Sponsor

Protocol Number

Д

240 Cambridge Science Park
Cambridge, England CB4 OWD
+ 44 (0) 1223 420-305

ABX-EGF 20020408

CASE REPORT FORMS

AMENDMENT 2.0

An Open-label, Randomized, Phase 3 Clinical Trial of ABX-EGF Plus Best Supportive Care Versus Best Supportive Care in Subjects with Metastatic Colorectal Cancer

INSTRUCTIONS FOR COMPLETING CASE REPORT FORMS

- 1. The Case Report Forms must be completed in **ENGLISH**
- 2. Type or print using only **BLACK BALLPOINT INK**
- 3. Corrections should be made **ONLY** as follows:
 - a. Draw a single line through the incorrect entry
 - b. Enter correct data
 - c. Initial and date the correction
 - d. DO NOT ERASE, WRITE OVER, OR USE CORRECTION FLUID OR CORRECTION TAPE.
- 4. Do not write in shaded areas
- 5. Complete date boxes as per the following example:

Day	Month	Year				
3 1	JAN	2,0,0,2				

6. Add comments to the General Comments CRF or "Specify" fields only

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	

AMENDMENT 2.0

SUBJECT ELIGIBILITY CRITERIA WORKSHEET **Inclusion Criteria**

If any of the below questions are answered **NO**, then the subject **SHOULD NOT ENTER** the

stu		
Code 101	Yes Pathologic diagnosis of colorectal adenocarcinoma (diagnostic tissue obtained by tissue biopsy) □	No
101	ratifologic diagnosis of colorectal adenocalcinoma (diagnostic tissue obtained by tissue biopsy) 🗖	J
102	Metastatic colorectal carcinoma	
103	ECOG performance status of 0, 1, or 2	
104	Subject must have documented evidence of disease progression during, or following treatment with a fluoropyrimidine, irinotecan, and oxaliplatin for metastatic colorectal cancer (as defined in Section 3.1. Radiographic documentation of disease progression during or within 6 months following the most recent regimen is required. The time interval between documented tumor progression and study entry must not exceed 6 months. Before randomization the investigator or designee must review all relevant clinical documents to ensure the subject has developed progressive disease or relapsed while onor after prior chemotherapy (as defined in Section 3.1.1). In addition, the investigator or designee will review existing radiological images to confirm disease progression on the most recent chemotherapy regimen. Radiographic documentation for disease progression is only required for the most recent chemotherapy regimen. The prior chemotherapy case report form, the prior radiotherapy case report form and these radiological images will be sent post-randomization to an IERC who will conduct a second review to confirm the subject met this inclusion criterion	ŕ
105	Unidimensionally measurable disease must be greater than or equal to 20mm using conventional techniques (CT scan or MRI) or spiral CT scan	
106	If history of other primary cancer subject will be eligible only if she or he has: curatively resected non-melanomatous skin cancer, curatively treated cervical carcinoma in situ, other primary solid tumor curatively treated with no known active disease present and no treatment administered for the last 5 years	
107	Man or woman 18 years of age or older	
108	Paraffin-embedded tumor tissue [primary or metastasis] available for immunohistochemistry studies of EGFr expression (archived tissue is acceptable)	
109	Tumor expressing EGFr by immunohistochemistry (membrane staining must be positive in ≥ 1% of evaluated tumor cells; eligibility will be based on staining and evaluation will be conducted at a central laboratory)	
110	Hematologic function, as follows: ANC \geq 1.5 x 10 9 cells/L and platelet count \geq 100 x 10 9 /L	
111	Renal function, as follows: Creatinine < 2.0mg/dL	
112	Hepatic function, as follows: AST \leq 3 x ULN (\leq 5 x ULN if liver metastases), ALT \leq 3 x ULN (\leq 5 x ULN if liver metastases) and bilirubin \leq 2 ULN	
113	Subject may have received prior radiotherapy (target lesions must not have been irradiated) \Box	
114	Subject must be competent to comprehend, sign and date a written IEC/IRB approved informed consent form (see Section 12.1 of study protocol)	
115	Subject must have received at least 2 but no more than 3 prior chemotherapy regimins for metastatic colorectal cancer	

Α	Site No.	Subject ID No.	Subject Initials
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AMENDMENT 2.0

SUBJECT ELIGIBILITY CRITERIA WORKSHEET Exclusion Criteria

If ar	ny of the below questions are answered YES , then the subject SHOULD NOT EN	ITER th	ne
	dy e no.	Yes	No
201	Symptomatic brain metastases requiring treatment		
202	Myocardial infarction within 1 year before randomization		
203	Unresolved complication that in the opinion of the investigator does not qualify the subject for randomization in the study		
204	History of any chronic medical or psychiatric condition or laboratory abnormality that in the opinio of the investigator may increase the risks associated with study participation or study drug administration or may interfere with the interpretation of study results		
205	Use of systemic chemotherapy or radiotherapy within 30 days before randomization		
206	Prior EGFr targeting agents		
207	Prior anti-tumor therapies including prior experimental agents or approved anti-tumor small molecu and biologics with short serum half-life (less than 1 week) within 30 days before randomization, or prior experimental or approved proteins/antibodies with longer serum half-life (eg, Avastin) within 3 months before randomization		
208	Chemotherapy other than fluoropyrimidines (or raltitrexed), irinotecan, or oxaliplatin for colorectal carcinoma in accordance with the regimens specified (leucovorin and levamisole are not conside as chemotherapy in this exclusion criterion)	red	
209	Subject who, in the absence of disease progression, discontinued therapy with fluoropyrimidine, irinotecan and/or oxaliplatin because of toxicity	🗅	
210	Subject allergic to the ingredients of the study medication or to Staphylococcus protein A		
211	Any kind of disorder that compromises the ability of the subject to give written informed consent and/or comply with study procedures	🗅	
212	Female subject of childbearing potential not consenting to use adequate contraceptive precautions during the course of the study and for 6 months after the last ABX-EGF infusion		
213	Subject who is pregnant or breast feeding		
214	Subject known to be human immunodeficiency virus positive		
215	Subject unwilling or unable to comply with study requirements		
216	Subject with a history of interstitial pneumonitis or pulmonary fibrosis or evidence of interstitial pneumonitis or pulmonary fibrosis on baseline chest CT-scan	🗅	
217	Male subject of reproductive potential not consenting to use adequate contraceptive precautions during the course of the study and for 1 months after the last ABX-EGF infusion		

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SCREENING

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		EM	OGF	RAF	H	CS	3							

		Ethnic	Group / Race (enter one code)		Date of Birth			
Sex	Code	Specify if "88 Other"	ETHNIC GROUP / RACE CO 01 White or Caucasian	DES: 06 American Indian or	Day	Month	Year	
₀□ M ₁□ F			 02 Black or African American 03 Hispanic or Latino 04 Asian (eg Chinese, Bangladeshi, Indian, Pakistani) 05 Japanese 	Alaska Native Native Hawaiian or Other Pacific Islander				

INFORMED CONSENT

Date Day	e Informed Co	onsent Signed Year	
ı	1 1		

Protocol Amendment Number
2

RANDOMIZATION

Day	Date of Rand Month	lomization Year	Randomization Number	Treatment group ①
① TREA 01 02	TMENT GROUP ABX-EGF plus Best Supportion	s Best Supportive Care		

ELIGIBILITY CRITERIA

Did subject meet all	I eligibility criteria? f No, please specify criteria number(s) from <i>Eligibility Worksheet</i> :
Enter "999" if subject	ct met Eligibility Criteria but did not enroll.
	Comments:
	Comments:
	Comments:

For Amgen Use	Only
Tick when	
data checked.	

Α	1///	Site No.		Sı	ubject	ID No				Subj	ect Initials
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Screening

Code	Diagnosis	₀No ✓	₁Yes	If yes, specify etiology	Continuing	√ Resolved
08	Diabetes					
02	Hypertension (HTN)					
02	Cerebrovascular Accident (CVA)					
02	Transient Ischemic Attack (TIA)					
02	Peripheral Vascular Disease PVD)					
02	Myocardial Infarction (MI)					
02	Coronary Artery Disease (CAD)					
02	Congestive Heart Failure (CHF)					
02	Cardiac Arrythmia					
10	Thromboembolic Event					
03	Pulmonary Disease					
10	Blood Dyscrasia					
11	Seizure					
13	Autoimmune Disease					
02 C 03 R		05 ⊢ 07 R	lepati Renal	major diagnosis? ₀ No ₁ Yes - If yes, list specific diagnosis c / Biliary 09 Musculoskeletal 13 Immunologic 10 Hematologic / Lymphatic 88 Other rine / Metabolic 11 Neurologic / Psychiatric	belo	w.
Code (as listed above			Li	Diagnosis ist one entry per line.	Continuing	√ Resolved
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Screening

PRIOR SURGERY for COLORECTAL CANCER

Were there any prior surgeries for colorectal cancer? ₀ No ₁ Yes - If yes, specify below.

	SURGERY (including biops	y)			
Pro- cedure Code	Description or Type	Intent Code		Date	•
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① DDOC	EDURE CODES: © INTENT CODES:				
01 B	iopsy 88 Other (Specify 01 Curative		known ner <i>(speci</i>	fy in General (Comments)
	Specify PROCEDURE "88 Other"				
			· · ·		

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AM	AMENDMENT 2.0	PRI	OR	뿡	MOT	里	RAP		First	Lin	e of	PRIOR CHEMOTHERAPY - First Line of Treatment	ent	-	SCR
				Please	Please record prior chemotherapy for metastatic cancer	prior	chemot	herap	y for n	netasta	tic can	cer		ı	
		Regimen Name:	Name:												
		-							_			-			
Line #	Agent Name		Dose	Freq	Dose	Date	Date First Administered	ninister		ate Last /	Date Last Administered	ered		Name of Hospital	a
		2	(9	© ©	Day	Month	Year	Day	/ Month		Year			
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G O2 O2	© FREQUENCY CODES: CI Continuous infusion Q Q2WK Every 2 weeks Q	Q12H Every Q4WK Every	Every 12 hours Every 4 weeks		Q3WK Every 3 weeks QMO Once a month	/ 3 week a montl		OT O	nce a da ther (spe	Once a day Other (specify below)	0	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	ODES: dose on due to t	88	Missed dose (specify below) Other (specify below)
Line #	Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	otherapy Do d Dose"	se Line	-	Specify Reason for Chemotherapy Dose Change "88 Other"	Chemo "88 Oth	therapy Do er"	se Line		Specify Fre	, douence	Specify Frequency "OT Other"	Line #	Specify Frequei	Specify Frequency "OT Other"

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				lease	Please record prior chemotherapy for metastatic cancer	prior (hemo	thera	py for	r meta	static	canc	er		ı			
	_	Regimen Name:	ame:															
		_	\mid						ŀ				_					_
Line #	Agent Name	Dose (mg/m²)		Freq	Dose Status	Date	Date First Administered	Iminist	ered	Date L	Date Last Administered	ministe	red		Name of Hospital	lospital		
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4					_	_		_			_	_						
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⊝ၓၓ	© FREQUENCY CODES: CI Continuous infusion G Q2WK Every 2 weeks C	Q12H Every 12 hours Q4WK Every 4 weeks	hours reeks	aa	Q3WK Every 3 v	3 weeks a month		96	Once a Other (Once a day Other (sp <i>ecify below)</i>	celow)	© DO 03	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	DES: dose n due to to:	88 03	Aissed dose Other (<i>specif</i>)	Missed dose (specify below) Other (specify below)	
Line #	e Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	notherapy Dose	Line #	Specify F	Specify Reason for Chemotherapy Dose Change "88 Other"	Chemot 88 Othe	herapy [\vdash	Line #	Speci	fy Frequ	ency "(Specify Frequency "OT Other"	Line #	Specify F	Specify Frequency "OT Other"	OT Other"	$\overline{}$

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AB	ABX-EGF 20020408	~						<u> </u>	/////	_	_		_	_		_
AM	AMENDMENT 2.0	PRIO	S C	果	MOT	HER	AP	-	Seco	l puc	ine (PRIOR CHEMOTHERAPY - Second Line of Treatment	ıtmen			SCR
				lease/	record	prior c	hemot	herap	/ for n	netasta	Please record prior chemotherapy for metastatic cancer	er.				
		Regimen Name:	ame:													
			-						-							
Line #	Agent Name	Dose		Freq	Dose	Date F	Date First Administered	ninister		ate Last /	Date Last Administered	ed	_	Name of Hospital	pital	
:		(Bur)	<u> </u>)	Status ©	Day	Month	Year	Day	/ Month	Year					
_					_	_	_	_	_	_	_					
2					_	_		_		_	_					
3					_			_		_	_	_				
4					_			<u> </u>		_	_					
2					_	_		_ _		_	_					
9					_	_		_		_	_					
7					_	_		_ _		_	_					
∞					_			_ _		_	_	_				
တ					_	_		_		_	_					
CI Q2\C	© FREQUENCY CODES: CI Continuous infusion Q Q2WK Every 2 weeks Q	Q12H Every 12 hours Q4WK Every 4 weeks	hours	88	Q3WK Every 3 QMO Once a	3 weeks a month		00 00 00	nce a da ther (spe	Once a day Other (specify below)	@	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	ODES: dose n due to toxi	88 03	ed dose (specify b	Missed dose (specify below) Other (specify below)
Line #	Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	otherapy Dose	Line #	Specify F	Specify Reason for Chemotherapy Dose Change "88 Other"	Chemoth '88 Othe	erapy Do	se Line		Specify Fre	Specify Frequency "OT Other"	T Other"	Line #	Specify Frequency "OT Other"	uency "OT	Other"

⋖									Site	Site No.			Subject ID No.	D No.	Subject Initials
AB.	ABX-EGF 20020408	~						<u>////</u>		_	_	<u></u>	_		_
AMI	AMENDMENT 2.0	PRIC	JR (黑	MOT	HER	APY	S -	∋cor	nd Li	ne o	PRIOR CHEMOTHERAPY - Second Line of Treatment	tme	nt	SCR
	•			lease/	Please record prior chemotherapy for metastatic cancer	prior c	hemoth	erapy	for me	tastatic	cance			ı	
		Regimen Name:	ame:												
			-												
Line #	Agent Name	Dose (mg/m²)		Freq	Dose Status	Date Fi	Date First Administered	nistered	Date	Date Last Administered	ministere			Name of Hospital	=
7					8	Day	Month	Year	Day	Month	Year				
						_			_	_	_				
7					_	_	_	_	_	_	_	_			
က					_		_	_	_	_	_	_			
4					_			_ _ _	_	_ _	_ _	_			
2					_			_ _ _	_	_	_				
9					_		_	_ _ _	_	_ _	_				
7					_		_			_	_	_			
∞					_		_	_ _ _		_ _	_	_			
တ					_		_			_	_	_			
GI Q2V	© FREQUENCY CODES: CI Continuous infusion Q Q2WK Every 2 weeks Q	Q12H Every 12 hours Q4WK Every 4 weeks	hours weeks	. 8g	Q3WK Every 3 v	a month	9P		Once a day Other (specify below)	' below)	© DOSE 01 F	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	DES: tose I due to to	88 83	Missed dose (specify below) Other (specify below)
Line #	Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	otherapy Dose d Dose"	Line #	Specify R	Specify Reason for Chemotherapy Dose Change "88 Other"	ason for Chemother Change "88 Other"	erapy Dos	e Line	Spe	Specify Frequency "OT Other"	ency "OT	Other"	Line #	Specify Frequency "OT Other"	cy "OT Other"

△								/	S /	Site No.			Subject ID No.	ID No.	Subject Initials
AB	ABX-EGF 20020408	~						<u>////</u>		_	_		_	_	_
AM	AMENDMENT 2.0	PRIC	R (뿡	MOT	HER	AP	7	hirc-	Lin	e of	PRIOR CHEMOTHERAPY - Third Line of Treatment	nent		SCR
				Please	Please record prior chemotherapy for metastatic cancer	prior c	hemot	herapy	for m	etastati	ic can	cer		[
		Regimen Name:	ame:												
Did	Did subject receive third line of treatment	of treatment	°	No T	☐ Yes - If	If yes, s	yes, specify below.	elow.				-		1	
Line #	Agent Name	Dose (ma/m²)	3.6	Freq	Dose	Date F	Date First Administered	ninistere		Date Last Administered	dminist	ered		Name of Hospital	
:		(Sec.)	ì)	Status ©	Day	Month	Year	Day	Month	۶	Year			
_					_	_	_	_	_	_	_	_			
7					_	_	_	_	_	_	_				
က					_		_	_	_	_	_	_			
4					_			_ _ _	_	_	_				
5					_	_	_	_ _ _	_	_	_	_			
9					_		_	_ _ _	_	_	_				
_										_	_				
∞					_	_				_	_				
6						_				_	_				
© 120	© FREQUENCY CODES: CI Continuous infusion Q Q2WK Every 2 weeks Q	Q12H Every 12 hours Q4WK Every 4 weeks	hours		Q3WK Ever	Every 3 weeks Once a month		00 00 00 00	nce a day her <i>(spec</i>	Once a day Other (specify below)	© DO 01	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	ODES: dose on due to t	88 03	Missed dose (specify below) Other (specify below)
Line #	Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	otherapy Dose d Dose"	Line #	\vdash	Specify Reason for Chemotherapy Dose Change "88 Other"	ason for Chemothe Change "88 Other"	erapy Do	se Line		oecify Frec	, kouenk	Specify Frequency "OT Other"	Line #	Specify Frequency "OT Other"	"OT Other"

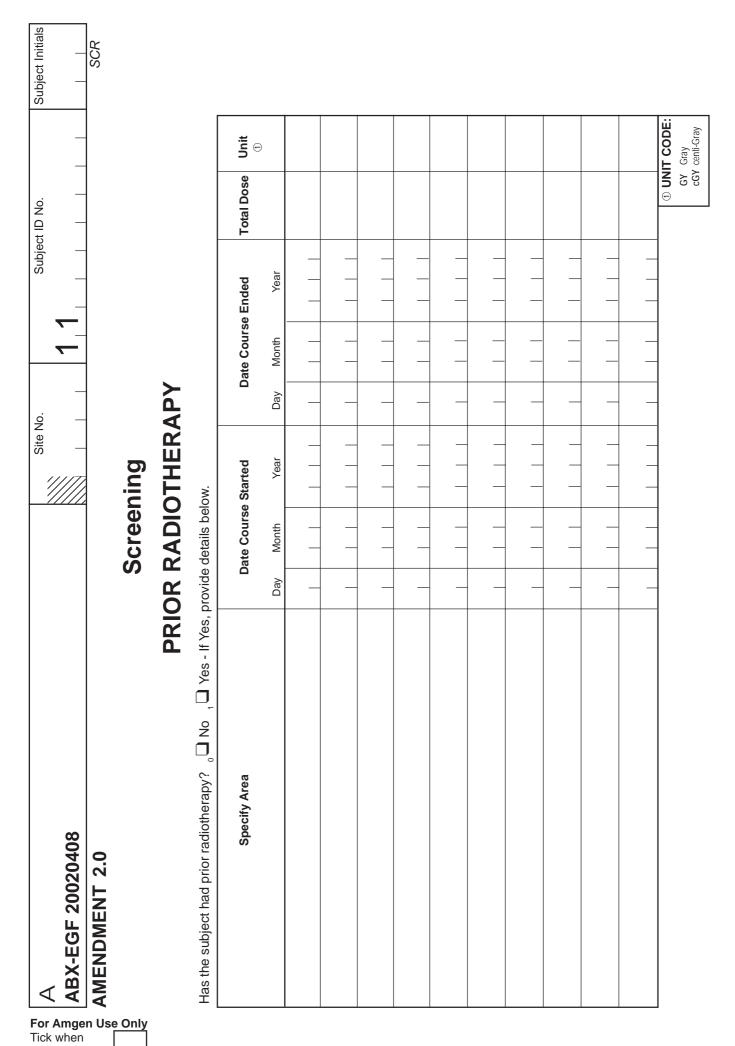
◁										Site No.	No.			Subject ID No.	No.	Subject Initials	SIE
AB	ABX-EGF 20020408	œ									_			_	_	_	
Z	AMENDMENT 2.0	PRIO	8	l 봇	MOT	単	AP	<u>}</u>	Th	<u>ב</u>	Line	of	PRIOR CHEMOTHERAPY - Third Line of Treatment	nent	-	SCR]
			F	Please	Please record prior chemotherapy for metastatic cancer	prior (shema	othera	apy fo	r meta	astatic	canc	er				
		Regimen Name:	ıme:														
		_	-						Ī								Γ
Line #	Agent Name	Dose (mg/m²)		Freq ⊝	Dose Status	Date	Date First Administered	dminist	ered	Date L	Date Last Administered	ministe	red		Name of Hospital	=	
					0	Day	Month	۶	Year	Day	Month	Year	T.				\Box
_					_	_	_	_	_	_	_						
2					_	_	_	_	_	_	_	_					
က					_	_	_	_	_		_	_					
4					_	_		_	_		_	_					
5					_	_	_ _	_	_	_	_	_	_				
9					_	_	_ _	_	_	_	_	_	_				
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∞					_	_	_	_	_	_	_	_					
တ					_	_	_	_	_	_	_	_					
⊝ၓၓ	© FREQUENCY CODES: CI Continuous infusion G Q2WK Every 2 weeks C	Q12H Every 12 hours Q4WK Every 4 weeks	hours reeks	aa	Q3WK Every 3 v	3 weeks a month		8P	Once a	Once a day Other (sp <i>ecify below)</i>	below)	© DO 03	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	DES: dose n due to toxi	88	Missed dose (specify below) Other (specify below)	
Line #	e Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	otherapy Dose	Line #	Specify F	Specify Reason for Chemotherapy Dose Change "88 Other"	Chemot 88 Othe	herapy		Line #	Spec	ify Frequ	ency "(Specify Frequency "OT Other"	Line #	Specify Frequency "OT Other"	cy "OT Other"	

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0	· · ·		SCR

Screening RESPONSE TO PRIOR CHEMOTHERAPY REGIMENS

Line of Treat-	Р	Date o	f Scan emotherapy	Best Response		e of B				wa	est Resp s CR or it confir	PR	Date o	of Diseas	e Progression
ment ①	Day	Month	Year		Day	Mor	th		Year		0 No	₁ Yes	Day	Month	Year
							1								
									1 1						
							1		1 1						
									1 1						
							1		1 1						
									1 1						
							1								
① LIN 01 02 03	1st I 2nd	TREATME Line of treatn Line of Treat Line of treatr	tment	•	2 BE CR PR SD PD	Co Pa St	mple artial able	ete Res Respo Diseas					'		

For Amgen Use	e Only
Tick when	
data checked.	



data checked.

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			SCR

Screening

PRIOR ADJUVANT CHEMOTHERAPY

Has the subject had prior adjuvant chemotherapy? ₀ ☐ No ₁ ☐ Yes - If yes, specify below.

Line #	Drug Name	Regimen Name		Date F Adminis			e Last nistered
			Day	Month	Year	Day Mont	h Year
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

PRIOR ANTI-TUMOR THERAPY

Has the subject had prior anti-tumor therapy? ₀ ☐ No ₁ ☐ Yes - If yes, specify below.

Line #	Line of Treat- ment	Drug Name		Date F Adminis			Date L Adminis	
	1		Day	Month	Year	Day	Month	Year
1								
2								
3								
4								
5								
① LIN 01		EATMENT CODES: of treatment 02 2nd Line of Treatment 03	3rd Lin	e of treatm	nent 04	Adjuva	ant	

For Amgen Use	e Only
Tick when	
data checked	1 1

A	1///	Site No.		_		Subjec	t ID No).			Subj	ect Initials
ABX-EGF 20020408		1 1	1	լ1 լ	1	ı	ı	1	I	I		
AMENDMENT 2.0												SCR

Screening PHYSICAL EXAMINATION

	Weight		
Day	Month	Year	l kg ₂□ lb
			1 - 1.9 2 - 1.5
	1 1		

D o	oes	the subject have any abnormal clinical findings below.	ings relating to the followi	ing required sites?	₀ No ₁ Yes - If yes,
uc	01 l	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04 Abdomen	07 Lymph nodes	10 Breast / Chest
		Cardiovascular	08 Neurological	11 Rectal	
					88 Other
		Indicate if a re	equired assessment was i	not done.	
Co	de				
	as		Describe findings		
	ted		List one entry per line.		
abo	ve)				
	l				
	ı				
	I				
	I				
	l				
	I				

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			SCR

Screening VITAL SIGNS

Pulse should be resting

	Date)	Blood Pressure	Pulse	Respiration	Temperature
Day	Month	Year	(mmHg)	(beats/minute)	(breaths/minute)	₁ □ °C ₂ □ °F
			1			

ECOG PERFORMANCE STATUS

Γ	Date of Assessment						ECOG Performance	
	Day	Mont	h		Y	ear		Status ①
L								
1	ECOG	PERFORI	MANC	E ST	ATUS	COI	DES:	
0		active, able				re-dis	sease	
1 2	and able to carry out work of a light or sedentary nature, ie, light housework or office work.							

PREGNANCY TEST

Is subject of child bearing potential? $_{_0}\square$ No $_{_1}\square$ Yes If Yes, specify below

	Date of Sa	Time of Sample		
Day	Month	Year	(24 hour clock)	
			:	
Spec	imen Type	₁₀ Urin	e ₃□ Serum	
Result		₀□ Nega	ative ₁ Positive	

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0	· · ·		SCR

Screening ELECTROCARDIOGRAM

Date F Day Month	erformed Year	Procedure Code ①	Body Site Code 2	PROCEDURE CO 13 Electrocardiog		
		1,3	0,9	BODY SITE CODE 09 Heart	ES:	
	Heart Rate (cycles/minute)	PR (msecs)	QRS (msecs)	QT (msecs)	QT _c (msecs)	
Result © RESULT CODES: On Normal On Abnormal, not clinically significant On Abnormal, clinically significant						
Result: If clinically significant abnormality, specify						

CANCER DIAGNOSIS

 ① PRIMARY TUMOR DIAGNOSIS CODE	Date o	f Colorectal Ca	ancer Diagnosis Year	Date I	Metastatic Dise	ease Diagnosed Year
1251 Colon cancer 1252 Rectal cancer						

For Amgen Use	e Only
Tick when	
data checked.	

А	////	Site No.				S	ubject	ID N	0.			Sub	ject Initials
ABX-EGF 20020408			I	1	1	1	ı	ı	ı	ı	ı		
AMENDMENT 2.0										·			SCR

Screening TUMOR EVALUATION - TARGET LESIONS

Date of Procedure													
Day Month Year													

Lesion Note: Always maintain the same order of lesion	Lesion Site Code ① Describe specific location		Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable Dimensions (mm)
numbers	U U			Diniensions (mm)
01				
02				
03				
04				
05				
06				
07				
08				
09				
10				
		Sum (of Target	

						Lesions
① LESION SITE CO 00 Lymph nodes 10 Pulmonary 20 Liver 30 Bone		ES: O Chest O Central nervous system Head Neck			Skin Other (specify in subsite above)	 ② METHOD OF ASSESSMENT: 03 Conventional Computed Tomography (CT) 04 Magnetic Resonance Imaging (MRI) 23 Spiral Computed Tomography (CT) 88 Other (specify below)
Line #			Specify if "88 O	the	" Method of Asses	ssment

For Amgen Use	e Only
Tick when	
data checked	

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0	· · ·		SCR

Screening

TUMOR EVALUATION - NON-TARGET LESIONS

Lesion Note: Always maintain the same order							Body Site Code	De	Subsite escribe specific	Method of Assessment	Measurable Lesions (mm) Must be unidimensionally measurable.			
of lesion numbers	Day	Mon	th		Ye	ar	1				2	Dimensions (mm)		
11														
12														
13														
14														
15														
16						I								
										Sum of N	on-Target Lesions			
1 BODY 00 Ly 10 Pt 20 Liv 30 Bo	mph n ılmona /er	odes	ES:			50 55	Chest Central ner Head Neck	vous system	75	Abdomen	al 86 88			
② METH 03 C 04 N		tional (DES: raphy (CT)	23 88	Spiral Compute Other (specify	ed Tomography ((below)	CT)			
Line #								Specify if "	'88 Other" Me	thod of Asses	ssment			

For Amgen Use	e Only
Tick when	
data checked.	



WEEKS 1 - 8

Α	1111	Site No.			Subjec	t ID No).			Sub	ect Initials
ABX-EGF 20020408			1 1	l [ı	ı	ı	ı		
AMENDMENT 2.0					·						W1

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Month	
IVIOLIUI	Year
	, , ,
	1 1

	I would like to ask you a few questions a have made to a doctor or	bout any additional visits (nan an outpatient facility in the l		hat you may								
1.	Emergency Room Visits Number of emergency room visits											
2.	Therapy Visits Number of therapy (mental health) visits											
3.	Outpatient visits to specialists (to valid addition to your routine care, such											
	Pain Management Specialist: Number of outpatient physician visits											
	Radiologist: Number of outpatient physician visits											
	Radiation Oncology: Number of outpatient physician visits											
4.	Outpatient Procedures Any outpatient surgical procedures		Yes	No								
	If yes, please describe:											
	Blood transfusions number of times											
	Other procedures?		Yes	No								
	If yes, please describe:											
5.	Caregiving In a typical (24 hour) day, how many hours of your illness:	s of support do you receive	from each of the followi	ng <i>because</i>								
	Т	rained Medical Person	Others									
	Paid caregiver	hours	hou	ırs								
	Unpaid caregiver	hours	hou	ırs								
6.	Nursing Home / Hospice Days Number of days spent in a nursing home											
For Ar	Amgen Use Only											

Tick when data checked.

\wedge	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W1

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

	Date of Exan	nination
Day	Month	Year
	1 1	

	the subject have any abnormal	l clinical fin	dings rela	ating to the	follow	ving requ	ired sites?	ONO 1	Yes - If yes,
descri	ibe findings below. Head, Ears, Eyes, Nose, Throat (HEE	ENT) / Nock	0.4	Abdomen		07	Lymph nodes	10	Breast / Chest
	Cardiovascular	INI)/INECK		Musculoske	letal		Neurological		Rectal
	Pulmonary			Skin	iciai		Genitourinary		Other
		Indicate if a		_	nt was				G
Code			7						
(as			De	scribe find	linas				
listed				one entry p					
above)				p					
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Ι,									
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ECOG PERFORMANCE STATUS

			Date (of Asse	ssme	nt			ECOG Performance		
Da	у		Mon	th			Year		Status ①		
1	ECOG										
0	Fully active, able to carry on all pre-disease performance without restriction										
1	Resti	ricted able to	in phy carry	sically st out worl	renuou k of a li	ght o			•		
2	Ambi	ulatory	and	capable	of all se	elf-cai			o carry ng hours.		
3			-	limited se	elf-care	, conf	ined to	bed or o	chair		
4				oled. Car o bed or		rry ou	t any se	elf-care.			
5	Dead	-									

Δ	//// 8	Site No.		Su	ıbject	ID No.				Subj	ect Ir	nitials
ABX-EGF 20020408			1 ′	ı	I	ı	1	ı	I		l	I
AMENDMENT 2.0											١	W3

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

	Date of Asse	essment
Day	Month	Year
I .		

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

			Toxicity that app				•	y if Skin l	Foxicity is inges"	0	1 Nail chan 2 Erythema	
										0		ne/acneiform) squamation (non-acneiform)
		e of Skin list all that a		•	Specif	fy if Typ	oe of Sk	in Lesion	is "88 Other"	00 01	None (IN LESION CODES: 07 Dry flaking 08 Desquamation (sloughing) 09 Comedones
										04	Macular	10 Cysts 88 Other (specify)
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Locationst all tha	on ④ at apply)		Specify if Loc	ation is	"88 Other"	4 LOCATION CODES:09 Face10 Trunk
	05 ≤ 50% BSA											11 Extremities 12 Total body 88 Other (specify)
1. If prior radiation, is area of radiation port involved?												es
2. W	2. Was crusting present?											
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes			
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes			
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications	
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1	
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1	
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year			
											J	

А	////	Site No.				S	Subject	ID No			Subj	ect Initials
ABX-EGF 20020408		1 1	I	1	1	1	1	ı	1	ı		
AMENDMENT 2.0												W3

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

	Date of Asse	essment
Day	Month	Year

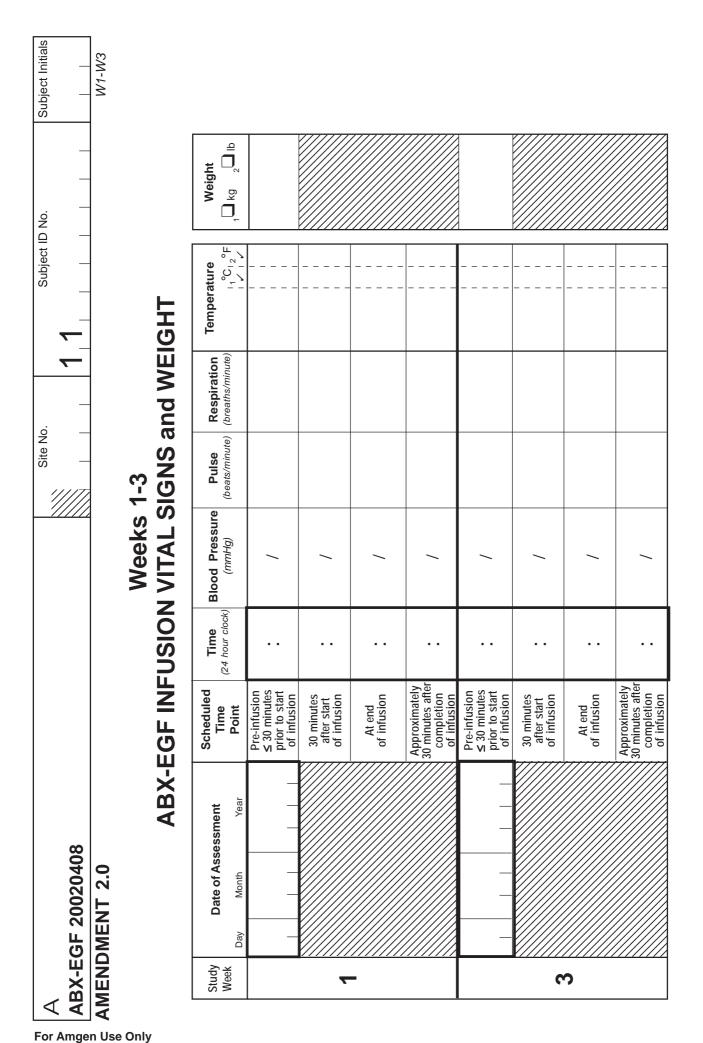
	₀ No.✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?			
Was Honey Yellow Crusting present?		 	
Was Erythema present?		! 	
Was Paronychia present?		1	
Were Fissures present? (Photo-based scale does not apply)		I I	
Does the following dermatological toxicity interfere with activitie	s of daily	/ living?	
Paronychia: ₀ No ₁ Yes ₆₆ N	/A		
Fissures: 0 No 1 Yes 66 N	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio			
 PHOTO-BASED CODING SCALE CODES: A B C D SUBJECT PERCEPTION CODES: Not at all 03 Modera A little 04 Very mu 		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

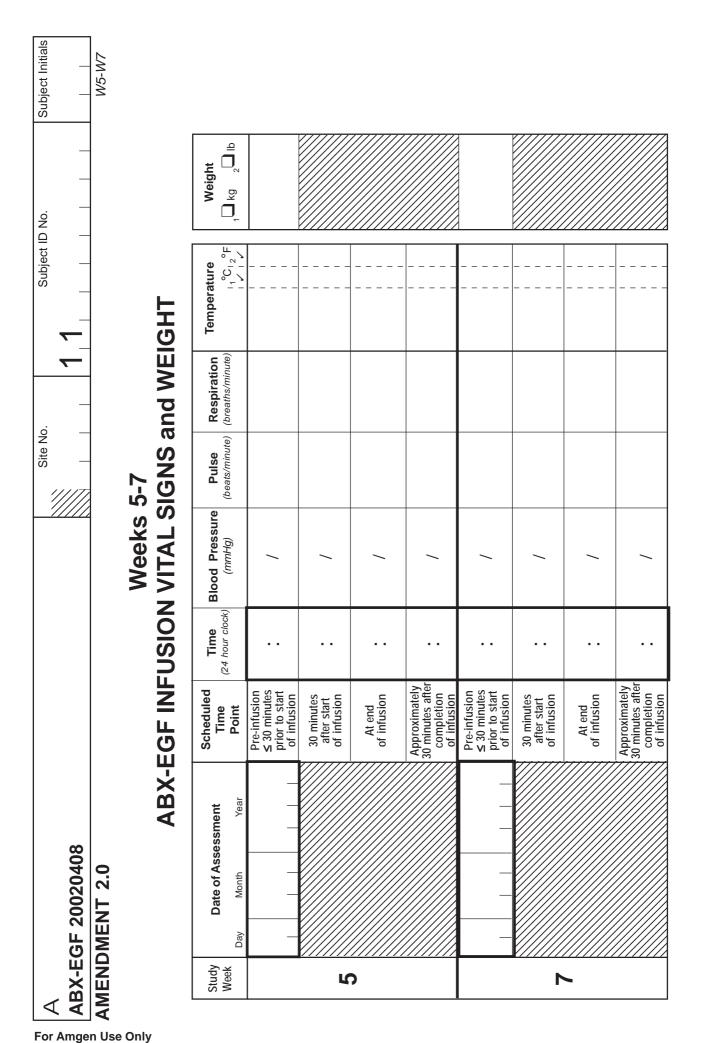
Treatment Phase VITAL SIGNS FOR ABX-EGF AND BSC

*Vital signs readings (every 2 weeks; within 30 minutes before the ABX-EGF infusion, approximately 30 minutes after the start of ABX-EGF infusion, upon completion of the ABX-EGF infusion, and approximately 30 minutes after completion of the ABX-EGF infusion, allowing a +/- 10 minute time window): blood pressure, resting pulse, respiration rate, and temperature (every 2 weeks).

*Weight (every 2 weeks, before the ABX-EGF infusion on ABX-EGF arm; every 4 weeks on BSC arm)



Tick when data checked.



Tick when data checked.

⋖								Site No.	No.	Subject ID No.	Subject Initials
AB	ABX-EGF 20020408	020408						- ////	_	-	_
AME	AMENDMENT 2.0	Г 2.0							-	-	W1-W7
					We	Weeks 1-7	1-7				
	Sub	INV jects receiving	ESTIG	ATION of receive In	VAL PF	SODL Il Produc	JCT,	ADMIN istration, ple	INVESTIGATIONAL PRODUCT ADMINISTRATION Subjects receiving BSC will not receive Investigational Product Administration, please score through the page	ION ugh the page	
Study Week	Da Month	Date	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume (mL)	Reason for in Dose Change	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code		If Reason for Dose Change is "88 Other", please specify	
1	-						_	_ _			
က	_	_ 					_				
2							_				
7							_				
lf subj	ect did not comp	If subject did not complete investigational product administration, provide any	al product adn	ninistration, p	rovide any add	additional relevant information:	vant infor	mation:			
DOS ⊕	① DOSE CHANGE CODES:	ij	② "04 Per p	② "04 Per protocol" DOSE CHANGE	E CHANGE CC	CODES:					
20 0 88 8 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9	Adverse event Noncompliance Dose administration error Per protocol Other (Specify above)	e)	100 Wei 118 Syn 0r ft	100 Weight change 118 Symptomatic skin or felt to be intoler 120 Skin infection requ	Weight change Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject Skin infection requiring systemic IV antibiotic or IV antifungal treatment	requiring r	narcotics, &	systemic steroi 'ungal treatmer		 121 Need for surgical debridement 122 Any skin-related serious adverse event 200 Dose reinstated 201 Dose increase (after reinstatement) 	

data checked.

