

IND Study # _____

Physical Exam

Pg of

Visit

Subject ID: # # *

Day

Month

Year

Subject Initials:

Check here if assessment was not performed

	WNL	ABN	√ if ND	Comment if Abnormal
General	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Chest Wall	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Pulmonary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Psych	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Completed by: _____

Date:
Day

Month

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IRB # _____

Visit

Subject ID: # *

Day

Month

Year

Subject Initials:

Check here if tumor assessment was not performed

Target Lesion Measurement

Tumor laterality (check one) Left Right

Site

Horizontal
 . x

Vertical
 .

Product (cm)
 .

√ if Not Applicable

. x .

.

Product of all target lesions .

Site codes: UOQ=Upper Outer Quadrant, LOQ=Lower Outer Quadrant, UIQ=Upper Inner Quadrant, LIQ=Lower Inner Quadrant, CEN=Centrally Located

Regional Nodes/Axilla

Does the subject have involvement of the regional nodes/axilla? Yes – complete below No

Site

Palpable?

Non-palpable?

Measurable? →

Horizontal
 . x

Vertical
 .

Product (cm)
 .

Product of all target lesions .

Site codes: RAX=Right Axilla, LAX=Left Axilla, RSC=Right Supraclavicular, LSC=Left Supraclavicular

Completed by: _____

On:
Day

Month

Year

Visit Early Termination

Subject ID: I N D # # U A * Discontinued Date Day Month Year

Subject Initials:

Check here if vital signs were not performed

Date of this exam: Day Month Year

Height: . cm In

Weight: . kg lbs

Blood Pressure: /

Pulse: / minute

Temperature: . °C °F

Respirations: / minute

Performance Status: 0 1 2

Check here if Vital Signs were not performed

Post Treatment Time: :
H H M M

Blood pressure: /

Pulse: / minute

Temperature: . °C °F

Respirations: / minute

Completed by: _____

On: Day Month Year

Visit Early Termination

Subject ID: I N D # # U A * [][]

Discontinued Date [][] Day [][][] Month [][][][] Year

Subject Initials: [][][]

Specimen Collection Date: [][] Day [][][] Month [][][][][] Year

WBC (K/ μ L)	[][] . [][]	<input type="checkbox"/>	^{√ if ND}	Neutrophils (%)	[][] . []	<input type="checkbox"/>	^{√ if ND}
Absolute Neutrophil Count	[][][][][][]	<input type="checkbox"/>		Total bilirubin (mg/dL)	[][] . []	<input type="checkbox"/>	
Platelets (K/ μ L)	[][][][]	<input type="checkbox"/>		LDH (IU/L)	[][][][][]	<input type="checkbox"/>	
RBC (M/ μ L)	[][] . [][]	<input type="checkbox"/>		Alk. phos. (IU/L)	[][][][][]	<input type="checkbox"/>	
Hemoglobin (g/dL)	[][][] . []	<input type="checkbox"/>		SGOT/AST (IU/L)	[][][]	<input type="checkbox"/>	
BUN (mg/dL)	[][][]	<input type="checkbox"/>		SGPT/ALT (IU/L)	[][][]	<input type="checkbox"/>	
Creatinine (mg/dL)	[][][] . []	<input type="checkbox"/>		GGT (IU/L)	[][][]	<input type="checkbox"/>	
Sodium (mEq/L)	[][][]	<input type="checkbox"/>		PT (sec)	[][] . []	<input type="checkbox"/>	
Potassium (mEq/L)	[] . []	<input type="checkbox"/>		PTT (sec)	[][] . []	<input type="checkbox"/>	
CO ₂ (mEq/L)	[][][]	<input type="checkbox"/>		INR	[][][] . []	<input type="checkbox"/>	
Chloride (mEq/L)	[][][]	<input type="checkbox"/>					

Assay Collection

_____ [][] Day [][][] Month [][][][][] Year [][][] H [][][] H : [][][] M [][][] M []

_____ [][] Day [][][] Month [][][][][] Year [][][][] H [][][] H : [][][] M [][][] M []

Completed by: _____

On: [][] Day [][][] Month [][][][][] Year

IND Study # _____

Urine Analysis

Visit

Subject ID: *

Discontinued Date
Day

Month

Year

Subject Initials:

Specimen Collection Date:
Day

Month

Year

Check here if tumor assessment was not performed

UPC

√ if
ND

Protein (mg/dL)

Creatinine (mg/dL) .

Protein / Creatinine ratio .

Completed by: _____

On:
Day

Month

Year

IRB # _____

Visit Early Termination

Subject ID: I N D # # U A *

Discontinued Date
Day

Month

Year

Subject Initials:

Specific reason for discontinuing this subject:

- Grade 4 hypertension or hemorrhage, symptomatic Grade 4 venous thromboembolic event, nephrotic syndrome
- Any grade arterial thromboembolic event
- Gastrointestinal perforation
- Wound dehiscence requiring medical or surgical intervention
- Inability of subject to comply with study requirements
- Determination by the investigator that it is no longer safe for the subject to continue therapy
- Voluntary discontinuation by the subject who is at any time free to discontinue her participation in the study, without prejudice to further treatment
- Incorrect enrollment of the subject
- Death
- Subject lost to follow-up
- Objective progression of disease

Note: All deaths that occur within the trial period or within 30 days after administration of the last dose of trial drug must be reported to Genentech primarily for the purposes of serious adverse event (SAE) reporting; however, deaths due unequivocally to progression are not SAEs.

Completed by: _____

On:
Day

Month

Year

Principal Investigator Signature: _____

Date: _____