

DO NOT WRITE ON THIS PACKET!

SOLID TUMOR GROUP

INSTRUCTIONS: Complete the two provided **CALGB: 30303 Respiratory Follow-Up and Relapse Forms (C-1182)** for the time periods listed below and answer the questions for each time period for this sample patient. In order to complete the response section on the forms, we need you to refer to the response section of the protocol provided for you and the C-660 Measurement form filled out.

Study 30303

A

Patient ID# 99999 Patient Initials: (F., F. F.), Hospital ID# 012345 at Duke University Medical Center. The patient is alive and on initial treatment. The reporting start date was 11/30/05 and the date of last contact was 12/14/2005. The date the patient was evaluated was 12/1/2005. The patient did not receive any non-protocol therapy and did not have a new primary diagnoses.

Did the patient achieve a response during this time period?

If yes, what is the response and what is the date of response?

If the patient progressed, what is the site of progression?

Would this patient meet the study's endpoint?

What was the patient's best overall response to date?

B

Patient ID# 99999 Patient Initials: (F., F. F.), Hospital ID# 012345 at Duke University Medical Center. The patient is alive and on initial treatment. The reporting start date was 1/11/2006 and the date of last contact was 3/9/2006. The date the patient was evaluated was 3/3/2006. The patient did not receive any non-protocol therapy and did not have a new primary diagnoses.

Did the patient achieve a response during this time period?

If yes, what is the response and what is the date of response?

If the patient progressed, what is the site of progression?

Would this patient meet the study's endpoint?

What was the patient's best overall response to date?

Was the response confirmed?

CALGB: SOLID TUMOR EVALUATION FORM

INSTRUCTIONS: Complete and submit this form as required by the protocol. Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. The same method of evaluation should be used to characterize each reported lesion at baseline and during follow-up. After a site is recorded as a "target" lesion or "non-target" lesion, it should continue to be followed as such. Retain a copy for your records and submit the original to the CALGB Statistical Center, Data Operations.

CALGB Form	C-660
CALGB Study No.	30303
CALGB Patient ID	999999
Are data amended?	____ Yes

Patient Initials E, F F Participating Group _____
Last, First Middle
 Patient Hospital No. 012345 Participating Group Study No. _____
 Institution/Affiliate Duke University Participating Group Patient ID _____

LIST ALL TARGET AND NON-TARGET SITES TO BE USED FOR RESPONSE:

Treating Physician:		KMA	KMA	KMA	KMA
Date of evaluation (MM/DD/YYYY):		10/6/2005	12/1/2005	1/10/2006	3/3/2006
TARGET LESION(S)					
Response status at this assessment (CR, PR, SD, PD):		BASELINE			
Lesion, anatomic site, target	Method of Evaluation	Longest diameter of lesion(s) (cm)	Longest diameter of lesion(s) (cm)	Longest diameter of lesion(s) (cm)	Longest diameter of lesion(s) (cm)
1. LEFT UPPER LOBE	CT SCAN	2.8 cm	2.0 cm	2.1 cm	3.4 cm
2. AORTOPULMONARY WINDOW	CT SCAN	5.7 cm	5.0 cm	4.3 cm	4.5 cm
3. LEFT HILAR L.N.	CT SCAN	2.0 cm	0.0 cm	0.0 cm	0.0 cm
4.					
5.					
6.					
7.					
8.					
9.					
10.					
Sum of longest diameters of all target lesions:					
NON-TARGET LESION(S)					
Response status at this assessment (CR, Incomplete Response/SD, PD):					
Lesion, anatomic site, non-target	Method of Evaluation	Follow-up Status of Lesion*	Follow-up Status of Lesion*	Follow-up Status of Lesion*	Follow-up Status of Lesion*
1. PRETRACHEAL L.N.	CT SCAN	PRESENT	PRESENT	PRESENT	PRESENT
2.					
3.					
4.					
5.					
6.					