For Amgen Use Only Tick when

A	////	Site No.		Subjec	t ID No).			Subje	ect Init	ials
ABX-EGF 20020408			1,1	1 1	I	1	ı	ı			
AMENDMENT 2.0									<i>V</i>	<u>V1-W</u>	7

Weeks 1-7 INVESTIGATIONAL PRODUCT LOT NUMBER

Study Week	ABX-EGF Package Lot Number	ABX-EGF Package Lot Number
1		
3		
5		
7		

Δ	Site No.			Su	bject	ID No.				Sub	ject Initials
ABX-EGF 20020408			1,1,	ı	ı	ı	1	ı	ı		1 1
AMENDMENT 2.0											W5

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment									
Day	Month	Year							
L	1 1	, , ,							

	I would like to ask you a few question have made to a doct	ons about any additional visits (r or or an outpatient facility in the		nat you may
1.	Emergency Room Visits Number of emergency room visits			
2.	Therapy Visits Number of therapy (mental health) v	isits		
3.	Outpatient visits to specialists addition to your routine care, s			
	Pain Management Specialist: Number of outpatient physician visits	3		
	Radiologist: Number of outpatient physician visits	3		
	Radiation Oncology: Number of outpatient physician visits	3		
4.	Outpatient Procedures Any outpatient surgical procedures		Yes	No
	If yes, please describe:			
	Blood transfusions number of times			
	Other procedures?		Yes	No
	If yes, please describe:			
5.	Caregiving In a typical (24 hour) day, how many of your illness:	hours of support do you receive	from each of the following	ng <i>because</i>
		Trained Medical Person	Others	
	Paid caregiver	hours	hou	irs
	Unpaid caregiver	hours	hou	rs
6.	Nursing Home / Hospice Days Number of days spent in a nursing he	ome		

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Tick when data checked.

Δ	////	Site No.		S	Subject	ID No				Subj	ect Initials	3
ABX-EGF 20020408		1 1 1	1,1,	I	1	ı	I	I	1		l I	
AMENDMENT 2.0											W5	

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination									
Day	Month	Year							

	the subject have any abnormal clinical find	ings relating to the followi	ing required sites?	$_{0}$ No $_{1}$ Yes - If yes,						
01 l 02 l	be findings below. Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Pulmonary	04 Abdomen05 Musculoskeletal06 Skin		11 Rectal						
	Indicate if a required assessment was not done.									
Code (as listed above)		Describe findings List one entry per line.								

ECOG PERFORMANCE STATUS

		ECOG Performance								
Day	у	M	Month Year					Status ①		
① I	① ECOG PERFORMANCE STATUS CODES:									
0	Fully active, able to carry on all pre-disease performance without restriction									
1	Rest	ricted in p able to ca	hysically stry out work work or offi	renuou k of a li	ght or					
2	Amb	, ulatory ar	d capable	of all se	elf-car					
3	out any work activities. Up and about > 50% of waking hours. 3 Capable of only limited self-care, confined to bed or chair > 50% of waking hours									
4	 50% or waking nours Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair 									
5	Dead	i l								

For Amgen Use Only
Tick when

Tick when data checked.

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	l l
AMENDMENT 2.0			W5

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment									
Day	Month	Year							
I .									

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

	Skin Toxicity (list all that apply)						•	y if Skin l	Foxicity is inges"	0	SKIN TOXICITY CODES: 1 Nail changes (specify) 2 Erythema 3 Pratitus libeling						
										0		ne/acneiform) squamation (non-acneiform)					
		e of Skin list all that a		•	Specif	ecify if Type of Skin Lesion is "88 Other"				00 01	 2 TYPE OF SKIN LESION CODE 00 None 07 Dry flaking 01 Pustular 08 Desquamation 02 Vesicular 09 Comedones 						
											Macular	O Cysts Other (specify)					
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Locationst all tha	on ④ at apply)		Specify if Loc	ation is	 4 LOCATION CODES:09 Face10 Trunk						
	05 ≤ 50% BSA 11 Extremities 12 Total body 88 Other (specify)																
1. If	1. If prior radiation, is area of radiation port involved? 66 Not applicable 0 No 1 Yes																
2. W	/as c	rusting p	resent	?					No ₁☐ Yes								
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes								
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes								
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications						
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1						
7 14	(Record on Concomitant Medications CRF)																
/ · · · ·	7. Was dose held, changed or discontinued for skin toxicity? Date																
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year								
											J						

For Amgen Use Only
Tick when
data checked.

Δ	1111	Site No.				Su	bject	ID No				Sub	ject I	nitials
ABX-EGF 20020408			1	1	I	1	ı	ı	1	ı	ſ		I	I
AMENDMENT 2.0														W5

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment									
Day	Month	Year							

	₀No✓		* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		' 	
Was Honey Yellow Crusting present?		 	
Was Erythema present?		1	
Was Paronychia present?		1	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activities	s of daily	/ living?	
Paronychia: ₀ ☐ No ₁ ☐ Yes 66 ☐ N	/A		
Fissures: 0 No 1 Yes 66 No	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio	n		
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Moderate 02 A little 04 Very mu		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site No.			Subjec	t ID No.				Subj	ject Ir	nitials
ABX-EGF 20020408		1 1		1	I	ſ	ı	1		l	
AMENDMENT 2.0	_	•								V	N7

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment										
Day	Month	Year								
l .										

Did the subject have skin toxicity? $_{_{0}}\square$ No $_{_{1}}\square$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

TOXIO	ty / 13	0000	111011	io page	, and re	COIG SKIII (OXIOIL	y 0117 (L	- 0111.						
				Skin Toxicity St all that apply) The standard of the standard			① SKIN TOXICITY 01 Nail change 02 Erythema 03 Pruritus/itch	es (specify)							
											04 Rash (acne				
			Skin L that a	esions	5	Speci	fy if Ty	pe of Sk	kin Lesion	is "88 Other"	01 Pustular 08	LESION CODES: Dry flaking Desquamation (sloughing) Comedones			
			I								04 Macular 10	Cysts Other (specify)			
Total % Affec		04	> 50	% BSA (% BSA	ODES:	(lis	Locati st all th	ion ④ at apply)		Specify if Locat	ion is "88 Other"	 LOCATION CODES:09 Face10 Trunk			
		05	≤ 50	% BSA				ı				11 Extremities 12 Total body 88 Other (specify)			
1. If prior radiation, is area of radiation port involved?															
2. V	Vas c	rusti	ng pi	resent	?					No ₁☐ Yes					
3. S	ince	the I	ast a	ssessr	nent, di	d the rash	cause	e pain?		No ₁☐ Yes					
4. S	ince	the l	ast a	ssessr	nent, di	d the rash	cause	e itchin	g? ₀□	No ₁☐ Yes					
5. S	5. Since the last assessment, did the rash require treatment with narcotics? © No 1 Yes (Record on Concomitant Medications CRF)														
6. S	6. Since the last assessment, did the rash require treatment with systemic steroids? $_{_0}$ \square No $_{_4}$ \square Yes														
									(Re	cord on Concomit	ant Medications C	CRF)			
7. V	Vas d	lose	held,	chang	jed or d	iscontinue	d for s	skin tox	cicity?						
ı	۱ ــ	No 1	☐ Ye	es - If y	es, pro	vide date.	Da	ау	Month D	Year Year					

For Amgen Use Only
Tick when

data checked.

A	////	Site No.				Subj	ect II	O No.				Subj	ect I	nitials
ABX-EGF 20020408			1	1	I			l	ſ	I	l		I	1
AMENDMENT 2.0														W7

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment										
Day Month Year										

		₀ No√	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present	?		1	
Was Honey Yellow Crusting pres	sent?		 	
Was Erythema present?			 	
Was Paronychia present?			1	
Were Fissures present? (Photo	p-based scale does not apply)		 	
Does the following dermatologic	cal toxicity interfere with activitie	s of daily	/ living?	
Paronychi	a: ₀ No ₁ Yes ₆₆ N	/A		
Fissures:	₀ No ₁ Yes 66 N	/A		
How bothered do you perceive t by the dermatologic toxicities ?	the subject to be Subject Perception			
① PHOTO-BASED CODING SCALE CODES: A B C D	 SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera 02 A little 04 Very m 		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Δ	////	Site No.			S	ubject	ID N	0.			Subj	ect Initials
ABX-EGF 20020408		1 1	1	1,	ı	ı	ı	ı	ı	ı		
AMENDMENT 2.0				·	·							W8

Week 8 TUMOR EVALUATION - TARGET LESIONS

Date of Procedure									
Day Month Year									
1 1									

Lesion Note: Always maintain the same order of lesion	Lesion Site Code	Subsite Describe specific location	Method of Assessment	measurable
numbers	1			Dimensions (mm)
01				
02				
03			-	
04				
05				
06				
07				
08				
09				
10				
		Sum	of Target	

		Lesions
D LESION SITE CODES: 00 Lymph nodes 10 Pulmonary 20 Liver 30 Bone 55 Head 56 Neck	60 Gastrointestinal 70 Abdomen 75 Pelvic Site 86 Skin 88 Other (specify in subsite above) 85 Spleen	METHOD OF ASSESSMENT: X-Ray Conventional Computed Tomography (CT) Magnetic Resonance Imaging (MRI) Spiral Computed Tomography (CT) Other (specify below)

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use	e Only
Tick when	
data checked.	

Α	////	Site No.				S	ubject	ID N	0.		Subj	ect Initials
ABX-EGF 20020408		1 1	I	1	1,	1	ı	ı	ı	ı		
AMENDMENT 2.0												W8

TUMOR EVALUATION - NON-TARGET LESIONS

Lesion Note: Always maintain the same order of lesion						Body Site Code	Site Subsi			Method of Assessment	Les	ew ions	Measurable Lesions (mm) Must be unidimensionally measurable.	
numbers	Day	Mor	nth		Ye	ar	1				2	₀No ✓	₁Yes	Dimensions (mm)
11													 	
12													 	
13													 	
14													 	
15													 	
16													 	
										Sum	of Non-T Le	arç sio		
1 BODY 00 Ly 10 Pt 20 Liv 30 Bo	mph n ulmona ver	odes	ES:			50 55	Chest Central ner Head Neck	vous system	n 70 75		Site		86 88	Skin Other (specify in subsite above)
② METH 01 × 03 ((-Ray						DES:	23	Magnetic Reso Spiral Compute Other (specify	ed Tomog	naging (MRI) graphy (CT)			
Line #								Specify if '	"88 Other" Me	thod of	Assessmer	nt		

For Amgen Use	e Only
Tick when	
data checked.	

Δ	////	Site No.			Subject ID No.								Sub	ject In	itials
ABX-EGF 20020408		1 1	ı	1	1		1	ı	ı	ı	ı	1			I
AMENDMENT 2.0														V	<i>N</i> 8

Week 8 OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study		Date)		Tumor Response
Week	Day	Month		Year	Code ①
8					
① TUMOF	RESPON	SE CODE:			
PD F	Complete Re Progressive I Partial Respo	Disease	SD UE	Stable Disease Unable to evalua	ate

v.2.0 30Jun04camb

	Site No	Subject ID	No Subject Initials		
	////	1	- Casjeet IIIIIII		
ABX-EGF 20020408					
AMENDMENT 2.0			W1-W8		
ABX-EGF 20020408 AMENDMENT 2.0 Weeks 1-8 PROCEDURES CYTOLOGY Was any cytology performed? Indiagram of the procedure of the					
Was any cytology performed?	CYTOI No ₁□ Yes - If yes, spe	LOGY cify below			
	Procedure Malignant		Specify if Body Site ① PROCEDURE		
			31 Thoracentesis		
	_		88 Other (Specify,		
Equivocal findings:			·		
	SURG	ICAL			
Were any surgical procedures perfo					
Date of Procedure					
Day Month Year	0000	"88 Other"			
	2 2				
Findings:					
			 -		
	BIOF	PSY			
Was biopsy performed? ₀☐ No ₁□					
Date of Procedure			16 13		
Day Month Year		oo Other			
	116		Ι ο Βιορεί		
] 0				
Findings:					
	ENDOC	NOODY			
Was endoscopy performed? ₀☐ N	o ₁☐ Yes - If yes, spec	cify below.			
Date of Procedure	Procedure Body S	pecify if Procedure Speci	fy if Body Site ⑤ PROCEDURE		
Day Month Year	⑤ Site (Code is "88 Other" is	"88 Other" CODE:		
			33 Colonoscopy 34 Sigmoidoscopy		
			88 Other (Specify)		
Findings:					
BODY SITE 01 Abdomen 05 Ches CODES: 02 Brain 06 Eye	t 09 Heart 10 Kidne		17 Total body 88 Other (Specify above)		
	rointestinal tract 11 Liver	15 Retroperitoneum	19 Extremity(ies) 23 Neck		
For Amgen Use Only					

Tick when data checked.

WEEKS 9 - 16

A	1///	Site No.	Subject ID No.								ect Initials
ABX-EGF 20020408			$ 1_{ }1_{ }$	1	I	ı	ı	ı	1		
AMENDMENT 2.0				·					·		W9

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment											
Day	Month	Year									

I would like to ask yo have r			additional visits tient facility in th			rial) that y	ou m
Emergency Room Number of emergency							
Therapy Visits Number of therapy (m	ental health) vis	sits					
Outpatient visits to addition to your ro							
Pain Management Number of outpatient	Specialist:	·	·				
Radiologist: Number of outpatient	physician visits						
Radiation Oncolog Number of outpatient	jy: physician visits						
Outpatient Proced Any outpatient surgica					Yes		lo
If yes, please describ	e:						
Blood transfusions nu	mber of times						
Other procedures?					Yes		lo
If yes, please describe	e:						
Caregiving In a typical (24 hour) of your illness:	lay, how many h	nours of supp	ort do you recei	ve from ea	ch of the fo	ollowing <i>b</i>	ecaus
		Trained M	edical Person		Others		
Paid ca	aregiver		hours			hours	
Unpaid	l caregiver		hours			hours	
Nursing Home / Ho Number of days spent		me					

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Tick when	
data checked.	

Δ	1111	Site No.		Subje	ct ID No	ο.			Sub	ject Initials
ABX-EGF 20020408			1,1,	1 1	1	ı	ı	1		1 1
AMENDMENT 2.0										W9

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination								
Day	Month	Year						

	the subject have any abnormal clinical to	indings relating to the follow	ving required sites?	$_{0}$ No $_{1}$ Yes - If yes,
01	be findings below. Head, Ears, Eyes, Nose, Throat (HEENT) / Necl	04 Abdomen	07 Lymph nodes	10 Breast / Chest
	Cardiovascular	05 Musculoskeletal		
	Pulmonary	06 Skin	09 Genitourinary	
		f a required assessment was		
Code		•		
(as		Describe findings		
listed		List one entry per line.		
above)				
l 1				
1 1				
l .				
l .				
١.				
Ι.,				

ECOG PERFORMANCE STATUS

		ECOG Performance						
Da	у	M	onth			Year		Status ①
0 1 2 3	Fully performed Restrand a ie, light Amburout a Capar > 50% Comp	active, abormance wricted in pable to caught housevalutory anny work able of only of wakingletely dispersion.	sabled. Car	on all priction trenuou k of a li ce work of all sepand a lelf-care	ore-di is acti ght or c elf-car about , conf	sease ivity, bu r seden re, but to > 50% ined to	tary natous unable to of wakin bed or o	ure, o carry og hours.
5	Dead	•	d to bed or	cnair				

For Amgen Use Only
Tick when
data checked.

Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	1 1
AMENDMENT 2.0			W9

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment									
Day	Month	Year							
I .									

Did the subject have skin toxicity? $_{_{0}}\square$ No $_{_{1}}\square$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

TOXIO	ty / 13	0000	111011	io page	, and re	COIG SKIII (OXIOIL	y 0117 (L	- 0111.								
				Toxicity that app	•		Specify if Skin Toxicity is "01 Nail Changes"				SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching						
											04 Rash (acne						
			Skin L that a	esions	5	Speci	fy if Ty	pe of Sk	kin Lesion	is "88 Other"	00 None 07 01 Pustular 08	LESION CODES: Dry flaking Desquamation (sloughing) Comedones					
			I								04 Macular 10	Cysts Other (specify)					
Total % Affec		04	> 50	% BSA (% BSA	ODES:	(lis	Location Specify if Location (list all that apply)				ion is "88 Other"	 LOCATION CODES:09 Face10 Trunk					
		05	≤ 50	% BSA				ı				11 Extremities 12 Total body 88 Other (specify)					
1. If	prio	rad	iatior	ı, is are	ea of rac	diation port	tinvol	ved?	66	Not applicable	₀□ No ₁□ Yes						
2. V	Vas c	rusti	ng pi	resent	?					No ₁☐ Yes							
3. S	ince	the I	ast a	ssessr	nent, di	d the rash	cause	e pain?		No ₁☐ Yes							
4. S	ince	the l	ast a	ssessr	nent, di	d the rash	cause	e itchin	g? ₀□	No ₁☐ Yes							
5. S	ince	the l	ast a	ssessr	nent, di	d the rash	requi	re treat		h narcotics? cord on Concomit	₀☐ No ₁☐ tant Medications C						
6. S	6. Since the last assessment, did the rash require treatment with systemic steroids? $_{_0}$ No $_{_1}$ Yes																
									(Re	cord on Concomit	ant Medications C	CRF)					
7. V	Vas d	lose	held,	chang	jed or d	iscontinue	d for s	skin tox	cicity?								
ı	۱ ــ	No 1	☐ Ye	es - If y	es, pro	vide date.	Da	ау	Month D	Year Year							

For Amgen Use Only
Tick when

data checked.

Δ	Site No	э.		Sub	ect ID N	lo.		Subj	ect Initia	ıls
ABX-EGF 20020408		, <i>,</i>	1 ₁ 1 ₁	1	l I	1	ı			
AMENDMENT 2.0									W9	

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment									
Day	Month	Year							

	₀ No.✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		 	
Was Honey Yellow Crusting present?		 	
Was Erythema present?		 	
Was Paronychia present?		 	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activitie	s of daily	living?	
Paronychia: ₀ ☐ No ₁ ☐ Yes 66 ☐ N	/A		
Fissures: ₀ ☐ No ₁ ☐ Yes 66 ☐ N	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio	n		
① PHOTO-BASED CODING SCALE CODES: CODES: A B C D ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Moderation O4 Very multiple		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Δ	////	Site No.			S	ubject	ID No				Sub	ject Ir	nitials
ABX-EGF 20020408			1,1	1	1	ı	I	1	ı	ı		I	
AMENDMENT 2.0												И	/11

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

	Date of Asse	essment
Day	Month	Year

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

			Toxicity that app				•	y if Skin l	Foxicity is inges"	0	1 Nail chan 2 Erythema	
										0		ne/acneiform) squamation (non-acneiform)
		e of Skin list all that a		•	Specif	fy if Typ	oe of Sk	in Lesion	is "88 Other"	00 01	None (IN LESION CODES: 07 Dry flaking 08 Desquamation (sloughing) 09 Comedones
										04	Macular	10 Cysts 88 Other (specify)
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Locationst all tha	on ④ at apply)		Specify if Loc	ation is	"88 Other"	 4 LOCATION CODES:09 Face10 Trunk
		05 ≤ 50	J% BSA				ı					11 Extremities 12 Total body 88 Other (specify)
1. If	prio	radiatio	n, is are	a of rac	diation port	involv	ved?	66	Not applicabl	e ₀ 🖵 I	No ₁☐ Ye	es
2. W	/as c	rusting p	resent	?					No ₁☐ Yes			
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes			
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes			
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications	
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1	
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1	
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year			
											J	

For Amgen Use Only
Tick when
data checked.

Δ	1111	Site No.		Su	bject	ID No.				Subj	ect Ir	nitials
ABX-EGF 20020408		1 1 1	1,1,	1		ı	ı	I	1		I	
AMENDMENT 2.0											И	/11

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

	Date of Asse	essment
Day	Month	Year

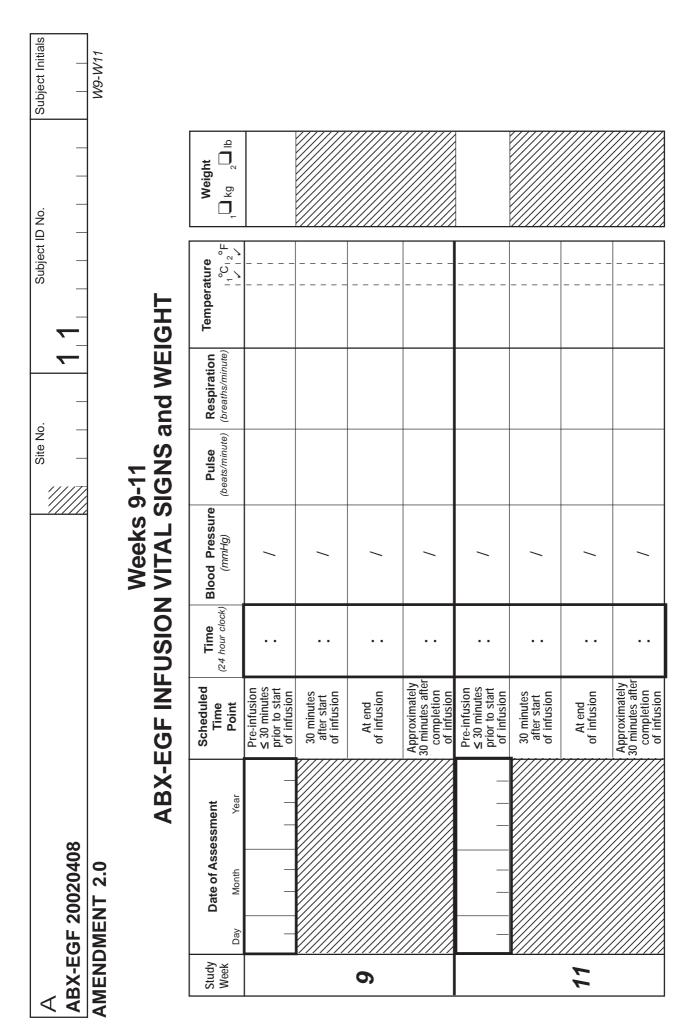
		_o No ✓	I 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?	,			
Was Honey Yellow Crusting pres	ent?		1	
Was Erythema present?			1	
Was Paronychia present?			1	
Were Fissures present? (Photo-	based scale does not app	oly)	 	
Does the following dermatological	al toxicity interfere with act	ivities of daily	/ living?	
Paronychia	ı: ₀☐ No ₁☐ Yes ₆₆	☐ N/A		
Fissures:	₀ No ₁ Yes 66	☐ N/A		
How bothered do you perceive the by the dermatologic toxicities?	Perc	oject eption ②		
① PHOTO-BASED CODING SCALE CODES:	SUBJECT PERCEPTION COI01 Not at all03 M	DES: oderate	05 Intoler	able
A B C D	02 A little 04 V	ery much		

For Amgen Use	e Only
Tick when	
data checked.	

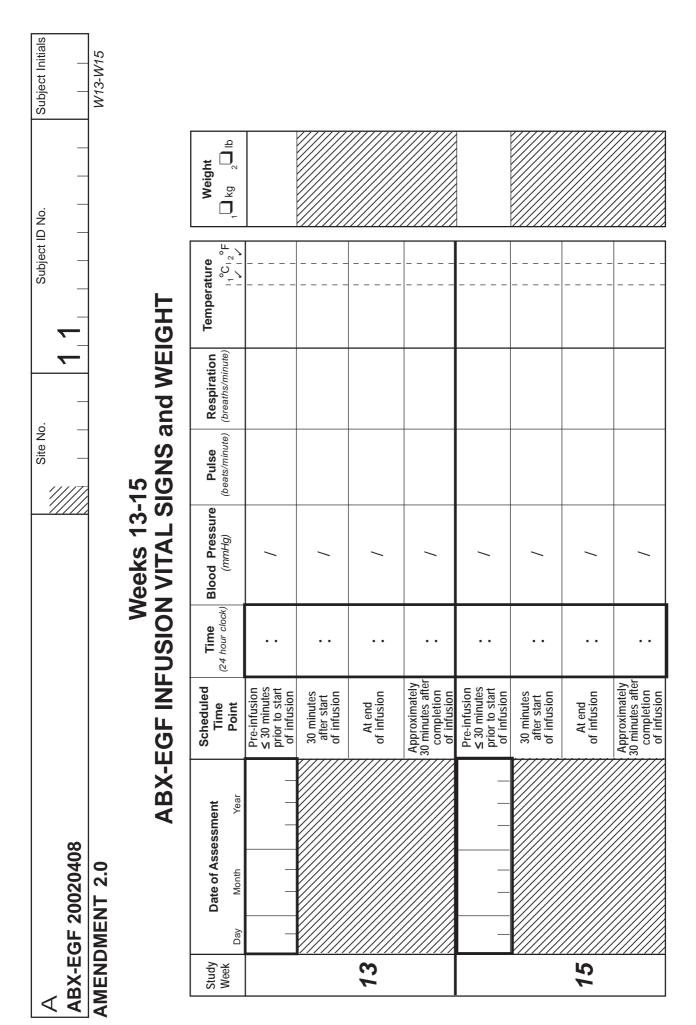
Treatment Phase VITAL SIGNS FOR ABX-EGF AND BSC

*Vital signs readings (every 2 weeks; within 30 minutes before the ABX-EGF infusion, approximately 30 minutes after the start of ABX-EGF infusion, upon completion of the ABX-EGF infusion, and approximately 30 minutes after completion of the ABX-EGF infusion, allowing a +/- 10 minute time window): blood pressure, resting pulse, respiration rate, and temperature (every 2 weeks).

*Weight (every 2 weeks, before the ABX-EGF infusion on ABX-EGF arm; every 4 weeks on BSC arm)



For Amgen Use Only Tick when data checked.



For Amgen Use Only
Tick when
data checked.

4										Site No.		Subject ID No.	Subject Initials
AB	X-EG	3F 200	ABX-EGF 20020408							_	<u></u>	- - -	_
Z	ENDI	AMENDMENT 2.0	2.0							-	-	-	W9-W15
						We	eeks 9-15	9-15					
		Subje	IN ects receivin	VESTIG 19 BSC will no	SATIOI ot receive II	NAL PF	SODI 1 Produc	JCT,	ADM istration,	INVESTIGATIONAL PRODUCT ADMINISTRATION Seiving BSC will not receive Investigational Product Administration, please score through the	INVESTIGATIONAL PRODUCT ADMINISTRATION Subjects receiving BSC will not receive Investigational Product Administration, please score through the page	ab.	
tudy		Date	a)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered	Total Volume	Reason for in Dose Change	If "04 Per protocol" is indicated for "Reason for Dose Change",)T	If Reason "88 Ott	If Reason for Dose Change is "88 Other", please specify	
	Day	Month	Year			(mg)	(ML)	' ⊖	indicate codo	a.			
6	_		_					_	_				
11	_	_	- - -					_	_				
3	_							_	_				
15	_							_	-				
igns :	ject did ı	not comple	te investigatio	f subject did not complete investigational product administration, provide any	ministration, p	rovide any add	itional rele	additional relevant information:	mation:				
000	SECHAN	DOSE CHANGE CODES:		② "04 Per p	② "04 Per protocol" DOSE CHANGE		CODES:						
2000 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 9 9 9 9	Adverse event Noncompliance Dose administra Per protocol Other (Specify a	Adverse event Noncompliance Dose administration error Per protocol Other (Specify above)	arror)	100 We 118 Syr or fr 120 Ski	Weight change Symptomatic skin or felt to be intoler Skin infection req	Weight change Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject Skin infection requiring systemic IV antibiotic or IV antifungal treatment	requiring IV antibioti	narcotics, t	systemic s fungal trea	teroids, tment	121 Need fo 122 Any skir 200 Dose rei 201 Dose in	Need for surgical debridement Any skin-related serious adverse event Dose reinstated Dose increase (<i>after reinstatement</i>)	

data checked.

Α	Site N	lo.		S	Subject	ID No				Subje	ct Ini	tials
ABX-EGF 20020408			1 1	I	ı	I	ı	ı	I		1	
AMENDMENT 2.0										W:	9-W1	15

Weeks 9-15 INVESTIGATIONAL PRODUCT LOT NUMBER

Study Week	ABX-EGF Package Lot Number	ABX-EGF Package Lot Number
9		
11		
13		
15		

Δ	////	Site No.				S	ubject	ID N	0.			Sub	ject Initials
ABX-EGF 20020408		1 1	ı	1	1,	ı	ı	ı	1	ı	ı		
AMENDMENT 2.0					·	·							W12

Week 12 TUMOR EVALUATION - TARGET LESIONS

	Date of Pro	cedure
Day	Month	Year

Lesion Note: Always maintain the same order of lesion	Lesion Site Describe specific location Code ①		Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable Dimensions (mm)			
numbers 01							
02							
03							
04							
05							
06							
07							
08							
09							
10							
		Sum	of Target Lesions				

1 LESIO 00 Lymp 10 Pulm 20 Liver 30 Bone	onary 50	Chest 6 Central nervous 7 system 7	0 Abd	lomen vic Site		Skin Other (specify in subsite above)	 @ METHOD OF ASSESSMENT: 01 X-Ray 03 Conventional Computed Tomography (CT) 04 Magnetic Resonance Imaging (MRI) 23 Spiral Computed Tomography (CT) 88 Other (specify below) 				
Line #	Line # Specify if "88 Other" Method of Assessment										

Line #	Specify if "88 Other" Method of Assessment									

For Amgen Use Only									
Tick when									
data checked.									

А	////	Site No.				S	Subject	t ID N	0.		Sub	ject Initials
ABX-EGF 20020408			ı	1	1,	1		ı	ſ	ı		
AMENDMENT 2.0												W12

		10	JIV	IU	אי			_	_				ites of dis			SIONS
Lesion Note: Always maintain the same order		Date	of Pr	roce	dur	e		Body Site Code	Des	Subsite Describe specific location			Method of Assessment	1	ew sions	Measurable Lesions (mm) Must be unidimensionally measurable.
of lesion numbers	Day	Мс	nth		Υ	′ear		1				2	₀No ✓	₁Yes ✓	Dimensions (mm)	
11																
12															 	
13															 	
14															 	
15															 	
16			I				l								 	
			·	·								Sum	of Non-l	Tarç sio	_	
10 BOD' 00 Ly 10 P 20 Li 30 B	mph r ulmona ver	nodes	DES): 		5(5)	0 (5 H	Chest Central ner Head Neck	ous systen	n	60 70 75 85	Abdom Pelvic	Site		86 88	
01	 METHOD OF ASSESSMENT CODES: 01 X-Ray 03 Conventional Computed Tomography (CT) 04 Magnetic Resonance Imaging (MRI) 23 Spiral Computed Tomography (CT) 88 Other (specify below) 															
Line #	Line # Specify if "88 Other" Method of Assessment															

roi Ailigeli Usi	e Only
Tick when	
data checked.	

Α	1111.	Site No.			S	ubject	ID N	0.			Subj	ect Initials
ABX-EGF 20020408			1,	1 ု	ı		ı	1	ı	1		
AMENDMENT 2.0												W13

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment							
Day	Month	Year					
Ι.							

•	Emergency Room Visits Number of emergency room visits		
) <u>.</u>	Therapy Visits Number of therapy (mental health) vis	sits	
•	Outpatient visits to specialists (addition to your routine care, so		•
	Pain Management Specialist: Number of outpatient physician visits		
	Radiologist: Number of outpatient physician visits		
	Radiation Oncology: Number of outpatient physician visits		
4.	Outpatient Procedures Any outpatient surgical procedures		Yes N
	If yes, please describe:		
	Blood transfusions number of times		
	Other procedures?		Yes N
	If yes, please describe:		
5.	Caregiving In a typical (24 hour) day, how many hof your illness:	nours of support do you receive	from each of the following <i>be</i>
		Trained Medical Person	Others
	Paid caregiver	hours	hours
	Unpaid caregiver	hours	hours

DISTRIBUTION: White & Yellow - Amgen; Blue - CRA; White Card - Investigator

Tick when data checked.

Δ	////	Site No.		5	Subject	ID No				Sub	ject Ir	nitials
ABX-EGF 20020408			1_1	1	1	ı	ı	ı	ı		I	I
AMENDMENT 2.0		_									W	/13

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination									
Day	Month	Year							

	the subject have any abnormal clinical findi	ngs relating to the followi	ng required sites?	No 1 Yes - If yes,							
descr	ibe findings below.	04.41.1		40.5							
	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04 Abdomen	07 Lymph nodes	10 Breast / Chest							
	Cardiovascular	05 Musculoskeletal06 Skin	08 Neurological09 Genitourinary	11 Rectal							
03	Pulmonary	88 Other									
	Indicate if a required assessment was not done.										
Code											
(as		Describe findings									
listed		List one entry per line.									
above)											
l 1											

ECOG PERFORMANCE STATUS

		ECOG Performance						
Da	у	Month			Year			Status ①
0 1 2 3	Fully performed Restrand a ie, light Amburout a Capar > 50% Comp	active, abormance wricted in pable to caught housevalutory anny work able of only of wakingletely dispersion.	sabled. Car	on all priction trenuou k of a li ce work of all sepand a lelf-care	ore-di is acti ght or c elf-car about , conf	sease ivity, bu r seden re, but to > 50% ined to	tary natous unable to of wakin bed or o	ure, o carry og hours.
5	Dead	•	d to bed or	cnair				

For Amgen Use Only
Tick when
data checked.

Δ	////	Site No.		S	Subject	ID No.			Subj	ect Ir	nitials
ABX-EGF 20020408			1,1,	1	I	ı	1	ı		l	I
AMENDMENT 2.0										W	/13

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

	Date of Assessment												
Day	Month	Year											

Did the subject have skin toxicity? $_{_0}$ No $_{_1}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

	Skin Toxicity (list all that apply)						•	y if Skin l	Foxicity is inges"	0	SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching			
										0	4 Rash (acı	ne/acneiform) squamation (non-acneiform)		
Type of Skin Lesions (list all that apply) © Specify if Type of S					oe of Sk	in Lesion	is "88 Other"	00 01	None (IN LESION CODES: 07 Dry flaking 08 Desquamation (sloughing) 09 Comedones				
										04	Macular	10 Cysts 88 Other (specify)		
Total % Affec	- 1	04 > 50	04 > 50% BSA (list all that apply)						ation is	ation is "88 Other" LOCATION 09 Face 10 Trunk				
		05 ≤ 50	J% BSA				ı					11 Extremities 12 Total body 88 Other (specify)		
1. If prior radiation, is area of radiation port involved? 66 Not applicable 0 No 1 Yes														
2. W	/as c	rusting p	resent	?					No ₁☐ Yes					
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes					
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes					
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications			
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1			
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)		
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1			
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year					
											J			

For Amgen Use Only
Tick when

data checked.

Δ	////	Site No.			Sı	ubject	ID No).			Subj	ect Ir	nitials
ABX-EGF 20020408			1	1_	1	ı	ı	1	ı	ı		I	
AMENDMENT 2.0								·				N	/13

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment												
Day	Month	Year										
l .												

		_o No ✓	I 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?	,			
Was Honey Yellow Crusting pres	ent?		1	
Was Erythema present?			1	
Was Paronychia present?		1		
Were Fissures present? (Photo-	oly)	 		
Does the following dermatological	al toxicity interfere with act	ivities of daily	/ living?	
Paronychia	ı: ₀☐ No ₁☐ Yes ₆₆	☐ N/A		
Fissures:	₀ No ₁ Yes 66	☐ N/A		
How bothered do you perceive the by the dermatologic toxicities?	Perc	oject eption ②		
① PHOTO-BASED CODING SCALE CODES:	SUBJECT PERCEPTION COI01 Not at all03 M	DES: oderate	05 Intoler	able
A B C D	02 A little 04 V	ery much		

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W15

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment												
Day	Month	Year										

Did the subject have skin toxicity? $_{_{0}}\square$ No $_{_{1}}\square$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

TOXIO	ty / 13	0000	111011	io page	, and re	COIG SKIII (OXIOIL	y 0117 (L	- 0111.						
				Toxicity that app	•			•	fy if Skin ⁻ 1 Nail Cha	Toxicity is nges"	SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching				
											04 Rash (acne	e/acneiform) uamation (non-acneiform)			
			Skin L that a	esions	5	Speci	fy if Ty	pe of Sk	kin Lesion	is "88 Other"	TYPE OF SKIN LESION CODES: 00 None				
			I								04 Macular 10	Cysts Other (specify)			
Total % Affec		04	> 50	% BSA (% BSA	ODES:	(lis	Locati st all th	ion ④ at apply)		Specify if Locat	ion is "88 Other"	 LOCATION CODES:09 Face10 Trunk			
		05	≤ 50	% BSA				ı				11 Extremities 12 Total body 88 Other (specify)			
1. If prior radiation, is area of radiation port involved? 66 Not applicable 0 No 1 Yes															
2. V	Vas c	rusti	ng pi	resent	?					No ₁☐ Yes					
3. S	ince	the I	ast a	ssessr	nent, di	d the rash	cause	e pain?		No ₁☐ Yes					
4. S	ince	the l	ast a	ssessr	nent, di	d the rash	cause	e itchin	g? ₀□	No ₁☐ Yes					
5. S	ince	the l	ast a	ssessr	nent, di	d the rash	requi	re treat		h narcotics? cord on Concomit	₀☐ No ₁☐ tant Medications C				
6. S	ince	the I	ast a	ssessr	nent, di	d the rash	requi	re treat		-	oids?₀☐ No ₁☐				
									(Re	cord on Concomit	ant Medications C	CRF)			
7. V	Vas d	lose	held,	chang	jed or d	iscontinue	d for s	skin tox	cicity?						
ı	۱ ــ	No 1	☐ Ye	es - If y	es, pro	vide date.	Da	ау	Month D	Year Year					

For Amgen Use Only
Tick when

data checked.

А	////	Site No.				S	ubject	ID N	0.		S	ubjec	t Initial	s
ABX-EGF 20020408			ı	1	1	1	I	ı	ı				ı	
AMENDMENT 2.0													W15	

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment												
Day	Month	Year										
l .												

