

**CALGB 40101 REGISTRATION WORKSHEET**

*Cyclophosphamide and Doxorubicin (CA x 4 cycles) versus Paclitaxel (4 cycles) as Adjuvant Therapy for Breast Cancer in Women with 0-3 Positive Axillary Lymph Nodes: A Phase III Randomized Study*

Lead Institution _____	Physician of Record _____						
Inst/Affiliate _____	Participating Group _____						
If the patient has been on a previous CALGB protocol, specify CALGB Patient ID <table border="1" style="display: inline-table;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr></table>							

**Protocol Administration**

IRB/REB Approval Date 


/ 


/ 


  
 Date Informed Consent Signed 


/ 


/ 


  
 Projected Treatment Begin Date 


/ 


/ 


  
 HIPAA Authorization Date 

M M	D D	Y Y Y Y
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Contact person at Institution \_\_\_\_\_

Phone (\_\_\_\_\_) \_\_\_\_ - \_\_\_\_\_

FAX (\_\_\_\_\_) \_\_\_\_ - \_\_\_\_\_

**Patient Demographics/Pre-Treatment Characteristics**

Patient Initials 

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      Last, First Middle  
 Patient's date of birth 

M M	D D	Y Y Y Y

      Patient Hospital No. 

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      Gender  Male  Female

Race  American Indian or Alaskan Native  Asian  Black or African American  
*(Mark all that apply)*  Native Hawaiian or Other Pacific Islander  Unknown  White

Ethnicity *(Mark one)*  Hispanic or Latino  Non-Hispanic  Unknown

Performance Status  Height 

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 cm      Weight 

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 kg      BSA 

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 m<sup>2</sup>  
*(ECOG/Zubrod scale)*

**Method of Payment (USA only)(Mark one)**

<input type="checkbox"/> Medicaid	<input type="checkbox"/> Medicaid and Medicare	<input type="checkbox"/> Medicare
<input type="checkbox"/> Medicare and Private Insurance	<input type="checkbox"/> Military (including CHAMPUS and TRICARE)	<input type="checkbox"/> No means of payment (no insurance)
<input type="checkbox"/> Other	<input type="checkbox"/> Private Insurance (Aetna, Blue Cross, Kaiser Permanente, and employer-sponsored insurers)	<input type="checkbox"/> Veterans Sponsored
<input type="checkbox"/> Self Pay (no insurance)	<input type="checkbox"/> Unknown	<input type="checkbox"/> Unknown

Patient Zip Code 

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      Country *(If not USA)* \_\_\_\_\_

**Certification Of Eligibility**

In the opinion of the investigator, is the patient eligible?  No  Yes

**Protocol Design**

Stratification Factors:

## Menopausal Status

Premenopausal  Postmenopausal

## ER/PgR

Both or either positive or unknown  Both negative

## HER-2/neu status

Negative  Positive  Unknown

Assigned Treatment Arm:

CA Therapy — 4 cycles (C-600 mg/m<sup>2</sup> A-60 mg/m<sup>2</sup> q-14 days)

Paclitaxel — 4 cycles (175 mg/m<sup>2</sup> q-14 days)

(Continue to next page.)

## CALGB 40101 REGISTRATION WORKSHEET

Cyclophosphamide and Doxorubicin (CA x 4 cycles) versus Paclitaxel (4 cycles) as Adjuvant Therapy for Breast Cancer in Women with 0-3 Positive Axillary Lymph Nodes: A Phase III Randomized Study

### Protocol Design (continued from previous page)

#### 40101 Companion Studies:

Is the patient registering to the Pharmacogenetic companion study 60202 (titled "Drug Metabolism and Transport PG in Breast CA")?  
*NOTE TO REGISTRAR: If the patient answers "Yes" to the first question in the "Related Blood Studies" portion of the consent form, then answer "Yes" here.*

No     Yes

Patient's Initial Consent given for: Blood specimen use for genetic research on patient's cancer?     No     Yes  
If Yes, did patient consent to DNA specimen use in future research studies?     No     Yes

#### Initial Patient Consent For 40101 Tissue Specimen Use

Patient's Initial Consent given for: Tissue specimen use for research on patient's cancer?     No     Yes  
Tissue specimen use for research unrelated to the patient's cancer?     No     Yes  
Further contact regarding specimen?     No     Yes

#### Registration Information

CALGB Patient ID

Participating Group Patient ID

Date of Registration  /  /   
M M    D D    Y Y Y Y

Registrar \_\_\_\_\_

What race do you consider yourself to be? (Check one or more)

African American Black/Multi-ethnic — A person having origins in any group of one or more of the original peoples of Africa, including Central Africa and the continent of Africa and people in the United States who are African Americans.