* Non-target lesions should be recorded as "present" initially and then followed as "present," or "absent."

Completed by: _____ Date form originally completed / /
(Print or Type Name) MM DD YYYY

30303
F.F.F
999999

RADIOLOGY REPORT

Location:

MRN:
DOB:
Sex:

Ordering MD:

Study Date	Accession #	Procedure Code	Procedure/Reason For Study
10/6/2005			CT THORAX W/O CONTRAST /

*** Final Report ***

CT of the thorax.

History - NSCL cancer staging studies

There are some mildly prominent nodes in the axilla but they have fatty hila. There is a mass in the portopulmonary window which measures approximately 3 x 5.7 cm. Mildly enlarged pretracheal nodes are noted. There is a 10 x 20 mm enlarged node in the left hilum. There is also an enlarged subcarinal lymph node. The pericardial space is within expected limits. No evidence of pleural effusion is appreciated.

The examination reveals an oval mass in the left lung apex measuring 1.9 x 2.8 cm.

On the right side there is some nonspecific linear thickening in the right apex of uncertain significance. Small bullae are noted in the right upper lung field as well. Limited visualization of the upper abdominal structures reveals some calcific densities along the dome of the right hemidiaphragm posterior to the liver. Their significance is uncertain. The liver is otherwise within expected limits. The visualized portion of the pancreas is within normal limits. There is a lesion within the right adrenal gland. The lesion is approximately 1.5 cm in diameter with an enhancing rim and central nonenhancing region. The left adrenal gland is within expected limits.

Impression:

1. 2.8 x 1.9 cm mass in the apex of the left upper lobe.
2. Mediastinal and left hilar adenopathy.
3. 1.5 cm lesion in the right adrenal gland.

FS:rb

Dictated on: 10/6/2005 2:57:36PM
 Interpreted by:
 Transcribed by:
 Signed by:

2005/10/06 14:59:05.6
2005/10/06 16:16:13.6

MAR 28 2005

Patient Name: [REDACTED]

DOB: [REDACTED]

Chest Computed Tomography (CT) with Contrast

Performed: December 1, 2005, 14:19 Final

CT chest and abdomen with contrast

History: Enlarged lymph nodes. Follow-up examination.

Standard CT images of the chest and abdomen were performed following oral contrast administration and during intravenous contrast infusion.

Delayed images of the abdomen were also obtained.

Chest CT: Chest demonstrates an oval-shaped mass at the left lung apex which measures approximately 2 x 1.2 cm in size. The mass appears smaller today than on the prior CT examination of 10/6/2005. On the prior examination the mass measured 1.9 x 2.8 cm. Subjective measurement suggests a significant improvement. Lower neck and axillary regions are grossly negative. Evaluation of the mediastinum shows adenopathy in the aortopulmonary window region. The mass of lymph nodes measures 5 x 3 cm in size. On the previous examination this measured approximately 6 x 4 cm in size. It clearly is improved subjectively compared to the prior examination. The lung fields appear to be clear.

CT Chest Summary:

1. Improvement in left apical mass compared to the prior CT examination of 10/6/05.
2. Considerable improvement in mediastinal adenopathy when today's exam is compared to the prior examination of 10/6/05.

CT abdomen: There are several calcifications near the dome of the liver that suggest prior granulomatous disease. There are no focal lesions within the liver. The spleen is grossly negative. Low density mass is seen within the mid-pole of the right kidney. This mass measures approximately 15 mm in long axis. This mass is unchanged compared with the patient's prior CT examination of 10/6/2005. It likely represents a small simple cyst. A right adrenal mass was described on the patient's prior CT of the chest examination of 10/6/2005. This mass appears to have low density centrally. This apparent adrenal mass is not visible on the current examination. Perhaps this represents resolution of the mass? The gallbladder is grossly negative. The pancreas is grossly negative. The left kidney is normal. The bowel is grossly negative. Atherosclerotic change is noted within the abdominal aorta.