	₀ No ✓	1 Yes √ Enter corre- sponding code from Photonumeric Scale*	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		! 	
Was Honey Yellow Crusting present?		 	
Was Erythema present?		 	
Was Paronychia present?		 	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activitie Paronychia: O No No Yes 66 N	/A	v living?	
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio	n		
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mu		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Δ	////	Site No.			S	ubject	ID N	0.			Sub	ject Initials
ABX-EGF 20020408		1 1	1	1,	ı	l	ı	1	ı	ı		
AMENDMENT 2.0												W16

Week 16 TUMOR EVALUATION - TARGET LESIONS

Date of Procedure											
Day	Month	Year									

Lesion Note: Always maintain the same order of lesion	Lesion Site Code	Subsite Describe specific location	Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable Dimensions (mm)
numbers	1			Differisions (IIIIII)
01	ı		I	
02				
03				
04				
05				
06				
07				
08				
09				
10				
	· · · · · · · · · · · · · · · · · · ·	Sum		

				Lesions
10 LESION SITE CO 00 Lymph nodes 10 Pulmonary 20 Liver 30 Bone	CODES: 40 Chest 50 Central nervous system 55 Head 56 Neck	60 Gastrointestinal70 Abdomen75 Pelvic Site85 Spleen	86 Skin 88 Other (specify in subsite above)	METHOD OF ASSESSMENT: 1 X-Ray 3 Conventional Computed Tomography (CT) Magnetic Resonance Imaging (MRI) Spiral Computed Tomography (CT) 8 Other (specify below)
Line #		Specify if "88 (Other" Method of Asse	
Line #		Specify if "88 (Other" Method of Asse	
Line #		Specify if "88(Other" Method of Asse	

For Amgen Use	e Only
Tick when	
data checked.	

Α	1111.	Site No.			S	ubject	ID N	0.			Subj	ect Initials
ABX-EGF 20020408			1,	1	1	1	ı	ı	ı	1		
AMENDMENT 2.0												W16

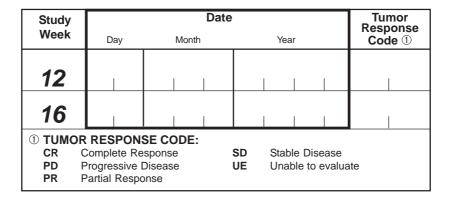
		•	U	IVI	U	רוי					her lesio							SIONS
Lesion Note: Always maintain the same order		Date of Procedure			Date of Procedure Site Code			Des	Subsite cribe specifi	specific location Assessm			sment	New Lesions		Measurable Lesions (mm) Must be unidimensionally measurable.		
of lesion numbers	Day	. !	Mont	th		Υ	'ear		1		-			(2	2)	₀No ✓	₁Yes ✓	Dimensions (mm)
11												 						
12			1				1										 	
13			1				1										 	
14							1										 	
15																	 	
16			1	1		ı	ı	ı									 	
													Sum	of N		arç sio		
10 BODY 00 Ly 10 Pt 20 Li 30 Bo	mph i ulmona ver	node		ES:	<u> </u>		5 5	0 (5 l	Chest Central ner Head Neck	vous system	1	60 70 75 85	Abdom Pelvic	Site	al		86 88	
② METH 01) 03 ((-Ray								DES:	04 23 88	Spiral Cor	npute	d Tomoo	maging (graphy ((MRI) CT)			
Line #									,	Specify if	"88 Other	" Met	hod of	f Asses	ssmer	nt		

For Amgen Use Only Tick when data checked.

Δ	S	Site No.			Subject ID No.									
ABX-EGF 20020408			1	1,	1		ı	1	ı	1		ı		
AMENDMENT 2.0												W12-	W16	

Weeks 12-16 OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria



v.2.0 30Jun04camb

	0	NIa		ikia at ID NI-	Outer Charles
A	Site	IVU.		ıbject ID No.	Subject Initials
ABX-EGF 20020408		1 1	1,1, ,		
AMENDMENT 2.0					W9-W16
	1	Neeks	9-16		
			DURES		
	• • •	CYTOL			
Was any cytology performed? ₀□		If yes, spec	cify below.		
Date of Procedure	Procedure 1	Malignant B	ody Specify if Pro Site Code is #88		
Day Month Year			4	15 00 0	30 Paracentesis
					31 Thoracentesis 88 Other (Specify,
		<u> </u>			GG Galler (Gpeelly)
Equivocal findings:					
		SURG	CAL		
Were any surgical procedures perfo	_		, , , , , , , , , , , , , , , , , , , 		
Date of Procedure	Procedure Body Site Code Code		Specify if "88	② PROCEDURE CODE:	
Day Month Year	2	4		- Ctriei	32 Surgical
	3.2				
	J 0 Z				
Findings:					
Was biopsy performed? ₀☐ No ₁		BIOP	SY		
Was biopsy performed? ₀☐ No ₁	_		elow.		
Date of Procedure	Procedure Body Site Code Code		Specify if	③ PROCEDURE CODE:	
Day Month Year	3	4	00	Other"	16 Biopsy
	1 1 6				
] 1 0				
Findings:					
Was endoscopy performed? ₀☐ N	lo ₁□ Yes -	ENDOS	COPY fv below.		
Date of Procedure	Procedure	Body Sp	ecify if Procedure	Specify if Body S	ite ⑤ PROCEDURE
Date of Procedure Day Month Year	(5)		ode is "88 Other"	is "88 Other"	CODE:
					33 Colonoscopy 34 Sigmoidoscopy
					88 Other (Specify)
Findings:		<u> </u>			I
					· · · · · · · · · · · · · · · · · · ·
BODY SITE 01 Abdomen 05 Ches	et	09 Heart	13 Pleura	17 Total bo	dy 88 Other
CODES: 02 Brain 06 Eye	rointestinal tract	09 Heart 10 Kidney 11 Liver 12 Lung		18 Thorax	(Specify above)

Tick when

data checked.

WEEKS 17 - 24

Α	Site	No.		S	Subject	t ID No).			Sub	ject In	itials
ABX-EGF 20020408		1 1	$ 1_{\scriptscriptstyle{1}}1_{\scriptscriptstyle{1}}$	ı	1	ı	ı	ı	ı		I I	
AMENDMENT 2.0				·	·						W	17

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment						
Day	Month	Year				
L	1 1	, , ,				

	I would like to ask you a few questions have made to a doctor of	about any additional visits (nor an outpatient facility in the						
1.	Emergency Room Visits Number of emergency room visits							
2.	Therapy Visits Number of therapy (mental health) visits	8						
3.	Outpatient visits to specialists (to whom your doctor referred you, in addition to your routine care, such as a pain specialist or radiologist)							
	Pain Management Specialist: Number of outpatient physician visits							
	Radiologist: Number of outpatient physician visits							
	Radiation Oncology: Number of outpatient physician visits							
4.	Outpatient Procedures Any outpatient surgical procedures		Yes No					
	If yes, please describe:							
	Blood transfusions number of times							
	Other procedures?	Yes No						
	If yes, please describe:							
5.	Caregiving In a typical (24 hour) day, how many hours of support do you receive from each of the following because of your illness:							
		Trained Medical Person	Others					
	Paid caregiver	hours	hours					
	Unpaid caregiver	hours	hours					
6.	Nursing Home / Hospice Days Number of days spent in a nursing home	е						

For Amgen Use Only Tick when

data checked.

Δ	////	Site No.		S	Subject	ID No.				Sub	ect In	itials
ABX-EGF 20020408			1,1,	ı	I	ı	1	ı	ı			
AMENDMENT 2.0							·				W	17

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination											
Day	Month	Year									
İ											

	the subject have any abnormal clinical findi	ngs relating to the followi	ng required sites?	No 1 Yes - If yes,								
descr	ibe findings below.	40.5										
	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04 Abdomen	07 Lymph nodes	10 Breast / Chest								
	Cardiovascular	05 Musculoskeletal	08 Neurological	11 Rectal								
03	Pulmonary	06 Skin	09 Genitourinary	88 Other								
	Indicate if a required assessment was not done.											
Code												
(as		Describe findings										
listed		List one entry per line.										
above)												
l 1												

ECOG PERFORMANCE STATUS

	ECOG Performance							
Da	Day Month					Year	Status ①	
0 1 2 3	Fully performed Restrand a ie, light Amburout a Capar > 50% Comp	active, abormance wricted in pable to caught housevalutory anny work able of only of wakingletely dispersion.	sabled. Car	on all priction trenuou k of a li ce work of all sepand a lelf-care	ore-di is acti ght or c elf-car about , conf	sease ivity, bu r seden re, but to > 50% ined to	tary natous unable to of wakin bed or o	ure, o carry og hours.
5	Dead	•	d to bed or	cnair				

Δ	////	Site No.		Sub	oject ID	No.			Sub	ject Initials
ABX-EGF 20020408			1,1,	1		ı	ı	ı		1 1
AMENDMENT 2.0										W17

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment											
Day	Month	Year									
I .											

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

TOXIO	ty / 13	0000	111011	io page	, and re	COIG SKIII (OXIOIL	y 0117 (L	- 0111.								
Skin Toxicity (list all that apply)								•	fy if Skin ⁻ 1 Nail Cha	Toxicity is nges"	SKIN TOXICITY CODES: 1 Nail changes (specify) 2 Erythema 3 Pruritus/itching						
								/acneiform) lamation (non-acneiform)									
Type of Skin Lesions (list all that apply)						Specify if Type of Skin Lesion is "88 Other"					 TYPE OF SKIN LESION CODES: 00 None 07 Dry flaking 01 Pustular 08 Desquamation (slough) 02 Vesicular 09 Comedones 						
			I								04 Macular 10	Cysts Other (specify)					
Total % Affec		04	> 50	% BSA (% BSA	ODES:	(lis	Locati st all th	ion ④ at apply)		Specify if Locat	ion is "88 Other"	 LOCATION CODES:09 Face10 Trunk					
		05	≤ 50	% BSA				ı				11 Extremities 12 Total body 88 Other (specify)					
1. If	1. If prior radiation, is area of radiation port involved?																
2. V	Vas c	rusti	ng pi	resent	?					No ₁☐ Yes							
3. S	ince	the I	ast a	ssessr	nent, di	d the rash	cause	e pain?		No ₁☐ Yes							
4. S	ince	the l	ast a	ssessr	nent, di	d the rash	cause	e itchin	g? ₀□	No ₁☐ Yes							
5. S	ince	the l	ast a	ssessr	nent, di	d the rash	requi	re treat		h narcotics? cord on Concomit	₀☐ No ₁☐ tant Medications C						
6. S	ince	the I	ast a	ssessr	nent, di	d the rash	requi	re treat		-	oids?₀☐ No ₁☐						
									(Re	cord on Concomit	ant Medications C	CRF)					
7. V	Vas d	lose	held,	chang	jed or d	iscontinue	d for s	skin tox	cicity?								
Date Day Month Year																	

For Amgen Use Only
Tick when

data checked.

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1,	
AMENDMENT 2.0			W17

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment										
Day	Month	Year								
l .										

		₀ No√	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①				
Were Pustules/Papules present	?		1					
Was Honey Yellow Crusting pres	sent?		 					
Was Erythema present?			 					
Was Paronychia present?		1						
Were Fissures present? (Photo		 						
Does the following dermatologic	cal toxicity interfere with activitie	s of daily	/ living?					
Paronychi	a: ₀ No ₁ Yes ₆₆ N	/A						
Fissures:	₀ No ₁ Yes 66 N	/A						
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception								
① PHOTO-BASED CODING SCALE CODES: A B C D	 SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera 02 A little 04 Very m 		05 Intoler	able				

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site N	lo.		Su	ıbject	ID No.				Subj	ect In	itials
ABX-EGF 20020408			1,1,	I	ı		1	ı	I			l
AMENDMENT 2.0											W	′19

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

	Date of Asse	essment
Day	Month	Year
I .		

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

			Toxicity that app				•	y if Skin l	Foxicity is inges"	0	1 Nail chan 2 Erythema					
										0	03 Pruritus/itching 04 Rash (acne/acneiform) 05 Rash/desquamation (non-acn 06 Ulceration					
		e of Skin list all that a		•	Specif	fy if Typ	oe of Sk	in Lesion	is "88 Other"	00 01	 TYPE OF SKIN LESION CODES: None Typ flaking Pustular Desquamation (sloug) Vesicular Comedones 					
										04	Macular	10 Cysts 88 Other (specify)				
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Locationst all tha	on ④ at apply)		Specify if Loc	ation is	ion is "88 Other"					
		05 ≤ 50	J% BSA				ı					11 Extremities 12 Total body 88 Other (specify)				
1. If	prio	radiatio	n, is are	a of rac	diation port	involv	ved?	66	Not applicabl	e ₀ 🖵 I	No ₁☐ Ye	es				
2. W	2. Was crusting present?															
3. S	3. Since the last assessment, did the rash cause pain? $_{\scriptscriptstyle 0}\Box$ No $_{\scriptscriptstyle 1}\Box$ Yes															
4. S	4. Since the last assessment, did the rash cause itching? ₀ □ No ₁ □ Yes															
5. S	5. Since the last assessment, did the rash require treatment with narcotics? (Record on Concomitant Medications CRF)															
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1					
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)				
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1					
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year							
											J					

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0	_		W19

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

	Date of Asse	essment
Day	Month	Year

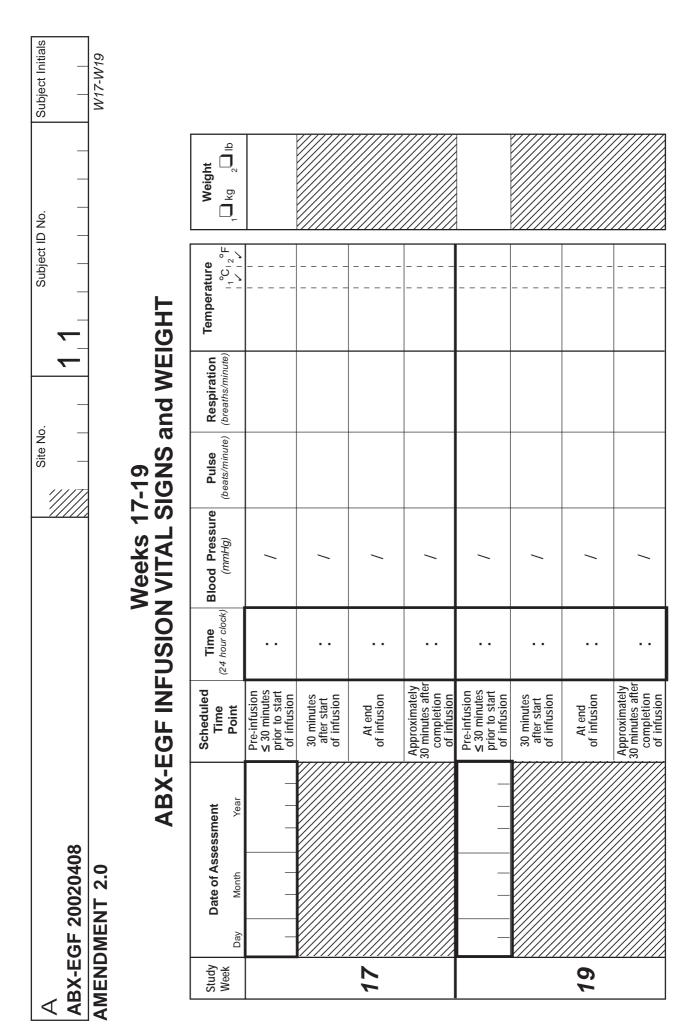
	₀ No ✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		! ! !	
Was Honey Yellow Crusting present?		1	
Was Erythema present?		1	
Was Paronychia present?		1	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activitie	s of daily	/ living?	,,,,,,
Paronychia: ₀☐ No ₁☐ Yes 66☐ N	/A		
Fissures: 0 No 1 Yes 66 N	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio ②	n		
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mu		05 Intoler	able

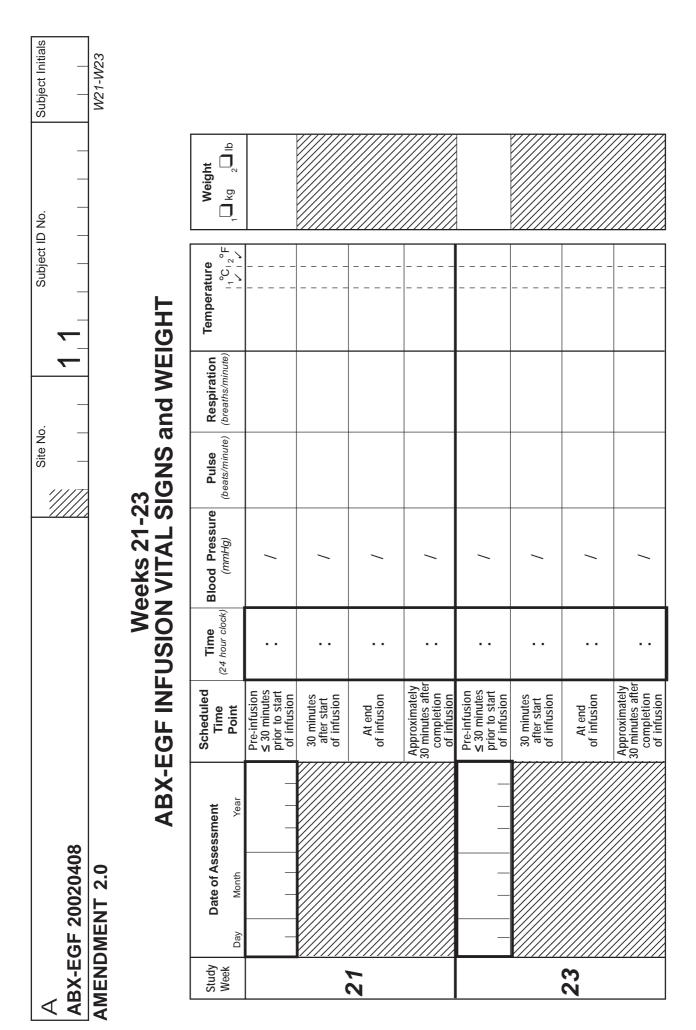
For Amgen Use	e Only
Tick when	
data checked.	

Treatment Phase VITAL SIGNS FOR ABX-EGF AND BSC

*Vital signs readings (every 2 weeks; within 30 minutes before the ABX-EGF infusion, approximately 30 minutes after the start of ABX-EGF infusion, upon completion of the ABX-EGF infusion, and approximately 30 minutes after completion of the ABX-EGF infusion, allowing a +/- 10 minute time window): blood pressure, resting pulse, respiration rate, and temperature (every 2 weeks).

*Weight (every 2 weeks, before the ABX-EGF infusion on ABX-EGF arm; every 4 weeks on BSC arm)





⋖									Site No.	Subject ID No.	Subject Initials
AB	ABX-EGF 20020408	020408							_	-	_
AM	AMENDMENT 2.0	T 2.0									W17-W23
					Wee	sks 1	7-23		Weeks 17-23		
	Sut	IN Sjects receivin	VESTIG 19 BSC will no	SATION of receive In	NAL PF	SODL al Produc	JCT ,	ADM istration,	INISTR/	INVESTIGATIONAL PRODUCT ADMINISTRATION Subjects receiving BSC will not receive Investigational Product Administration, please score through the page	
Study		Date	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered	Total	Reason for i Dose	If "04 Per protocol" is indicated for "Reason for Dose Change",	٥٠	If Reason for Dose Change is "88 Other", please specify	
	Day Month	Year			(mg)	(mL)	9	indicate code	Ф		
17	_						_	_			
19	_	_					_	_			
21	_						_	_ _			
23							_	_			
lf subj	If subject did not complete investigational product administration, provide any	plete investigatio	inal product adr	ministration, p	rovide any ado	additional relevant information:	vant infor	mation:			
⊕ DOS	① DOSE CHANGE CODES:	ES:	② "04 Per ß	② "04 Per protocol" DOSE CHANGE		CODES:					
00 00 00 00 00 00 00 00 00 00 00 00 00	Adverse event Noncompliance Dose administration error Per protocol Other (Specify above)	in error ve)	100 We 118 Syr 0rf,	Weight change Symptomatic skin or felt to be intoler Skin infection req	Weight change Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject Skin infection requiring systemic IV antibiotic or IV antifungal treatment	/ requiring 1 t IV antibiotic	narcotics, :	systemic s fungal trea	teroids, tment	 121 Need for surgical debridement 122 Any skin-related serious adverse event 200 Dose reinstated 201 Dose increase (after reinstatement) 	

data checked.

For Amgen Use Only Tick when

A	1/1/.	Site No.		Subjec	t ID No.		Subject Initials
ABX-EGF 20020408			 1 1		1 1	1	
AMENDMENT 2.0							W17-W23

Weeks 17-23 INVESTIGATIONAL PRODUCT LOT NUMBER

Study Week	ABX-EGF Package Lot Number	ABX-EGF Package Lot Number
17		
19		
21		
23		

А	////	Site No.		5	Subject	ID No.				Subj	ect Initials
ABX-EGF 20020408			1,1	ſ	I	ı	1	ı	ſ		
AMENDMENT 2.0		_					·				W21

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

	Date of Ass	essment
Day	Month	Year
	l	l
	1 1 1	

	I would like to ask you a few questions about a have made to a doctor or an ou			you may
1.	. Emergency Room Visits Number of emergency room visits			
2.	Therapy Visits Number of therapy (mental health) visits			
3.	3. Outpatient visits to specialists (to whom addition to your routine care, such as a	-		
	Pain Management Specialist: Number of outpatient physician visits			
	Radiologist: Number of outpatient physician visits			
	Radiation Oncology: Number of outpatient physician visits			
4.	 Outpatient Procedures Any outpatient surgical procedures 		Yes	No
	If yes, please describe:			
	Blood transfusions number of times			
	Other procedures?		Yes	No
	If yes, please describe:			
5.	Caregiving In a typical (24 hour) day, how many hours of s of your illness:	upport do you receive fro	om each of the following	because
	Traine	d Medical Person	Others	
	Paid caregiver	hours	hours	
	Unpaid caregiver	hours	hours	
6.	Nursing Home / Hospice Days Number of days spent in a nursing home	1		_

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W21

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination											
Day	Month	Year									

	the subject have any abnormal clinical findia ibe findings below.	ngs relating to the followi	ng required sites?	₀ No ₁ Yes - If yes,					
01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	07 Lymph nodes	10 Breast / Chest						
	Cardiovascular	08 Neurological	11 Rectal						
	Pulmonary	09 Genitourinary	88 Other						
Indicate if a required assessment was not done.									
Code									
(as		Describe findings							
listed		List one entry per line.							
above)									

ECOG PERFORMANCE STATUS

	ECOG Performance			
Day	Month	Year	Status ①	
 Fully performance Restormance Ambout a Cap > 50 Com 	e PERFORMANCE S active, able to carry ormance without restricted in physically st able to carry out work able to carry out work able of carpy out work any work activities. Up able of only limited se of waking hours pletely disabled. Car ly confined to bed or	on all pre-disease riction renuous activity, but k of a light or sedentice work of all self-care, but up and about > 50% celf-care, confined to lanot carry out any se	ary natunable to see the see t	o carry g hours.

For Amgen Use Only
Tick when
data checked.

DISTRIBUTION: White & Yellow - Amgen; Blue - CRA; White Card - Investigator

Δ	////	Site No.		5	Subject	ID No.				Subj	ect Initials
ABX-EGF 20020408			$\left 1_{\scriptscriptstyle{1}}1_{\scriptscriptstyle{1}}\right $	1	1	ı	1	ı	1		
AMENDMENT 2.0											W21

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment									
Day	Month	Year							

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)					Specify if Skin Toxicity is "01 Nail Changes"					SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching					
										0	4 Rash (acı	ne/acneiform) squamation (non-acneiform)			
	Type of Skin Lesions (list all that apply) Specify if Type of Skin Lesion is "88 Other"				00 01	None (IN LESION CODES: 07 Dry flaking 08 Desquamation (sloughing) 09 Comedones								
										04	Macular	O Cysts Other (specify)			
						ation is	"88 Other"	 4 LOCATION CODES:09 Face10 Trunk							
		05 ≤ 50	J% BSA				ı					11 Extremities 12 Total body 88 Other (specify)			
1. If	1. If prior radiation, is area of radiation port involved?														
2. W	/as c	rusting p	resent	>					No ₁☐ Yes						
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes						
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes						
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications				
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1				
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)			
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1				
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year						
											J				

Δ	////	Site No.			Sı	ubject	ID No).			Subj	ect Ir	nitials
ABX-EGF 20020408			1	1,	ı	I	ı	ı	ı	I		I	I
AMENDMENT 2.0												N	/21

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment										
Day	Month	Year								

		_o No ✓	I 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①			
Were Pustules/Papules present?	,						
Was Honey Yellow Crusting pres	ent?		1				
Was Erythema present?			1				
Was Paronychia present?			1				
Were Fissures present? (Photo-	oly)	 					
Does the following dermatological	al toxicity interfere with act	ivities of daily	/ living?				
Paronychia	ı: ₀☐ No ₁☐ Yes ₆₆	☐ N/A					
Fissures:	₀ No ₁ Yes 66	☐ N/A					
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception ②							
① PHOTO-BASED CODING SCALE CODES:	SUBJECT PERCEPTION COI01 Not at all03 M	DES: oderate	05 Intoler	able			
A B C D	02 A little 04 V	ery much					

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site No.		Su	ıbject	ID No				Subj	ject Initials
ABX-EGF 20020408		1,1,	1	ı	I	1	ı	ı		1 1
AMENDMENT 2.0										W23

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment									
Day	Month	Year							

Did the subject have skin toxicity? $_{_{0}}\square$ No $_{_{1}}\square$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Toxidity A35633ments page and record skin toxicity of the office																
				Toxicity that app	•			•	fy if Skin ⁻ 1 Nail Cha	Toxicity is nges"	SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching					
											04 Rash (acne/acneiform) 05 Rash/desquamation (non-acneiform) 06 Ulceration					
	Type of Skin Lesions (list all that apply) Specify				ify if Type of Skin Lesion is "88 Other"				00 None 07 01 Pustular 08	LESION CODES: Dry flaking Desquamation (sloughing) Comedones						
			I								04 Macular 10	Cysts Other (specify)				
Total % Affec		04	> 50	% BSA (% BSA	ODES:	(lis	Locati st all th	ion ④ at apply)		Specify if Locat	ion is "88 Other"	 LOCATION CODES:09 Face10 Trunk				
		05	≤ 50	% BSA				ı				11 Extremities 12 Total body 88 Other (specify)				
1. If	1. If prior radiation, is area of radiation port involved?															
2. V	Vas c	rusti	ng pi	resent	?					No ₁☐ Yes						
3. S	ince	the I	ast a	ssessr	nent, di	d the rash	cause	e pain?		No ₁☐ Yes						
4. S	ince	the l	ast a	ssessr	nent, di	d the rash	cause	e itchin	g? ₀□	No ₁☐ Yes						
5. S	ince	the l	ast a	ssessr	nent, di	d the rash	requi	re treat		h narcotics? cord on Concomit	₀☐ No ₁☐ tant Medications C					
6. S	ince	the I	ast a	ssessr	nent, di	d the rash	requi	re treat		-	oids?₀☐ No ₁☐					
									(Re	cord on Concomit	ant Medications C	CRF)				
7. V	Vas d	lose	held,	chang	jed or d	iscontinue	d for s	skin tox	cicity?							
ı	۱ ــ	No 1	☐ Ye	es - If y	es, pro	vide date.	Da	ау	Month D	Year Year						

For Amgen Use Only
Tick when

data checked.

Δ	Site No.		Su	ıbject	ID No				Subj	ject Initials
ABX-EGF 20020408		1,1,	1	ı	I	1	ı	ı		1 1
AMENDMENT 2.0										W23

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment									
Day	Month	Year							

		₀ No ✓	I 1 Yes ✓ I Enter I corre- I sponding I code from I Photo- numeric Scale*	* Photo- based Coding Scale (Record one code only) ①			
Were Pustules/Papules present?			' ! !				
Was Honey Yellow Crusting prese	ent?		1				
Was Erythema present?			1				
Was Paronychia present?			1				
Were Fissures present? (Photo-		1					
Does the following dermatological	al toxicity interfere with activitie	es of daily	/ living?				
Paronychia	: ₀ No ₁ Yes 66 N	I/A					
Fissures:	₀ No ₁ Yes 66 N	I/A					
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception ②							
① PHOTO-BASED CODING SCALE CODES:	SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera	ate	05 Intolera	able			
A B C D	02 A little 04 Very m		- Intolore				

For Amgen Use	e Only
Tick when	
data checked.	

A	1///	Site No.			_	Sı	ubject	ID No).			Subj	ect Initials
ABX-EGF 20020408		1 1	I	1	1_	ı	ı	ı		ı	1		
AMENDMENT 2.0			·		·	·	·		•		·		W24

Week 24 TUMOR EVALUATION - TARGET LESIONS

Date of Procedure										
Day	Month	Year								

Lesion Note: Always maintain the same order of lesion	Lesion Site Code	Subsite Describe specific location	Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable
numbers	1		,	Dimensions (mm)
01			I	
02				
03				
04				
05				
06	,			
07			,	
08				
09				
10			,	
	'	Sum	of Target	

			Lesions
① LESION SITE Control00 Lymph nodes10 Pulmonary20 Liver30 Bone	40 Chest 60 50 Central nervous 70 system 75	Gastrointestinal 86 Skin Abdomen 88 Other (specify Pelvic Site in subsite above) Spleen	 ② METHOD OF ASSESSMENT: 01 X-Ray 03 Conventional Computed Tomography (CT) 04 Magnetic Resonance Imaging (MRI) 23 Spiral Computed Tomography (CT) 88 Other (specify below)
Line #		Specify if "88 Other" Method of Asses	ssment

For Amgen Use	Only
Tick when	
data checked.	

Δ	Sit	e No.			Sı	ubject	ID No.				Subj	ect Init	tials
ABX-EGF 20020408			1	1			ı	I	I	ı			
AMENDMENT 2.0												W2	4

TUMOR EVALUATION - NON-TARGET LESIONS

		10							ord all othe			ites of dis			.010110
Lesion Note: Always maintain the same order		Date o	of Pr	oceo	lure		Si	Body Site Subsite Code Describe specifi			Method of Assessment			ew sions	Measurable Lesions (mm) Must be unidimensionally measurable.
of lesion numbers	Day	Mor	nth		Υe	ar	(1			,		2	₀No ✓	₁Yes ✓	Dimensions (mm)
11														 	
12			ı		1	ı									
13						i								 	
14			1											 	
15			1											 	
16			1											1	
	'	'	'	·	'						Sum	of Non-	Tare esio		
① BODY 00 Ly 10 Pt 20 Li 30 Bo	mph r ulmona ver	nodes	ES	:		50 55	Chest Centra Head Neck	l ner	vous system	75	Gastro Abdom Pelvic Spleen	Site		86 88	Skin Other (specify in subsite above)
② METH 01 〉 03 ((-Ray						DDES:	(CT)	23 S	lagnetic Resor piral Compute other (specify l	d Tomog	naging (MRI) graphy (CT)			
Line #									Specify if "88	Other" Me	thod of	f Assessme	nt		

For Amgen Use	e Only
Tick when	
data checked.	

Δ	////	Site No.					Subje	ct ID N	ο.			Subj	ject Initials
ABX-EGF 20020408		1 1	ı	1	1		1	ı	ı	ı	ı		l I
AMENDMENT 2.0							·						W24

Week 24 OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study		Date									
Week	Day	Month		Year	Response Code ①						
24											
① TUMO	① TUMOR RESPONSE CODE:										
PD	Complete Re Progressive I Partial Respo	Disease	SD UE	Stable Disease Unable to evalua	ate						

Weeks 17-24 PROCEDURES CYTOLOGY Was any cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure Day Month Year	acentesis racentesis
Weeks 17-24 PROCEDURES CYTOLOGY Was any cytology performed? ON ON Service of Procedure Date of Procedure Day Month Year Procedure ONO NO	CEDURE E: acentesis racentesis
Weeks 17-24 PROCEDURES CYTOLOGY Was any cytology performed? OND OND AND AND AND AND AND AND AND AND AND A	CEDURE E: acentesis racentesis
PROCEDURES CYTOLOGY Was any cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure Procedure Cell? Site Code is "88 Other" Specify if Body Site © PROCEDURE Site Code is "88 Other" Specify if Body Site Specify if Body Site © PROCEDURE Site Code is "88 Other" Specify if Body Site Specify if Body Site © PROCEDURE Surgical Procedure Procedure Procedure Procedure Body Site Specify if Body Site is © PROCEDURE Procedure Procedure Body Site Specify if Body Site is © PROCEDURE Pro	E: acentesis racentesis
PROCEDURES CYTOLOGY Was any cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure Procedure Cell? Site Code is "88 Other" Specify if Body Site © PROCEDURE Site Code is "88 Other" Specify if Body Site Specify if Body Site © PROCEDURE Site Code is "88 Other" Specify if Body Site Specify if Body Site © PROCEDURE Surgical Procedure Procedure Procedure Procedure Body Site Specify if Body Site is © PROCEDURE Procedure Procedure Body Site Specify if Body Site is © PROCEDURE Pro	E: acentesis racentesis
CYTOLOGY Was any cytology performed? □ No 1 Yes - If yes, specify below. Date of Procedure Procedure O No 1 Yes - If yes, specify if Procedure Specify if Body Site O PROCEDURE O No 1 Yes O No 1 Ye	E: acentesis racentesis
Was any cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure	E: acentesis racentesis
Date of Procedure ① Cell? Site Code is "88 Other" is "88 Other" ONO 1 Yes 1 4 4	E: acentesis racentesis
Day Month Year ONO 1 Yes 4 30 Par 31 Tho 88 Oth Equivocal findings: SURGICAL Were any surgical procedures performed? ONO 1 Yes - If yes, specify below. Date of Procedure Procedure Body Site Specify if Body Site is PROCEDI	acentesis racentesis
Equivocal findings: SURGICAL Were any surgical procedures performed? One of Procedure Procedure Procedure Body Site Specify if Body Site is PROCEDITION P	racentesis
Equivocal findings: SURGICAL Were any surgical procedures performed? Procedure Body Site Specify if Body Site is PROCEDI	or (Coosifi.
SURGICAL Were any surgical procedures performed? □□ No □□ Yes - If yes, specify below. Date of Procedure Procedure Body Site Specify if Body Site is ② PROCEDURE	er <i>(Specify,</i>
Were any surgical procedures performed? ₀☐ No ₁☐ Yes - If yes, specify below. Procedure Body Site Specify if Body Site is ② PROCEDITY Procedure Body Site Specify if Body Site is □ PROCEDITY	
Were any surgical procedures performed? $_{0}\square$ No $_{1}\square$ Yes - If yes, specify below. Page of Procedure Procedure Procedure Body Site Specify if Body Site is PROCEDIA	
Were any surgical procedures performed? $_{0}\square$ No $_{1}\square$ Yes - If yes, specify below. Page of Procedure Procedure Procedure Body Site Specify if Body Site is PROCEDIA	
Were any surgical procedures performed? ₀☐ No ₁☐ Yes - If yes, specify below. Procedure Body Site Specify if Body Site is ② PROCEDITY Procedure Body Site Specify if Body Site is □ PROCEDITY	
Date of Procedure	
	JRE
Code Code "88 Other" Day Month Year ② ④ 32 Surgic	al
Findings:	
BIOPSY	
Was biopsy performed? ₀☐ No ₁☐ Yes - If yes, specify below.	
Date of Procedure Procedure Body Site Specify if Body Site is © PROCEDU CODE:	RE
Day Month Year ③ ④	
16 Biops	/
Findings:	
ENDOSCOPY Was endoscopy performed? ₀☐ No ₁☐ Yes - If yes, specify below.	
Procedure Rody Specify if Procedure Specify if Rody Site Reprocess	RF
Date of Procedure Site Code is "88 Other" Specify if Procedure	
33 Colon	oscopy idoscopy
	(Specify)
Findings:	
T manigo	
⊕ BODY SITE 01 Abdomen 05 Chest 09 Heart 13 Pleura 17 Total body 88 Other	
4 BODY SITE CODES: 01 Abdomen O5 Chest O6 Eye 09 Heart O6 Eye 13 Pleura O7 Flevic site O7 Gastrointestinal tract O7 Gastrointe	y above)

Tick when data checked.

WEEKS 25 - 32

Α	1111.	Site No.		Ş	Subjec	t ID N	0.			Subje	ect Initials
ABX-EGF 20020408			1 ₁ 1		ı		1	ı	1		
AMENDMENT 2.0											W25

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment										
Day	Month	Year								

	I would like to ask you a few question have made to a doct	ons about any additional visits (no or or an outpatient facility in the l		you may
1.	Emergency Room Visits Number of emergency room visits			
2.	Therapy Visits Number of therapy (mental health) v	risits		
3.	Outpatient visits to specialists addition to your routine care, s	•	•	
	Pain Management Specialist: Number of outpatient physician visits	S		
	Radiologist: Number of outpatient physician visits	s		
	Radiation Oncology: Number of outpatient physician visits	S		
4.	Outpatient Procedures Any outpatient surgical procedures		Yes	No
	If yes, please describe:			
	Blood transfusions number of times			
	Other procedures?		Yes	No
	If yes, please describe:			
5.	Caregiving In a typical (24 hour) day, how many of your illness:	hours of support do you receive	from each of the following $\it k$	because
		Trained Medical Person	Others	
	Paid caregiver	hours	hours	
	Unpaid caregiver	hours	hours	
6.	Nursing Home / Hospice Days Number of days spent in a nursing h	ome		

^	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W25

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination									
Day	Month	Year							

Does	the subject have any abnormal	clinical findin	gs relating to the follow	ving required sites?	₀ No ₁ Yes - If yes,				
descri	be findings below.								
01	Head, Ears, Eyes, Nose, Throat (HEE	NT) / Neck	04 Abdomen	07 Lymph nodes	10 Breast / Chest				
02	Cardiovascular		05 Musculoskeletal	08 Neurological	11 Rectal				
03	Pulmonary		06 Skin	09 Genitourinary	88 Other				
	Indicate if a required assessment was not done.								
Code									
(as			Describe findings						
listed			List one entry per line.						
above)									

ECOG PERFORMANCE STATUS

		ECOG Performance						
Da	Day Month			Year			Status ①	
0 1 2 3	Fully performed Restrand a ie, light Amburout a Capar > 50% Comp	active, abormance wricted in pable to caught housevalutory anny work able of only of wakingletely dispersion.	sabled. Car	on all priction trenuou k of a li ce work of all sepand a lelf-care	ore-di is acti ght or c elf-car about , conf	sease ivity, bu r seden re, but to > 50% ined to	tary natous unable to of wakin bed or o	ure, o carry og hours.
5	Dead	•	d to bed or	cnair				

Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W25

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment								
Day	Month	Year						
I .								

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)				Specify if Skin Toxicity is "01 Nail Changes"			0	SKIN TOXICITY CODES: 1 Nail changes (specify) 2 Erythema				
										0		ne/acneiform) squamation (non-acneiform)
		e of Skin list all that a		•	Specif	fy if Typ	oe of Sk	in Lesion	is "88 Other"	00 01	IN LESION CODES: 07 Dry flaking 08 Desquamation (sloughing) 09 Comedones	
										04	Macular	10 Cysts 88 Other (specify)
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Location (list all that apply) Specify if Location				ation is	 4 LOCATION CODES:09 Face10 Trunk	
		05 ≤ 50	J% BSA								11 Extremities 12 Total body 88 Other (spec	
1. If	1. If prior radiation, is area of radiation port involved?											
2. W	/as c	rusting p	resent	>					No ₁☐ Yes			
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes			
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes			
5. S	5. Since the last assessment, did the rash require treatment with narcotics? © No 1 Yes (Record on Concomitant Medications CRF)											
6. S	6. Since the last assessment, did the rash require treatment with systemic steroids?₀☐ No ₁☐ Yes											
7 14	loc o	loco hold	chanc	od or d	iccontinuo	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)
/ · · · ·	7. Was dose held, changed or discontinued for skin toxicity? Date											
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year			
											J	

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1,	
AMENDMENT 2.0			W25

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment								
Day	Month	Year						
l .								