Asian — A person having origins in any of the original populations of the Far East, Southeast Asia, and the Indian subcontinent including, for example, Cambodian, Chinese, Indian, Japanese, Korean, Pakistani, Philippine, Thai, Vietnamese, and Pakistani.

Black or African American — A person having origins in any of the black racial groups of Africa including, for example, Nigerian, Congolese, Kenyan, Tanzanian, Ugandan, Malawian, Zambian, and Zulu.

Hispanic Latino or other Pacific Islander — A person having origins in any of the original inhabitants of the West Indies, Puerto Rico, or other Pacific Islands.

White — A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

#### Refusal

I (We) do not wish to provide any or all of the above information.



53625

## CALGB: REMARKS ADDENDA

**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-260
CALGB Study No.	[ ] [ ] [ ] [ ]
CALGB Patient ID	[ ] [ ] [ ] [ ]
Are data amended?	<input type="checkbox"/> Yes

Patient Initials ,    
Last, First Middle

Participating Group \_\_\_\_\_

Patient Hospital  
No. \_\_\_\_\_

Participating Group  
Study No. \_\_\_\_\_

Institution/Affiliate \_\_\_\_\_ Participating Group Patient ID \_\_\_\_\_

**ADDITIONAL INSTRUCTIONS**

Record patient's initials, time period covered and page number. Addenda pages should be numbered sequentially in the order of submission. If an addenda is used to supplement a flow sheet, then use the flow sheet page number when numbering the addenda (e.g., flow sheet no. 1 would be supplemented by addenda no. 1a, etc.).

Make any notes needed to supplement information submitted on data forms or flow sheets for this patient. Write clearly and legibly.

Reporting Period  /  /      
Start Date *M M* / *D D* / *Y Y Y Y*

Reporting Period  /  /      
End Date *M M* / *D D* / *Y Y Y Y*

Page: \_\_\_\_\_

**COMMENTS**

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Completed by: \_\_\_\_\_  
(Last name, First name)

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

53625





924

## CALGB: 40101 ON-STUDY 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. Circle amended items and check "Amended data" box to the right. If submitting by mail, retain a copy for your records and send the original to the CALGB Statistical Center, Data Operations. If faxing, 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 PDF version of the form.

CALGB Form:	C-924
CALGB Study No:	4 0 1 0 1
CALGB Patient ID:	_____
Amended data?	<input type="checkbox"/> Yes

Patient's Name: \_\_\_\_\_ Participating Group: \_\_\_\_\_

Patient Hospital Number: \_\_\_\_\_ Participating Group Protocol No. \_\_\_\_\_

Main Member Institution/Adjunct \_\_\_\_\_ Participating Group Patient No. \_\_\_\_\_

Menopausal Status (mark one with an X) oh001

- 1  Pre (<6 mo since LMP AND no prior bilateral ovariectomy AND not on estrogen replacement)
- 2  Post (prior bilateral ovariectomy OR >12 mo since LMP with no prior hysterectomy)
- 3  Above categories not applicable AND Age <50
- 4  Above categories not applicable AND Age ≥50

Disease Description

Tumor Laterality (mark one with an X) oh002

- 1  Left
- 2  Right
- 3  Bilateral

oh003 Receptor Status, ER (mark one with an X)

- 1  Negative
- 2  Positive
- 2  Unknown

(If measured in fmols/mg cytosol protein ≥ 10 is positive.  
If other measures are used apply institutional standards;  
borderline results should be reported as positive)

oh004 Receptor Status, PgR (mark one with an X)

- 1  Negative
- 2  Positive
- 1  Unknown

oh005 Histologic Grade (combined histologic grade is used according to SBR/ELSTON classification.) (mark one with an X)