CT Abdomen Summary:

1. Right adrenal mass seen on the prior CT examination of 10/6/05 is
-
- [REDACTED]

Patient Name: [REDACTED]

DOB: [REDACTED]

Chest Computed Tomography (CT) with Contrast

Performed: January 10, 2006, 13:38 Final

CT of the chest and abdomen, 1/10/2006:

History: Non small-cell lung cancer, on chemotherapy. Follow-up.

Technique: Transaxial helical imaging was performed through the chest and abdomen during intravenous infusion of 100 ml of Optiray-350.

Oral

contrast was also administered. Seven millimeter images were reconstructed.

CT thorax findings: Comparison is made to the previous examination of 12/1/2005. A slight further decrease is seen in the size of the patient's left apical lung mass. This currently measures about 10 x 21

mm in transverse dimension, decreased from about 15 x 28 mm at the time of the prior study. The patient's abnormal enlarged left para-aortic mediastinal nodal mass has also decreased in size. It now measures about 2 x 4.3 cm in transverse dimension, decreased from 2.9 x 5.1 cm at the time of the prior study. Some minimal streaky scarring

persists at the right lung apex and at the left lung base. Some pleural plaque is seen about the hemithorax, suggesting asbestos related pleural disease. Recommend correlation. No pleural effusions are evident.

CT thorax impression:

1. Further slight decreases in the size of the patient's left apical lung mass and mediastinal nodal mass since the prior study, as detailed above.
2. Evidence of asbestos related pleural disease. Recommend correlation.
3. Minimal stable streaky scarring at the right lung apex and left lung base. There are no developing pulmonary lesions.

CT abdomen findings: Comparison is made to the prior study of 12/1/2005. The spleen, adrenal glands, liver, and pancreas remain unremarkable in appearance. Evaluation of the kidneys again reveals the presence of an apparent cyst in the mid right kidney, without change. The kidneys are otherwise unremarkable. Oral contrast material

has not yet passed into the colon and the colon is not optimally assessed on this examination. However, there is a suggestion of some wall thickening involving the proximal transverse colon. A similar appearance was present at the time of the prior examination. This is of uncertain significance. Are there any symptoms referable to the colon? Is there any history of inflammatory bowel disease? If clinically warranted, a barium enema or colonoscopy could be

CALCB-DWC
APR 14 2006

Chest Computer Tomography (CT) with Contrast

Performed: March 3, 2006, 14:56 Final

CT of the chest and abdomen, 3/3/2006:

History: Non small-cell lung, cancer, on chemotherapy. Follow-up.

Technique: Transaxial helical imaging was performed through the chest and abdomen during intravenous infusion of 100ml of Optiray-350.

Oral

Contrast was also administered. Seven millimeter images were reconstructed.

CT thorax findings: Comparison is made to the previous examination of 1/10/2006. A slight increase is seen in the size of the patient's left apical lung mass. This currently measures about 11 x 34 mm in transverse dimension, increased from about 10 x 21 mm at the time of prior study. The patient's abnormal enlarged left para-aortic mediastinal nodal mass has also increased in size. It now measures about 2 x 4.5 cm in transverse dimension, increased slightly from 2 x 4.3 cm at the time of the prior study. So minimal streaky scarring persists at the right lung apex at the left lung base.

2.0 OBJECTIVES

2.1 Primary Objectives

- 2.1.1 To compare the incidence and severity of peripheral neuropathy from dose-dense docetaxel and cisplatin therapy with and without BNP7787 in patients with advanced (stage IIIB and IV) non-small cell lung cancer
- 2.1.2 To assess the feasibility (defined by febrile neutropenia and treatment delays) of administering dose-dense cisplatin and docetaxel with and without BNP7787
- 2.1.3 To determine the objective response rate to dose-dense cisplatin and docetaxel with and without BNP7787 in patients with advanced (stage IIIB and IV) non-small cell lung cancer

2.2 Secondary Objectives

- 2.2.1 To describe the survival and failure-free survival of patients treated with dose-dense docetaxel and cisplatin with and without BNP7787 for advanced non-small cell lung cancer.
- 2.2.2 To evaluate the toxicity profile of dose dense docetaxel and cisplatin with and without BNP7787.
- 2.2.3 To evaluate the incidence and severity of cisplatin induced nephrotoxicity with and without BNP7787.