	₀ No ✓	1 Yes √ Enter corre- sponding code from Photonumeric Scale*	* Photo- based Coding Scale (Record one code only) ①			
Were Pustules/Papules present?		' 				
Was Honey Yellow Crusting present?		 				
Was Erythema present?		 				
Was Paronychia present?		 				
Were Fissures present? (Photo-based scale does not apply)		 				
Does the following dermatological toxicity interfere with activities of daily living? Paronychia: O No Yes 66 N/A Fissures: O NO Yes 66 N/A						
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception ②						
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Moderat A B C D 02 A little 04 Very mu		05 Intoler	able			

For Amgen Use	e Only
Tick when	
data checked.	

А	Site I	No.		Sul	oject ID	No.			Subj	ect Initials
ABX-EGF 20020408			1,1,		1 1		ı	ı		
AMENDMENT 2.0										W27

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment									
Day	Month	Year							
	1 1								

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)				Specify if Skin Toxicity is "01 Nail Changes"			0	SKIN TOXICITY CODES: 1 Nail changes (specify) 2 Erythema				
										0		ne/acneiform) squamation (non-acneiform)
		e of Skin list all that a		•	Specif	fy if Typ	oe of Sk	in Lesion	is "88 Other"	00 01	IN LESION CODES: 07 Dry flaking 08 Desquamation (sloughing) 09 Comedones	
										04	Macular	10 Cysts 88 Other (specify)
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Location (list all that apply) Specify if Location				ation is	 4 LOCATION CODES:09 Face10 Trunk	
		05 ≤ 50	J% BSA								11 Extremities 12 Total body 88 Other (spec	
1. If	1. If prior radiation, is area of radiation port involved?											
2. W	/as c	rusting p	resent	>					No ₁☐ Yes			
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes			
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes			
5. S	5. Since the last assessment, did the rash require treatment with narcotics? © No 1 Yes (Record on Concomitant Medications CRF)											
6. S	6. Since the last assessment, did the rash require treatment with systemic steroids?₀☐ No ₁☐ Yes											
7 14	loc o	loco hold	chanc	od or d	iccontinuo	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)
/ · · · ·	7. Was dose held, changed or discontinued for skin toxicity? Date											
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year			
											J	

For Amgen Use Only
Tick when

data checked.

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W27

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment								
Day	Month	Year						

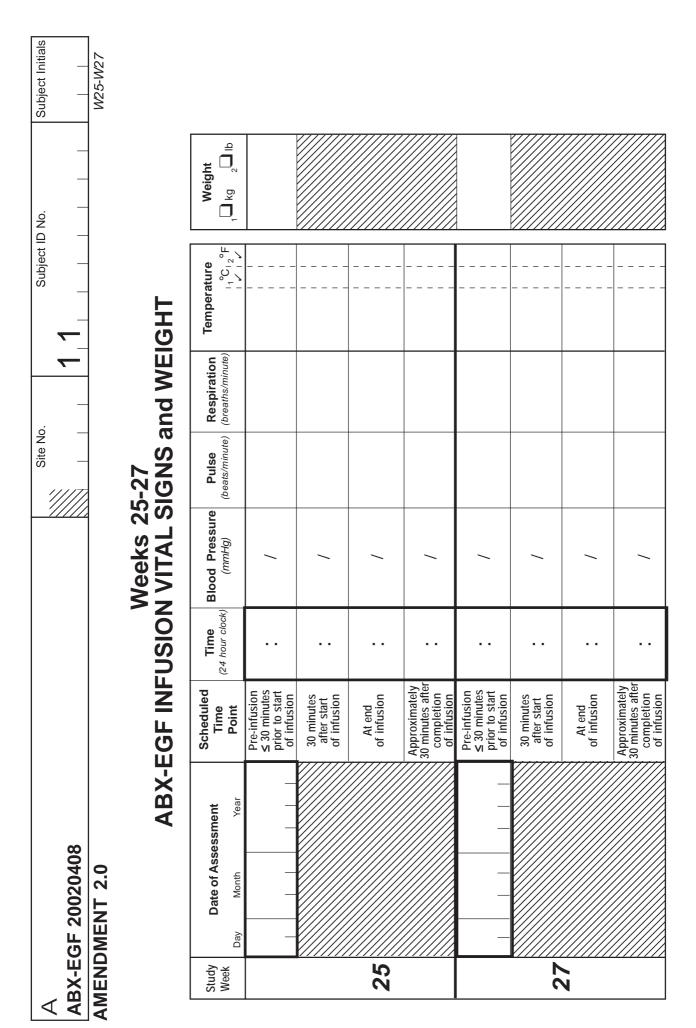
	₀ No ✓	Language 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		' 	
Was Honey Yellow Crusting present?		 	
Was Erythema present?		 	
Was Paronychia present?		 	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activitie	s of daily	living?	
Paronychia: ₀☐ No ₁☐ Yes 66☐ N	/A		
Fissures: □ No □ Yes 66 □ N	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio ②	n		
 PHOTO-BASED CODING SCALE CODES: A B C D SUBJECT PERCEPTION CODES: Not at all Modera A little Very mu 		05 Intoler	able

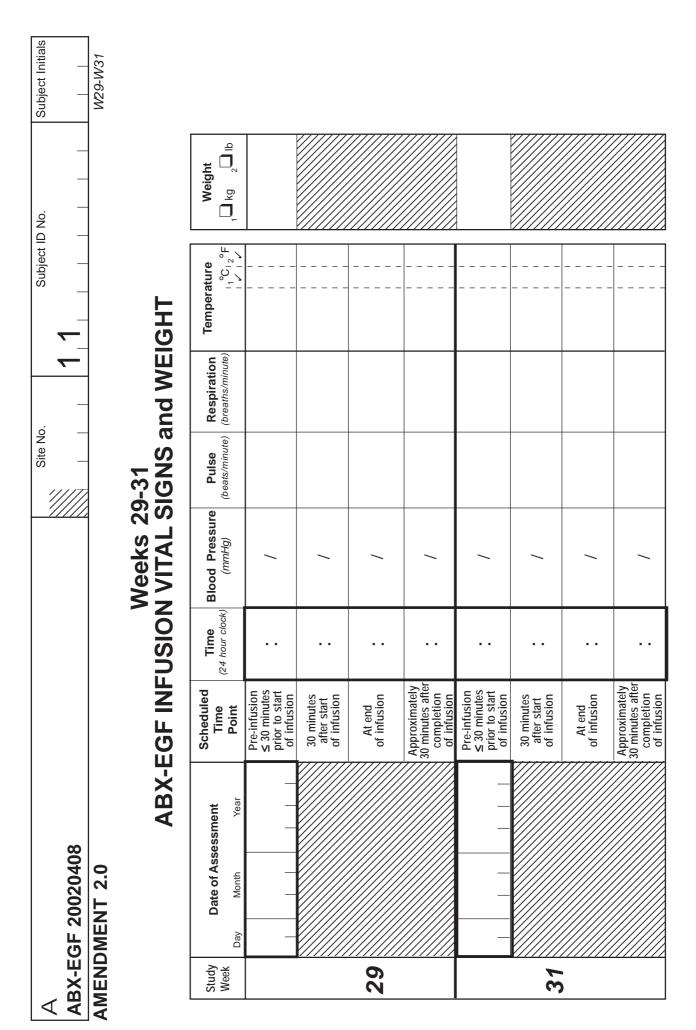
For Amgen Use	e Only
Tick when	
data checked.	

Treatment Phase VITAL SIGNS FOR ABX-EGF AND BSC

*Vital signs readings (every 2 weeks; within 30 minutes before the ABX-EGF infusion, approximately 30 minutes after the start of ABX-EGF infusion, upon completion of the ABX-EGF infusion, and approximately 30 minutes after completion of the ABX-EGF infusion, allowing a +/- 10 minute time window): blood pressure, resting pulse, respiration rate, and temperature (every 2 weeks).

*Weight (every 2 weeks, before the ABX-EGF infusion on ABX-EGF arm; every 4 weeks on BSC arm)





⋖								,		Site No.		Subject ID No.		Subject Initials	<u>v</u>
AB	X-EG	ABX-EGF 20020408	20408							-	<u>_</u>	-	-	_	
M	END	AMENDMENT 2.0	2.0											W25-W31	1
						Wee	eeks 25-31	25-31							
		Subje	IN cts receivin	VESTIG 19 BSC will no	ATIOP ot receive In	NAL PR	SODL 11 Produc	JCT,	ADM istration,	INVESTIGATIONAL PRODUCT ADMINISTRATION Seiving BSC will not receive Investigational Product Administration, please score through the	INVESTIGATIONAL PRODUCT ADMINISTRATION Subjects receiving BSC will not receive Investigational Product Administration, please score through the page	e <i>ō</i> i			
tudy		Date		Start Time	Stop Time	Total Dose	Total Volume	Reason for i Dose	If "04 Per protocol" is indicated for "Reason for		If Reason "88 Ott	If Reason for Dose Change is "88 Other", please specify	e is		
מפע	Day	Month	Year		ì			Cnange	indicate code						
5		-	_ _ _					_	_ _						
7	_	-	_ _ 					_	_						
6		_						_	_						
31	_	_						_	_						
[subj	ect did r	not complet	te investigatio	subject did not complete investigational product administration, provide any	ninistration, p		additional relevant information:	vant infor	mation:						
DO	SE CHAN	DOSE CHANGE CODES:		② "04 Per r	orotocol" DOS	② "04 Per protocol" DOSE CHANGE CODES:	DES:								
03 03 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Adverse event Noncompliance Dose administra Per protocol Other (Specify a	Adverse event Noncompliance Dose administration error Per protocol Other (Specify above)	rror	100 Wei 118 Syn or ft 120 Skii	Weight change Symptomatic skin or felt to be intoler Skin infection req	Weight change Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject Skin infection requiring systemic IV antibiotic or IV antifungal treatment	requiring r	narcotics, :	systemic st ungal treat	eroids, ment	121 Need for 122 Any skin 200 Dose rei 201 Dose inc	Need for surgical debridement Any skin-related serious adverse event Dose reinstated Dose increase (<i>after reinstatement</i>)	nent dverse event tatement)		

data checked.

For Amgen Use Only Tick when

Α	1111	Site No.					Sul	bject	ID No).			Sul	oject	Initials
ABX-EGF 20020408		1 1	I	1	1	I	ı	ı	ı	1	ı	1		ı	ı
AMENDMENT 2.0													И	/25-1	N31

Weeks 25-31 INVESTIGATIONAL PRODUCT LOT NUMBER

Study Week	ABX-EGF Package Lot Number	ABX-EGF Package Lot Number
25		
27		
29		
31		

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W29

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

	Date of Asse	essment
Day	Month	Year
L	1 1 1	

	I would like to ask you a few questions have made to a doctor o	about any additional visits (no r an outpatient facility in the l		ou ma
1.	Emergency Room Visits Number of emergency room visits			
2.	Therapy Visits Number of therapy (mental health) visits			
3.	Outpatient visits to specialists (to addition to your routine care, such			
	Pain Management Specialist: Number of outpatient physician visits			
	Radiologist: Number of outpatient physician visits			
	Radiation Oncology: Number of outpatient physician visits			
4.	Outpatient Procedures Any outpatient surgical procedures		Yes No)
	If yes, please describe:			
	Blood transfusions number of times			
	Other procedures?		Yes No)
	If yes, please describe:			
5.	Caregiving In a typical (24 hour) day, how many hou of your illness:	ırs of support do you receive	from each of the following bed	caus
		Trained Medical Person	Others	
	Paid caregiver	hours	hours	
	Unpaid caregiver	hours	hours	
6. For An	Nursing Home / Hospice Days Number of days spent in a nursing home			

Tick when data checked.

\wedge	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			W29

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

	Date of Exan	nination
Day	Month	Year

	the subject have any abnormal clinical find	ings relating to the followi	ing required sites?	$_{0}$ No $_{1}$ Yes - If yes,
01 l 02 l	be findings below. Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Pulmonary	04 Abdomen05 Musculoskeletal06 Skin		11 Rectal
		required assessment was i		ou outor
Code (as listed above)		Describe findings List one entry per line.		

ECOG PERFORMANCE STATUS

			Date (of Asse	ssme	nt			ECOG Performance
Da	у		Mon	th			Year		Status ①
1	ECOG	PER	FORN	IANCE S	TATUS	COI	DES:		
0	•		•	to carry		ore-di	sease		
1	Resti	ricted able to	in phy carry	sically st out worl	renuou k of a li	ght o			•
2	Ambi	ulatory	and	capable	of all se	elf-cai			o carry ng hours.
3			-	limited se	elf-care	, conf	ined to	bed or o	chair
4				oled. Car o bed or		rry ou	t any se	elf-care.	
5	Dead	-							

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		111, , , , , , , ,	
AMENDMENT 2.0	_		W29

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment					
Day	Month	Year			
I .					

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

			Toxicity that app	•	Specify if Skin Toxicity is "01 Nail Changes"		SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema				
										O3 Pruritus/it O4 Rash (acr O5 Rash/deso O6 Ulceration	ne/acneiform) quamation (non-acneiform)
		e of Skin list all that a		•	Specif	fy if Typ	oe of Sk	in Lesion	is "88 Other"	00 None 0	N LESION CODES: 77 Dry flaking 8 Desquamation (sloughing) 9 Comedones
										04 Macular	10 Cysts 38 Other (specify)
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Locationst all tha	on ④ at apply)		Specify if Loca	tion is "88 Other"	4 LOCATION CODES:09 Face10 Trunk
		05 ≤ 50	1% BSA				-				11 Extremities12 Total body88 Other (specify)
1. If	prio	r radiatio	n, is are	a of rac	diation port	involv	/ed?	66	Not applicable	₀□ No ₁□ Ye	es
2. W	/as c	crusting p	resent	>					No ₁☐ Yes		
3. Since the last assessment, did the rash cause pain? $_{\scriptscriptstyle 0}\Box$ No $_{\scriptscriptstyle 1}\Box$ Yes											
4. Since the last assessment, did the rash cause itching? $_{\scriptscriptstyle 0}\Box$ No $_{\scriptscriptstyle 1}\Box$ Yes											
5. Since the last assessment, did the rash require treatment with narcotics?											
6. Since the last assessment, did the rash require treatment with systemic steroids? One of the last assessment, did the rash require treatment with systemic steroids? One of the last assessment as the state of the last as the last as the state of the last as the state of the last as the											
(Record on Concomitant Medications CRF)											
7. Was dose held, changed or discontinued for skin toxicity? Date											
(N 🗖	No 1 Ye	es - If y	es, prov	vide date.	Day	/	Month	Year		

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Tick when

data checked.

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			W29

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment				
Day	Month	Year		

o d		Enter corre- sponding code from Photo- numeric Scale*	based Coding Scale (Record one code only) ①	
Were Pustules/Papules present?	į			
Was Honey Yellow Crusting present?				
Was Erythema present?	1			
Was Paronychia present?	1			
Were Fissures present? (Photo-based scale does not apply)				
Does the following dermatological toxicity interfere with activities of daily living?				
Paronychia: ₀☐ No ₁☐ Yes ₀₀☐ N/A				
Fissures: ₀ ☐ No ₁ ☐ Yes 66 ☐ N/A				
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception ②				
1 PHOTO-BASED CODING SCALE CODES: CODES: A B C D 2 SUBJECT PERCEPTION CODES: 01 Not at all 03 Moderate 04 Very much		05 Intoler	able	

For Amgen Use Only				
Tick when				
data checked.				

Δ	Site N	lo.		Su	ıbject	ID No.				Subj	ect In	itials
ABX-EGF 20020408			1,1,	1		ı	ſ	I	1			
AMENDMENT 2.0											W.	31

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment									
Day	Month	Year							
I .									

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

TOXIO	ty / 13	0000	111011	io page	, and re	COIG SKIII (OXIOIL	y 0117 (L	- 0111.						
Skin Toxicity (list all that apply)							•	fy if Skin ⁻ 1 Nail Cha	Toxicity is nges"	SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching					
											04 Rash (acne				
			Skin L that a	esions	5	Speci	ecify if Type of Skin Lesion is "88 Other"				00 None 07 01 Pustular 08	LESION CODES: Dry flaking Desquamation (sloughing) Comedones			
			I								04 Macular 10	Cysts Other (specify)			
Total % Affec		04	> 50	% BSA (% BSA	ODES:	(lis	Location ④ Specify if Locat				ion is "88 Other"	 LOCATION CODES:09 Face10 Trunk			
		05	≤ 50	% BSA				ı				11 Extremities 12 Total body 88 Other (specify)			
1. If	1. If prior radiation, is area of radiation port involved?														
2. V	Vas c	rusti	ng pi	resent	?					No ₁☐ Yes					
3. S	ince	the I	ast a	ssessr	nent, di	d the rash	cause	e pain?		No ₁☐ Yes					
4. S	ince	the l	ast a	ssessr	nent, di	d the rash	cause	e itchin	g? ₀□	No ₁☐ Yes					
5. S	ince	the l	ast a	ssessr	nent, di	d the rash	requi	re treat		h narcotics? cord on Concomit	₀☐ No ₁☐ tant Medications C				
6. S	ince	the I	ast a	ssessr	nent, di	d the rash	requi	re treat		-	oids?₀☐ No ₁☐				
									(Re	cord on Concomit	ant Medications C	CRF)			
7. V	Vas d	lose	held,	chang	jed or d	iscontinue	d for s	skin tox	cicity?						
ı	۱ ــ	No 1	☐ Ye	es - If y	es, pro	vide date.	Da	ау	Month D	Year Year					

For Amgen Use Only
Tick when

data checked.

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W31

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment									
Day	Month	Year							
l .									

		_o No ✓	1 Yes √ Enter corre- sponding code from Photonumeric Scale*	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules preser	t?		1	
Was Honey Yellow Crusting pre	esent?			
Was Erythema present?			1	
Was Paronychia present?			1	
Were Fissures present? (Photos	o-based scale does not apply)			
Does the following dermatolog	ical toxicity interfere with activiti	es of daily	/ living?	
Paronych	iia: ₀☐ No ₁☐ Yes ₆₆ ☐ I	N/A		
Fissures:	₀ ☐ No ₁ ☐ Yes 66 ☐ I	N/A		
How bothered do you perceive by the dermatologic toxicities ?	' D(!			
① PHOTO-BASED CODING SCALE CODES:	② SUBJECT PERCEPTION CODES 01 Not at all 03 Moder	ate	05 Intoler	able
A B C D	02 A little 04 Very n	nuch		

For Amgen Use	e Only
Tick when	
data checked.	

Δ	////	Site No.				S	ubject	ID N	0.			Sub	ject Initials
ABX-EGF 20020408		1 1	ı	1	1,	ı	ı	ı	ı	ı	I		
AMENDMENT 2.0			·			·			·				W32

Week 32 TUMOR EVALUATION - TARGET LESIONS

Date of Procedure									
Day	Month	Year							

Lesion Note: Always maintain the same order of lesion	Lesion Site Code	Subsite Describe specific location	Method of Assessment	measurable
numbers	1		!	Dimensions (mm)
01				
02				
03				
04				
05				
06			'	
07				
08				
09				
10				
		Sum (of Target	

				Lesions
① LESION SITE CO 00 Lymph nodes 10 Pulmonary 20 Liver 30 Bone	40 Chest 60 50 Central nervous system 75	Abdomen 88	Skin Other (specify in subsite above)	 @ METHOD OF ASSESSMENT: 01 X-Ray 03 Conventional Computed Tomography (CT) 04 Magnetic Resonance Imaging (MRI) 23 Spiral Computed Tomography (CT) 88 Other (specify below)
Line #		" Method of Asses	ssment	

For Amgen Use Only								
Tick when								
data checked.								

A	1111	Site No.					Subj	ect ID	No.			Subj	ect Initials
ABX-EGF 20020408		1 1	I	1	1	l		ı	1	ı	I		
AMENDMENT 2.0													W32

	•	TUM			JATION - Nord all other lesion				SIONS
Lesion Note: Always maintain the same order of lesion		Date of Pro	ocedure	Body Site Code	Subsit Describe specif		Method of Assessment	New Lesions	Measurable Lesions (mm) Must be unidimensionally measurable.
numbers	Day	Month	Year	①			2	₀No ₁Yes	Dimensions (mm)
11				1				 	
12								 	
13								 	
14									
15									
16									
						Sum	of Non-T Les	arget sions	
00 L	ymph no ulmona iver		40 C	entral ner ead	ous system	60 Gastro 70 Abdom 75 Pelvic 85 Spleen	Site	86 88	_
01	X-Ray		SMENT COE		04 Magnetic23 Spiral Co88 Other (sp	Resonance In mputed Tomogrecify below)	naging (MRI) graphy (CT)		
Line #					Specify if "88 Othe	" Method of	f Assessmen	it	

roi Ailigeli Usi	# Offing
Tick when	
data checked.	

Δ	////	Site No.					Subje	ect ID	No.			Sub	ject Initials
ABX-EGF 20020408		1 1	ı	1	1	I		I	ı	ı	1		1 1
AMENDMENT 2.0			'										W32

Week 32 OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study		Date)		Tumor Response
Week	Day	Month		Year	Code ①
32					
① TUMOF	RESPON	SE CODE:			
PD I	Complete Re Progressive I Partial Respo	Disease	SD UE	Stable Disease Unable to evalua	ate

Weeks 25-32 PROCEDURES CYTOLOGY Vas any cytology performed? Indings: Date of Procedure		1				<u> </u>					
Weeks 25-32 PROCEDURES CYTOLOGY Vas any cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure Day Month Vasar Surgical S	A	Site N	No.		ibject ID No.	Subject Initials					
Weeks 25-32 PROCEDURES CYTOLOGY Vas any cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure Day Month Vasar Surgical S	ABX-EGF 20020408	\/// ₁	<u> </u>	1,1,							
Weeks 25-32 PROCEDURES CYTOLOGY Vas any cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure Day Month Vear Day Date of Procedure Day Month Vear Day Date of Procedure Day Month Vear Day Date of Procedure Day Date of Procedure Day Month Vear Day Date of Procedure D		1///				W25-W32					
PROCEDURES Cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure Procedure Code Security Procedure Security Security Procedure Security Security Security Procedure Security AMENDMENT Z.V											
PROCEDURES Cytology performed? □ No □ Yes - If yes, specify below. Date of Procedure Procedure Colif Security Procedure Security Procedure Security Security Security Procedure Security Security Procedure Security		1/1	looks '	25-32							
Vere any surgical procedure Date of Procedure Day Month Verar Procedure Code C											
Vas any cytology performed?		1 1									
Date of Procedure Day Month Vear O	Was any cytology performed? ₀☐ N	No ₁☐ Yes-	If yes, spec	ify below.							
Equivocal findings: Surgical Surgical procedure Procedure Body Site Specify if Body Site is "88 Other" Surgical Surgical Procedure Surgical Procedure Surgical Procedure Surgical Surgical Procedure Surgical S	Date of Procedure										
Equivocal findings: Surgical	Day Month Year				otner" is "88 Oin						
SURGICAL Vere any surgical procedure Procedure Code Code (b) Specify if Body Site is CODE: 32 Surgical						31 Thoracentesis					
SURGICAL Vere any surgical procedures performed? □ No □ Yes - If yes, specify below. Date of Procedure Code Code Code © 3 2 Surgical Procedure Code © 6 Specify if Body Site is Code: "88 Other" Date of Procedure Day Moreh Year Procedure Code © © Specify if Body Site is "88 Other" Date of Procedure Code © © Specify if Body Site is "88 Other" Date of Procedure Code © © Specify if Body Site is "88 Other" Date of Procedure Code © © Specify if Body Site is "88 Other" Findings: PROCEDURE CODE: "88 Other" CODE: "88 Other" CODE: "88 Other" CODE: "88 Other" Specify if Body Site is "88 O			1			88 Other (Specify					
Date of Procedure Procedure Code Code Specify if Body Site Specify if Body Sit	Equivocal findings:										
Date of Procedure Procedure Code Code Specify if Body Site Specify if Body Sit											
Date of Procedure Procedure Code Code Specify if Body Site Specify if Body Sit											
Date of Procedure Procedure Code Code Specify if Body Site Specify if Body Sit			SURGI	CAL							
Date of Procedure Day Month Vear Section Specify	Were any surgical procedures perform	rmed? ₀☐ No			elow.						
Body Site Specify if Body Site is Specify if Body Site Site Specify if Body Site Specify Specify if Body Site Specify if Body Site Specify Specify if Body Site Sp	Date of Procedure										
Findings: BIOPSY Date of Procedure Procedure Code Code Code Specify if Body Site is PROCEDURE To Body Site Specify if Procedure Specify if Procedure Specify if Procedure Specify if Procedure Specify if Body Site Specify if Procedure Specify if Body Site Specify if Procedure Specify if Procedure Specify if Procedure Specify if Body Site Specify i	Day Month Year			88	Other"						
Findings: Date of Procedure		2 2									
Was biopsy performed? o☐ No ☐ Yes - If yes, specify below. Date of Procedure		$[\mathcal{S}_1 \mathcal{Z}_1]$									
Date of Procedure Day Month Year Procedure Code (3)	Findings:										
Date of Procedure Day Month Year Procedure Code (3)				· · · · · · · · · · · · · · · · · · ·		 					
Date of Procedure Day Month Year Procedure Code (3)											
Date of Procedure Day Month Year Procedure Code (3)			BIOD	ev							
Date of Procedure Day Month Year	Was biopsy performed? ₀☐ No ₁Ū	Tes - If yes	, specify be	low.							
Date of Procedure Day Month Year Date of Procedure Specify if Procedure Code is "88 Other" Specify if Body Site is "88 Other" CODE: 33 Colonoscopy 34 Sigmoidoscopy 38 Other (Specify) Specify above) Description Findings: Description Descripti	Date of Procedure										
Findings: Date of Procedure	Day Month Year			"88	Other"						
Findings: Nas endoscopy performed? No Yes - If yes, specify below.		1 6				16 Biopsy					
Was endoscopy performed? o☐ No 1☐ Yes - If yes, specify below. Date of Procedure Day Month Year											
Nas endoscopy performed? o☐ No 1☐ Yes - If yes, specify below. Date of Procedure Day Procedure Month Body Site Site Code is "88 Other" Specify if Procedure Code is "88 Other" Specify if Body Site is "88 Other" © PROCEDURE CODE: 33 Colonoscopy 34 Sigmoidoscopy 3	Findings:										
Nas endoscopy performed? o☐ No 1☐ Yes - If yes, specify below. Date of Procedure Day Procedure Site Day Body Site Site Code is "88 Other" Specify if Procedure Code is "88 Other" Specify if Body Site is "88 Other" © PROCEDURE CODE: 33 Colonoscopy 34 Sigmoidoscopy 34 Sigmoidoscop											
Nas endoscopy performed? o☐ No 1☐ Yes - If yes, specify below. Date of Procedure Day Procedure Month Body Site Site Code is "88 Other" Specify if Procedure Code is "88 Other" Specify if Body Site is "88 Other" © PROCEDURE CODE: 33 Colonoscopy 34 Sigmoidoscopy 3											
Date of Procedure Day Month Year Procedure Site Code is "88 Other" Specify if Procedure Code is "88 Other" Specify if Body Site is "88 Other" Specify if Procedure Code: 33 Colonoscopy 34 Sigmoidoscopy 88 Other (Specify) Findings: DBODY SITE 01 Abdomen CODES: 02 Brain 06 Eye 01 Kidney 03 Breast 07 Gastrointestinal tract 11 Liver 15 Retroperitoneum 19 Extremity(ies) 19 Extremity(ies) 23 Neck Or Amgen Use Only		I	ENDOS	COPY							
BODY SITE 01 Abdomen 05 Chest 09 Heart 13 Pleura 17 Total body 18 Other (Specify) BODY SITE 02 Brain 06 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) 03 Breast 07 Gastrointestinal tract 11 Liver 15 Retroperitoneum 19 Extremity(ies) 04 Bone 08 Head 12 Lung 16 Skin 23 Neck CODE: Site Code is "88 Other" is "88 Other" CODE: 33 Colonoscopy 34 Sigmoidoscopy 88 Other (Specify) 88 Other (Specify above) 17 Total body 18 Thorax (Specify above) 18 Thorax (Specify above)	Was endoscopy performed? ₀┕ N				Charles if Dady Cita	I					
Findings: BODY SITE 01 Abdomen O5 Chest O9 Heart 13 Pleura 17 Total body 14 Pelvic site 18 Thorax (Specify above) O BODY SITE 01 Abdomen O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) O BODY SITE O1 Abdomen O5 Chest O7 Gastrointestinal tract 11 Liver 15 Retroperitoneum 19 Extremity(ies) O BODY SITE O1 Abdomen O5 Chest O7 Gastrointestinal tract 11 Liver O7 Gastrointestinal tract 12 Lung O7 Gastrointestinal tract 12 Lung O7 Gastrointestinal tract O7 Gastrointestinal tr	Date of Procedure		Site Co								
Findings: BODY SITE 01 Abdomen O5 Chest O9 Heart 13 Pleura 17 Total body 14 Pelvic site 18 Thorax (Specify above) OBODY SITE 01 Abdomen O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O5 Chest O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O5 Chest O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O5 Chest O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O5 Chest O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O5 Chest O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O5 Chest O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O5 Chest O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) OBODY SITE O1 Abdomen O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above)	Day Month Year		4								
Findings: BODY SITE 01 Abdomen O5 Chest O9 Heart 13 Pleura 17 Total body Size ODES: 02 Brain O6 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) 03 Breast O7 Gastrointestinal tract 11 Liver 15 Retroperitoneum 19 Extremity(ies) O4 Bone O8 Head 12 Lung 16 Skin O7 S											
BODY SITE 01 Abdomen 05 Chest 09 Heart 13 Pleura 17 Total body 14 Pelvic site 18 Thorax (Specify above) 03 Breast 07 Gastrointestinal tract 04 Bone 08 Head 12 Lung 16 Skin 23 Neck 88 Other (Specify above) 15 Retroperitoneum 19 Extremity(ies) 23 Neck						ou other (Specify)					
CODES: 02 Brain 06 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) 03 Breast 07 Gastrointestinal tract 04 Bone 08 Head 12 Lung 16 Skin 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 12 Lung 16 Skin 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 16 Skin 16 Skin 17 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 16 Skin 17 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 17 Retroperitoneum 19 Extremity(ies) 24 Retroperitoneum 19 Extremity(ies) 25 Retroperitoneum 19 Extremity(ies) 26 Retroperitoneum 19 Extremity(ies) 27 Retroperitoneum 19 Extremity(ies) 28 Retroperitoneum 19 Extremity(ies) 29 Retroperitoneum 19 Extremity(ies) 29 Retroperitoneum 19 Extremity(ies) 20 Re	Findings:										
CODES: 02 Brain 06 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) 03 Breast 07 Gastrointestinal tract 04 Bone 08 Head 12 Lung 16 Skin 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 12 Lung 16 Skin 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 16 Skin 16 Skin 17 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 16 Skin 17 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 17 Retroperitoneum 19 Extremity(ies) 24 Retroperitoneum 19 Extremity(ies) 25 Retroperitoneum 19 Extremity(ies) 26 Retroperitoneum 19 Extremity(ies) 27 Retroperitoneum 19 Extremity(ies) 28 Retroperitoneum 19 Extremity(ies) 29 Retroperitoneum 19 Extremity(ies) 29 Retroperitoneum 19 Extremity(ies) 20 Re						 					
CODES: 02 Brain 06 Eye 10 Kidney 14 Pelvic site 18 Thorax (Specify above) 03 Breast 07 Gastrointestinal tract 04 Bone 08 Head 12 Lung 16 Skin 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 12 Lung 16 Skin 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 15 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 16 Skin 16 Skin 17 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 16 Skin 17 Retroperitoneum 19 Extremity(ies) 23 Neck (Specify above) 17 Retroperitoneum 19 Extremity(ies) 24 Retroperitoneum 19 Extremity(ies) 25 Retroperitoneum 19 Extremity(ies) 26 Retroperitoneum 19 Extremity(ies) 27 Retroperitoneum 19 Extremity(ies) 28 Retroperitoneum 19 Extremity(ies) 29 Retroperitoneum 19 Extremity(ies) 29 Retroperitoneum 19 Extremity(ies) 20 Re	DODY CITE			40 =:							
04 Bone 08 Head 12 Lung 16 Skin 23 Neck or Amgen Use Only	CODES: 02 Brain 06 Eye		10 Kidney	14 Pelvic site	18 Thorax	(Specify above)					
						es)					
num water to the first term of	or Amgen Use Only										

DISTRIBUTION: White & Yellow - Amgen; Blue - CRA; White Card - Investigator

data checked.

WEEKS 33 - 40

Α	1111.	Site No.			S	ubject	ID N	0.			Subj	ect Initials
ABX-EGF 20020408			1,	1	ı	1	ı	ı	ı	1		
AMENDMENT 2.0												W33

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment											
Day Month Year											
L	1 1	, , ,									

I would like to ask yo have r			additional visits tient facility in th			rial) that y	ou m
Emergency Room Number of emergency							
Therapy Visits Number of therapy (m	ental health) vis	sits					
Outpatient visits to addition to your ro							
Pain Management Number of outpatient	Specialist:	·	·				
Radiologist: Number of outpatient	physician visits						
Radiation Oncolog Number of outpatient	jy: physician visits						
Outpatient Proced Any outpatient surgica					Yes		lo
If yes, please describ	e:						
Blood transfusions nu	mber of times						
Other procedures?					Yes		lo
If yes, please describe	e:						
Caregiving In a typical (24 hour) of your illness:	lay, how many h	nours of supp	ort do you recei	ve from ea	ch of the fo	ollowing <i>b</i>	ecaus
		Trained M	edical Person		Others		
Paid ca	aregiver		hours			hours	
Unpaid	l caregiver		hours			hours	
Nursing Home / Ho Number of days spent		me					

Δ	Site No).		Subje	ect ID No).			Subj	ect In	itials
ABX-EGF 20020408			1 1	1 1	ı	ı	ı	1			
AMENDMENT 2.0	1,7,7,7	•	'	'				•		W	33

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination											
Day Month Year											

	the subject have any abnormal	clinical find	ings relati	ng to the	followin	ng requ	ired sites?	₀ No	₁☐ Yes - If yes,		
descri	be findings below.										
	Head, Ears, Eyes, Nose, Throat (HEEI	NT) / Neck		odomen			Lymph nodes		10 Breast / Chest		
	Cardiovascular			usculoskel	etal		Neurological		11 Rectal		
03	Pulmonary		06 SI				Genitourinary		38 Other		
	Indicate if a required assessment was not done.										
Code											
(as			Desc	ribe find	ings						
listed			List on	e entry pe	er line.						
above)											
l											
l 1											
l 1											
l											
I +											

ECOG PERFORMANCE STATUS

		ECOG Performance						
Da	Day Month		onth			Status ①		
0 1 2 3	Fully performed Restrand a ie, light Amburout a Capar > 50% Comp	active, abormance wricted in pable to caught housevalutory anny work able of only of wakingletely dispersion.	sabled. Car	on all priction trenuou k of a li ce work of all sepand a lelf-care	ore-di is acti ght or c elf-car about , conf	sease ivity, bu r seden re, but to > 50% ined to	tary natous unable to of wakin bed or o	ure, o carry og hours.
5	Dead	•	d to bed or	cnair				

Δ	Site No.	Site No.			Subject ID No.							
ABX-EGF 20020408			1,1,	I		I	I	ı				ļ
AMENDMENT 2.0											W.	33

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment												
Day	Month	Year										
I .												