- 1  Low
- 2  Intermediate
- 3  High

oh006 HER-2 neu Status: (mark one with an X)

- 1  Dako Herceptest 3+    3  Dako Herceptest <3+/FISH+
- 5  Unknown    7  Not done
- 2  FISH+ (IHC not done)    4  IHC (non-Dako Herceptest) strong positive    6  Negative

.  Pathologic primary tumor size (cm) (maximum diameter of the invasive component; if multiple lesions, use longest lesion) oh007

Disease stage (pathology report)

T

N

M

oh008

oh009

oh010

Continue to next page



924

## CALGB: 40101 ON-STUDY FORM

CALGB Form:	C-924				
CALGB Study No:	4	0	1	0	1
CALGB Patient ID:					

Patient's Name: \_\_\_\_\_

## Prior Systemic Therapy

oh011

Prior hormonal therapy? (do not include steroids given with chemotherapy)

1  No2  Yes, complete below:oh012 Tamoxifen 1  No 2  Yesoh013 Raloxifene 1  No 2  Yesoh014 Other, 1  No 2  Yesspecify: oh015

oh016

Prior adjuvant chemotherapy for this malignancy?  
(include pre-op chemotherapy at diagnosis)1  No2  Yes, specify: oh017

## Surgical Procedures

   /    /       Date of first positive biopsy  
 oh024 M oh025 D oh026 Y

oh027 Type of biopsy (mark one with an X)

- 1  Core needle  
 2  Incisional  
 3  Excisional

oh028 Most extensive primary surgery (mark one with an X)

- 1  Partial mastectomy/lumpectomy/excisional biopsy  
 2  Mastectomy, NOS

Date of most extensive primary surgery  
(if required, use date of last re-excision)
   /    /        
 M D Y

oh029 oh030 oh031

## Required Pre-Study Laboratory Values

   .    WBC ( $\times 10^3$ ) oh018

   .    ANC ( $\times 10^3$ ) oh019

   .    Platelets ( $\times 10^3$ ) oh020

   .    Serum Creatinine (mg/dl) oh021

   .    Bilirubin (mg/dl) oh022

   .    Bilirubin (upper limit of normal) oh023

Sentinel node biopsy oh032

1  No2  Yes, date:    /    /        
 M D Y
oh033 oh034 oh035  
If done, sentinel node biopsy results (per protocol)  
(mark one with an X) oh0361  Negative 2  Positive

Was axillary dissection performed? oh037

1  No2  Yes, date:    /    /        
 M D Y
oh038 oh039 oh040  
Total number of axillary lymph nodes examined oh041
   Number of positive axillary lymph nodes oh042
Completed By: \_\_\_\_\_ Date Completed:    /    /        
 (Print or Type Name) M D Y



45631

## CALGB: 40101 TREATMENT SUMMARY FORM

All Patients

**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. Circle amended items and check "Amended data" box to the right. If submitting by mail, retain a copy for your records and send the original to the CALGB Statistical Center, Data Operations. If faxing, 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 PDF version of the form.

CALGB Form	C-925			
CALGB Study No.	4	0	1	0
CALGB Patient ID				
From: (first date protocol therapy given)		/		/
To (last date protocol therapy was given):		/		/
M M D D Y Y Y Y				
Are data amended?	<input type="checkbox"/> Yes			

tt001

tt002

Patient Initials  ,    
Last, First Middle

Participating Group \_\_\_\_\_

Patient Hospital No. \_\_\_\_\_ Participating Group Protocol No. \_\_\_\_\_

Institution/Affiliate \_\_\_\_\_ Participating Group Patient ID \_\_\_\_\_

Patient's vital status (Mark one with an X.) tt026

1  Alive 8  Dead 9  Lost

## DISEASE ASSESSMENT

Has the patient had a documented clinical assessment for this cancer? 1  No 2  Yes

If Yes, specify below:

Date of last clinical assessment  /  /    
 M M P D Y Y Y Y  
 tt028 tt029 tt030

Initial dose of cycle 1	Chemotherapy	# Completed cycles	Cumulative dose
tt003	Cyclophosphamide	tt004	tt005
tt006	Doxorubicin	tt007	tt008
tt009	Paclitaxel	tt010	tt011

## TREATMENT SCHEDULE

Were there any dose modifications or additions/omissions to protocol treatment? (Mark one with an X.) tt012

- 1  No  
 2  Yes, planned (i.e., the treatment was changed according to protocol guidelines)  
 3  Yes, unplanned (i.e., the treatment change was not part of protocol guidelines)  
 -1  Unknown

If Yes, specify treatment modifications: tt013

Were any optional protocol therapies given? tt014

1  No 2  Yes, optional protocol therapy name(s): tt015

(Continue to next page.)