3.0 ON STUDY GUIDELINES

The following guidelines are to assist physicians in selecting patients for whom protocol therapy is safe and appropriate.

- Patients with medical conditions which in the opinion of the treating physician would make this protocol unreasonably hazardous for the patient should not be enrolled. Such conditions include uncontrolled infection (including HIV), poorly controlled diabetes mellitus, and active cardiac disease (including unstable angina, myocardial infarction within 6 months, or congestive heart failure).
- Patients with psychiatric illness which would prevent the patient from giving informed consent or would prevent compliance with treatment should not be enrolled.
- Women and men of reproductive potential should agree to use an appropriate method of birth control throughout their participation in this study. Appropriate methods of birth control include abstinence, oral contraceptives, implantable hormonal contraceptives (Norplant), or the double barrier method (diaphragm plus condom).
- Patients with a "currently active" second malignancy, other than non-melanoma skin cancer, should not be enrolled. Patients are not considered to have a "currently active" malignancy if they have completed therapy for a prior malignancy and are considered by their physician to be at less than 30% risk of relapse.

4.0 ELIGIBILITY CRITERIA

- 4.1 **Histologic Documentation:** Either histologic or cytologic documentation of non-small cell carcinoma (NSCLC) is necessary, and the following diagnostic categories are acceptable: squamous carcinoma, basaloid carcinoma, adenocarcinoma,

non-cancer-related conditions (e.g., insulin for diabetes); and intermittent use of dexamethasone as an antiemetic.

10.3 Palliative radiation therapy may **not** be administered. Patients requiring radiation therapy during protocol treatment will be considered to have progressed and will be removed from protocol treatment and treated at the discretion of the physician.

10.4 Use of Growth Factors

Darbepoetin alfa and pegfilgrastim are to be used as described in this protocol (see Section 7.0). The use of other growth factors is not allowed.

10.5 Bisphosphonates are permitted on this protocol.

11.0 CRITERIA FOR RESPONSE, PROGRESSION, AND RELAPSE

Overall response will be determined based upon criteria defined for target and non-target lesions.

For the purposes of this study, patients should be evaluated for response every 6 weeks. In addition to a baseline scan, confirmatory scans should also be obtained ≥ 4 weeks following initial documentation of objective response.

11.1 Criteria for Target Lesions

All measurable lesions up to a maximum of 10 lesions representative of all involved organs should be identified as target lesions and will be recorded and measured at baseline. Target lesions should be selected on the basis of their size to include lesions with the longest diameter. These lesions should also be selected based on their suitability for accurate repetitive measurements either by imaging techniques or clinical examination. For each target lesion the longest diameter will be measured and recorded. A sum of the longest diameter (LD) for all target lesions will be calculated and reported as the baseline sum LD. The baseline sum LD will be used as reference to further characterize the objective tumor response of the measurable dimension of the disease.

11.1.1 Complete Response: Disappearance of all target lesions. Changes in tumor measurements must be confirmed by repeat studies performed no less than 4 weeks after the criteria for response are first met.

11.1.2 Partial Response (PR): At least a 30% decrease in the sum of the longest diameter (LD) of target lesions taking as reference the baseline sum LD. Changes in tumor measurements must be confirmed by repeat studies performed no less than 4 weeks after the criteria for response are first met.

11.1.3 Stable Disease (SD): Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD taking as references the smallest sum LD since the treatment started. Follow-up measurements must have met the SD criteria at least once after study entry no less than 6 weeks after the initial measurement. Patients having a documented response with no reconfirmation of the response will be listed with stable disease.