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

	Skin Toxicity (list all that apply)						•	y if Skin l	Foxicity is inges"	0	SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching				
										0	4 Rash (acı	ne/acneiform) squamation (non-acneiform)			
	Type of Skin Lesions (list all that apply) © Specify if Type of Skin Lesion is "88 Other"					00 01	 TYPE OF SKIN LESION CODES: 00 None 07 Dry flaking 01 Pustular 08 Desquamation (slough 02 Vesicular 09 Comedones 								
										04	Macular	10 Cysts 88 Other (specify)			
Total % Affec	- 1	od Cocation & Specify if Location is accepted Cocation is accept							"88 Other"	 4 LOCATION CODES:09 Face10 Trunk					
		05 ≤ 50	J% BSA				ı					11 Extremities 12 Total body 88 Other (specify)			
1. If	1. If prior radiation, is area of radiation port involved?														
2. W	/as c	rusting p	resent	>					No ₁☐ Yes						
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes						
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes						
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications				
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1				
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)			
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1				
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year						
											J				

А	////	Site No.				S	ubject	ID N	0.		S	ubjec	t Initials	s
ABX-EGF 20020408		1 1	ı	1	1	I		ı	ı	1		ı	I	
AMENDMENT 2.0													W33	_

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment												
Day	Month	Year										
	1 1											

		_o No ✓	I 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?	,			
Was Honey Yellow Crusting pres	ent?		1	
Was Erythema present?			1	
Was Paronychia present?		1		
Were Fissures present? (Photo-	oly)	 		
Does the following dermatological	al toxicity interfere with act	ivities of daily	/ living?	
Paronychia	ı: ₀☐ No ₁☐ Yes ₆₆	☐ N/A		
Fissures:	₀ No ₁ Yes 66	☐ N/A		
How bothered do you perceive the by the dermatologic toxicities?	Perc	oject eption ②		
① PHOTO-BASED CODING SCALE CODES:	SUBJECT PERCEPTION COI01 Not at all03 M	DES: oderate	05 Intoler	able
A B C D	02 A little 04 V	ery much		

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	1 1
AMENDMENT 2.0			W35

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment												
Day	Month	Year										

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

	Skin Toxicity (list all that apply)						•	y if Skin l	Foxicity is inges"	0	SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching				
										0	4 Rash (acı	ne/acneiform) squamation (non-acneiform)			
	Type of Skin Lesions (list all that apply) © Specify if Type of Skin Lesion is "88 Other"					00 01	 TYPE OF SKIN LESION CODES: 00 None 07 Dry flaking 01 Pustular 08 Desquamation (slough 02 Vesicular 09 Comedones 								
										04	Macular	10 Cysts 88 Other (specify)			
Total % Affec	- 1	od Cocation & Specify if Location is accepted Cocation is accept							"88 Other"	 4 LOCATION CODES:09 Face10 Trunk					
		05 ≤ 50	J% BSA				ı					11 Extremities 12 Total body 88 Other (specify)			
1. If	1. If prior radiation, is area of radiation port involved?														
2. W	/as c	rusting p	resent	>					No ₁☐ Yes						
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes						
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes						
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications				
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1				
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)			
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1				
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year						
											J				

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			W35

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

	Date of Asse	essment
Day	Month	Year

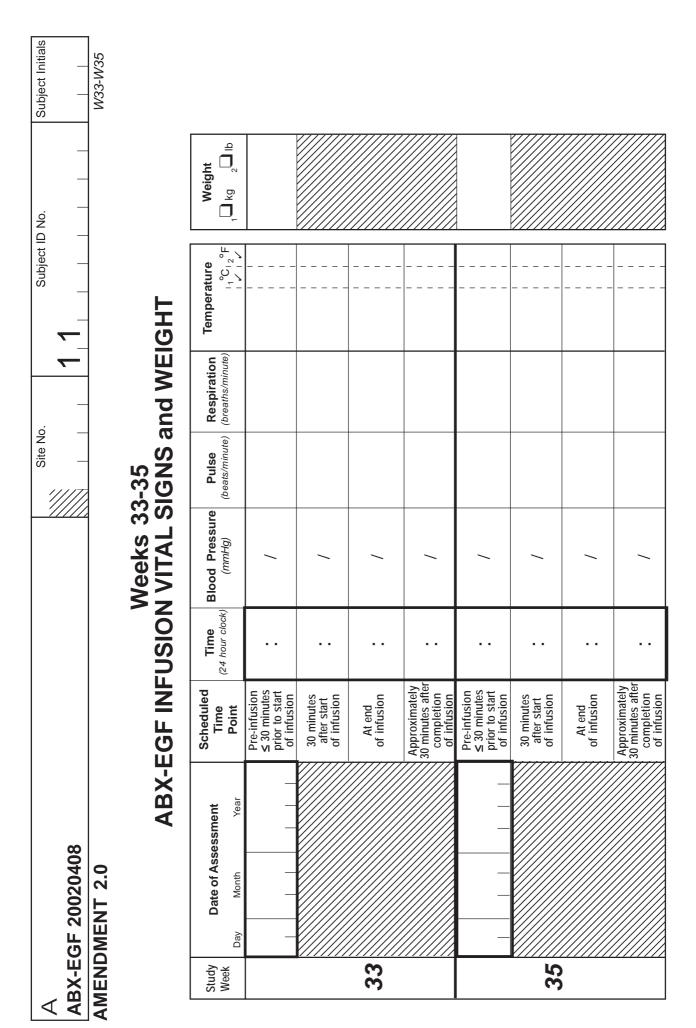
	₀ No√	Yes V Enter corre- sponding code from Photonumeric Scale*	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		1	
Was Honey Yellow Crusting present?		1	
Was Erythema present?		1	
Was Paronychia present?		1	
Were Fissures present? (Photo-based scale does not apply)		1	
Does the following dermatological toxicity interfere with activities	s of daily	y living?	,,,,,,
Paronychia: ₀☐ No ₁☐ Yes 66☐ N	I/A		
Fissures: 0 No 1 Yes 66 N	I/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception 2			
 PHOTO-BASED CODING SCALE CODES: SUBJECT PERCEPTION CODES: Not at all Modera 	ate	05 Intoler	able
A B C D 02 A little 04 Very m	uch		

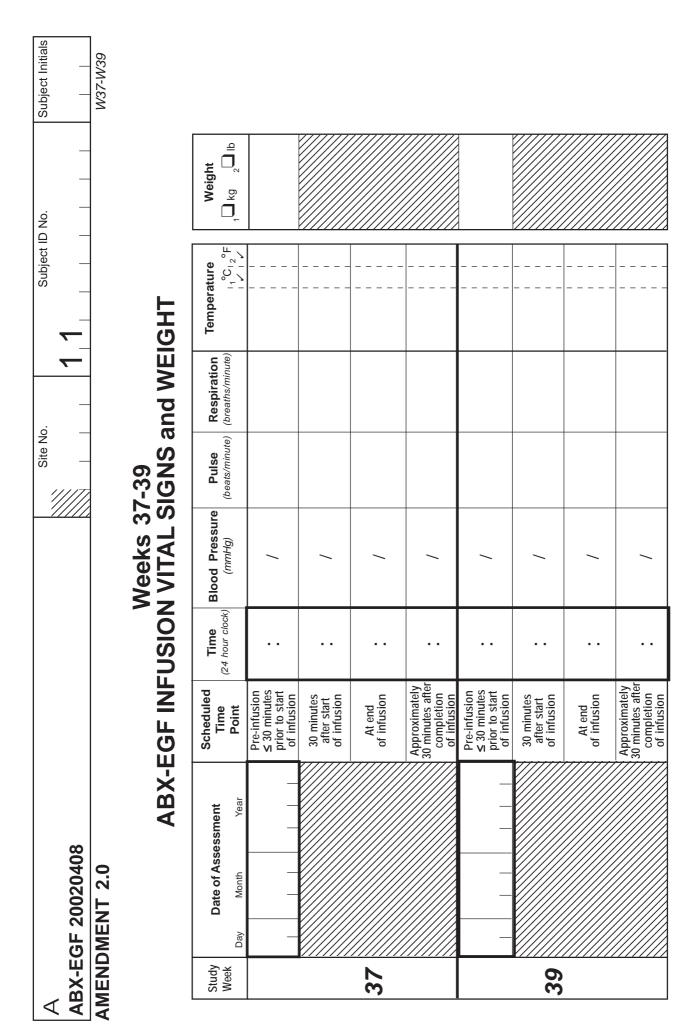
For Amgen Use	e Only
Tick when	
data checked.	

Treatment Phase VITAL SIGNS FOR ABX-EGF AND BSC

*Vital signs readings (every 2 weeks; within 30 minutes before the ABX-EGF infusion, approximately 30 minutes after the start of ABX-EGF infusion, upon completion of the ABX-EGF infusion, and approximately 30 minutes after completion of the ABX-EGF infusion, allowing a +/- 10 minute time window): blood pressure, resting pulse, respiration rate, and temperature (every 2 weeks).

*Weight (every 2 weeks, before the ABX-EGF infusion on ABX-EGF arm; every 4 weeks on BSC arm)





1								-, /	Site No.		Subject ID No.	Subject Initials
AB	ABX-EGF 20020408	80					· / / / /		_		- - -	_
Σ	MENDMENT 2.0									-	-	W33-W39
					Wee	Weeks 33-39	3-39					
	Subjects re	INVE ceiving E	ESTIG 3SC will no	ATION of receive Ir	INVESTIGATIONAL PRODUCT ADMINISTRATION seiving BSC will not receive Investigational Product Administration, please score through the	ODI Il Produc	JCT /	ADM Stration,	INISTR please score	INVESTIGATIONAL PRODUCT ADMINISTRATION Subjects receiving BSC will not receive Investigational Product Administration, please score through the page		
udy	Date Month	Year	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume	Reason for bose Dose Dose Dose Dose Dose Dose Dose D	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code		If Reason fo "88 Other"	If Reason for Dose Change is "88 Other", please specify	
33		_					_	_				
35		_					_	_				
37							_					
62							_					
gns	subject did not complete investigational product administration, provide any	stigational	product adm	ninistration, pr	rovide any addi	itional rele	additional relevant information:	nation:				
				=		0						
000 P P P P P P P P P P P P P P P P P P	DOSE CHANGE CODES: 11 Adverse event 12 Noncompliance 13 Dose administration error 14 Per protocol 18 Other (Specify above)		204 Per p 100 Wei 118 Sym or fe 120 Skin	 2. "04 Per protocol" DOSE CHANGE 100 Weight change 118 Symptomatic skin-related toxi or felt to be intolerable by subj 120 Skin infection requiring system 		CODES: city requiring r ect nic IV antibiotio	narcotics, s	iystemic st ungal treat	eroids, ment	121 Need for surgica 122 Any skin-related 200 Dose reinstated 201 Dose increase (Need for surgical debridement Any skin-related serious adverse event Dose reinstated Dose increase (after reinstatement)	

data checked.

For Amgen Use Only Tick when

Δ	////	Site No.		Sı	ubject	ID No	٥.		Subj	ect I	nitials
ABX-EGF 20020408			1 1 1	ı	ı	ı	ı	ı			
AMENDMENT 2.0									W.	33- <i>V</i>	/39

Weeks 33-39 INVESTIGATIONAL PRODUCT LOT NUMBER

Study Week	ABX-EGF Package Lot Number	ABX-EGF Package Lot Number
33		
35		
37		
39		

Δ	Site No.		,	Subjec	t ID No.				Sub	ect In	itials
ABX-EGF 20020408		1,1,	1	ı	ı	1	ı	ı			ļ
AMENDMENT 2.0										W.	37

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

	Date of Asse	essment
Day	Month	Year

	I would like to ask you a few questions have made to a doctor o	about any additional visits (no r an outpatient facility in the l		ou ma
1.	Emergency Room Visits Number of emergency room visits			
2.	Therapy Visits Number of therapy (mental health) visits			
3.	Outpatient visits to specialists (to addition to your routine care, such			
	Pain Management Specialist: Number of outpatient physician visits			
	Radiologist: Number of outpatient physician visits			
	Radiation Oncology: Number of outpatient physician visits			
4.	Outpatient Procedures Any outpatient surgical procedures		Yes No)
	If yes, please describe:			
	Blood transfusions number of times			
	Other procedures?		Yes No)
	If yes, please describe:			
5.	Caregiving In a typical (24 hour) day, how many hou of your illness:	ırs of support do you receive	from each of the following bed	caus
		Trained Medical Person	Others	
	Paid caregiver	hours	hours	
	Unpaid caregiver	hours	hours	
6. For An	Nursing Home / Hospice Days Number of days spent in a nursing home			

Tick when data checked.

Δ	////	Site No.			Sı	ubject	ID No.				Subj	ject Ir	nitials
ABX-EGF 20020408		1 1 1	1	1	ı		ı	ı	ı	ı		ı	ı
AMENDMENT 2.0	1////											W	/37

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

	Date of Exan	nination
Day	Month	Year
	1 1	

	the subject have any abnormal clinical findi	ngs relating to the followi	ing required sites?	$_{0}$ No $_{1}$ Yes - If yes,
045011	be findings below. Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04 Abdomen	07 Lymph nodes	10 Breast / Chest
	Cardiovascular	05 Musculoskeletal		
	Pulmonary	06 Skin	09 Genitourinary	
	•	equired assessment was i	,	
Code		-		
(as		Describe findings		
listed		List one entry per line.		
above)				
l .				
Ι.				
l ,				
l ,				
L				
\mathbf{I}_{-1}				

ECOG PERFORMANCE STATUS

Date of Assessment								ECOG Performance	
Da	Day Month					Year	Status ①		
1	ECOG	PER	FORN	IANCE S	TATUS	COI	DES:		
0	•		•	to carry		ore-di	sease		
1	Resti	ricted able to	in phy carry	sically st out worl	renuou k of a li	ght o			•
2	Ambi	ulatory	and	capable	of all se	elf-cai			o carry ng hours.
3			-	limited se	elf-care	, conf	ined to	bed or o	chair
4	> 50% of waking hours4 Completely disabled. Cannot carry out any self-caTotally confined to bed or chair						elf-care.		
5	Dead	-							

Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1,	
AMENDMENT 2.0	· · · · · ·		W37

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment										
Day	Month	Year								
I .										

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)						Specify if Skin Toxicity is "01 Nail Changes"					SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching					
									0	 03 Pruritus/itching 04 Rash (acne/acneiform) 05 Rash/desquamation (non-acneiform) 06 Ulceration 						
Type of Skin Lesions (list all that apply)				•	Specify if Type of Skin Lesion is "88 Other"					00 01	TYPE OF SKIN LESION CODES: ON None Type of Skin Lesion Codes: O					
										04	Macular	09 Comedones10 Cysts88 Other (specify)				
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Locationst all tha	on ④ at apply)		Specify if Loc	ation is	"88 Other"	 4 LOCATION CODES:09 Face10 Trunk				
		05 ≤ 50	J% BSA				ı				11 Extremities 12 Total body 88 Other (specify)					
1. If	1. If prior radiation, is area of radiation port involved?															
2. W	/as c	rusting p	resent	?					No ₁☐ Yes							
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes							
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes							
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications					
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1					
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)				
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1					
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year							

For Amgen Use Only
Tick when

data checked.

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1,	
AMENDMENT 2.0			W37

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment											
Day	Month	Year									
l .											

		₀ No√	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①		
Were Pustules/Papules present		1				
Was Honey Yellow Crusting pres	sent?		 			
Was Erythema present?			 			
Was Paronychia present?			1			
Were Fissures present? (Photo	p-based scale does not apply)		 			
Does the following dermatologic	cal toxicity interfere with activitie	s of daily	/ living?			
Paronychi	a: ₀ No ₁ Yes ₆₆ N	/A				
Fissures:	₀ No ₁ Yes 66 N	/A				
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception ②						
PHOTO-BASED CODING SCALE CODES: A B C D	 SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera 02 A little 04 Very m 		05 Intoler	able		

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W39

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment											
Day	Month	Year									

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)						Specify if Skin Toxicity is "01 Nail Changes"					SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching					
									0	 03 Pruritus/itching 04 Rash (acne/acneiform) 05 Rash/desquamation (non-acneiform) 06 Ulceration 						
Type of Skin Lesions (list all that apply)				•	Specify if Type of Skin Lesion is "88 Other"					00 01	TYPE OF SKIN LESION CODES: ON None Type of Skin Lesion Codes: O					
										04	Macular	09 Comedones10 Cysts88 Other (specify)				
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Locationst all tha	on ④ at apply)		Specify if Loc	ation is	"88 Other"	 4 LOCATION CODES:09 Face10 Trunk				
		05 ≤ 50	J% BSA				ı				11 Extremities 12 Total body 88 Other (specify)					
1. If	1. If prior radiation, is area of radiation port involved?															
2. W	/as c	rusting p	resent	?					No ₁☐ Yes							
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes							
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes							
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications					
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1					
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)				
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1					
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year							

For Amgen Use Only
Tick when

data checked.

А	////	Site No.			S	ubject	ID N	0.		S	ubjec	t Initials	3
ABX-EGF 20020408			1	1,	1	ı	ı	ı			ı		
AMENDMENT 2.0												W39	

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment													
Day	Month	Year											

	₀No✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		 	
Was Honey Yellow Crusting present?		1	
Was Erythema present?		1	
Was Paronychia present?		1	
Were Fissures present? (Photo-based scale does not apply)		I I	
Does the following dermatological toxicity interfere with activitie	s of daily	/ living?	
Paronychia: ₀ No ₁ Yes ₆₆ N	/A		
Fissures: 0 No 1 Yes 66 N	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio	n		
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mode		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

А	////	Site No.				,	Subjec	t ID N	0.			Subj	ect Initials
ABX-EGF 20020408		1 1	ı	1	1,	1	ı	ı	ı	ı	ı		
AMENDMENT 2.0													W40

Week 40 TUMOR EVALUATION - TARGET LESIONS

Date of Procedure													
Day	Month	Year											
	1 1												

Lesion Note: Always maintain the same order	Lesion Site Code	Subsite Describe specific location	Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable
of lesion numbers	1		•	Dimensions (mm)
01				
02				
03				
04				
05				
06			·	
07				
08				
09			,	
10				
		Sum (of Target	

				Lesions
① LESION SITE CO 00 Lymph nodes 10 Pulmonary 20 Liver 30 Bone	ODES: 40 Chest 50 Central nervous system 55 Head 56 Neck	60 Gastrointestinal 86 70 Abdomen 88 75 Pelvic Site 85 Spleen	METHOD OF ASSESSMENT: 1 X-Ray 3 Conventional Computed Tomography (CT) 4 Magnetic Resonance Imaging (MRI) 23 Spiral Computed Tomography (CT) 88 Other (specify below)	
				, ,
Line #		Specify if "88 Othe	er" Method of Asse	, ,
Line #		Specify if "88 Other	er" Method of Asse	, ,
Line #		Specify if "88 Other	er" Method of Asse	, ,

For Amgen Use	Only
Tick when	
data checked	

Δ	////	Site No.		5	Subject	ID No				Subj	ect Ir	nitials
ABX-EGF 20020408			1 1	l I		ı	1	ı	I		I	1
AMENDMENT 2.0		_					·				W	'40

TUMOR EVALUATION - NON-TARGET LESIONS

I DOUVI			10	' I V I						ord all ot		ons a		ites c				.010140
Day Month Year Dimensions (mm) 11 12 13 14 15 16 BODY SITE CODES: 00 Lymph nodes	Note: Always maintain the same order	Note: Always maintain the same order Date of Procedure							Site	Des			tion	Asses	sment	ı	ew.	Measurable Lesions (mm) Must be unidimensionally measurable.
13 14 15 16 Sum of Non-Target Lesions © BODY SITE CODES: © Lymph nodes 40 Chest 50 Central nervous system 70 Abdomen 75 Pelvic Site 88 Other (specify in subsite above) © METHOD OF ASSESSMENT CODES: © METHOD O		Day	Мо	nth		Ye	ar		1						2)	1"		Dimensions (mm)
Sum of Non-Target Lesions Sum of Non-Target Lesions	11																 	
The state of the s	12																 	
Sum of Non-Target Lesions O	13																i	
Sum of Non-Target Lesions O Lymph nodes 40 Chest 60 Gastrointestinal 70 Abdomen 88 Other (specify in subsite 20 Liver 55 Head 75 Pelvic Site 30 Bone 56 Neck 85 Spleen O METHOD OF ASSESSMENT CODES: O METHOD OF ASSE	14																[[
Sum of Non-Target Lesions 1 BODY SITE CODES: 00 Lymph nodes	15															ı		
DESIONS ① BODY SITE CODES: 00 Lymph nodes 40 Chest 50 Central nervous system 20 Liver 30 Bone 56 Neck 60 Gastrointestinal 70 Abdomen 75 Pelvic Site 88 Other (specify in subsite above) ② METHOD OF ASSESSMENT CODES: 01 X-Ray 03 Conventional Computed Tomography (CT) 88 Other (specify in subsite Abdomen 75 Pelvic Site 85 Spleen Magnetic Resonance Imaging (MRI) Spiral Computed Tomography (CT) 86 Other (specify below) Other (specify below)	16								1								 	
00 Lymph nodes 40 Chest 60 Gastrointestinal 70 Abdomen 70 Abdomen 75 Pelvic Site 88 Other (specify in subsite above) 20 Liver 55 Head 75 Pelvic Site 85 Spleen 2 METHOD OF ASSESSMENT CODES: 01 X-Ray 03 Conventional Computed Tomography (CT) 46 Gastrointestinal 70 Abdomen 70 Abdomen 75 Pelvic Site 88 Other (specify in subsite above) 86 Skin 88 Other (specify in subsite above) 87 Magnetic Resonance Imaging (MRI) Spiral Computed Tomography (CT) Other (specify below)		•						•					Sum	of N				
10 Pulmonary 50 Central nervous system 70 Abdomen 75 Pelvic Site 75 Pelvic Site 85 Spleen 88 Other (specify in subsite above) © METHOD OF ASSESSMENT CODES: 01 X-Ray 03 Conventional Computed Tomography (CT) 04 Magnetic Resonance Imaging (MRI) 25 Spiral Computed Tomography (CT) 26 Other (specify below)	① BODY	Y SITI	E COE	ES	:													
01 X-Ray 03 Conventional Computed Tomography (CT) 04 Magnetic Resonance Imaging (MRI) 23 Spiral Computed Tomography (CT) 88 Other (specify below)	10 Pi 20 Li	ulmon ver	nodes ary				50 55	Cen Hea	tral ne d	rvous system	n	70 75	Abdom Pelvic	nen Site	al			Other (specify in subsite
Line # Specify if "88 Other" Method of Assessment	01 >	X-Ray								2 3	Spiral Cor	mpute	d Tomog	naging ((MRI) (CT)			
	Line #									Specify if	"88 Other	" Me	thod of	Asse	ssmer	nt		

For Amgen Use	e Only
Tick when	
data checked.	

Δ	////	Site No.					Subj	ect II	O No.				Subj	ect Ir	nitials
ABX-EGF 20020408		1 1	ı	1	1	I			I	ı	ı	1		I	l
AMENDMENT 2.0			'											W	/40

Week 40 OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study		Tumor Response									
Week	Day	Month		Year	Code ①						
40											
① TUMOF	① TUMOR RESPONSE CODE:										
PD	Complete Re Progressive I Partial Respo	Disease	SD UE	Stable Disease Unable to evalu	ate						

v.2.0 30Jun04camb

A	Site	No.	Sı	ubject ID No.	Subject Initials
ABX-EGF 20020408			1.1.		
AMENDMENT 2.0					**************************************
	,	Nooks	22 40		
		Neeks	DURES		
	Г	CYTOL			
Was any cytology performed? ₀☐ N	No ₁□ Yes	- If yes, spe	cify below.		
Date of Procedure	Procedure	Malignant E	Sody Specify if Pro		
Day Month Year	① 	No ✓ ₁Yes ✓	Site Code is #88	Other" is "88 Oth	eer" CODE: 30 Paracentesis
					31 Thoracentesis
		l I			88 Other (Specify)
Equivocal findings:					
		SURG	ICAL		
Were any surgical procedures perform	rmed? ₀□			elow.	
Date of Procedure	Procedure Code	Body Site Code		Body Site is	② PROCEDURE CODE:
Day Month Year	2	4	88	Other"	32 Surgical
	3,2				
	3,2				
Findings:					
					<u>.</u>
	_	BIOF	PSY		
Was biopsy performed? ₀☐ No ₁☐	Yes - If ye	es, specify b	elow.		
Date of Procedure	Procedure Code	Body Site Code	Specify if	Body Site is	3 PROCEDURE CODE:
Day Month Year	3	4	88	Other"	
	1 6				16 Biopsy
	<u> </u>				
Findings:					
			· · · · · · · · · · · · · · · · · · ·	 	
Was endoscopy performed? ₀☐ N	o . D Voc	ENDOS	COPY		
	Procedure		pecify if Procedure	Specify if Body Site	⑤ PROCEDURE
Date of Procedure	5	Site C	ode is "88 Other"	is "88 Other"	CODE:
Day Month Year		4			33 Colonoscopy
					34 Sigmoidoscopy 88 Other (Specify)
Findings:				I	
rilidings					
					-
BODY SITE 01 Abdomen 05 Ches	t	09 Heart	13 Pleura	17 Total body	88 Other
CODES: 02 Brain 06 Eye	ointestinal trac	10 Kidne		18 Thorax	(Specify above)
04 Bone 08 Head		12 Lung	16 Skin	23 Neck	,
For Amgen Use Only					

Tick when data checked.

WEEKS 41 - 48

Δ	1111	Site No.			Subje	ct ID No				Sub	ject Ir	nitials
ABX-EGF 20020408			1,1	I		ı	1	ı	ı		I	I
AMENDMENT 2.0											W	/41

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

	Date of Assessment											
ı	Day Month Year											
ı												
	1	1 1										

	I would like to ask you a few questi have made to a doc	ons about any additional visits (no tor or an outpatient facility in the la	
1.	Emergency Room Visits Number of emergency room visits		
2.	Therapy Visits Number of therapy (mental health)	visits	
3.	Outpatient visits to specialists addition to your routine care,	•	
	Pain Management Specialist: Number of outpatient physician visit	s	
	Radiologist: Number of outpatient physician visit	s	
	Radiation Oncology: Number of outpatient physician visit	s	
4.	Outpatient Procedures Any outpatient surgical procedures		Yes No
	If yes, please describe:		
	Blood transfusions number of times		
	Other procedures?	Yes No	
	If yes, please describe:		
5.	Caregiving In a typical (24 hour) day, how many of your illness:	hours of support do you receive	rom each of the following <i>because</i>
		Trained Medical Person	Others
	Paid caregiver	hours	hours
	Unpaid caregiver	hours	hours
6.	Nursing Home / Hospice Days Number of days spent in a nursing h		

Tick when data checked.

For Amgen Use Only

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			W41

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination										
Day Month Year										

	the subject have any abnormal clinical find ibe findings below.	lings relating to the followi	ng required sites?	₀ No ₁ Yes - If yes,		
01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	10 Breast / Chest				
	Cardiovascular	04 Abdomen05 Musculoskeletal	07 Lymph nodes08 Neurological	11 Rectal		
03	Pulmonary	06 Skin		88 Other		
	Indicate if a	required assessment was i	not done.			
Code						
(as		Describe findings				
listed		List one entry per line.				
above)						
l .						
١.						
Ι.						
Ι,						
Ι,						
Ι,						
l .						
1						

ECOG PERFORMANCE STATUS

	ECOG Performance							
Da	Day Month					Year	Status ①	
0 1 2 3	Fully performed Restrand a ie, light Amburout a Capar > 50% Comp	active, abormance wricted in pable to caught housevalutory anny work able of only of wakingletely dispersion.	sabled. Car	on all priction trenuou k of a li ce work of all sepand a lelf-care	ore-di is acti ght or c elf-car about , conf	sease ivity, bu r seden re, but to > 50% ined to	tary natous unable to of wakin bed or o	ure, o carry og hours.
5	Dead	•	d to bed or	cnair				

Δ	////	Site No.		S	Subject	ID No.				Subj	ect In	iitials
ABX-EGF 20020408		1 1 1	$\left 1_{1}1_{1}\right $			ı	1	ı	I			
AMENDMENT 2.0											W	41

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment											
Day	Month	Year									
I .											

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply) ①						Specify if Skin Toxicity is "01 Nail Changes"					SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching				
										0	4 Rash (acı	ne/acneiform) squamation (non-acneiform)			
	Type of Skin Lesions (list all that apply) ② Specify if Type of Skin Lesion is "88 Other"				00 01	© TYPE OF SKIN LESION CODES: 00 None 07 Dry flaking 01 Pustular 08 Desquamation (slough 02 Vesicular 09 Comedones									
										04	Macular	10 Cysts 88 Other (specify)			
						ation is	 4 LOCATION CODES:09 Face10 Trunk								
		05 ≤ 50	J% BSA				ı					11 Extremities 12 Total body 88 Other (specify)			
1. If prior radiation, is area of radiation port involved?															
2. W	/as c	rusting p	resent	?					No ₁☐ Yes						
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes						
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes						
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications				
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1				
7 14	loc o	loco hold	chanc	od or d	iscontinue	d for c	kin tov		cord on Concon	nitant IV	dedications	(CRF)			
/ · · · ·	as C	1101U	, Griang	jeu oi u	13committe	101 8	INIT IOX		ate		1				
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year						
											J				

A	////	Site	No.					Su	ıbject	ID N	٥.			Sub	oject I	Initials
ABX-EGF 20020408				ı	1	1	1	ı	ı	ı	1	ı	1		ı	I
AMENDMENT 2.0															V	V41

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment									
Day	Month	Year							
l .									

		₀ No√		* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present	?		1	
Was Honey Yellow Crusting pres	sent?		 	
Was Erythema present?			1	
Was Paronychia present?			1	
Were Fissures present? (Photo	p-based scale does not apply)		 	
Does the following dermatologic	cal toxicity interfere with activitie	s of daily	/ living?	
Paronychi	a: ₀ No ₁ Yes ₆₆ N	/A		
Fissures:	₀ No ₁ Yes 66 N	/A		
How bothered do you perceive t by the dermatologic toxicities ?	the subject to be Subject Perception			
① PHOTO-BASED CODING SCALE CODES: A B C D	 SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera 02 A little 04 Very m 		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site	e No.		,	Subject	ID No.				Subj	ect In	iitials
ABX-EGF 20020408		1 1	1,1		ı	ı	ı	I	1		'	l
AMENDMENT 2.0											W	<i>'</i> 43

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment									
Day	Month	Year							

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

			Toxicity that app			Specify if Skin Toxicity is "01 Nail Changes"				0	TY CODES: ges (specify)	
										0	Pruritus/ito Rash (acn Rash/deso Ulceration	
		e of Skin list all that a		•	Specif	fy if Typ	oe of Sk	in Lesion	is "88 Other"	00 01	None 0 Pustular 0	N LESION CODES: 7 Dry flaking 8 Desquamation (sloughing) 9 Comedones
										04	Macular 1	O Cysts Other (specify)
Total % Affec	- 1	3 TOTAL 04 > 50	0% BSA	ODES:	(lis	Locationst all tha	on ④ at apply)		Specify if Loc	ation is	"88 Other"	DOCATION CODES:09 Face10 Trunk
		05 ≤ 50	1% BSA				ı					11 Extremities12 Total body88 Other (specify)
1. If prior radiation, is area of radiation port involved?												
2. W	/as c	crusting p	resent	?					No ₁☐ Yes			
3. S	ince	the last a	ssessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle{0}}$	No ₁☐ Yes			
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? ₀□	No ₁☐ Yes			
5. S	ince	the last a	issessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concor		₀☐ No ₁☐ Medications	
6. S	6. Since the last assessment, did the rash require treatment with systemic steroids? $_{_0}$ No $_{_1}$ Yes											
(Record on Concomitant Medications CRF) 7. Was dose held, changed or discontinued for skin toxicity?												
/ · · · ·	as C	1036 HEIU	, Griang	jou oi u	13committe	101 5	KIII LUX		ate		1	
(N 🗖	No 1 Ye	es - If y	es, prov	vide date.	Day	/	Month	Year			
											<u> </u>	

Δ	1111	Site No.					Subje	ct ID N	Ю.			Sub	ject In	itials
ABX-EGF 20020408		1 1	ı	1	1	I		I	1	ı	I			l
AMENDMENT 2.0													W	<i>'</i> 43

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment									
Day	Month	Year							
l .									

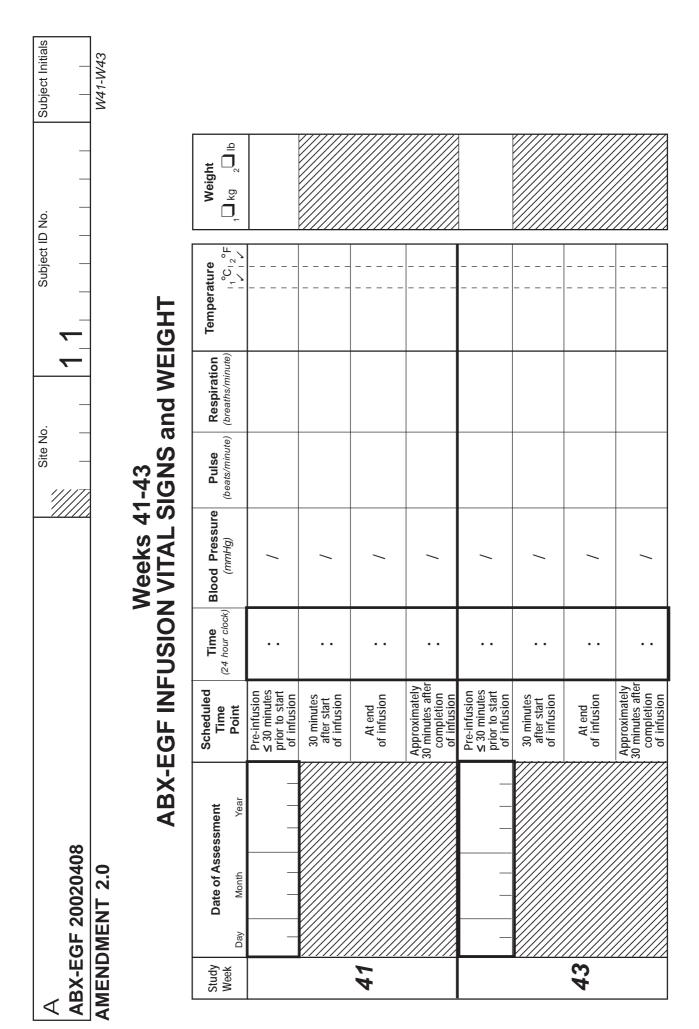
	₀No✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		 	
Was Honey Yellow Crusting present?		1	
Was Erythema present?		1	
Was Paronychia present?		1	
Were Fissures present? (Photo-based scale does not apply)		I I	
Does the following dermatological toxicity interfere with activitie	s of daily	/ living?	
Paronychia: ₀ No ₁ Yes ₆₆ N	/A		
Fissures: 0 No 1 Yes 66 N	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio	n		
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mode		05 Intoler	able

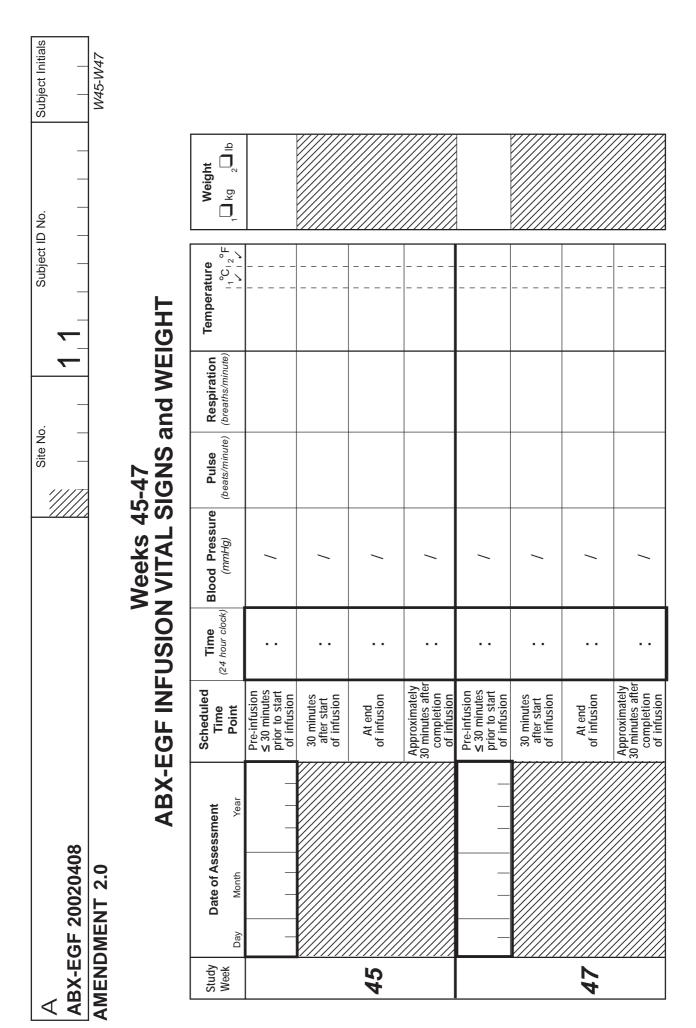
For Amgen Use	e Only
Tick when	
data checked.	

Treatment Phase VITAL SIGNS FOR ABX-EGF AND BSC

*Vital signs readings (every 2 weeks; within 30 minutes before the ABX-EGF infusion, approximately 30 minutes after the start of ABX-EGF infusion, upon completion of the ABX-EGF infusion, and approximately 30 minutes after completion of the ABX-EGF infusion, allowing a +/- 10 minute time window): blood pressure, resting pulse, respiration rate, and temperature (every 2 weeks).

*Weight (every 2 weeks, before the ABX-EGF infusion on ABX-EGF arm; every 4 weeks on BSC arm)





4							0) [/	Site No.	Subject ID No.		Subject Initials
AB	ABX-EGF 20020408					· / / / / /		_		_	_
Σ	MENDMENT 2.0							-	-	-	W41-W47
	2	ESTIG	ATIO	Wee	Weeks 41-47 L PRODUCT	1-47 JCT/	ADM	Weeks 41-47 INVESTIGATIONAL PRODUCT ADMINISTRATION	ATION		
	Subjects receiving	BSC will n	ot receive II	nvestigationa	al Produc	t Admini	stration,	please score	Subjects receiving BSC will not receive Investigational Product Administration, please score through the page		
udy	Dav Month Year	Start Time (24 hour clock)	Stop Time (24hourclock)	Total Dose Administered (mg)	Total Volume (mL)	Reason for it Dose Change	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code		If Reason for Dose Change is "88 Other", please specify	je is ify	
11						_					
13						_	_				
15						_	_				
17						_					
qns	subject did not complete investigational product administration, provide any	al product adr	ninistration, p	rovide any add	itional rele	additional relevant information:	nation:				
000 000 000 000 000 000 000 000 000 00	DOSE CHANGE CODES: 11 Adverse event 12 Noncompliance 13 Dose administration error 14 Per protocol 18 Other (Specify above)	004 Per p	 2 "04 Per protocol" DOSE CHANGE 100 Weight change 118 Symptomatic skin-related toxi or felt to be intolerable by subj 120 Skin infection requiring system 	er protocol" DOSE CHANGE CODES: Weight change Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject Skin infection requiring systemic IV antibiotic or IV antifungal treatment	CODES: city requiring rect	narcotics, s	ystemic ste ungal treati	eroids, ment	 121 Need for surgical debridement 122 Any skin-related serious adverse event 200 Dose reinstated 201 Dose increase (after reinstatement) 	ment tdverse event statement)	
		_									

data checked.

For Amgen Use Only
Tick when

A	1///	Site No.		Subjec	t ID No.		Subject Initials
ABX-EGF 20020408			1 _, 1 _,			1	
AMENDMENT 2.0							W41-W47

Weeks 41-47 INVESTIGATIONAL PRODUCT LOT NUMBER

Study Week	ABX-EGF Package Lot Number	ABX-EGF Package Lot Number
41		
43		
45		
47		

Α	1111.	Site No.			S	ubject	ID No	Э.			Subj	ect Initials
ABX-EGF 20020408			1	__ 1 __	ı	ı			ı	1		
AMENDMENT 2.0												W45

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

	Date of Ass	essment
Day	Month	Year
	l	l
	1 1 1	

	I would like to ask you a few question have made to a doct	ons about any additional visits (r or or an outpatient facility in the		nat you may
1.	Emergency Room Visits Number of emergency room visits			
2.	Therapy Visits Number of therapy (mental health) v	isits		
3.	Outpatient visits to specialists addition to your routine care, s			
	Pain Management Specialist: Number of outpatient physician visits	3		
	Radiologist: Number of outpatient physician visits	3		
	Radiation Oncology: Number of outpatient physician visits	3		
4.	Outpatient Procedures Any outpatient surgical procedures		Yes	No
	If yes, please describe:			
	Blood transfusions number of times			
	Other procedures?		Yes	No
	If yes, please describe:			
5.	Caregiving In a typical (24 hour) day, how many of your illness:	hours of support do you receive	from each of the following	ng <i>because</i>
		Trained Medical Person	Others	
	Paid caregiver	hours	hou	irs
	Unpaid caregiver	hours	hou	rs
6.	Nursing Home / Hospice Days Number of days spent in a nursing he	ome		

For Amgen Use Only Tick when

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1,	
AMENDMENT 2.0			W45

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

	Date of Exan	nination
Day	Month	Year

	the subject have any abnormal clinical find	ings relating to the followi	ing required sites?	$_{0}$ No $_{1}$ Yes - If yes,
01 l 02 l	be findings below. Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Pulmonary	04 Abdomen05 Musculoskeletal06 Skin		11 Rectal
		required assessment was i		oo owlor
Code (as listed above)		Describe findings List one entry per line.		