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## CALGB: 40101 TREATMENT SUMMARY FORM

All Patients

Patient Initials  ,    
Last, First Middle

CALGB Form	C-925				
CALGB Study No.	4	0	1	0	1
CALGB Patient ID					
First	<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>
Date:					

## TREATMENT SCHEDULE (continued from previous page)

tt016 Was any concurrent non-protocol therapy given during protocol treatment? (If patient is enrolled on a bisphosphonate study, indicate the agent and protocol number under "Other, specify.")

1  No  Yes, indicate below. (Mark all that apply with an X.)

- tt017  Concurrent non-protocol chemotherapy?  Concurrent non-protocol radiation therapy? tt020  
 tt018  Concurrent non-protocol hormonal therapy?  Concurrent non-protocol high dose chemotherapy/ autologous stem cell transplant? tt021  
 tt019  Concurrent non-protocol biologic response modifier therapy?  Other, specify: tt031

tt032

tt022

Was G-CSF given during protocol treatment? 1  No  Yes

If Yes, during which cycle(s) was G-CSF give? (Mark all that apply with an X.)

- Cycle 1  Cycle 2  Cycle 3  Cycle 4  Cycle 5  Cycle 6

tt033 tt034 tt035 tt036 tt037 tt038

Reason treatment ended (Mark one with an X.) tt023

- 18  Treatment completed per protocol criteria  
 19  Disease progression/relapse during active treatment  
 20  Toxicity/side effects/complications  
 21  Death on study  
 22  Patient withdrawal or refusal after beginning protocol therapy  
 23  Patient withdrawal or refusal prior to beginning protocol therapy  
 25  Other complicating disease  
 24  Alternative therapy  
 27  Other, specify:

tt024

## COMMENTS

tt025

Completed By: \_\_\_\_\_  
(Print or Type Name)

Date Completed:  /  /    
 M D Y

45631



TRSVSU



926

## CALGB: 40101 TREATMENT SUMMARY SUBSET 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.  
 Circle amended items and check "Amended data" box to the right. If submitting by mail, retain a copy for your records and send the original to the CALGB Statistical Center, Data Operations. If faxing, 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 PDF version of the form.

CALGB Form:	C-926				
CALGB Study No:	4	0	1	0	1
CALGB Patient ID:					
Cycle start date:					
Cycle end date:					
	M	D	Y		
Amended data?	<input type="checkbox"/> Yes				

tu001  
tu002

Patient's Name: \_\_\_\_\_ Participating Group: \_\_\_\_\_

Patient Hospital Number: \_\_\_\_\_ Participating Group Protocol No. \_\_\_\_\_

Main Member Institution/Adjunct \_\_\_\_\_ Participating Group Patient No. \_\_\_\_\_

tu003 

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 Current cycle number tu004 

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 BSA (m<sup>2</sup>)

Total dosage for this cycle (mg)	<i>tu008</i>	Dose adjustments (mark one with an X)	Reason for adjustment*	Specify, if applicable				
<table border="1"><tr><td> </td><td> </td><td> </td></tr></table>				Doxorubicin	<i>1</i> <input type="checkbox"/> Reduced	<i>tu009</i> <table border="1"><tr><td> </td></tr></table>		<i>tu010</i>
<table border="1"><tr><td> </td><td> </td><td> </td></tr></table>				Cyclophosphamide	<i>2</i> <input type="checkbox"/> Delayed			
<table border="1"><tr><td> </td><td> </td><td> </td></tr></table>				Paclitaxel	<i>3</i> <input type="checkbox"/> Reduced and delayed			

Comments:

tu011

\*Reasons for dose adjustment:

- 1 - Neutrophil count < 1000/mm<sup>3</sup>
- 2 - Platelets < 100,000/mm<sup>3</sup>
- 3 - Not satisfactorily recovered from hematologic toxicity, specify in specify box
- 4 - Grade 3 or 4 fatigue
- 5 - Grade 2 or 3 anaphylaxis/hypersensitivity
- 6 - Grade 3 or 4 diarrhea/nausea
- 7 - Grade 3 or 4 mucositis
- 8 - Grade 2 or higher neuropathy
- 9 - Grade 3 or higher cardiac toxicity
- 10 - Grade 3 or higher infection
- 11 - Grade 3 or 4 other non-hematologic toxicity, specify in specify box
- 12 - Holiday/vacation
- 13 - Other, specify in specify box

Completed By: \_\_\_\_\_ Date Completed: 

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(Print or Type Name) M D Y





41914

## CALGB: 40101 FOLLOW-UP FORM

OLLOWU

**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. Circle amended items and check "Amended data" box to the right. If submitting by mail, retain a copy for your records and send the original to the CALGB Statistical Center, Data Operations. If faxing, 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 PDF version of the form.

CALGB Form			C-929
CALGB Study No.			4 0 1 0 1
CALGB Patient ID			
From:		/	
To: (date of last contact or death)	M M	/	D D
		/	
			Y Y Y Y
Are data amended? <input type="checkbox"/> Yes			

OL 001  
OL 002Patient Initials , ,   
Last, First Middle

Participating Group \_\_\_\_\_

Patient Hospital Number \_\_\_\_\_ Participating Group Protocol No. \_\_\_\_\_

Institution/Affiliate \_\_\_\_\_ Participating Group Patient No. \_\_\_\_\_

**Patient's Vital Status** (Mark one with an X.) OL 0037  Alive 8  Dead 9  Lost

Cause of death (if dead): (Mark one with an X.) OL 004

- 2  Due to this disease  
 1  Due to protocol treatment  
 3  Due to other cause  
 -1  Unknown

Describe cause of death: OL 005

**Disease Assessment**OL 006 Has patient had a *documented* clinical assessment for this cancer since submission of the previous follow-up form?1  No 2  Yes, specify below:

<input type="checkbox"/> / <input type="checkbox"/> / <input type="checkbox"/> / <input type="checkbox"/>	Date of last clinical assessment (Only provide date if assessment was done since submission of previous follow-up form.)
M M      D D      Y Y Y Y	OL 007      OL 008      OL 009

**Notice of Progression**

OL 010 Has the patient been diagnosed with a first local-regional recurrence/progression since submission of the last follow-up form?

1  No 2  Yes, complete the following:

<input type="checkbox"/> / <input type="checkbox"/> / <input type="checkbox"/> / <input type="checkbox"/>	Date of first local-regional progression
M M      D D      Y Y Y Y	OL 011      OL 012      OL 013

Site(s) of first local-regional progression: (Mark all that apply with an X.)

- |   |  |
|---|--|
| <input type="checkbox"/> Ipsilateral breast OL 014    | <input type="checkbox"/> Chest wall OL 018             |
| <input type="checkbox"/> Axillary nodes OL 015        | <input type="checkbox"/> Internal mammary nodes OL 019 |
| <input type="checkbox"/> Supraclavicular nodes OL 016 | <input type="checkbox"/> Axilla (extranodal) OL 020    |
| <input type="checkbox"/> Infraclavicular nodes OL 017 |  |

OL 021 How was this progression information obtained? (Mark one with an X.)

1  Documented clinical assessment 2  Patient self report only

Continue to next page

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## CALGB: 40101 FOLLOW-UP FORM

CALGB Form	C-929
CALGB Study No.	4 0 1 0 1
CALGB Patient ID	
From:	

Patient Initials ,    
Last, First Middle

Notice of Progression (Continued)

**OL022** Has the patient been diagnosed with a **first distant recurrence/progression** since submission of the last follow-up form?

**1**  No **2**  Yes, complete the following:

**OL023** / **OL024** / **OL025**  
 /  /   Date of first distant progression  
M M      D D      Y Y Y Y

Site(s) of first distant progression: **OL026**

**OL027** How was this progression information obtained? (Mark one with an X.)

**1**  Documented clinical assessment **2**  Patient self report only

Notice of New Primary (Including second primary of the contralateral breast)

**OL028** Has a new primary cancer or myelodysplastic syndrome (MDS) been diagnosed that has not been previously reported?