11.1.4 Progression (PD): At least a 20% increase in the sum of the LD of target lesions taking as references the smallest sum LD recorded since the treatment started or the appearance of one or more new lesions.

SOLID TUMOR GROUP WORKSHEET:

To complete this exercise you are being provided:

- Case study with an example of partially completed CALGB: Solid Tumor Evaluation Form (C-660) [*This form has been amended for this exercise.]
- Two (2) blank CALGB: 30303 Follow-Up and Relapse Form (C-1182) forms
- A portion of the 30303 protocol sections covering the study's objectives; criteria for response, progression, and relapse; and the removal of patients from protocol therapy.
- Copies of the example patient's CT Scans

Tips:

- Be sure to calculate the sum of the Longest Diameter (LD) on the C-660.
- Convert millimeters (mm) to centimeters (cm). [Ex.: 23mm x 0.1 = 2.3 cm]
- Remember response confirmation takes place with an additional scan 4 weeks later.
- Remember the amounts of percentage for response in the particular disease you are evaluating. [Solid Tumors: $\geq 30\%$ decrease for PR; $\geq 20\%$ for PD]
- In determining response percentage:
- Finally, remember that different people interpret the CT Scans differently, so you may occasionally find that your measurements are off slightly.

A

Did the patient achieve a response during this time period? YES

If yes, what is the response and what is the date of response? PARTIAL RESPONSE

If the patient progressed, what is the site of progression? N/A

Would this patient meet the study's endpoint? NO

What was the patient's best overall response to date? PR

B

Did the patient achieve a response during this time period? YES

If yes, what is the response and what is the date of response? PROGRESSION

If the patient progressed, what is the site(s) of progression? MEDISTINAL NODES & PRIMARY LUNG

Would this patient meet the study's endpoint? YES

What was the patient's best overall response to date? PARTIAL RESPONSE

Was the response confirmed? YES



15055

CALGB: 30303 FOLLOW-UP AND RELAPSE FORM

INSTRUCTIONS: Complete and submit this form as required by the protocol. Information in the upper right box must be completed for this form to be accepted. For optimal accuracy use black ink. **Mark an X** in the appropriate box for fields with a choice. **Print text in capital letters.** Avoid contact with the edges of the boxes. If data are amended, circle amended items and check the "Yes" box. If submitting by mail, retain a copy for your records. If submitting by fax, use an original form for maximum clarity in transmission and fax to 919-416-4990. If submitting electronically, click the Send button when you have completed the form.

CALGB Form	C-1182									
CALGB Study No.		3	0	3	0	3				
CALGB Patient ID		9	9	9	9	9				
Reported period start date	0	1	/	1	1	/	2	0	0	6
To: (date of last contact or death)	0	3	/	0	9	/	2	0	0	6
	M	M		D	D		Y	Y	Y	Y
Are data amended?							<input type="checkbox"/> Yes			

Patient Initials , ,
Last, First Middle

Participating Group: CALGB

Patient Hospital No: 012345 Participating Group Study No: _____

Institution/Affiliate: DUKE UNIVERSITY Participating Group Patient ID: _____

Patient's vital status (Mark one with an X.)

Alive Dead Lost

Primary cause of death (Mark one with an X.)

Due to protocol treatment Due to this disease Due to other cause, specify: _____

BEST RESPONSE TO DATE

Best overall objective response to date (Mark one with an X.)

Complete response Partial response Stable Progression Unevaluable or not assessed adequately

NOTE: Attach copies of supporting documentation of response or progression as required by the protocol.

If any of the following have occurred during the time period covered by this form, enter the applicable date:

Date of complete response onset	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date of partial response onset	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	M	M		D	D		Y	Y	Y	Y

STAT USE ONLY	
Confirmed CR	<input type="checkbox"/> No <input type="checkbox"/> Yes
Confirmed PR	<input type="checkbox"/> No <input type="checkbox"/> Yes

NOTICE OF PROGRESSION/RELAPSE

Has the patient developed a progression (or relapse) during this time period that has not been previously reported?