ECOG PERFORMANCE STATUS

			Date (of Asse	ssme	nt			ECOG Performance	
Da	у		Mon	th			Year		Status ①	
1	① ECOG PERFORMANCE STATUS CODES:									
0	Fully active, able to carry on all pre-disease performance without restriction									
1	Resti	ricted able to	in phy carry	sically st out worl	renuou k of a li	ght o			•	
2	Ambi	ulatory	and	capable	of all se	elf-cai			o carry ng hours.	
3			-	limited se	elf-care	, conf	ined to	bed or o	chair	
4				oled. Car o bed or		rry ou	t any se	elf-care.		
5	Dead	-								

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			W45

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

	Date of Asse	essment
Day	Month	Year

Did the subject have skin toxicity? $_{_{0}}\square$ No $_{_{1}}\square$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

TOXIO	ty / 13	0000	111011	io page	, and re	COIG SKIII (OXIOIL	y 0117 (L	- 0111.					
Skin Toxicity (list all that apply)							•	fy if Skin ⁻ 1 Nail Cha	Toxicity is nges"	SKIN TOXICITY CODES: 1 Nail changes (specify) 2 Erythema 3 Pruritus/itching				
											04 Rash (acne			
			Skin L that a	esions	5	Speci	pecify if Type of Skin Lesion is "88 Other"			is "88 Other"	 TYPE OF SKIN LESION CODES: None Typ flaking Pustular Desquamation (slot Vesicular Comedones 			
			I								04 Macular 10	Cysts Other (specify)		
Total % Affec		04	> 50	% BSA (% BSA	ODES:	(lis	Location ④ Specify if Location (list all that apply)			Specify if Locat	ion is "88 Other"	4 LOCATION CODES: 09 Face 10 Trunk 		
		05	≤ 50	% BSA				ı				11 Extremities 12 Total body 88 Other (specify)		
1. If	1. If prior radiation, is area of radiation port involved?													
2. V	Vas c	rusti	ng pi	resent	?					No ₁☐ Yes				
3. S	ince	the I	ast a	ssessr	nent, di	d the rash	cause	e pain?		No ₁☐ Yes				
4. S	ince	the l	ast a	ssessr	nent, di	d the rash	cause	e itchin	g? ₀□	No ₁☐ Yes				
5. S	ince	the l	ast a	ssessr	nent, di	d the rash	requi	re treat		h narcotics? cord on Concomit	₀☐ No ₁☐ tant Medications C			
6. S	ince	the I	ast a	ssessr	nent, di	d the rash	requi	re treat		-	oids?₀☐ No ₁☐			
	(Record on Concomitant Medications CRF)													
7. V	7. Was dose held, changed or discontinued for skin toxicity?													
ı	۱ ــ	No 1	☐ Ye	es - If y	es, pro	vide date.	Da	ау	Month D	Year Year				

For Amgen Use Only
Tick when

А	////	Site N	lo.				Sı	ubject	ID N	0.		S	Subjec	ct Initials
ABX-EGF 20020408		ı		1	1 _ 1	1 ,	1	ı	ı	1	1		ı	I
AMENDMENT 2.0														W45

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment								
Day	Month	Year						
l .								

		₀ No ✓	1 Yes √ Enter corre- sponding code from Photonumeric Scale*	* Photo- based Coding Scale (Record one code only) ①						
Were Pustules/Papules preser	t?		1							
Was Honey Yellow Crusting pre	esent?									
Was Erythema present?			1							
Was Paronychia present?			1							
Were Fissures present? (Photo	o-based scale does not apply)									
Does the following dermatolog	Does the following dermatological toxicity interfere with activities of daily living?									
Paronych	iia: ₀☐ No ₁☐ Yes ₆₆ ☐ I	N/A								
Fissures:	₀ ☐ No ₁ ☐ Yes 66 ☐ I	N/A								
How bothered do you perceive by the dermatologic toxicities ?	' D(!									
① PHOTO-BASED CODING SCALE CODES:	② SUBJECT PERCEPTION CODES 01 Not at all 03 Moder	ate	05 Intoler	able						
A B C D	02 A little 04 Very n	nuch								

For Amgen Use	e Only
Tick when	
data checked.	

Δ	Site No.			Subjec	t ID No.			Subj	ect In	itials
ABX-EGF 20020408		1 1	1 1	I	ı	l	ı			l
AMENDMENT 2.0						·			W	47

SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

	Date of Assessment									
Day	Month	Year								
	1 1									

Did the subject have skin toxicity? $_{_{0}}$ No $_{_{1}}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)						Specify if Skin Toxicity is "01 Nail Changes"					SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching				
										0	4 Rash (acı	ne/acneiform) squamation (non-acneiform)			
		e of Skin list all that a		•	Specif	ecify if Type of Skin Lesion is "88 Other"			00 01	IN LESION CODES: 07 Dry flaking 08 Desquamation (sloughing) 09 Comedones					
										04	Macular	10 Cysts 88 Other (specify)			
	1 % BSA ③ TOTAL % BSA CODES: Location ④ Specify if Loca				ation is	 4 LOCATION CODES:09 Face10 Trunk									
		05 ≤ 50	J% BSA				ı					11 Extremities 12 Total body 88 Other (specify)			
1. If	1. If prior radiation, is area of radiation port involved?														
2. W	/as c	rusting p	resent	?					No ₁☐ Yes						
3. S	ince	the last a	assessr	nent, di	d the rash	cause	pain?	$\Box_{\scriptscriptstyle 0}$	No ₁☐ Yes						
4. S	ince	the last a	assessr	nent, di	d the rash	cause	itchin	g? 。□	No ₁☐ Yes						
5. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th narcotics? cord on Concon		₀☐ No ₁☐ Medications				
6. S	ince	the last a	assessr	nent, di	d the rash	requir	e treat		th systemic ste		0 1				
7 14	(Record on Concomitant Medications CRF)														
/ · · · ·	7. Was dose held, changed or discontinued for skin toxicity? Date														
(۱ 🗖	lo ₁□ Ye	es - If y	es, prov	vide date.	Day	y	Month	Year						
											J				

А	////	Site No.		Subjec	t ID No.			Subje	ct Initials
ABX-EGF 20020408			1,1,	1 1	ı	1 1	I		1
AMENDMENT 2.0									W47

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment								
Day	Month	Year						

	₀No✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①						
Were Pustules/Papules present?		 							
Was Honey Yellow Crusting present?		1							
Was Erythema present?		1							
Was Paronychia present?		1							
Were Fissures present? (Photo-based scale does not apply)		I I							
Does the following dermatological toxicity interfere with activities of daily living?									
Paronychia: ₀ No ₁ Yes ₆₆ N	/A								
Fissures: 0 No 1 Yes 66 N	/A								
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio	n								
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mode		05 Intoler	able						

For Amgen Use	e Only
Tick when	
data checked.	

Α	////	Site No.				S	ubject	ID No).			Subj	ect Initials
ABX-EGF 20020408			ı	1	1_		ı	ı	ı	ı	1	١ ,	
AMENDMENT 2.0					·	·					·		W48

Week 48 TUMOR EVALUATION - TARGET LESIONS

Date of Procedure												
Day Month Year												
1 1												

Lesion Note: Always maintain the same order of lesion	Lesion Site Code	Subsite Describe specific location	Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable
numbers	1		 '	Dimensions (mm)
01			l	
02				
03				
04				
05				
06				
07				
08				
09				
10				
		Sum (of Target Lesions	

		Ecsions
i annionary	ntral nervous 70 Abdomen 88 stem 75 Pelvic Site ad 85 Spleen	Skin Other (specify in subsite above) 9 METHOD OF ASSESSMENT: 10 1 X-Ray 10 3 Conventional Computed Tomography (CT) 10 4 Magnetic Resonance Imaging (MRI) 11 23 Spiral Computed Tomography (CT) 12 8 Other (specify below)
Line #	Specify if "88 Other	" Method of Assessment

For Amgen Use	Only
Tick when	
data checked.	

Δ	1111	Site No.		Subjec	t ID No				Subj	ect Ir	nitials
ABX-EGF 20020408			1,1		ı	ı	ı	I		l	l
AMENDMENT 2.0	·		·							W	48

TUMOR EVALUATION - NON-TARGET LESIONS

		10							ord all othe			ites of dis			.510115
Lesion Note: Always maintain the same order		Date o	of Pr	oceo	lure		Bo Si Co	te	Describ	Subsite e specific loca	tion	Method of Assessment	. I	ew sions	Measurable Lesions (mm) Must be unidimensionally measurable.
of lesion numbers	Day	Mor	nth		Υe	ar	(1			,		2	₀No ✓	₁Yes ✓	Dimensions (mm)
11														 	
12			ı		l	ı									
13						i								 	
14			1											 	
15			1											 	
16			1											1	
	'	'	'	·	'						Sum	of Non-	Tare esio		
① BODY 00 Ly 10 Pt 20 Li 30 Bo	mph r ulmona ver	nodes	ES	:		50 55	Chest Centra Head Neck	l ner	vous system	75	Gastro Abdom Pelvic Spleen	Site		86 88	Skin Other (specify in subsite above)
② METH 01 〉 03 ((-Ray						DDES:	(CT)	23 S	lagnetic Resor piral Compute other (specify l	d Tomog	naging (MRI) graphy (CT)			
Line #									Specify if "88	Other" Me	thod of	f Assessme	nt		

For Amgen Use	e Only
Tick when	
data checked.	

Δ	////	Site No.					Sub	ject	ID No				Subj	ect Ir	nitials
ABX-EGF 20020408		1 1	ı	1	1	ı	1	l	ı	ı	I	1		I	1
AMENDMENT 2.0	.,,,,		•		•		•		•				•	N	/48

Week 48 OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study		Da	te		Tumor Response		
Week	Week Day Month Year						
48							
① TUMO	RESPON	SE CODE:					
PD	Complete Re Progressive l Partial Respo	Disease	SD UE	Stable Disease Unable to evalu	ate		

Α	Site	e No.	Sı	ubject ID No.	Subject Initials
ABX-EGF 20020408			1,1,		
AMENDMENT 2.0					VV 7 1 - VV 40
	,	Neeks	/1_/Q		
			DURES		
	•	CYTOL			
Was any cytology performed? ₀☐ N	lo ₁☐ Yes	- If yes, spe	cify below.		
Date of Procedure	Procedure	Malignant E	Sody Specify if Pro Site Code is #88		
Day Month Year		No ✓ ₁Yes ✓	4	10 00 01	30 Paracentesis
		1			31 Thoracentesis 88 Other (Specify)
		i			
Equivocal findings:					
·		 			
		01156			
Were any surgical procedures perform	rmed? ¬□	SURG	_	elow	
Date of Procedure	Procedure	Body Site	T	Body Site is	② PROCEDURE
Day Month Year	Code	Code		Other"	CODE:
					- 32 Surgical
]3 2				
Findings:	·				
		RIO	ev.		
Was biopsy performed? ₀☐ No ₁☐	Yes - If ye	es, specify b	elow.		
Date of Procedure	Procedure Code	Body Site Code	Specify if	Body Site is	③ PROCEDURE CODE:
Day Month Year	3	4	**88	Other"	
	1,6				16 Biopsy
Findings:					
					<u>.</u>
		ENDOG	0007		
Was endoscopy performed? ₀☐ No	o 1 Yes-	ENDOS If yes, spec	ify below.		
Date of Procedure	Procedure		pecify if Procedure	Specify if Body Site	
Day Month Year	(5)	Site C	ode is "88 Other"	is "88 Other"	CODE:
					33 Colonoscopy 34 Sigmoidoscopy
					88 Other (Specify)
Findings:					
BODY SITE 01 Abdomen 05 ChesCODES: 02 Brain 06 Eye		09 Heart 10 Kidne	y 14 Pelvic site	17 Total body 18 Thorax	(Specify above)
03 Breast 07 Gastr 04 Bone 08 Head	ointestinal trac	t 11 Liver 12 Lung	15 Retroperitor16 Skin	neum 19 Extremity(23 Neck	ies)
		_	_		

Tick when data checked.

WEEKS 49 - PD

Α		(///	Site No.				S	ubject I	D No.		Subject Initia
	K-EGF 2002	0408	,	1	1	1	ı	1	1 1	1 1	
	NDMENT 2		,								
			V	/eek	(
									-OTI		IDE
	HEALIF	I RESOUF	KCE U		ZA —	110	אכ	JUE	:511	ONNA	IKE
				ate of As	ssessı	ment	: Year				
	I would like to	ask you a few que have made to a de									you may
1.	Emergency F Number of eme	Room Visits ergency room visits	i								
2.	Therapy Visi Number of ther	ts apy (mental health	n) visits								
3.	•	sits to specialis our routine care	•	-				-			
		ement Specialist patient physician vi									
	Radiologist: Number of outp	patient physician vi	sits								
	Radiation Or Number of outp	ncology: patient physician vi	sits								
4.	Outpatient P Any outpatient	rocedures surgical procedure	s						Yes		No
	If yes, please	describe:									
	Blood transfusi	ons number of time	es								
	Other procedur	es?							Yes		No
	If yes, please of	describe:									
5.	Caregiving	h a	mu hausa af		بر مامید			· · · · · · · · · · · · · · · · · · ·	- al- af 4l	a a fallousina	h
	of your illness:	hour) day, how ma	ny nours or	suppor	t do y	ou re	eceive	irom ea	ach of tr	ne rollowing	pecause
			Train	ed Med	dical P	erso	n		Othe	ers	
		Paid caregiver				ho	urs			hours	
		Unpaid caregiver				hou	urs			hours	
6.		ne / Hospice Day s spent in a nursing									

A	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	

Week ____

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination												
Day	Month	Year										

	the subject have any abnormal clinical findia ibe findings below.	ngs relating to the followi	ng required sites?	₀ No ₁ Yes - If yes,
01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	10 Breast / Chest		
	Cardiovascular	04 Abdomen05 Musculoskeletal	07 Lymph nodes08 Neurological	11 Rectal
	Pulmonary	06 Skin		88 Other
		equired assessment was i		
Code				
(as		Describe findings		
listed		List one entry per line.		
above)				

ECOG PERFORMANCE STATUS

Date of Assessment								ECOG Performance
Da	Day Month					Year	Status ①	
0 1 2 3	Fully performed Restrand a ie, light Amburout a Capar > 50% Comp	active, abormance wricted in pable to caught housevalutory anny work able of only of wakingletely dispersion.	sabled. Car	on all priction trenuou k of a li ce work of all sepand a lelf-care	ore-di is acti ght or c elf-car about , conf	sease ivity, bu r seden re, but to > 50% ined to	tary natous unable to of wakin bed or o	ure, o carry og hours.
5	Dead	•	d to bed or	cnair				

Α	Subject Initials							
	EGF 20020408		1.1.					
	DMENT 2.0							
, <u> </u>	J.W. 2.10							
		Wee	k					
		KIN TOXICITY						
Complet	e the following question	ns based on symptom	s and physical findin	ngs present at d	date of assessment.			
		Date of A	ssessment Year					
				1				
Did the s	ubject have skin toxicity?	₀ No ₁ Yes - If Y	es, specify below, com	plete the Additio	onal Dermatological			
	ssessments page and re							
	Skin Toxicity (list all that apply)		if Skin Toxicity is	① SKIN TOXICITY 01 Nail change				
	①	"01 N	lail Changes"	02 Erythema 03 Pruritus/itch				
				04 Rash (acne 05 Rash/desqu 06 Ulceration	uamation (non-acneiform)			
Ty	pe of Skin Lesions	Lesion is "88 Other"	② TYPE OF SKIN LESION CODES:					
	(list all that apply)	Specify if Type of Skill	Lesion is to other	00 None 07 Dry flaking 01 Pustular 08 Desquamation (slou 02 Vesicular 09 Comedones				
				04 Macular 10	Comedones Cysts Other (specify)			
Total % BS/	3 TOTAL % BSA CODES:	Location ④	Specify if Locat	ion is "88 Other"	LOCATION CODES: 09 Face			
3	04 > 50% BSA 05 ≤ 50% BSA	(list all that apply)			10 Trunk 11 Extremities			
					12 Total body 88 Other (specify)			
1. If pri	or radiation, is area of rac	diation port involved?	₆₆ Not applicable	₀ No ₁ Yes	6			
2. Was	crusting present?		₀☐ No ₁☐ Yes					
3. Sinc	e the last assessment, di	d the rash cause pain?	₀□ No ₁□ Yes					
		·	U I					
4. Since	e the last assessment, di	d the rash cause itching?	o □ No □ Yes					
5 Since	e the last assessment, di	d the rash require treatm	ent with parcetics?	₀□ No ₁□	Vac			
3. On o	e the last assessment, di	a the rash require treatm	(Record on Concomit					
6. Since	e the last assessment, di	d the rash require treatm	ent with systemic sterd	oids?₀□ No ₁□	Yes			
			(Record on Concomit					
7. Was	dose held, changed or d	iscontinued for skin toxic	ity?					
			Date					
ر ا	No 1 Yes - If yes, prov	∕ide date. <u>Day</u>	Month Year					

For Amgen Use Only Tick when

Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , , ,	

Week	
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ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment											
Day	Month	Year									

	₀ No ✓	1 Yes √ Enter corre- sponding code from Photonumeric Scale*	* Photo- based Coding Scale (Record one code only) ①							
Were Pustules/Papules present?		' 								
Was Honey Yellow Crusting present?		 								
Was Erythema present?		 								
Was Paronychia present?		 								
Were Fissures present? (Photo-based scale does not apply)		 								
Does the following dermatological toxicity interfere with activities of daily living? Paronychia: O No Yes 66 N/A Fissures: O NO 1 Yes 66 N/A										
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception										
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Moderat A B C D 02 A little 04 Very mu		05 Intoler	able							

For Amgen Use	e Only
Tick when	
data checked.	

Α				Site No.				Subj	ect ID N	√o.			Subject Initials		
1 '	GF 200204	108				1	1			ı					
	DMENT 2.0		<u> </u>												
				W	eek										
		Sk	(IN T	OXICI.	TY A	AS	SE	SSM	IEN	Т					
Complete	the following										at o	late of	asses	sment.	
			D		of Asse	essm									
			Day	Mont	h		Ye	ear	\dashv						
	bject have skin		•	•			cify be	elow, cor	mplete	the Ad	ditio	nal De	rmatolo	gical	
Toxicity As	sessments pag		cord skin to	oxicity on A	AE CRI	F			⊕ &k	IN TOY	ICITY	CODES	2.		
	Skin Toxicit (list all that app			•	cify if SI 01 Nail		-	is	01		ange	s (speci			
									04		acne	/acneifor		acifa rm)	
T									06	Ulcera	tion		(non-acr		
Type of Skin Lesions (list all that apply)			Specif	Specify if Type of Skin Lesion is "88 Other"				Other"	00 None07 Dry flaking01 Pustular08 Desquamation (sloughing						
									02 V 04 N	'esicular 1acular	09 10	Comed Cysts	lones	o.ougg/	
Total % BSA	3 TOTAL % BSA	CODES:				Т				apular		Other (specify) ATION C	ODES:	
Affected 3	04 > 50% BSA		(lis	Location ④ t all that app	ly)		Speci	ify if Loca	ition is "	88 Otne	er"	09 F 10 T	ace		
	05 ≤ 50% BSA											12 T	xtremitie	,	
												88	Other (sp	еспу)	
1. If prio	r radiation, is ar	ea of rac	diation port	involved?	6	66	Not a	pplicable	e _o N	o , 🗖	Yes				
2. Was o	crusting present	?				ا 🗖	No ₁Ū	Yes							
3 Since	the last assess	ment di	d the rash	cause nair	12		No [Yes							
0. 011100	the last assess	mont, ar	a tilo lasii	oddoc paii		0— '	10 1	100							
4. Since	the last assess	ment, di	d the rash	cause itch	ing?	ı □ ₀	No ₁Ū	Yes							
5 Since	the last assess	ment di	d the rash	require tre	atment	t with	narc	otics?		☐ No		Yes			
01 011100	110 1001 00000	morn, ar	a tilo raoii					Concom	U						
6. Since	the last assess	ment, di	d the rash	require tre	atment	t with	syste	emic ster	oids?	☐ No	1	Yes			
					((Rec	ord on	Concom	itant Me	edicatio	ns C	RF)			
7. Was o	dose held, chan	ged or d	iscontinue	d for skin to	oxicity?	?									
1 🔎	No 1 Yes - If y	es, prov	vide date.	Day	Mont	Dat th	te	Year							
3															

For Amgen Use Only Tick when

Α	Site No.			Subject ID No.								Subject Initials			
ABX-EGF 20020408				1	1		1	1	ı	ſ	ı	1		I	ı
	////		_								1		<u> </u>		

We	ek	
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ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

	Date of Asse	essment
Day	Month	Year

	₀ No ✓	Yes √ Enter corre- sponding code from Photo- numeric Scale*	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		 	
Was Honey Yellow Crusting present?		 	
Was Erythema present?		 	
Was Paronychia present?		 	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activitie	s of daily	/ living?	
Paronychia: ₀☐ No ₁☐ Yes 66☐ N	/A		
Fissures: ₀☐ No ₁☐ Yes 66☐ N			
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio ②	n		
1 PHOTO-BASED CODING SCALE CODES: CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mu		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Treatment Phase VITAL SIGNS FOR ABX-EGF AND BSC

*Vital signs readings (every 2 weeks; within 30 minutes before the ABX-EGF infusion, approximately 30 minutes after the start of ABX-EGF infusion, upon completion of the ABX-EGF infusion, and approximately 30 minutes after completion of the ABX-EGF infusion, allowing a +/- 10 minute time window): blood pressure, resting pulse, respiration rate, and temperature (every 2 weeks).

*Weight (every 2 weeks, before the ABX-EGF infusion on ABX-EGF arm; every 4 weeks on BSC arm)

⋖					<u>'/</u>	Site No.		Subject ID No.	ID No.	Subject Initials
ABX-E	ABX-EGF 20020408				<u> </u>	_ _ /////			_ _ _	_
AMEN	AMENDMENT 2.0									
				Weeks	S					
		ABX-I	EGF INF	·USION	ABX-EGF INFUSION VITAL SIGNS and WEIGHT	IGNS a	and WEI	GHT		
Study Week	Date of Assessment Day Month Yea	i ment Year	Scheduled Time Point	Time (24 hour clock)	Blood Pressure	Pulse (beats/minute)	Respiration (breaths/minute)	Temperature	Weight	
		_ _ _	Pre-infusion <a> 30 minutes prior to start of infusion		/					
			30 minutes after start of infusion		/					
			At end of infusion		/					
			Approximately 30 minutes after completion of infusion		/					
		_ _ _	Pre-infusion < 30 minutes prior to start of infusion		/					
			30 minutes after start of infusion		/					
			At end of infusion		/					
			Approximately 30 minutes after completion of infusion		/					

⋖					Site No.		Subject ID No.	D No.	Subject Initials
ABX-E	ABX-EGF 20020408			<u>////</u>	- - /////			_ _ _	_
AMENI	AMENDMENT 2.0								
			Weeks	S					
	ABX	EGF INF	·USION	ABX-EGF INFUSION VITAL SIGNS and WEIGHT	IGNS a	and WEI	GHT		
Study Week	Date of Assessment Day Month Year	Scheduled Time Point	Time (24 hour clock)	Blood Pressure (mmHg)	Pulse (beats/minute)	Respiration (breaths/minute)	Temperature	Weight The kg Lib lb	
	- - - - -	Pre-infusion <a> 30 minutes prior to start of infusion		/					
		30 minutes after start of infusion							
		At end of infusion							
		Approximately 30 minutes after completion of infusion		/					
		Pre-infusion < 30 minutes prior to start of infusion		/					
		30 minutes after start of infusion		1					
		At end of infusion		/					
		Approximately 30 minutes after completion of infusion		\					

			<u>'//</u>	Site No.		Subject ID No.	D No.	Subject Initials
ABX-EGF 20020408 AMENDMENT 2.0					_	- - -		
		Weeks	S					
ABX-	EGF INF	·USION	ABX-EGF INFUSION VITAL SIGNS and WEIGHT	IGNS a	Ind WEI	GHT		
Date of Assessment Month Year	Scheduled Time Point	Time (24 hour clock)	Blood Pressure	Pulse (beats/minute)	Respiration (breaths/minute)	Temperature	Weight 1	
- - - - -	Pre-infusion							
	30 minutes after start of infusion							
	At end of infusion		,					
	Approximately 30 minutes after completion of infusion		/					
	Pre-infusion < 30 minutes prior to start of infusion		/					
	30 minutes after start of infusion		/					
	At end of infusion		/					
	Approximately 30 minutes after completion of infusion		/					

For A									is ///	Site No.	Subject ID No.		Subject Initials
	BX-E(3F 200	ABX-EGF 20020408					,,,,				_	_
	MEND	AMENDMENT 2.0	2.0			Weeks	KS		ı				
		Subje	INV ects receiving	/ESTIG	ATION of receive In	VAL PR	SODI 11 Produc	JCT /	ADMI Stration, F	INVESTIGATIONAL PRODUCT ADMINISTRATION Seiving BSC will not receive Investigational Product Administration, please score through the	INVESTIGATIONAL PRODUCT ADMINISTRATION Subjects receiving BSC will not receive Investigational Product Administration, please score through the page		
Study Week	d y e k Day	Date	te Year	Start Time (24 hour clock)	Stop Time (24hourclock)	Total Dose Administered (mg)	Total Volume (mL)	Reason for bose Dose	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code		If Reason for Dose Change is "88 Other", please specify	S	
	-	_	_ _ _						-				
	_	_	_										
	_	_						_	_				
	_	_	_ _ _						_				
	_	_ _	_					_	_				
	_	_	- - -					_	_				
E S	subject did	I not comple	If subject did not complete investigational product administration, provide any	nal product adm	ninistration, pr		itional rele	additional relevant information:	nation:				
⊕	OSECHA	① DOSE CHANGE CODES:	.;	② "04 Per p	rotocol" DOS	② "04 Per protocol" DOSE CHANGE CODES:	DES:						
8 6 3 0 2		Adverse event Noncompliance Dose administration error Per protocol Other (Specify above)	error ?)	100 Weig 118 Sym 120 Skin	ght change hptomatic skin alt to be intoler infection requ	Weight change Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject Skin infection requiring systemic IV antibiotic or IV antifungal treatment	requiring I	narcotics, s cor IV antifi	systemic ste ungal treatm	roids, ent	 121 Need for surgical debridement 122 Any skin-related serious adverse event 200 Dose reinstated 201 Dose increase (after reinstatement) 	nt erse event (ement)	

A	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	

Weeks _____ INVESTIGATIONAL PRODUCT LOT NUMBER

Study Week	ı	Pack		X-E	GF Nun	nber		ı	Pack		X-E Lot	_	nbei	
													1	
		ı	ı	l	1	ı	ı		ı	<u> </u>	ı	ı	l <u> </u>	I

For Amgen Use	e Only
Tick when	
data checked.	

Α		1///	Site No.			Subj	ect ID N	lo.		Subject	t Initia
AB	X-EGF 20020408	\/// ₂		1,	1,	1		I	1 1		ı
AME	ENDMENT 2.0	1////			l						
			Week	.							
	HEALTH RE	SOURC	F UTILI	7 Δ	ΓΙΟ	N Q	UES	TIC	ANNO	IRF	
			Date of A								
		Day	Month			Year	_				
					ı	1 1					
	I would like to ask you	a few guestion	ns about anv a	ddition	al vis	its (not r	eauirea	by the	e trial) that	vou ma	av
		nade to a docto							<i>-</i>	,, , , , , , , , , , , , , , , , , , , ,	- 7
1.	Emergency Room Number of emergency										
2.	Therapy Visits Number of therapy (me	ental health) vis	sits								
3.	Outpatient visits to addition to your ro	•									
	Pain Management Number of outpatient p										
	Radiologist: Number of outpatient p	ohysician visits									
	Radiation Oncolog Number of outpatient p										
4.	Outpatient Procedu							1			
	Any outpatient surgical						`	es/es		No	
	If yes, please describ	e:									_
	Blood transfusions nur	nber of times									
	Other procedures?							/es		No	
	If yes, please describe	e:									_
5.	Caregiving										
J.	In a typical (24 hour) d of your illness:	ay, how many h	nours of suppo	rt do y	ou rec	ceive fro	m each	of the	following	because	е
			Trained Med	dical P	erson	1		Others	S		
	Paid ca	regiver			houi	rs			hours		
	Unpaid	caregiver			hour	rs			hours		
6.	Nursing Home / Ho	spice Days									
	Number of days spent	in a nursing ho	me								

	Subject ID No.				
ABX-EGF 20020408 1 1 1					

Week ____

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination												
Day	Month	Year										

	the subject have any abnormal clinical find	ings relating to the followi	ing required sites?	$_{0}$ No $_{1}$ Yes - If yes,						
01 l 02 l	be findings below. Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular	04 Abdomen05 Musculoskeletal06 Skin		11 Rectal						
	03 Pulmonary06 Skin09 Genitourinary8Indicate if a required assessment was not done.									
Code (as listed above)		Describe findings List one entry per line.								

ECOG PERFORMANCE STATUS

Date of Assessment									ECOG Performance				
Da	у	Month					Year	Status ①					
1	① ECOG PERFORMANCE STATUS CODES:												
0	•			to carry		ore-c	lisease						
1	and a	able to	carry		k of a li	ght c		ut ambula ntary nati					
2								unable to					
3			•	limited se hours	elf-care	, cor	nfined to	bed or o	chair				
4				oled. Car to bed or		rry o	ut any s	self-care.					
5	Dead	•											

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data checked.

DISTRIBUTION: White & Yellow - Amgen; Blue - CRA; White Card - Investigator

Λ	Site No.	Subje	ect ID No.	Subject Initials										
A DY FOE COSC 400		1.1.												
ABX-EGF 20020408		<u> </u>												
AMENDMENT 2.0														
	Week													
01/	(INI TOVIOITY													
_	(IN TOXICITY A													
Complete the following question	ns based on symptoms a	and physical findin	gs present at d	late of assessment.										
	Date of Asse	essment Year												
	Day World	Teal	1											
Did the subject have skin toxicity? Toxicity Assessments page and red			plete the Additio	nal Dermatological										
Skin Toxicity	Pord GRIT LOXIOLY GITTLE GIT		① SKIN TOXICITY	CODES:										
(list all that apply)		kin Toxicity is Changes"	01 Nail change 02 Erythema	es (specify)										
			03 Pruritus/itch 04 Rash (acne											
			05 Rash/desqu 06 Ulceration	namation (non-acneiform)										
Type of Skin Lesions	Consider if Towns of Older La	-ii- "00 Oth"	② TYPE OF SKIN											
(list all that apply)	Specify if Type of Skin Le	sion is "88 Other"	01 Pustular 08	Dry flaking Desquamation (sloughing)										
			04 Macular 10	Comedones Cysts										
			05 Papular 88	Other (specify)										
Total % BSA ③ TOTAL % BSA CODES: Affected	Location ④ (list all that apply)	Specify if Locat	ion is "88 Other"											
③ 04 > 50% BSA 05 ≤ 50% BSA	(not an that apply)			10 Trunk 11 Extremities										
				12 Total body 88 Other (specify)										
				, , , , ,										
If prior radiation, is area of rad	iation port involved?	66 Not applicable	₀ U No ₁U Yes											
2. Was crusting present?		₀□ No ₁□ Yes												
2. Was stasting procent.		0 10 1												
3. Since the last assessment, did	I the rash cause pain?	₀ No ₁ Yes												
4. Since the last assessment, dic	I the rash cause itching?	₀☐ No ₁☐ Yes												
5. Since the last assessment, dic		t with narcotics? (Record on Concomit	\square No \square											
		(Necord on Concomi	ant ineclications o	(M.)										
6. Since the last assessment, dic	I the rash require treatment	t with systemic sterc	oids? ₀ No ₁	Yes										
		(Record on Concomit	ant Medications C	RF)										
7. Was dose held, changed or dis	scontinued for skin toxicity	?												
□ No □ Yes - If yes provi	ide date Day Mon	Date th Year												

Α	////	Site No.				Sub	oject I	D No.				Subj	ect Ir	nitials
ABX-EGF 20020408				1	1	1	1	ı	ſ	ı	1		I	ı
	////		_							1		<u> </u>		

Week	
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ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment												
Day	Month	Year										

	₀No✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①					
Were Pustules/Papules present?		 						
Was Honey Yellow Crusting present?		1						
Was Erythema present?		1						
Was Paronychia present?		1						
Were Fissures present? (Photo-based scale does not apply)		I I						
Does the following dermatological toxicity interfere with activitie	s of daily	/ living?						
Paronychia: ₀ No ₁ Yes ₆₆ N	/A							
Fissures: 0 No 1 Yes 66 N	/A							
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception								
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mode		05 Intoler	able					

For Amgen Use	e Only
Tick when	
data checked.	

Α	Site No.	Subje	ect ID No.	Subject Initials
ABX-EGF 20020408		1,1, , ,		
AMENDMENT 2.0				
	Week			
CI	ZINI TOVICITY	ACCECCM	ENIT	
Complete the following question	KIN TOXICITY			tate of assessment
Complete the following question	Date of Ass]	ace or assessment.
	Day Month	Year	_	
			_	
Did the subject have skin toxicity? Toxicity Assessments page and re			plete the Additio	nal Dermatological
Skin Toxicity			① SKIN TOXICITY	
(list all that apply)		Skin Toxicity is Changes"	01 Nail change 02 Erythema	
			03 Pruritus/itch 04 Rash (acne 05 Rash/desqu	
Tuna of Chin Laciona			06 Ulceration	LESION CODES:
Type of Skin Lesions (list all that apply)	Specify if Type of Skin Le	esion is "88 Other"	00 None 07	Dry flaking Desquamation (sloughing)
② 			02 Vesicular 09	Comedones Cysts
				Other (specify)
Total % BSA Affected 3 TOTAL % BSA CODES:	Location ④ (list all that apply)	Specify if Locat	ion is "88 Other"	4 LOCATION CODES:09 Face
③ 04 > 50% BSA 05 ≤ 50% BSA				10 Trunk 11 Extremities
		1		12 Total body 88 Other (specify)
If prior radiation, is area of rad	diation port involved?	Not applicable	□ No □ Yes	
,	·		0 1	
2. Was crusting present?		₀ No ₁ Yes		
3. Since the last assessment, di	d the rash cause pain?	₀□ No ₁□ Yes		
4. Since the last assessment, di	d the rash cause itching?	₀ No ₁ Yes		
5. Since the last assessment, di	d the rash require treatmen	it with narcotics?	₀□ No ₁□	Yes
· · · · · · · · · · · · · · · · · · ·		(Record on Concomit		
6. Since the last assessment, di	d the rash require treatmen	t with systemic sterd	oids?₀□ No ₁□	Yes
		(Record on Concomit		
7. Was dose held, changed or d	iscontinued for skin toxicity	?		
. □ No . □ Yes - If ves. prov	vide date. Day Mor	Date onth Year		

For Amgen Use Only Tick when

Α	////	Site No.				Sub	oject I	D No.				Subj	ect Ir	nitials
ABX-EGF 20020408				1	1	1	1	ı	ſ	ı	1		I	ı
	////		_							1		<u> </u>		

Week

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment										
Day	Year									

	₀No✓		* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		' 	
Was Honey Yellow Crusting present?		 	
Was Erythema present?		 	
Was Paronychia present?		1	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activities	s of daily	/ living?	
Paronychia: ₀ ☐ No ₁ ☐ Yes 66 ☐ N	/A		
Fissures: 0 No 1 Yes 66 No	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio	n		
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: A B C D 01 Not at all 03 Moderat 02 A little 04 Very mu		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Α		1///	Site No.			Subj	ect ID No).		Subjec	ct Initia
ABX	K-EGF 20020408	<i>\\\\\</i>		1	1,		I	ſ			I
	NDMENT 2.0			ı		l	I		1	1	
			We	ek							
	HEALTH RE	SOURC	F UTI	Ι Ι 7 Δ	TIOI	N OI	IFS.	TIC	ΝΝΔ	IRF	
	HEALITIKE			of Assess							
		Day	Mont			'ear	_				
					ı						
	I would like to ask you	a few questio	ns about an	v addition	nal visit	s (not re	— Pauired	hy the	e trial) that	· vou m	av
		ade to a docto							Julian man	. y 50 1110	~ y
1.	Emergency Room V Number of emergency										
2.	Therapy Visits										
	Number of therapy (me	ental health) vi	sits								
3.	Outpatient visits to addition to your rou	•	•	-			•				
	Pain Management S Number of outpatient p										
	Radiologist: Number of outpatient p	hysician visits									
	Radiation Oncology Number of outpatient p										
	rumber or outpations p	nyororan viole									
4.	Outpatient Procedu Any outpatient surgical						Ye	es		No	
	If yes, please describe									140	
	, , , , , , , , , , , , , , , , , ,	·									_
	Blood transfusions num	ber of times									
	Other procedures?						Ye	es		No	
	If yes, please describe	:									
	, , ,										_
5.	Caregiving										
	In a typical (24 hour) da of your illness:	ıy, how many l	nours of sup	oport do y	ou rece	eive fror	n each o	of the	following	becaus _	e
			Trained	Medical F			C	Others			
	Paid car				hours				hours		
		caregiver			hours	5			hours		
6.	Nursing Home / Hos	spice Days	ome								

DISTRIBUTION: White & Yellow - Amgen; Blue - CRA; White Card - Investigator

data checked.

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A	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	

Week ____

PHYSICAL EXAMINATION

Record any new finding or change (worsening) of an existing finding on the Adverse Events Summary CRF.

Date of Examination									
Day	Month	Year							

	the subject have any abnormal clinical find	ings relating to the followi	ing required sites?	$_{0}$ No $_{1}$ Yes - If yes,
01 l 02 l	be findings below. Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Pulmonary	04 Abdomen05 Musculoskeletal06 Skin		11 Rectal
		required assessment was i		ou outer
Code (as listed above)		Describe findings List one entry per line.		

ECOG PERFORMANCE STATUS

		ECOG Performance								
Da	Day Month				Year				Status ①	
1	① ECOG PERFORMANCE STATUS CODES:									
0	•			to carry hout rest		pre-c	disease			
1	and a	able to	carry		k of a li	ight d		ut ambula ntary nati		
2								unable to		
3	 out any work activities. Up and about > 50% of waking hours. Capable of only limited self-care, confined to bed or chair > 50% of waking hours 								chair	
4	 4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair 									
5	Dead	•								

For Amgen Use Only
Tick when

Α				Site No.			Subje	ect ID No.		Subject Initials
` `	CE 2002040	10			1	.1.				
	GF 2002040	0	////							
AMENI	DMENT 2.0									
				Wed	ek _					
		C K	(INI T	OXICIT	V 10	29E	SCM	ENT		
Complete	the following qu			_					data of	accaceman
Complete	the following qu	<i>i</i> estioi	is based				ai iii'dii	ης ο ρι σσοιπ απο Τ	iale or e	assessificii
			Day	Date of Month	Assessi	nent Yea	r			
								1		
Did the su	bject have skin to	xicitv?	. D No	. Yes - If	Yes. sn	ecifv be	low. com	plete the Additio	nal Der	matological
	sessments page		0			oo,	,	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	= 0	atorograa
	Skin Toxicity	١		Snacif	v if Skin	Toxicity is		① SKIN TOXICITY 01 Nail change		
	(list all that apply	<i>,</i> 			Nail Ch			02 Erythema 03 Pruritus/itch	. , ,	′)
								04 Rash (acne	e/acneiforn	
								06 Ulceration		,
Type of Skin Lesions (list all that apply)				Specify if Type of Skin Lesion is "88 Other"				 TYPE OF SKIN LESION CODES: 00 None 07 Dry flaking		
	②							01 Pustular 08		mation (sloughing
									Cysts Cther (s	specify)
Total % BSA	3 TOTAL % BSA CO	DDES:		Location ④		Specify	, if Locat	ion is "88 Other"	4 LOCA	TION CODES:
Affected 3	04 > 50% BSA		(II	(list all that apply)						Face Trunk
	05 ≤ 50% BSA								11 E>	ktremities otal body
1										ther (specify)
1 If prio	r radiation, is area	of rad	iation por	rt involved?		Not an	plicable	₀□ No ₁□ Yes		
	. radiation, io area	· or raa	ilation poi	· · · · · · · · · · · · · · · · · · ·	66	- 1101 ap	pilodolo	0—110 1—100		
2. Was	crusting present?				0	No ₁□	Yes			
						·	1			
3. Since	the last assessm	ent, dic	d the rash	n cause pain?	0	l No ₁□	I Yes			
4 Cinas	the leat access	مائم عمدم	ما ده ما ۱	italaina	~o	Na □	l Vaa			
4. Since	the last assessm	ent, aic	ine rasr	i cause itching	g? ₀ —	l No ₁□	res			
5. Since	the last assessm	ent. dic	d the rash	require treat	ment wi	th narco	tics?	₀□ No ₁□	Yes	
		.,		,				tant Medications C		
6 Since	the last assessme	ent dic	the rash	require treat	ment wi	th syste	mic ster	oids? □ No □	Yes	
0. 000		J. 1., GIC						tant Medications C		
· · · ·			.,			017			/	
7. Was o	dose held, change	d or di	scontinue	ed for skin tox		-1-				
				I	ט	ate				

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 $_{\scriptscriptstyle{0}}$ No $_{\scriptscriptstyle{1}}$ Yes - If yes, provide date.