**1**  No **2**  Yes, complete the following: **OL031**

/  /   Date of diagnosis  
M M      D D      Y Y Y Y

**OL029** **OL030** Site(s) of New Primary: **OL032**

(If new primary site is AML/MDS, submit NCI AML/MDS form to CALGB Central Office)

Current Menopausal Status

**OL033** If premenopausal prior to chemotherapy (Mark one with an X.)

**1**  Regular menses continue/resume

/  /    Resumption date

**2**  Regular menses have stopped

/  /    Cessation date

M M      D D      Y Y Y Y

**OL034** / **35** / **36**

**OL037** / **38** / **39**

Continue on next page





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## CALGB: 40101 FOLLOW-UP FORM

Patient Initials ,    
Last, First Middle

CALGB Form	C-929			
CALGB Study No.	<input type="text"/> 4 0 1 0 1	<input type="text"/>	<input type="text"/>	<input type="text"/>
CALGB Patient ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
From:	<input type="text"/> / <input type="text"/>	<input type="text"/> / <input type="text"/>	<input type="text"/>	<input type="text"/>

Long-Term Adverse Event

Has the patient experienced (prior to diagnosis of recurrence or second primary) any severe (Grade  $\geq 3$ ), long term treatment related toxicity that has not been previously reported?

No  Yes (If Yes, indicate in the following two sections below.)

Long-Term Cardiac Toxicity

MedDRA Code	CTC Adverse Event Term	Grade (only 3, 4, 5)	Date of Onset
OL041 1 0 0 2 4 1 1 9	CARDIAC LEFT VENTRICULAR FUNCTION	43 M M 44	D D Y Y Y Y 46

Other Long-Term Toxicity

MedDRA Code	CTC Adverse Event Term	Grade (only 3, 4, 5)	Date of Onset
47 1 0 0 2 5 2 2 2	LYMPHATICS (LYMPHEDEMA)	49 S 0	5 1 / 5 2
53 1 0 0 3 5 7 5 5	PNEUMONITIS	55 5 6	5 7 / 5 8
59 1 0 0 3 7 3 8 3	PULMONARY FIBROSIS	61 6 2	6 3 / 6 4
65		67 6 8	6 9 / 7 0
71		73 7 4	7 5 / 7 6
77		79 8 0	8 1 / 8 2
83		85 8 6	8 7 / 8 8
		M M D D	Y Y Y Y

Non-Protocol Therapies

Did patient receive non-protocol cancer therapy prior to first recurrence and not previously reported? (If patient is enrolled on a **bisphosphonate** study, indicate the **agent** and **protocol number** under "Other, specify.")

OL089  No  Yes (Mark all that apply with an X.)

OL090  Non-protocol chemotherapy, specify:  OL091

OL092  Non-protocol hormonal therapy, specify:  OL093

OL094  Non-protocol biologic response modifier therapy, specify:  OL095

OL096  Non-protocol radiation therapy, specify:  OL097

OL098  Non-protocol high dose chemotherapy/autologous cell transplant

OL119  Other, specify:  OL119

Continue on next page





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## CALGB: 40101 FOLLOW-UP FORM

Patient Initials ,    
Last, First Middle

CALGB Form	C-929
CALGB Study No.	<input type="text"/> 4 0 1 0 1
CALGB Patient ID	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
From:	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>

Long-Term Therapy

OL099 Did this patient receive any tamoxifen?  No  Yes

If Yes:

OL100 Is the patient still receiving tamoxifen?  No  Yes

/  /     
 M M D D Y Y Y Y

Date tamoxifen started, if not previously reported

OL101 / 102 / 103

If patient discontinued tamoxifen since last follow-up, give date.

OL104 / 105 / 106

OL107 Did the patient receive any aromatase inhibitors?  No  Yes

If Yes:

OL108 Which aromatase inhibitor? (Mark one with an X.)