No Yes, date progressive or recurrent disease diagnosed: / /

Site(s) of progression/relapse (Mark all that apply with an X.)

<input type="checkbox"/> Hilar nodes	<input type="checkbox"/> Liver	<input type="checkbox"/> Other nodal, specify site: _____
<input checked="" type="checkbox"/> Mediastinal nodes	<input type="checkbox"/> Adrenal(s)	_____
<input type="checkbox"/> Supraclavicular/scalene nodes	<input type="checkbox"/> Bone	<input type="checkbox"/> Other, specify: _____
<input checked="" type="checkbox"/> Primary lung	<input type="checkbox"/> Bone marrow	_____
<input type="checkbox"/> Contralateral lung	<input type="checkbox"/> CNS/Brain	
<input type="checkbox"/> Pleura	<input type="checkbox"/> Skin	

STAT USE ONLY	
Location of relapse	<input type="checkbox"/> Local-regional <input type="checkbox"/> Distant

Completed by _____
 (First Name, Last Name)

Date form completed / /





15055

CALGB: 30303 FOLLOW-UP AND RELAPSE FORM

INSTRUCTIONS: Complete and submit this form as required by the protocol. Information in the upper right box must be completed for this form to be accepted. For optimal accuracy use black ink. **Mark an X** in the appropriate box for fields with a choice. **Print text in capital letters.** Avoid contact with the edges of the boxes. If data are amended, circle amended items and check the "Yes" box. If submitting by mail, retain a copy for your records. If submitting by fax, use an original form for maximum clarity in transmission and fax to 919-416-4990. If submitting electronically, click the Send button when you have completed the form.

CALGB Form	C-1182									
CALGB Study No.		3	0	3	0	3				
CALGB Patient ID		9	9	9	9	9				
Reported period start date	1	1	/	3	0	/	2	0	0	5
To: (date of last contact or death)	1	2	/	1	4	/	2	0	0	5
	M	M		D	D		Y	Y	Y	Y
Are data amended?							<input type="checkbox"/> Yes			

Patient Initials , ,
Last, First Middle

Participating Group: CALGB

Patient Hospital No: 012345

Participating Group Study No: _____

Institution/Affiliate: DUKE UNIVERSITY

Participating Group Patient ID: _____

Patient's vital status (Mark one with an X.)

Alive Dead Lost

Primary cause of death (Mark one with an X.)

Due to protocol treatment Due to this disease Due to other cause, specify: _____

BEST RESPONSE TO DATE

Best overall objective response to date (Mark one with an X.)

Complete response Partial response Stable Progression Unevaluable or not assessed adequately

NOTE: Attach copies of supporting documentation of response or progression as required by the protocol.

If any of the following have occurred during the time period covered by this form, enter the applicable date:

Date of complete response onset / /

Date of partial response onset / /
M M D D Y Y Y Y

STAT USE ONLY

Confirmed CR No Yes

Confirmed PR No Yes

NOTICE OF PROGRESSION/RELAPSE

Has the patient developed a progression (or relapse) during this time period that has not been previously reported?

No Yes, date progressive or recurrent disease diagnosed: / /
M M D D Y Y Y Y

Site(s) of progression/relapse (Mark all that apply with an X.)

Hilar nodes

Liver

Other nodal, specify site: _____

Mediastinal nodes

Adrenal(s)

Supraclavicular/scalene nodes

Bone

Other, specify: _____

Primary lung

Bone marrow

Contralateral lung

CNS/Brain

Pleura

Skin

STAT USE ONLY

Location of relapse Local-regional Distant

Completed by _____

(First Name, Last Name)

Date form completed / /
M M D D Y Y Y Y

