.

** Both hematologic (*except for the nadirs listed on page 1*) and nonhematologic Adverse Events must be graded on this form as applicable.