1 Anastrozole  2 Letrozole  3 Other, specify: OL109

OL110 Is the patient still receiving aromatase inhibitor?  No  Yes

/  /     
 M M D D Y Y Y Y

Date aromatase inhibitor started, if not previously reported

OL111 / 112 / 113

If patient discontinued aromatase inhibitor since last follow-up, give date.

OL114 / 115 / 116

OL120 Did the patient receive ovarian ablation/suppression?  No  Yes

OL121 Is the patient participating in an adjuvant hormonal study?  No  Yes

If Yes, specify trial: (Mark one with an X.) OL123

 1 SOFT 2 TEXT 3 Other, specify: OL123

## COMMENTS

OL117

Completed By: \_\_\_\_\_  
(Print or Type Name)Date Completed:   /   /     
 M M D D Y Y Y Y

41914





28180

## CALGB: HER-2/neu TESTING FORM

E10160

**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.

CALGB Form	C-1443
CALGB Study No.	[ ] [ ] [ ] [ ] [ ]
CALGB Patient ID	[ ] [ ] [ ] [ ]
Are data amended?	<input type="checkbox"/> Yes

Patient Initials  ,  First  Middle

Participating Group \_\_\_\_\_

Patient Hospital No. \_\_\_\_\_ Participating Group Study No. \_\_\_\_\_

Institution/Affiliate \_\_\_\_\_ Participating Group Patient ID \_\_\_\_\_

**TESTING DATA****HER-2/neu MARKER TESTS**

Immunohistochemistry (IHC) kit or test type  
(Mark all that apply with an X.)

*her2dako*  DAKO HercepTest™*her2dakoscore*  0  1+  2+  3+*her2cb11vent*  CB-11/Ventana kit*her2cb11ventscore*  0  1+  2+  3+*her2cb11oth*  CB-11 other*her2cb11othscore*  0  1+  2+  3+*her2ihcoth*  Other, specify:  *her2ihcothspecl**her2ihcothres* Results *1*  IHC not done *her2ihcnd***TESTING RESULTS**

HER-2/neu status (Mark one with an X.) (by institutional standards)

*her2stat**1*  Negative*2*  Positive

Completed by: \_\_\_\_\_

Date form completed  /  /  

Stat Use Only

28180



E10161



11906

## CALGB: TRASTUZUMAB MONITORING 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.

CALGB Form	C-1444
CALGB Study No.	_____
CALGB Patient ID	_____
Are data amended?	<input type="checkbox"/> Yes

Patient Initials  ,    
Last, First Middle

Participating Group \_\_\_\_\_

Patient Hospital No. \_\_\_\_\_ Participating Group Study No. \_\_\_\_\_

Institution/Affiliate \_\_\_\_\_ Participating Group Patient ID \_\_\_\_\_

## TRASTUZUMAB THERAPY

Did the patient receive trastuzumab?

trastind

No, specify reason:  trastnospec

1

Yes, complete questions below:

2

Date trastuzumab started  /  /   M M D D Y Y Y Y

trast start date mo/da/yr

Date trastuzumab discontinued  /  /   M M D D Y Y Y Y

trast end date mo/da/yr

trastofffrt

Reason for ending trastuzumab treatment (Mark one with an X.)

- 1  Completed per protocol criteria
- 2  Cardiac (LVEF value) adverse event
- 3  Other cardiac adverse event
- 4  Non-cardiac adverse event

5  Other, specify:  trastoff frt spec

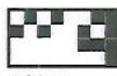
Completed by: \_\_\_\_\_  
(Last name, First name)

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

Stat Use Only  
 Page 1 of 1

11906





42247

## CALGB: CONFIRMATION OF LOST TO FOLLOW-UP FORM

E10473

**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.

CALGB Form	C-1742				
CALGB Study No.					
CALGB Patient ID					
Date Form Submitted	M	M	/	D	D
	Y	Y	/	Y	Y
Are data amended?	<input type="checkbox"/> Yes				

Patient Initials  ,    
Last, First Middle

Participating Group \_\_\_\_\_

Patient Hospital No. \_\_\_\_\_ Participating Group Study No. \_\_\_\_\_

Institution/Affiliate \_\_\_\_\_ Participating Group Patient ID \_\_\_\_\_

**CRA INSTRUCTIONS:** Submit this form to confirm that no further clinical or survival information can be obtained for this patient. (**NOTE:** Submit the entire form even if page 2 is left blank.) Routine attempts to obtain information must have been made over a two-year period, followed by an unsuccessful search of the Social Security Death Index and no response by the patient to a certified or registered international letter. After confirmed lost status is confirmed and approved by the Statistical Center, the patient will not be included in delinquency calculations. All protocol-required data obtained prior to the patient being lost to follow-up must still be submitted.