Month

Year

Day

Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , , ,	

AMENDMENT 2.0

Week

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment					
Day	Month	Year			

	₀ No ✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?		! ! !	
Was Honey Yellow Crusting present?		1	
Was Erythema present?		1	
Was Paronychia present?		1	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activitie	s of daily	/ living?	,,,,,,
Paronychia: 0 No 1 Yes 66 N	/A		
Fissures: 0 No 1 Yes 66 N	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio ②	n		
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mu		05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Λ		Site No.			Subje	ect ID No.	Subject Initials
ABX-EGF 20020408			,				
ABX-EGF 20020408			'				
AMENDMENT 2.0							
		\ \\	. 1 -				
		wee	ek_				
SI	KIN TO	DXICIT	Y AS	SSE	SSM	ENT	
Complete the following question	ons based	on symptor	ns and	physic	cal findin	gs present at o	date of assessmen
		Date of	Assessr			1	
	Day	Month		Ye	ar	1	
Did the subject have skin toxicity?		□ Voc - If	Voc en	ocify be	Now com	— unlete the ∧dditid	onal Dermatological
Toxicity Assessments page and re				ecity be	FIOW, COIT	ipiete trie Additio	onal Dermatological
Skin Toxicity		Specify	y if Skin	Toxicity i	is	① SKIN TOXICIT	
(list all that apply)			Nail Cha			02 Erythema 03 Pruritus/itcl	
						04 Rash (acne	
Type of Skin Lesions						06 Ulceration ② TYPE OF SKIN	I LESION CODES:
(list all that apply)	Specify	y if Type of Ski	in Lesion	is "88 C	Other"	00 None 07	7 Dry flaking 3 Desquamation (sloughing
						02 Vesicular 09	Comedones Cysts
						05 Papular 88	3 Other (specify)
Total % BSA ODES: Affected 3 TOTAL % BSA CODES:	1	Location ④ t all that apply)		Speci	fy if Locat	ion is "88 Other"	4 LOCATION CODES:09 Face
③ 04 > 50% BSA 05 ≤ 50% BSA							10 Trunk 11 Extremities
			ı				12 Total body 88 Other (specify)
1. If prior radiation, is area of ra	diation port	involved?		Not a	nnlicable	₀□ No ₁□ Yes	,
1. Il prior faulation, is area of fa	diation port	iiivoivea :	66	i Not a	opiicabie		•
2. Was crusting present?				No 1	Yes		
3. Since the last assessment, d	lid the rash (rause nain?		No ₁□) Ves		
o. Office the last assessment, a	ila tric rasir t	cause pair:	0	140 1	103		
4. Since the last assessment, d	id the rash	cause itching	g? □	No ,	Yes		
			0	,			
5. Since the last assessment, d	id the rash i	require treatr				$_{_0}$ No $_{_1}$ \Box	
6. Since the last assessment, d	id the rash i	require treatr					
			(Re	cord on	Concomit	ant Medications (CRF)
7. Was dose held, changed or o	discontinued	d for skin tox					
₀☐ No ₁☐ Yes - If yes, pro	vide date.	Day	Month D	ate	Year		

Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , , ,	

AMENDMENT 2.0

Week

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment						
Day	Month	Year				

	₀ No ✓	Yes √ Enter corre- sponding code from Photo- numeric Scale*	* Photo- based Coding Scale (Record one code only) ①		
Were Pustules/Papules present?		 			
Was Honey Yellow Crusting present?		 			
Was Erythema present?		 			
Was Paronychia present?		 			
Were Fissures present? (Photo-based scale does not apply)		 			
Does the following dermatological toxicity interfere with activitie	s of daily	/ living?			
Paronychia: ₀☐ No ₁☐ Yes 66☐ N	/A				
Fissures: ₀☐ No ₁☐ Yes 66☐ N	/A				
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception ②					
1 PHOTO-BASED CODING SCALE CODES: CODES: 01 Not at all 03 Modera A B C D 02 A little 04 Very mu		05 Intoler	able		

For Amgen Use	e Only
Tick when	
data checked.	

A	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	

AMENDMENT 2.0

Week ____ TUMOR EVALUATION - TARGET LESIONS

	Date of Pro	cedure
Day	Month	Year

Lesion Note: Always maintain the same order of lesion	Lesion Site Code	Subsite Describe specific location	Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable Dimensions (mm)
numbers	U			J ,
01				
02				
03				
04				
05				
06				
07				
08				
09				
10				
		Sum	of Target	

10 LESION SITE Control Lymph nodes 10 Pulmonary 20 Liver 30 Bone	ODES: 40 Chest 50 Central nervous system 55 Head 56 Neck	60 Gastrointestinal 86 Skin 70 Abdomen 88 Other (sp 75 Pelvic Site in subsite 85 Spleen	
Line #		Specify if "88 Other" Method	d of Assessment
Line #		Specify if "88 Other" Method	d of Assessment

For Amgen Use	Only
Tick when	
data checked.	

А	1///	Site N	No.					Sı	ubject	ID N	0.		Sub	ject Ir	nitials
ABX-EGF 20020408		ı	ı	I	1	1	1	1	ı		ı	ſ		I	
AMENDMENT 2.0															

Week ____

Lesion ote: Always naintain the same order of lesion	I	Date of Pro	ocedure	Body Site Code	Subsite Describe specific location	Method of Assessment	New Lesions	Measurable Lesions (mm) Must be unidimensionally measurable.
numbers	Day	Month	Year	1			₀No ₁Yes	Dimensions (mm)
11							! ! !	
12							 	
13								
14	_	1 1					1 1 1	
15								
16	1						1	
	'	1 1			Su	m of Non-T Le	arget sions	
00 Ly	mph no ulmona ver		40 50 55	Chest Central ner Head Neck	vous system 70 Abde	ic Site	86 88	
01 X	(-Ray		SMENT CO		04 Magnetic Resonance23 Spiral Computed Tom88 Other (specify below)	ography (CT)		
Line #					Specify if "88 Other" Method	of Assessmer	nt	

For Amgen Use	e Only	
Tick when		
data checked.		

A	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1 ,1, , , , , , , ,	

AMENDMENT 2.0

Week ____ OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study		Date)		Tumor Response
Week	Day	Month		Year	Code ①
① TUMOF	RESPON	SE CODE:			
PD F	Complete Re Progressive I Partial Respo	Disease	SD UE	Stable Disea Unable to ev	 te

	011 11	1 2	N N I -	Out of the
A	Site No.	Subject ID) NO.	Subject Initials
ABX-EGF 20020408		1,1,		
MENDMENT 2.0				
	307			
	Weeks			
	PROCE	EDURES		
√as any cytology performed? ₀☐	CYTC	LOGY pecify below		
	Procedure Malignant	Body Specify if Procedure	Specify if Body Site	① PROCEDURE
Date of Procedure Day Month Year	① Cell? ₀No ✓ ₁Yes ✓	Site Code is "88 Other"	is "88 Other"	CODE:
	1			30 Paracentesis31 Thoracentesi
				88 Other (Specif
Equivocal findings:	<u> </u>			
	SUR	GICAL		
Vere any surgical procedures perfo				
Date of Procedure	Procedure Body Si Code Code	te Specify if Body 5 "88 Other"	5110 10	ROCEDURE ODE:
Day Month Year	2 4	oo otner		2 Surgical
	3.2			
Findings.				
Findings:				
Vas biopsy performed? ₀☐ No ₁	D Vas - If yas, specify	PSY		
vas biopsy periorified: () 1	Procedure Body Si			ROCEDURE
Date of Procedure	Code Code	Specify if Body \$ "88 Other"		ODE:
Day Month Year	3 4		16	Biopsy
	11,6			
Findings:			<u> </u>	
	_ ENDO	SCOPY		
Vas endoscopy performed? ₀☐ N	lo ₁┗ Yes - If yes, spe	ecify below.	is is Dadi Cita	
Date of Procedure	© Site			PROCEDURE CODE:
Day Month Year	4		3:	
			3.	
Fig. Page				(-1, -2, -7,
Findings:				
BODY SITE 01 Abdomen 05 Che	st 09 Hea	art 13 Pleura	17 Total body 8	8 Other
CODES: 02 Brain 03 Breast 07 Gas	trointestinal tract 10 Kid	ney 14 Pelvic site r 15 Retroperitoneum	18 Thorax 19 Extremity(ies)	(Specify above)
04 Bone 08 Hea			23 Neck	
ck when				
ata checked bistr	IBUTION: White & Yellow - Amg	en; Blue - CRA; White Card - Investig	gator	•



End of Treatment

Subjects on both the ABX-EGF and BSC arms must complete End of Treatment

A	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			EOT

END OF TREATMENT

son for ending DES: Ineligibility of Protocol des Noncomplia Adverse ever Consent with Subject required Administration Lost to follow Death (Enter cause Serious Adverse)	ance [®] vent [®] (FAX this form to Amgen) ithdrawn [®] quest ogression [®] tive decision [®]
DDES: Ineligibility of Protocol des Noncomplia Adverse ever Consent with Subject required Administration Lost to follow Death (Enter cause Serious Adverse Serious Adverse Protocol specification)	determined © eviation © ance © vent © (FAX this form to Amgen) ithdrawn © quest ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
DDES: Ineligibility of Protocol des Noncomplia Adverse ever Consent with Subject required Administration Lost to follow Death (Enter cause Serious Adverse Serious Adverse Protocol specification)	determined © eviation © ance © vent © (FAX this form to Amgen) ithdrawn © quest ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
DDES: Ineligibility of Protocol des Noncomplia Adverse ever Consent with Subject required Administration Lost to follow Death (Enter cause Serious Adverse Serious Adverse Protocol specification)	determined © eviation © ance © vent © (FAX this form to Amgen) ithdrawn © quest ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
DDES: Ineligibility of Protocol des Noncomplia Adverse ever Consent with Subject required Administration Lost to follow Death (Enter cause Serious Adverse Serious Adverse Protocol specification)	determined © eviation © ance © vent © (FAX this form to Amgen) ithdrawn © quest ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Ineligibility of Protocol de Noncomplia Adverse eve Consent with Subject requirement of Administration Lost to follow Death (Enter cause Serious Adverse Protocol specification)	eviation © ance © vent © (FAX this form to Amgen) ithdrawn © quest ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Protocol de Noncomplia Adverse eve Consent wit Subject required Disease pro Administrati Lost to follo Death © (Enter cause Serious Adve Protocol spe	eviation © ance © vent © (FAX this form to Amgen) ithdrawn © quest ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Noncomplia Adverse eve Consent wit Subject required Disease pro Administrati Lost to follow Death (Enter cause Serious Adve Protocol spe	ence [©] yent [©] (FAX this form to Amgen) ithdrawn [©] quest ogression [©] tive decision [©] tive decision [©] ow-up [©] e of death on Adverse Events Summary CRF and FAX complete yerse Event form to Amgen within one working day.) becified criteria [©] CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Adverse everage Consent with Subject requirements of Administration Lost to follow Death (Enter cause Serious Adverse Protocol specification)	rent (FAX this form to Amgen) ithdrawn quest ogression tive decision ow-up e of death on Adverse Events Summary CRF and FAX complete rerse Event form to Amgen within one working day.) becified criteria CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Consent with Subject required Disease production Administration Lost to follow Death (Enter cause Serious Adversarious Adv	ithdrawn © quest ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Subject requirements of Subjec	quest ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Disease pro Administrati Lost to follogo Death © (Enter cause Serious Adve Protocol spe	ogression © tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) pecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Administrati Lost to follo Death © (Enter cause Serious Adve Protocol spe	tive decision © ow-up © e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) oecified criteria © CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Lost to follow Death (Enter cause Serious Adversarios Serious Adversarios Protocol specification)	e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) becified criteria CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Death © (Enter cause Serious Adve	e of death on Adverse Events Summary CRF and FAX complete verse Event form to Amgen within one working day.) oecified criteria CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Serious Adve	verse Event form to Amgen within one working day.) pecified criteria CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Protocol spe	CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
Criteria	CRITERIA CODES: 118 Symptomatic skin-related toxicity requiring narcotics, systemic
	118 Symptomatic skin-related toxicity requiring narcotics, systemic
Code	
1	120 Skin infection requiring systemic IV antibiotic or antifungal
	treatment 121 Need for surgical debridement
	122 Any skin-related serious adverse event
Pregnancy	© (complete Pregnancy Notification Worksheet)
Other ^①	
	de to end the treatment phase as Date Subject Ended Treatment Phase
eath as Date Sub	bject Ended Treatment Phase
additional rel	levant information on the PRIMARY reason for ending treatm
	3 · · · · · · · · · · · · · · · · · · ·
	Other [®] lecision was ma eath as Date Su



SAFETY FOLLOW-UP DEFINITION

Subjects in the ABX-EGF arm will have a safety follow-up visit conducted 4 weeks after their last assigned treatment.

Subjects in the BSC arm will have a safety follow-up visit conducted within 4 weeks after disease progression is observed (ie. if a subject on the BSC arm has the safety follow-up assessments on the day of terminating the treatment phase, the subject will be considered as having completed the safety follow-up visit)

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			FUP

Safety Follow-up HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment											
Day	Month	Year									
	1 1										

	I would like to ask you a few questions a have made to a doctor or	bout any additional visits (r an outpatient facility in the		ou may						
1.	Emergency Room Visits Number of emergency room visits									
2.	Therapy Visits Number of therapy (mental health) visits									
3.	Outpatient visits to specialists (to valid addition to your routine care, such	-	-							
	Pain Management Specialist: Number of outpatient physician visits									
	Radiologist: Number of outpatient physician visits									
	Radiation Oncology: Number of outpatient physician visits									
4.	Outpatient Procedures Any outpatient surgical procedures Yes N									
	If yes, please describe:									
	Blood transfusions number of times									
	Other procedures?		Yes No)						
	If yes, please describe:									
5.	Caregiving In a typical (24 hour) day, how many hour of your illness:	s of support do you receive	from each of the following bea	cause						
	Т	rained Medical Person	Others							
	Paid caregiver	hours	hours							
	Unpaid caregiver	hours	hours							
6.	Nursing Home / Hospice Days Number of days spent in a nursing home									
For An	mgen Us <u>e Only</u>									

Tick when data checked.

A	V FOE 200204	J00	Site No.		1.1.	Subject ID No.		Subject Initials				
AE	3X-EGF 200204	108	<u>// </u>		1							
AM	ENDMENT 2.0)	Cofoty	. Eall				FUP				
	Safety Follow-up											
	VITAL SIGNS											
Pulse should be resting												
	Date Blood Pressure Pulse Respiration (beats/minute) (breaths/minute) Temperature (mmHg) (beats/minute) (breaths/minute)											
			1									
_	PHYSICAL EXAMINATION											
	Record any new find	ling or change	(worsening) o	f an exis	ting finding o	on the Adverse	Events Sum	nmary CRF.				
			Day Mon	of Examii	nation Year							
Do	es the subject have an	v abnormal oli	inical findings r	olatina ta	the followin	a roquirod citos	2	Yes - If yes,				
des	cribe findings below.						Ü	1 res - II yes,				
	 Head, Ears, Eyes, Nose Cardiovascular 	, Throat (HEENT		04 Abdome 05 Muscule		07 Lymph node08 Neurologica		O Breast / Chest Rectal				
	3 Pulmonary	Ind		06 Skin	mont was n	09 Genitourina		8 Other				
Cod	e	ma	icate if a require			ot done.						
(as listed				Describe st one ent	ry per line.							
_above												
		ECOG	PERFC	PRM	ANCE	STATUS						
			Date of Asse			ECOG	7					
		Day	Month	331116111	Year	Performance Status ①						
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		1	PERFORMANCE S									
		perforr	ctive, able to carry nance without rest	riction.								
			cted in physically st ble to carry out work									
		ie, ligh	t housework or offi atory and capable	ce work.	•							
		out any	y work activities. U	p and abou	ut > 50% of wal	king hours.						
			le of only limited so of waking hours.	elf-care, co	ntined to bed o	r chair						
		4 Compl	etely disabled. Car confined to bed or		out any self-car	e.						
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Safety Follow-up SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment										
Day Month Year										

Did the subject have skin toxicity? On No Larrow Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)						Specify if Skin Toxicity is "01 Nail Changes"					SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching							
														04 Rash (acne/acneiform) 05 Rash/desquamation (non-acneiform) 06 Ulceration				
		e of Skir list all tha			s		Spe	ecify if T	ype of SI	kin Lesioi	is "88	Other"	00 01	LESION CODES: Dry flaking Desquamation (sloughing) Comedones				
				I									04	Macular	10	Cysts Other (specify)		
Total % Affect		③ TOTA 04 >	50%	6 BSA	CO	DES:			tion ④ hat apply,)	Spec	cify if Locati	ion is 88 Other			LOCATION CODES: 09 Face 10 Trunk		
		05 ≤	50%	o BSA												11 Extremities 12 Total body 88 Other (specify)		
1. If	1. If prior radiation, is area of radiation port involved?																	
2. W	/as c	rusting	pre	esent	?					\Box_0	No 1	☐ Yes						
3. S	ince	the last	as	sess	me	ent, di	id the ras	sh caus	se pain?	0	l No 1	☐ Yes						
4. S	ince	the last	as	sess	me	ent, di	id the ras	sh caus	e itchin	g? _₀ □	l No 1	☐ Yes						
5. S	ince	the last	as	sess	me	∍nt, di	id the ras	sh requ	ire trea			cotics? n Concomit	ant N	₀☐ No ₁ ∕ledications				
6. S	ince	the last	as	sess	me	ent, di	d the ras	sh requ	ire treat		-	temic stero		0 1				
7 14	loo o	logo bo	4	ohon	a o	dord	liooontini	und for	akin ta	•	cord oi	n Concomit	ant N	/ledications	s CI	RF)		
/. V\	as c	iose ne	u, i	CHari	ge	u oi u	liscontini		SKIII (O)					1				
C	N 🗖	No 1	Yes	s - If y	/es	s, prov	vide date	e	ay	Month	ate	Year		-				
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Safety Follow-up

ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment											
Day Month Year											

	₀ No ✓	1 Yes √ Enter corre- sponding code from Photonumeric Scale*	* Photo- based Coding Scale (Record one code only) ①					
Were Pustules/Papules present?		' 						
Was Honey Yellow Crusting present?		 						
Was Erythema present?		 						
Was Paronychia present?		 						
Were Fissures present? (Photo-based scale does not apply)		 						
Does the following dermatological toxicity interfere with activities of daily living? Paronychia: O No Yes 66 N/A Fissures: O No 1 Yes 66 N/A								
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception ②								
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Moderat A B C D 02 A little 04 Very mu		05 Intoler	able					

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Safety Follow-up TUMOR EVALUATION - TARGET LESIONS

	Date of Pro	cedure
Day	Month	Year

Lesion Note: Always maintain the same order of lesion	Lesion Site Code	Subsite Describe specific location	Method of Assessment	measurable
numbers	1			Dimensions (mm)
01			l	
02				
03				
04				
05				
06				
07				
08			,	
09				
10				
	'	Cum	of Target	

			Lesions
D LESION SITE CODES: 00 Lymph nodes 40 Chest 10 Pulmonary 50 Centra 20 Liver syster 30 Bone 55 Head 56 Neck	al nervous 70 Abdomen 75 Pelvic Site 85 Spleen	86 Skin 88 Other (specify in subsite abo	o l o conventional compated fornography (or

Line #	Specify if "88 Other" Method of Assessment

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data checked.	

Δ	1111	Site No.					Su	bject	ID No).			Subj	ect Initials
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Safety Follow-up

		IU	IVI	O					ord all ot								SIONS
Lesion Note: Always maintain the same order		Date o	of Pro	oced	ure		Bo Si Co	te	Desc	Subsite		tion	Asses	od of sment	1	ew sions	Measurable Lesions (mm) Must be unidimensionally measurable.
of lesion numbers	Day	Mor	nth		Yea	ar	()						2)	₀No ✓	₁Yes ✓	Dimensions (mm)
11																 	
12																 - - -	
13																 	
14						1										 - - -	
15																 	
16																 	
			•		•	•	•		•			Sum	of N	on-T		_	
10 P	mph r ulmona ver	nodes	ES:	:		50 55	Chest Centra Head Neck	l ner	vous system	ı		Gastro Abdom Pelvic Spleen	Site	al		86 88	
	K-Ray						DDES:	(CT)	04 23 88	U	npute	d Tomog	naging graphy ((MRI) (CT)			
Line #									Specify if '	'88 Other	" Me	thod of	f Asse	ssmer	nt		
																	_

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Safety Follow-up OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study		Da	ate			Tumor Response
Week	Day	Month		Year		Code ①
① TUMOF	RESPON	SE CODE:				
PD F	Complete Re Progressive l Partial Respo	Disease	SD UE		Disea e to ev	te

Λ	Site No.		Subject II	O No.	Subject Initials
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AMERICANEI LIV					
	Safet	y Follo	w-up RFS		
Was any cytology performed? ₀☐	C,	YTOLOG	Υ		
Date of Procedure Day Month Year	Procedure Maligi	nant Body I? Site	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	① PROCEDURE CODE: 30 Paracentesis
					31 Thoracentesis 88 Other (Specify)
Equivocal findings:					
				· · · · · · · · · · · · · · · · · · ·	
Were any surgical procedures perfo		URGICA Yes - If y			
Date of Procedure	Code	ody Site Code	Specify if Body "88 Other"	JII J	PROCEDURE CODE:
Day Month Year	2	4		3	32 Surgical
	3 2				
Findings:					
Was biopsy performed? ₀☐ No ₁	Yes - If yes, sp	BIOPSY below.			
Date of Procedure Day Month Year	Procedure Bo	ody Site Code	Specify if Body "88 Other"	5110 10	ROCEDURE ODE:
Day Monar	4 0			16	6 Biopsy
] 1, 6				
Findings:					
Was endoscopy performed? ₀☐ N	EN lo ₁□ Yes - If ye	IDOSCO s, specify be	PY elow.		
Date of Procedure	Procedure Body Site	Specify i	f Procedure Spe		PROCEDURE CODE:
Day Month Year	4			3	3 Colonoscopy
				3 8	
Findings:			<u> </u>		
	1 rointestinal tract	0 Kidney 1 1 Liver 1	13 Pleura 14 Pelvic site 15 Retroperitoneum	18 Thorax 19 Extremity(ies)	38 Other (Specify above)
04 Bone 08 Head	1	2 Lung 1	16 Skin	23 Neck	

Tick when data checked.

CLINICAL EVENTS

△						Site	Site No.				Subject ID No.	D No.			Subje	Subject Initials
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4	AMENDMENT 2.0					<u>.</u>							_			CM1
	CONCOMITANT MEDICATIONS For dosage changes, record as second entry. If concomitant medication is for an adverse event, please enter event on Adverse Event Summary CRF.	dicatio	CONCOMITANT MEDICATIONS For dosage changes, record as second entry. n is for an adverse event, please enter event on Adverse E	AITAN changes, re	T ME	Secon	d entry.	ONS	S Event 8	Summa	ry CRF					
We	Were any concomitant medications used from enrollment to End of	rollme		Safety Follow-Up?			☐ Yes - If yes, specify below.	lf yes,	specify	below.						
Line	Medication	six	Indication		Dose	Piriting ∈	Route	Freq.	L	Date	<u> </u>		-	Date	,	gniunitnoo notiboli Vby
*		✓ Prophyla)))	Day I	Month	Year	Day	Month	- av	Year	Check if med
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7										_	_	_	_		_	
OCAP CCAP CCC GM GR GTT IU MCG	© UNIT CODES: MEQ Milliequivalent AMP Ampule MEQ Milliequivalent CAP Capsule MC Milliter (cc) GM Gram Tablet GR Grain TB GT Drop TSP Total Unit MCG Microgram OT Other *Specify below	9 CT	© ROUTE CODES: DL Intraducdenal TET Endoracheal ube GG Gastrostomy JA Intra-arterial NG In Intrademal NG IM Inhaled IM Inhaled IM Intramuscular PR IP Intraperitoneal	Intrathecal Intravenous Joint injection S Nasogastric tube Ophthalmic Oral R Rectal	SC TD TP OT	Subcutaneous Sublingual Transdermal Topical Other * Specify below	s íy below	© FREC BID BIW CI CI HS OTO PRN QH		UENCY CODE: Twice a day Twice a week Twice a week Continuous intusion At bedtime One time only As needed Every hour	Q2WK Q3WK Q4WK Q4H Q6H Q6H Q8H QD	Every 2 weeks Every 3 weeks Every 4 weeks Every 4 hours Every 6 hours Every 8 hours Once a day	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	QIW 4t QMO Or QOD EV QWK EV STAT Imi TID 3ti TIM 3ti OT Ot	4 times a week Once a month Conce a month Every other day Every week Immedialely 3 times a week Other * Specify below	морес
	Line # Specify UNIT "OT Other"		Line #	Specify F	Specify ROUTE "OT	OT Other"	,lé		Fine #		Specify I	Specify FREQUENCY "OT	"INCY	OT Oth	Other"	

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Line #	Medication Record one per line	line	if medication continued revious Con Med form	sixalyAq	Indication	ion	Dose	Onit ⊝	Route	Freq. ⊚		Date FIRST Taken	(en		D _e LAST	Date LAST Taken	d of Study k if medication continuing	(nnic io n
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O UN AMP CAP CC GM GR GTT IU IU	AMP Ampule MEQ Millieq CAP Capsule MG Millight CC Cubic centimeter ML Millipt GM Gram TAB Tabler GR Grain TAB Tabler GT Drop TSP Teaspool IU International unit U Unit MCG Microgram OT Other 'X	Milliequivalent Milligram Millitler (cc) Tablet Tablespoon Teaspoon Unit			© ROUTE CODES: DL intraduodenal ET Endotracheal tube GT Gastrostomy IA Intra-arterial ID intradermal IH inhaled IM intramuscular IP intraperitoneal	IT Intrathecal IV Intravenous JI Joint injection NG Nasogastric tube OP Ophthalmic PO Oral PR Rectal	S S C F D	Subcutaneous Sublingual Transdermal Topical Other* Specify below	woled /	E = 510100	BID Twice a day BID Twice a day BIW Twice a week C Continuous infuri K Ataletime onto One time only PRN As needed QH Every hour	SEQUENCY CODES BID Twice a day BIW Twice a week Continuous infusion HS At bedtine OTO One time only PRN As needed QH Every hour Q12H Every 12 hours	02WK 03WK 04WK 04H 06H 06H 0D 0D	Every 2 weeks Every 3 weeks Every 4 weeks Every 4 hours Every 6 hours Every 8 hours Once a day		auw 4 times a week awo Once a month aoD Every other day auw Every week stat immedately tib 3 times a day time 3 times a week or Other Specify.	4 times a week Once a month Every other day Immediately 3 times a day 3 times a week Other* Specify below	Γ .
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# E.	Medication Record one per	Medication Record one per line	previous Con Med form	sixalydq	Indication	tion	Dose	Unit ⊝	Route	Freq.		Date FIRST Taken	u u		D	Date LAST Taken		d of Study
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AMP Ampule CAP Capsule CC Cubic cc GM Gram GR Grain GT Drop IU Internatif	AMP Ampule CAP Capsule CC Cubic centimeter GM Gram GR Grain GT Drop IU International unit MCG Microgram	MEQ Milliequivalent MG Milligram ML Milliter (cc) TAB Tablet TBS Tablespoon TSP Tesspoon U Unit OT Other *Specify below			© ROUTE CODES: DL Intraduodenal ET Endotracheal tube GT Gastrostomy A Intra-arterial ID Intradermal III Inhaled III Inhaled III Intraperitoneal	IT Intrathecal IV Intravenous J Joint injection NG Nasogastric tube OP Ophthalmic PO Oral PR Rectal	S S C F D	Subcutaneous Sublingual Transdermal Topical Other* Specify below	s 'y below	⊗ E m m O I O F Q Q	SEQUENCY CODES BID Twice a day BIW Twice a week Continuous infusion HS At bedtine OTO One time only PRN As needed QH Every hour Q12H Every 12 hours	CODES: Yy Sek Sinfusion Inly Inly Inly Inly Inly Inly Inly Inl	Q2WK E Q4WK E Q4H E G6H E G8H E G0BH E G0BH E G0D O O O O O O O O O O O O O O O O O O O	Every 2 weeks Every 3 weeks Every 4 weeks Every 4 hours Every 6 hours Every 8 hours Once a day		QIW 4 tim QMO Once QOD Even QWK Even STAI Imme TID 3 tim TIW 3 tim OT Othe	4 times a week Once a month Every other day Immediately 3 times a day 3 times a week Other* Specify below	Now
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	If c	oncomitant me	3dic.	CONCOMITANT MEDICATIONS For dosage changes, record as second entry. If concomitant medication is for an adverse event, please enter event on Adverse Event Summary CRF.	NCOMITANT MEDICATI -or dosage changes, record as second entry. or an adverse event, please enter event on Ac	rord as	EDIC s secon rter ever	d entry.	ON	S	Summar	y CRF.					
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Line #	Medication Record one per line	k if medication continued 'k if medication continued	phylaxis	Indication		Dose	Unit	Route ©	Freq. ⊚		Date FIRST Taken	en		D. LAST	Date LAST Taken	k if medication continuing rk if medication	(nnic ia n
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Line #	# Specify UNIT "OT Other"	T Other"	$\parallel \parallel$	Line#	Specify ROUTE "OT	OUTE"	OT Other"	,		Line #		pecify F	Specify FREQUENCY "OT	NCY "O	T Other"		1

Adverse Events Summary Instructions

- 1. Record all adverse events occurring after the first dose of investigational product whether considered related to investigations product or not. If changes in baseline condition are to be collected from an earlier time point (eg, after informed consent ha been obtained) this will be defined in the protocol.
- 2. In general, abnormal laboratory findings which are collected elsewhere on CRFs should not be recorded as adverse events; however, any associated clinical sequelae should be reported as adverse events.
- Each adverse event / medical concept must be listed on a separate line. For example, nausea and vomiting are two separate Diagnoses or syndromes should be recorded rather than signs or symptoms. For example, congestive heart failure should be events and should be recorded on two separate lines. Muscle and joint aches should also be recorded on two separate lines. reported instead of individual symptoms of shortness of breath, tachycardia and dependent edema. რ
- Do not record unconfirmed diagnoses using "rule out, presumed or possible", instead record signs or symptoms.
- Do not record treatments or procedures as adverse events (ie, "pleural effusion" could be recorded as an adverse event but not "thoracentesis" which is the treatment for the event). Avoid "due to" or "related to" or "secondary to." 5.
- The adverse event description should be complete and unambiguous, using medical terminology when possible. When reporting chest pain, indicate the nature of the pain, ie, cardiac or musculoskeletal. Avoid use of abbreviations. Avoid concurrent reporting of like or similar events, for example, hypoxia and respiratory insufficiency, or anxiety and nervousness. 9
- "Date Ended" means the date the event resolved, worsened (became more severe, more frequent, or increased in duration during investigational product treatment), or resulted in the death of the subject. If the event continues, but with a change in severity, enter the stop date as the last date of the old severity. Then re-enter the event with the new severity code and the new start date of the event. If the adverse event continues beyond the treatment period or the period covered by one Adverse Events Summary form, leave "Date Ended" blank and check "continuing".
- "Intermittent" column should be checked if an event does not occur continuously, but involves several episodes (eg, cluster headaches, bouts of nausea) unless otherwise specified in the protocol. ω.
- Under "Action Taken For This Event", "Investigational product dose altered" means any investigational product alteration including dose increased, decreased, interrupted or delayed. "Investigational product discontinued" means investigational product was stopped and not restarted . ර
- For serious adverse events (SAEs), data entered on the Adverse Events Summary CRF must be consistent with that provided 10.

ABVEGF 20020408 MENDMENT 2.0 ADVERSE EVENTS SI For assessing Severity, use CTC v2.0 for all AEs, where protocol specified CTCAE v3.0 as modified in Section Syndrome Signt (if known) Signt (if known) Signt(s) / Symptom(s) List one per line **Criteria for Serious Adverse Event: **Criteria for Serious Adverse Event	<							SS (Site No.				Subject ID No.	No.	S	Subject Initials
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Where there any AEs up to End of Study? □ No □ Yes - If yes, specify below. Adverse Event Diagnosis or Syndrome Sign(s) / Symptom(s) List one per line ***Criteria for Serious Adverse Event Serious Adverse event includes any event that (is): □ If the serious adverse event i	MEND	MENT 2.0		Q	ERS	EV	/ENT	IS S.	M M D	AR	<u></u> ≿	-	-	-	-	AE1
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Adverse Event Diagnosis or Syndrome Syndrome Sign(s) / Symptom(s) Sign(s) / Symptom(s) Sign(s) / Symptom(s) Sign(s) / Symptom(s) List one per line Noo' 'Yes List one per line Noo' 'Yes List one per line Noo' 'Yes Noonth Near Noonth Near Date Started	ere there	any AEs up to End of Study? $$	No Y	ss - If y	es, spec	sify belov	۸.									
se Event:	9 tr	Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s)	Did event start before random -ization on 'Yes	Dav	Date Started	- Year	<u>ڭ</u>	te Endec langed it werity or ted in Do	Check if event continuing	at End of Study	Severity (use (use CTCAE Grading Scale) Record one code 01 02 03 04*	"If CTCAE Grade 04, did the event place the subject immediate risk of death?	Relationshi Is there a reasonable possibility that the event may have been caused by investigationa investigation on Vor	This E (record all 1)	Action Taken for This Event (record all that apply) 10 No action taken (2 Investigational product dose altered 3 Medicalion taken 4 Hospitalized Protonged Hospitalized Protonged 6 Hospitalization 6 Removed from study 6 Investigational product discontinued 6 Removed from study 7 Transtitision performed 88 Other "Specify below	Serious ?
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If ev form	 other significant medical hazard If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day. 	Adver	'se Event	Report													
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If e	If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day.	Adver.	se Event	Report													

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	For assessing Severity, use CTC v2.0 for all AEs, except for skin related toxicities where protocol specified CTCAE v3.0 as modified in Section 6.2.2 of the protocol should be used	ssin	ified C	erity, :TCA	use (E v3.(CTC v) as n	2.0 fc nodifi	or all t	4Es, ex Sectio	rcept n 6.2	for 2 0	skin f the	related protocc	CTC v2.0 for all AEs, except for skin related toxicities 0 as modified in Section 6.2.2 of the protocol should	s be used		
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	List one per line	Ched from		Day	Month	Year		Day Month	nth Year			8.48	0	product?	8468	discontinued	No Yes
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ABX-EGF 20020408	0020408		_	_		_	_
AMENDMENT 2.0	JT 2.0						RAT
		RADIOT	RADIOTHERAPY				
Has the subject h	Has the subject had radiotherapy during the treatment phase? $\ \ _{0}lacktriangledown$	I No , ☐ Yes	₀ No ₁ Yes - If Yes, provide details below.	letails below.			
Body Site	Subsite	Date Cou	Date Course Started	Date Co	Date Course Ended	Total Dose Unit	
9000 ⊝	Describe specific location	Day Month	Year	Day Month	Year	€	
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(a) LESION SITE CODES: (b) Lymph nodes 40 (c) Lymph nodes 50 (c) Liver 55 (d) Bone 56	40 Chest60 Gastrointestinal50 Central nervous system70 Abdomen55 Head75 Pelvic Site56 Neck85 Spleen	estinal 86	Skin Other (specify in subsite above)	ubsite above)		① UNIT CODE: GY Gray cGY centi-Gray	

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AMENDMENT 2.0														TRA	NS

TRANSFUSIONS

Were there any transfusions from Screening to Safety Follow-Up?
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				Type of Blood Product
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	DD PRODUC			Note blood of the
01 02 03 04	Pac Wh	telets cked red blood o ole blood sh frozen plasm	cells 0	White blood cells Peripheral Blood Progenitor Cells (PBPC) Bone marrow Other (specify above)

For Amgen Use	e Only
Tick when	
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Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			HOSP

HOSPITALIZATIONS

If hospitalization was due to an Adverse Event, record event on the AE Summary page and complete a Serious Adverse Event Report (SAER) form.

Were there any hospitalizations from Screening to Safety Follow-Up? Do No Do Yes - If yes, specify below.

	ate	9 0	f Ad	lmis	ssic	on				Date	of	Di	sch	arç	је		Check if not discharged at End of Study	Primary Re Enter p				Reason for Admission r primary reason code Specify if "88 Other"									
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Δ	Site No.	Subject ID No.	Subject Initials
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AMENDMENT 2.0			THER

ADDITIONAL THERAPIES

Best Supportive Care may include psychotherapy, counselling or any other symptomatic therapy as clinically indicated

Has the subject had any additional therapies during treatment phase? $_{_{0}}\Box$ No $_{_{1}}\Box$ Yes - If Yes, provide details below.

Line #	Therapy	Start Date Stop Date Day Month Year Day Month Year										Check if continuing at End of Study			
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END OF STUDY

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AMENDMENT 2.0									·		·		EOS

END OF STUDY

	Date Subject Ended Study									
	Day Month Year									
f subject did	not complete end of study, enter PRIMARY reason for ending study:									
	00050									
Enter Code:	CODES:									
02 Ineligibility determined [®] 03 Protocol deviation [®]										
03 Protocol deviation © 04 Noncompliance ®										
05 Adverse event [®] (FAX this form to Amgen)										
05 Adverse event * (<i>FAX this form to Amgert)</i>										
	07 Disease progression [®]									
	09 Administrative decision ^①									
	10 Lost to follow-up [®]									
	11 Death [®]									
	(Enter cause of death on Adverse Events Summary CRF and FAX completed									
	Serious Adverse Event form to Amgen within one working day.)									
	14 Pregnancy © (complete Pregnancy Notification Worksheet)									
	88 Other [®]									
	te of last on-study contact as Date Subject Ended Study									
	te of death as Date Subject Ended Study									
	not complate the and of ctildy, provide any additional relevant information:									
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A	Site No.	Subject ID No.	Subject Initials
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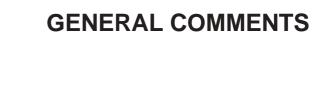
AMENDMENT 2.0

INVESTIGATOR VERIFICATION

I have reviewed and approve the completed CRFs, Laboratory Data and documentation of data changes.

Signature of Principal Investigator		Date Signed Day Month Year								
oignature of i interpar investigator		Month	Year							

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Record any additional relevant information which cannot be captured elsewhere in the casebook. Was there any additional information? \square No \square Yes - If yes, specify below.