## FOR THE PATIENT WHO HAS BEEN LOST FOR FEWER THAN 2 YEARS:

Submit this form every six months. Once the two-year period without contact with the patient has passed and the criteria for lost to follow-up status have been met, the confirmation of lost status will be approved by the Statistical Center. During this two-year period, this patient will continue to appear on the delinquency list.

## CRITERIA FOR LOST TO FOLLOW-UP STATUS

1. Has it been at least 2 years since you were last able to contact the patient?  No  Yes *earliest cont*

**NOTE:** If the answer is No, your patient is not eligible to be confirmed as lost, however you should submit this form instead of the follow up form. *last cntc*

Date of last contact prior to this confirmation  /  /  *lastcntc mm/dd/yy*

**NOTE:** This date should correspond to the patient survival date on the last delinquent data report. If this date is more recent, send any required data for the interim period.

2. Please indicate when steps were taken to contact the patient. Both Social Security Death Index and Certified/Registered Letter methods must be attempted without success after 2 years without contact before a patient can be declared lost.

Researched Social Security Death Index and found no information for this patient; specify most recent date:

/  /  *ssdth*

Sent certified or registered international letter to last known address; specify most recent date sent: (Mark one with an X.)

/  /  *regltst*

Letter returned unclaimed or marked addressee unknown

No response 1 month after confirmed receipt of letter

Required for patients who have been lost for 2 years:

I verify that the above information is correct and that all attempts to contact this patient have failed. *verified date*

Date  /  /

(Signature of Principal Investigator)

Form completed by: *Completed by*  
(Last Name, First Name)

Email *email*



E10473



42247

## CALGB: CONFIRMATION OF LOST TO FOLLOW-UP FORM

Patient Initials  ,  First  Middle  
Last, First Middle

CALGB Form

C-1742

CALGB Study No.

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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CALGB Patient ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Date Form Submitted

<input type="text"/> M	<input type="text"/> M	/	<input type="text"/> D	<input type="text"/> D	/	<input type="text"/> Y	<input type="text"/> Y	<input type="text"/> Y	<input type="text"/> Y
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## PATIENT NO LONGER LOST TO FOLLOW-UP

If data are now available to change this patient's survival or clinical status (from "lost to follow-up status"), check the "amended" box on the top of page 1 and complete the following:

New information for this patient is now available for: (Mark one with an X.)

Survinfo

- 1  Survival status only. This patient is no longer lost to survival follow-up.  
 2  Clinical and survival status. This patient is no longer lost. Both survival and clinical follow-up are now available.  
 (Send new clinical data to the CALGB Statistical Center on protocol-required data submission forms.)

Survival status based on new data (Mark one with an X.)

vitstat

- 1  Alive

- a  Dead (If patient is dead, also submit C-113 Notification of Death Form or study specific form that collects death information.)

Date patient was last known alive, or date of death

<input type="text"/> M	<input type="text"/> M	/	<input type="text"/> D	<input type="text"/> D	/	<input type="text"/> Y	<input type="text"/> Y	<input type="text"/> Y	<input type="text"/> Y
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survdate

NOTE: For data submission instructions for patients no longer lost to follow-up see CALGB Policies and Procedures Chapter 8.

## CALGB STATISTICAL CENTER USE ONLY

Patient accepted as Confirmed Lost to Follow-Up? (That is, has it been at least two years since the patient has been contacted?)  No  Yes

1 a

confirmlost

If No, specify reason:  specify

Data Coordinator's name  dcname

Review	<input type="text"/> M	<input type="text"/> M	/	<input type="text"/> D	<input type="text"/> D	/	<input type="text"/> Y	<input type="text"/> Y	<input type="text"/> Y	<input type="text"/> Y
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42247

dcreviewdate