			1 No 1 Tes - II yes, specify below.
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Record any additional relevant information which cannot be captured elsewhere in the casebook.

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Record any additional relevant information which cannot be captured elsewhere in the casebook.

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Record any additional relevant information which cannot be captured elsewhere in the casebook.

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For Amgen Use Only

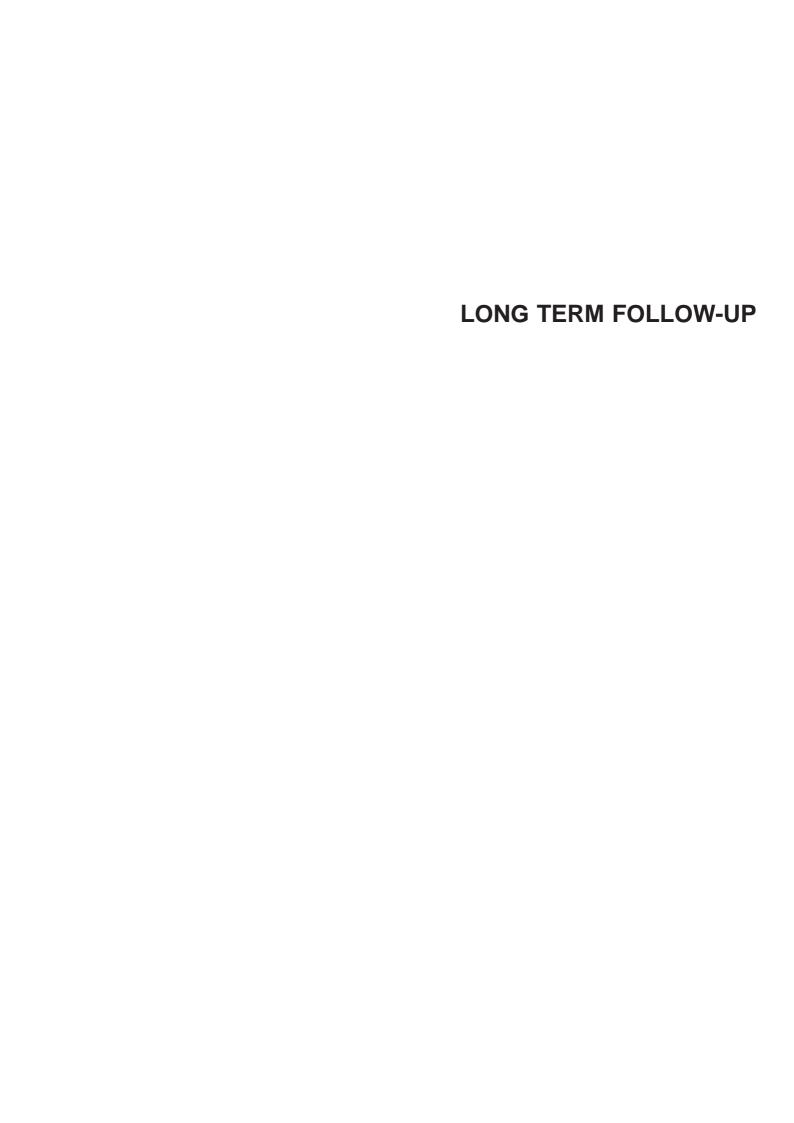
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Record any additional relevant information which cannot be captured elsewhere in the casebook.

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data checked.



Long Term Follow-Up Phase

Every effort should be made to collect Tumor Evaluation Assessments during the Long Term Follow-Up Phase. Please use the extra forms as necessary.

Α	1/1/	Site No.				Su	ubject	ID No			Sub	ject Ir	nitials
ABX-EGF 20020408		1 1	ı	1	1_		1	ı	ı	1		ı	
AMENDMENT 2.0												FUP	М3

Long Term Follow-up Status MONTH 3

Was Long Term I	Follow-up	performed?	₀☐ No ₁☐ Yes	If yes, specify below
		Date of Ass	essment	
	Day	Month	Year	

Subject Status ①	① SUBJECT STATUS CODES 01 Alive	Specify if Subject Status is "88 Other"
	Dead (specify date of death below) Lost to Follow-Up (specify date below) Consent withdrawn Disease progression (specify date below) Other (specify)	

Tum Respor	-	D	Date of Disease Progression							Date of Death or Last Contact if Lost to Follow-U								
		Day	1	Month		Year			1	ay		Montl		Year			•	
													1		1			
2 TUMO	OR RES	PONSE C	ODES															
CR PD PR	CR Complete Response SD PD Progressive Disease UE				le Dise	ease evaluat	e											

Signature of Principal Investigator	Date Signed									
	Day	Month	Year							

For Amgen Use	e Only
Tick when	
data checked.	

Long Term Follow-Up Phase

Every effort should be made to collect Tumor Evaluation Assessments during the Long Term Follow-Up Phase. Please use the extra forms as necessary.

А	1111	Site No.			;	Subjec	t ID No).			Sub	ject li	nitials
ABX-EGF 20020408			1	1	1	ı		ı	ı	1		I	
AMENDMENT 2.0												FUP	M6

Long Term Follow-up Status MONTH 6

Was Long Term I	Follow-up	performed?	₀□ No ₁□ Yes	If yes, specify below
		Date of Ass	essment	
	Day	Month	Year	

Subject Status ①	① SUBJECT STATUS CODES 01 Alive	Specify if Subject Status is "88 Other"
	Dead (specify date of death below) Lost to Follow-Up (specify date below) Consent withdrawn Disease progression (specify date below) Other (specify)	

Tum Respor	-	D	Date of Disease Progression							Date of Death or Last Contact if Lost to Follow-Up								
		Day	1	Month		Year			1	ay		Montl		Year			•	
													1		1			
2 TUMO	OR RES	PONSE C	ODES															
CR PD PR	CR Complete Response SD PD Progressive Disease UE				le Dise	ease evaluat	e											

Signature of Principal Investigator	Date Signed										
Signature of Principal Investigator	Day	Month	Year								

For Amgen Use	e Only
Tick when	
data checked.	

Long Term Follow-Up Phase

Every effort should be made to collect Tumor Evaluation Assessments during the Long Term Follow-Up Phase. Please use the extra forms as necessary.

Α	1/1/	Site No.				Su	ıbject	ID No				Sub	ject Ir	nitials
ABX-EGF 20020408			I	1	1,		1	ı	ı	ı	ı			l
AMENDMENT 2.0													FUP	M9

Long Term Follow-up Status MONTH 9

Was Long Term I	Follow-up	performed?	₀☐ No ₁☐ Yes	If yes, specify below
		Date of Ass	essment	
	Day	Month	Year	

Subject Status ①	① SUBJECT STATUS CODES 01 Alive	Specify if Subject Status is "88 Other"
	Dead (specify date of death below) Lost to Follow-Up (specify date below) Consent withdrawn Disease progression (specify date below) Other (specify)	

Tum Respor	-	Date of Disease Progression							Date of Death or Last Contact if Lost to Follow-Up								
	Day Month				Year			1	ay		Montl		Year				
													1		1		
2 TUMO	OR RES	PONSE C	ODES														
CR Complete Response SD PD Progressive Disease UE PR Partial Response				le Dise	ease evaluat	e											

Signature of Principal Investigator	Date Signed										
Signature of Principal Investigator	Day	Month	Year								

For Amgen Use	e Only
Tick when	
data checked.	

Long Term Follow-Up Phase

Every effort should be made to collect Tumor Evaluation Assessments during the Long Term Follow-Up Phase. Please use the extra forms as necessary.

Α	Site	No.		Sı	ubject	ID No.				Subjec	ct Initials
ABX-EGF 20020408		1 1	1 _, 1 _,	1	ı	ı	ſ	l	1		
AMENDMENT 2.0										FU	IPM12

Long Term Follow-up Status MONTH 12

Was Long Term I	Follow-up	performed?	₀□ No ₁□ Yes	If yes, specify below
		Date of Ass	essment	
	Day	Month	Year	

Subject Status ①	① SUBJECT STATUS CODES 01 Alive	Specify if Subject Status is "88 Other"
	02 Dead (specify date of death below) 03 Lost to Follow-Up (specify date below) 06 Consent withdrawn 07 Disease progression (specify date below) 88 Other (specify)	

Tum Respor	-	Date of Disease Progression							Date of Death or Last Contact if Lost to Follow-Up								
	Day Month				Year			1	ay		Montl		Year				
													1		1		
2 TUMO	OR RES	PONSE C	ODES														
CR Complete Response SD PD Progressive Disease UE PR Partial Response				le Dise	ease evaluat	e											

Signature of Principal Investigator		Date Sig	ned
Signature of Principal Investigator	Day	Month	Year

For Amgen Use	e Only
Tick when	
data checked.	

EXTRA FORMS

ABX-EGF 20020408 MENDMENT 2.0 Screening DEMOGRAPHICS Sex Code Specify if '88 Other" ETHNIC GROUP / RACE CODES: 01 White or Caucasian 06 American Indian or 02 Black or African American 03 Hispanic or Latino 03 Hispanic or Latino 07 Native Hawaiian or Of Na	A		Site No.		Subject II	No.		Subject Initial
Sex Ethnic Group / Race (enter one code) Date of Birth	•	N20408		111				
Sex Ethnic Group / Race (enter one code) Sex Code Specify if *88 Other* O M Sian (eg Chinese, or Other Pacific Islander Bangledeshi, Indian, Pakistani) 8 Other Date Informed Consent Signed Day Month Year Date Informed Consent Signed Day Month Year Date of Randomization Date of Randomization Day Month Year Date of Randomization Randomization Day Month Year Date of Randomization Randomization Day Month Year Date of Randomization Randomization Number Treatment group ① TREATMENT GROUP CODES 01 TREATMENT GROUP CODES 01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care 03 ELIGIBILITY CRITERIA				' '				SCR
DEMOGRAPHICS Sex	AMENDMEN	1 2.0						30/1
DEMOGRAPHICS Sex								
Sex Ethnic Group / Race (enter one code)			Scre	ening				
Sex Ethnic Group / Race (enter one code)								
Sex Code Specify if "88 Other" Of Month Year Of American Indian or Of American Indian or Of Alaska Native Of Native Hawaiian or Of N			DEMOG	RAPHI	CS			
Code Specify if "88 Other" Of White or Caucasian Of American Indian or Alaska Native Autive Hawaiian or Other Pacific Islander Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Banqladeshi, Indian, Pakistani) Of Aborgine Bandladeshi, Indian, Pakistani, Of Aborgine Bandladeshi, Indian, Pakistani, Of Aborgine Bandladeshi, Indian, Pakistani, Of Aborgine Bandladeshi, Indian, India	Sav	Ethnic	Group / Race (enter one	code)			Date of	Birth
S Hispanic or Latino Of Native Hawaiian or Other Pacific Islander Bangladeshi, Indian, Pakistani) Of Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pacific Islander Bangladeshi Other Pac		ecify if "88 Other"			rican Indian or	Day	Month	Year
INFORMED CONSENT Date Informed Consent Signed Day Month Year Protocol Amendment Number 2 RANDOMIZATION Date of Randomization Day Month Year Randomization Number Group Codes 01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care ELIGIBILITY CRITERIA	□м							
INFORMED CONSENT Date Informed Consent Signed Day Month Year Protocol Amendment Number 2 RANDOMIZATION Date of Randomization Day Month Year Randomization Number group ① TREATMENT GROUP CODES 01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care ELIGIBILITY CRITERIA	□F							
Date Informed Consent Signed Year Date Month Year								
RANDOMIZATION Date of Randomization Day Month Year Randomization Number Group ① Treatment group ① TREATMENT GROUP CODES 01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care ELIGIBILITY CRITERIA				Consent Sigi	nea		i Olocoi Ai	menament
RANDOMIZATION Date of Randomization Day Month Year Randomization Number Group ① Treatment group ① TREATMENT GROUP CODES 01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care ELIGIBILITY CRITERIA								
Date of Randomization Day Month Year Randomization Number group ① Treatment group ① TREATMENT GROUP CODES 01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care							Num	nber
Date of Randomization Day Month Year Randomization Number group ① Treatment group ① TREATMENT GROUP CODES 01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care							Num	nber
Day Month Year Number group ① TREATMENT GROUP CODES 01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care ELIGIBILITY CRITERIA			Day Month	Ye	ar		Num	nber
01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care ELIGIBILITY CRITERIA		Date of F	Day Month	MIZATI	ON		Num	nber
01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care ELIGIBILITY CRITERIA			RANDOI Randomization	MIZATI	ON andomization		Num 2	nber
01 ABX-EGF plus Best Supportive Care 02 Best Supportive Care ELIGIBILITY CRITERIA			RANDOI Randomization	MIZATI	ON andomization		Num 2	nber
ELIGIBILITY CRITERIA		Day Month	RANDOI Randomization Year	MIZATI	ON andomization		Num 2	nber
		Day Month TREATMENT GR 01 ABX-EGI	RANDOI Randomization Year OUP CODES Folia Best Supportive Care	MIZATI	ON andomization		Num 2	nber
		Day Month TREATMENT GR 01 ABX-EGI	RANDOI Randomization Year OUP CODES Folia Best Supportive Care	MIZATI	ON andomization		Num 2	nber
Did subject meet all eligibility criteria?		Day Month TREATMENT GR 01 ABX-EGI	RANDOI Randomization Year OUP CODES Folia Best Supportive Care	MIZATI	ON andomization		Num 2	nber
		Day Month TREATMENT GR 01 ABX-EGI	RANDOI Randomization Year OUP CODES F plus Best Supportive Care portive Care	WIZATI Ra	ON Indomization Number		Num 2	nber

Did subject meet all eligibility criteria?
₁ Yes 0 No - If No, please specify criteria number(s) from <i>Eligibility Worksheet</i> :
Enter "999" if subject met Eligibility Criteria but did not enroll.
Comments:
Comments:
Comments:

Δ	////	Site No.			Sul	bject	ID No				Sub	ect In	itials
ABX-EGF 20020408		1 1 1	1,	1	ſ	ı	ı	ı	I	ı			
AMENDMENT 2.0					·	·						SCF	₹X

Screening MEDICAL & SURGICAL HISTORY

(continued)

	02 Cardiovascular03 Respiratory04 Gastrointestinal05 Hepatic / Biliary	07 Renal08 Endocrine / Metabolic09 Musculoskeletal10 Hematologic / Lymphatic	11 Neurologic / Psychiatric 88 Other	;	
Code (as listed above		Diagnosis List one entry per line		Continuing Continuing	√ Resolved
1					
l					
1					

For Amgen Use	e Only
Tick when	
data checked.	

٥										Site No.			Subject ID No.	ID No.	Subject Initials
AB	ABX-EGF 20020408	•						<u>////</u>		_	_	<u></u>	_	_ _ _	_
ΔM	AMENDMENT 2.0	PRI	OR	뜅	MOT	皇	3AP	_	Firs	t Lin	e 0	PRIOR CHEMOTHERAPY - First Line of Treatment	ent	-	SCR
				Please	Please record prior chemotherapy for metastatic cancer	prior	chemoi	herap	y for n	netasta	atic ca	ıncer			
		Regimen Name:	Name:												
		-							-			-			
Line #	Agent Name		Dose	Freq	Dose	Date	Date First Administered	ninister		Date Last Administered	Admin	istered		Name of Hospital	
			\)	© ©	Day	Month	Year	Day	/ Month	۲	Year			
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7					_	_		_							
က					_	_	_	<u> </u>			_				
4								<u> </u>							
5					_	_		_ _		_					
9					_	_		_ _	_	_					
7					_	_	_	_							
∞					_	_	_	_ _	_		_				
6					_	_		_ _	_	_	_				
_ ⊕26	© FREQUENCY CODES: CI Continuous infusion Q: Q2WK Every 2 weeks Q.	Q12H Every Q4WK Every	Every 12 hours Every 4 weeks		Q3WK Every 3 weeks QMO Once a month	3 week a montl		OD OT	once a da Other (spe	Once a day Other (specify below)	(2)	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	ODES: dose on due to to	88	Missed dose (specify below) Other (specify below)
Line #	Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	therapy Do I Dose"	se Line	-	Specify Reason for Chemotherapy Dose Change "88 Other"	Chemo '88 Oth	therapy Doer"	ose Line	υ	Specify F	requenc	Specify Frequency "OT Other"	Line #	Specify Frequency "OT Other"	y "OT Other"

◁										Site No.	9			Subject ID No.	No.	Subject Initials	<u>s</u>
AB	ABX-EGF 20020408	œ								_	_		<u></u>	_	_	_	
Z	AMENDMENT 2.0	PRIO	A O	뽔	MOT	単	\AP	-	Se	Con	ا ا ا	ne	PRIOR CHEMOTHERAPY - Second Line of Treatment	ıtmer	+	SCR	1
				?lease	Please record prior chemotherapy for metastatic cancer	prior (hemo	thera	ipy foi	meta	static	canc	er				
	_	Regimen Name:	ıme:														
Line #	Agent Name	Dose (mg/m²)		Freq	Dose Status	Date	Date First Administered Day Month Year	Iminister Year	ered	Date L	Date Last Administered Day Month Year	ninister Year	red	_	Name of Hospital	=	
_					_	_	_ _	_	_	_	_		_				
7						_	_	_	_	_	_	_	_				
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∞					_		_				_	_	_				
တ					_	_	_		_	_	_	_	_				
⊝ၓၓ	① FREQUENCY CODES: CI Continuous infusion G Q2WK Every 2 weeks C	Q12H Every 12 hours Q4WK Every 4 weeks	hours reeks	aa	Q3WK Every 3 v QMO Once a r	3 weeks a month		96	Once a Other (Once a day Other (<i>specify below)</i>	celow)	© DO 01	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	DES: lose n due to toxi	88	Missed dose (specify below) Other (specify below)	
Line #	e Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	otherapy Dose	Line #	Specify F	Specify Reason for Chemotherapy Dose Change "88 Other"	Chemot 88 Othe	herapy [-	Line #	Speci	fy Frequ	ency "C	Specify Frequency "OT Other"	Line #	Specify Frequency "OT Other"	cy "OT Other"	

٥									/	Site No.			Subject ID No.	No.	Subject Initials
AB	ABX-EGF 20020408	~						<u> </u>		_	_	<u>_</u>	_	_ _	_
Δ	AMENDMENT 2.0	PRI	OR	뿡	MOT	皇	(AP)		Thir	d Lir)e 0	PRIOR CHEMOTHERAPY - Third Line of Treatment	nent	-	SCR
	'			Please	Please record prior chemotherapy for metastatic cancer	prior	chemot	herap	y for n	netasta	itic cai	ncer			
		Regimen Name:	Name:												
									-			-			
Line #	Agent Name	<u> </u>	Dose	Freq	Dose Status	Date	Date First Administered	ninister		Date Last Administered	Adminis	stered		Name of Hospital	
			ì)	0	Day	Month	Year	Day	/ Month		Year			
_					_	_	_	_	_		_				
7					_	_	_	_							
က					_		_	<u> </u>	_	_					
4					_		_ _	_ _	_	_		_ _ _			
5					_	_	_	_ _		_	_				
9					_	_	_	_ _		_	_				
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∞					_		_	_ _	_	_		_ _ _			
တ					_	_	_	_		_	_				
228	© FREQUENCY CODES: CI Continuous infusion Q: Q2WK Every 2 weeks Q.	Q12H Every Q4WK Every	Every 12 hours Every 4 weeks		Q3WK Every 3 weeks QMO Once a month	3 week a month		OTO OTO	once a da	Once a day Other (specify below)	0	DOSE STATUS CODES: 01 Full intended dose 02 Dose reduction due to toxicity	ODES: dose n due to tox	88	Missed dose (specify below) Other (specify below)
Line #	Specify Reason for Chemotherapy Dose Change "03 Missed Dose"	otherapy Do d Dose"	se Line	-	Specify Reason for Chemotherapy Dose Change "88 Other"	Chemot '88 Oth	:herapy Do	se Line		Specify Fr	equency	Specify Frequency "OT Other"	Line #	Specify Frequency "OT Other"	"OT Other"

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			SCR

Screening PRIOR ADJUVANT CHEMOTHERAPY

Line #	Drug Name	Regimen Name		Date F Adminis		Date L Adminis	
			Day	Month	Year	Day Month	Year
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

PRIOR ANTI-TUMOR THERAPY

Line #	Line of Treat- ment	Drug Name		Date F Adminis		Date Last Administered			
	1		Day	Month	Year	Day	Month	Year	
1									
2									
3			ı						
4									
5									
① LIN 01	1 LINE OF TREATMENT CODES: 01 1st Line of treatment 02 2nd Line of Treatment 03 3rd Line of treatment 04 Adjuvant								

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1,	
AMENDMENT 2.0			SCRX

Screening PRIOR ADJUVANT CHEMOTHERAPY

Line #	Drug Name	Regimen Name		Date F Adminis		Date Last Administered			
			Day Month Year				Month	Year	
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

PRIOR ANTI-TUMOR THERAPY

Line #	Line of Treat- ment	Drug Name		Date F Adminis		Date Last Administered			
	1		Day	Month	Year	Day	Month	Year	
1	I								
2									
3									
4									
5									
	① LINE OF TREATMENT CODES: 01 1st Line of treatment 02 2nd Line of Treatment 03 3rd Line of treatment 04 Adjuvant								

A	////	Site No.		_	S	ubject	ID N	0.			Subje	ct Initials
ABX-EGF 20020408			1	$_{ }1_{ }$			I	1	ı	1		
AMENDMENT 2.0												TEX

Week ____ **TUMOR EVALUATION - TARGET LESIONS**

Date of Procedure										
Day Month Year										
	1 1									

Lesion Note: Always maintain the same order of lesion	Lesion Site Code	Subsite Describe specific location	Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable Dimensions (mm)
numbers				Dinionoron (mm.)
01				
02				
03				
04				
05				
06				
07				
08				
09				
10				
		Sum (of Target	

	Sum of Target Lesions	
	Lesions	

Line #		Specify if "99 Other" Method	A of Association
00 Lymph nodes 10 Pulmonary 20 Liver 30 Bone	JDES: 40 Chest 50 Central nervous system 55 Head 56 Neck	60 Gastrointestinal 70 Abdomen 75 Pelvic Site 85 Spleen 86 Skin 88 Other (sp in subsite	

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use	e Only
Tick when	
data checked.	

Α	////	Site No.				(Subjec	t ID N	o.		Subj	ect Initials
ABX-EGF 20020408		1 1	I	1	1,	ı	ı	ı	ı	ı		
AMENDMENT 2.0												TEX

Week ____

	•	TUM			JATION - NON-T ord all other lesions and s			SIONS
Lesion Note: Always maintain the same order of lesion	lways in the Date of Procedure order		ocedure	Body Site Subsite Code Describe specific loca		Method of Assessment	New Lesions	Measurable Lesions (mm) Must be unidimensionally measurable.
numbers	Day	Month	Year	1		2	₀No ₁Yes	Dimensions (mm)
11							1	
12							 	
13							1 1	
14							1	
15							i i i	
16				I				
					Sun	n of Non-T Le	arget sions	
00 L:	ymph no ulmona iver		40 C 50 C 55 H		vous system 60 Gastro 70 Abdor 75 Pelvic 85 Spleen	nen Site	86 88	
01	X-Ray		SMENT COE		04 Magnetic Resonance II23 Spiral Computed Tomo88 Other (specify below)	graphy (CT)		
Line #					Specify if "88 Other" Method o	f Assessmer	nt	

For Amgen Use Only									
Tick when									
data checked.									

Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			STAX

Week ____ SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment												
Day	Month	Year										

Did the subject have skin toxicity? $_{_0}$ No $_{_1}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)							•	y if Skin l Nail Cha	Toxicity is nges"	SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching			
										04 Rash (acne/acneiform) 05 Rash/desquamation (non-acneiform) 06 Ulceration			
		e of Skin		3	Spe	Specify if Type of Skin Lesion is "88 Other"					LESION CODES: Dry flaking Desquamation (sloughing)		
										04 Macular 10	Comedones Cysts Other (specify)		
Total % Affect		3 TOTAL04 > 5005 ≤ 50	0% BSA	ODES:		Locat (list all th	ion ④ nat apply)		Specify if Locati	on is "88 Other"	 LOCATION CODES:09 Face10 Trunk		
		03 ≥ 30	J70 D3A								11 Extremities12 Total body88 Other (specify)		
1. If	prio	radiation	n, is are	ea of rac	diation po	ort invo	lved?	66	Not applicable	₀☐ No ₁☐ Yes			
2. W	/as c	rusting p	resent	?					No ₁☐ Yes				
3. S	ince	the last a	assessr	nent, di	id the ras	h caus	e pain?	\Box_0	No ₁☐ Yes				
4. S	ince	the last a	assessr	nent, di	id the ras	h caus	e itchin	g? 。🖵	No ₁☐ Yes				
5. S	ince	the last a	assessr	nent, di	id the ras	h requi	ire treat		h narcotics? cord on Concomit	₀ No ₁ Qant Medications C			
6. Si	ince	the last a	assessr	nent, di	d the ras	h requi	ire treat		h systemic stero	-			
(Record on Concomitant Medications CRF) 7. Was dose held, changed or discontinued for skin toxicity?													
₀☐ No ₁☐ Yes - If yes, provide da							ay		Year				

For Amgen Use Only
Tick when

data checked.

Α	////	Site No.			Su	bject	ID No				Sub	ject Ir	nitials
ABX-EGF 20020408			1,	1	ſ	I	ı	ı	ı	I		l	l
AMENDMENT 2.0												ADT	AX

Week ____ ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment												
Day Month Year												

	₀ No ✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①
Were Pustules/Papules present?			
Was Honey Yellow Crusting present?		1	
Was Erythema present?		 	
Was Paronychia present?		 	
Were Fissures present? (Photo-based scale does not apply)		 	
Does the following dermatological toxicity interfere with activities	s of daily	/ living?	
Paronychia: ₀☐ No ₁☐ Yes 66☐ N	/A		
Fissures: 0 No 1 Yes 66 N	/A		
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perceptio	n		
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Moderation 02 A little 04 Very mu	-	05 Intoler	able

For Amgen Use	e Only
Tick when	
data checked.	

Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			STAX

Week ____ SKIN TOXICITY ASSESSMENT

Complete the following questions based on symptoms and physical findings present at date of assessment.

Date of Assessment												
Day	Month	Year										

Did the subject have skin toxicity? $_{_0}$ No $_{_1}$ Yes - If Yes, specify below, complete the Additional Dermatological Toxicity Assessments page and record skin toxicity on AE CRF.

Skin Toxicity (list all that apply)							•	y if Skin l Nail Cha	Toxicity is nges"	SKIN TOXICITY CODES: 01 Nail changes (specify) 02 Erythema 03 Pruritus/itching			
										04 Rash (acne/acneiform) 05 Rash/desquamation (non-acneiform) 06 Ulceration			
		e of Skin		3	Spe	Specify if Type of Skin Lesion is "88 Other"					LESION CODES: Dry flaking Desquamation (sloughing)		
										04 Macular 10	Comedones Cysts Other (specify)		
Total % Affect		3 TOTAL04 > 5005 ≤ 50	0% BSA	ODES:		Locat (list all th	ion ④ nat apply)		Specify if Locati	on is "88 Other"	 LOCATION CODES:09 Face10 Trunk		
		03 ≥ 30	J70 D3A								11 Extremities12 Total body88 Other (specify)		
1. If	prio	radiation	n, is are	ea of rac	diation po	ort invo	lved?	66	Not applicable	₀☐ No ₁☐ Yes			
2. W	/as c	rusting p	resent	?					No ₁☐ Yes				
3. S	ince	the last a	assessr	nent, di	id the ras	h caus	e pain?	\Box_0	No ₁☐ Yes				
4. S	ince	the last a	assessr	nent, di	id the ras	h caus	e itchin	g? 。🖵	No ₁☐ Yes				
5. S	ince	the last a	assessr	nent, di	id the ras	h requi	ire treat		h narcotics? cord on Concomit	₀ No ₁ Qant Medications C			
6. Si	ince	the last a	assessr	nent, di	d the ras	h requi	ire treat		h systemic stero	-			
(Record on Concomitant Medications CRF) 7. Was dose held, changed or discontinued for skin toxicity?													
₀☐ No ₁☐ Yes - If yes, provide da							ay		Year				

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Tick when

data checked.

Α	////	Site No.			Su	bject	ID No				Sub	ject Ir	nitials
ABX-EGF 20020408			1,	1	ſ	I	ı	ı	ı	I		l	l
AMENDMENT 2.0												ADT	AX

Week ____ ADDITIONAL DERMATOLOGICAL TOXICITY ASSESSMENTS

★ ★ Not to be substituted for modified CTCAE Version 3.0 Grading ★ ★

Date of Assessment				
Day	Month	Year		

	₀ No ✓	1 1 1 1 1 1 1 1 1 1	* Photo- based Coding Scale (Record one code only) ①		
Were Pustules/Papules present?					
Was Honey Yellow Crusting present?		1			
Was Erythema present?		 			
Was Paronychia present?		 			
Were Fissures present? (Photo-based scale does not apply)					
Does the following dermatological toxicity interfere with activities of daily living?					
Paronychia: ₀☐ No ₁☐ Yes ₀₀☐ N/A					
Fissures: 0 No 1 Yes 66 N	/A				
How bothered do you perceive the subject to be by the dermatologic toxicities? Subject Perception ②					
① PHOTO-BASED CODING SCALE CODES: ② SUBJECT PERCEPTION CODES: 01 Not at all 03 Moderation 02 A little 04 Very mu	-	05 Intoler	able		

For Amgen Use	e Only
Tick when	
data checked.	

Α	1111	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408			1,1, , , , , , ,	
AMENDMENT 2.0				DRX

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Week	Date Tumor Respons				
	Day	Month	Yea	ar	Code ①
	·				
					·
① TU	① TUMOR RESPONSE CODE:				
CR		te Response	SD	Stable Dise	
PD PR	Progres Partial I	sive Disease Response	UE	Unable to	evaluate

Α	1111	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408			1,1, , , , , , ,	
AMENDMENT 2.0				DRX

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Week	Date Tumor Respons				
	Day	Month	Yea	ar	Code ①
	·				
					·
① TU	① TUMOR RESPONSE CODE:				
CR		te Response	SD	Stable Dise	
PD PR	Progres Partial I	sive Disease Response	UE	Unable to	evaluate

Λ	Site	No.	Su	oject ID No.	Subject Initia
A ABX-EGF 20020408		•	1 1		
MENDMENT 2.0	<u> ////</u>		<u> </u>		
WILIADIVILIA 2.0					
		Week			
	P	ROCED	URES		
/as any cytology performed? ₀☐ l	No ₁□ Yes	CYTOLC - If yes, specify	GY v below.		
Date of Procedure	Procedure	Malignant Bod	y Specify if Prod		
Day Month Year	① ₀ N	Cell? Site	Code is "88 C	other" is "88 Oth	ner" CODE: 30 Paracente
					31 Thoracent 88 Other (Spe
		1			
Equivocal illiulings					
		SURGIC	AL		
ere any surgical procedures perfo		No ₁☐ Yes - I	f yes, specify be		T
Date of Procedure	Procedure Code	Code		Body Site is Other"	② PROCEDURE CODE:
Day Month Year	2	4			32 Surgical
]3,2				
Findings:					
	_	BIOPS	Υ		
Vas biopsy performed? ₀☐ No ₁□	_		W.		T
Date of Procedure	Procedure Code	Code	Specify if "88	Body Site is Other"	③ PROCEDURE CODE:
Day Month Year	3	4			16 Biopsy
] 1 6				
Findings:					
		ENDOGO	ODV		
Vas endoscopy performed? ₀☐ N	o ₁☐ Yes -	ENDOSC If yes, specify	below.		
Date of Procedure	Procedure (5)		ify if Procedure e is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE:
Day Month Year	+ +	4			33 Colonoscopy
					34 Sigmoidosco 88 Other (Specify
Findings:					
BODY SITE 01 Abdomen 05 Ches CODES: 02 Brain 06 Eye		09 Heart 10 Kidney	13 Pleura 14 Pelvic site	17 Total body 18 Thorax	(Specify above
04 Bone 08 Head	rointestinal tract	t 11 Liver 12 Lung	15 Retroperitone 16 Skin	eum 19 Extremity(23 Neck	(25)
or Amgen Use Only ck when					
ata checked DISTR	IBUTION: White &	& Yellow - Amgen; B	lue - CRA; White Card	- Investigator	

DISTRIBUTION: White & Yellow - Amgen; Blue - CRA; White Card - Investigator

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1,	
AMENDMENT 2.0			FUPX

Long Term Follow-up Status MONTH

Was Long Term F	-ollow-up	performed?	₀□ No ₁□ Yes	- If yes, specify below
		Date of Ass	essment	1
	Day	Month	Year	
				1

Subject Status ①	① SUBJECT STATUS CODES 01 Alive	Specify if Subject Status is "88 Other"
	Dead (specify date of death below) Lost to Follow-Up (specify date below) Consent withdrawn Disease progression (specify date below) Other (specify)	

Tum Respor	-	D	ate of	Diseas	e Pro	gress	ion			Last	_		of D	 	low-	Up		
		Day	1	Month		Υ	'ear		1	ay		Montl		or Follow-Up Year				
													1	1				
2 TUMO	OR RES	PONSE C	ODES															
CR PD PR	Progre	lete Respo essive Dis- I Respons	ease		SD UE		le Dise	ease evaluat	e									

Signature of Principal Investigator		Date Sig	ned
Signature of Principal Investigator	Day	Month	Year

For Amgen Use	e Only
Tick when	
data checked.	

Long Term Follow-Up Phase

Every effort should be made to collect Tumor Evaluation Assessments during the Long Term Follow-Up Phase. Please use the extra forms as necessary.

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1,	
AMENDMENT 2.0			FUPX

Long Term Follow-up Status MONTH

Was Long Term F	-ollow-up	performed?	₀□ No ₁□ Yes	- If yes, specify below
		Date of Ass	essment	1
	Day	Month	Year	
				1

Subject Status ①	① SUBJECT STATUS CODES 01 Alive	Specify if Subject Status is "88 Other"
	Dead (specify date of death below) Lost to Follow-Up (specify date below) Consent withdrawn Disease progression (specify date below) Other (specify)	

Tum Respor	-	D	ate of	Diseas	e Pro	gress	ion			Last	_		of D	 	low-	Up		
		Day	1	Month		Υ	'ear		1	ay		Montl		or Follow-Up Year				
													1	1				
2 TUMO	OR RES	PONSE C	ODES															
CR PD PR	Progre	lete Respo essive Dis- I Respons	ease		SD UE		le Dise	ease evaluat	e									

Signature of Principal Investigator		Date Sig	ned
Signature of Principal Investigator	Day	Month	Year

For Amgen Use	e Only
Tick when	
data checked.	

Long Term Follow-Up Phase

Every effort should be made to collect Tumor Evaluation Assessments during the Long Term Follow-Up Phase. Please use the extra forms as necessary.



		<u>_</u>		
	_ _ 			_
				CMX
CONCOMITAN For dosage changes, ation is for an adverse event, p	OMITANT MEDICATIONS age changes, record as second entry. Averse event, please enter event on Adverse E	ONS Werse Event Summ	ary CRF.	
Indication	Dose Unit Route	Freq. Dat		Date .ff medication continuing
		Day Month	Year Day Month	Year
			_	
© ROUTE CODES: DL Intrathocal ET Endotracheal tube IT Intravenous GT Gastrostomy JI Joint injection IM Intra-arterial ID Intrademal IM Inhaled IM Intramuscular IM Intraperitoneal IM In	SC Subcutaneous SL Subingual TD Transdemal e TP Topical OT Other Specify below	FREQUENCY CODI BID Twice a day BIW Twice a week CI Continuous infusik HS At beddime OTO One time only PRN As needed QH Every hour Q12H Every 12 hours	aczwk Every 2 weeks aczwk Every 3 weeks aczwk Every 4 weeks acz we	alw 4 times a week aMO Once a month aOD Everyother day aWK Everyother day TID 3 times a day TIW 3 times a week OT Other*Specify below
Line # Specify	ROUTE "OT Other"	Fine #	Specify FREQUENCY "OT	OT Other"
#fior	Indication Indication Indication Indication Indication Intrace event, p Intrac	Indication Dose Unit Route OUTE CODES: Trintaneous State of the Fourtement on Act of the Management	Indication Dose Unit Route Freq. Event Summ. OUTECODES: Transcaler Transcaler Event on Adverse Event Summ. Dose Unit Route Freq. FIRST Ti Transcaler Transcaler Event on Adverse Event Summ. Dose Worth Dose Unit Route Freq. FIRST Ti Transcaler Event on Adverse Event Summ. Dose Month Dose Month Dose Worth Dose Month Dose Worth Dose Worth Dose Worth Dose Worth Dose Worth Expenditure Bread Bre	ion Dose Unit Route Freq. Freq. Fired. Summary CRF. Dose Unit Route Freq. Date

											-				-	
<								1/2	Site No	Ċ.			Subject ID No.	No.	Sus	Subject Initials
AB	ABX-EGF 20020408								_	_	_		_	_		_
A	AMENDMENT 2.0									-	-	-	-	-	-	AEX
			•	AD	-4	SEE	≣VE	SE EVENTS SUMMARY	SUN	M	RY					
	For assessing Severity, use CTC v2.0 for all AEs, except for skin related toxicities where protocol specified CTCAE v3.0 as modified in Section 6.2.2 of the protocol should be used	ssir	ng Sev iffied C	erity, ;TCA	use (E v3.(STC v.) as m	2.0 fo odifi	r all AE ed in S	s, exce	ept foi 5.2.2 c	· skil of th	n related ϶ protocα	CTC v2.0 for all AEs, except for skin related toxicities 0 as modified in Section 6.2.2 of the protocol should	s I be used		
Line #	Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s)	ck if event continued mrevious AE form	Did sł		Date Started	e e		Date Ended, Changed in Severity or Resulted in Death	nded, led in ity or in Death	ck if event continuing nd of Study	S S S S S S S S S S S S S S S S S S S	Severity "If CTCAE CTCAE CTCAE Grading did the Scale) event place Record the subject at immediate irisk of death?	Relationship Is there a reasonable possibility that the event may have been caused by investigational	Action Taken for The For This Event (record all that apply) 10 No action telen 02 Investigational product dose aftered of Medication taken 04 Hospitalizacip Produced Produce	ken nt apply) idose altered	serious
	List one per line	Che from		Day	Month	Year	Day	ay Month	Year			03 CCCCCC 04* ONO Yes 05 /		8028	discontinued	No Yes
1				_	- -	_			_					_	_	
7					_	_									_	
3					_	_		_							_	
4				_	_	_	_	_	_						_	
2						_ _		_ _						_	_	
9					_	_		_						_	_	
^						_								_	_	
∞					_	_		_						_	_	
Seri	** Criteria for Serious Adverse Event: Serious adverse event includes any event that (is):	erse	Event:			Line #				Spec	Specify if	"88 Other"	Action Taken	ue ue		
• • •	 fatal life threatening (places subject at immediate risk of death) requires inpatient hospitalization or prolongation of existing 	sk of	death) xisting ho	snitaliza	tion											
• • •	results in persistent or significant disability / incapacity a congenital anomaly / birth defect other significant medical hazard	capac	iity													
for	If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day.	Adve	rse Event	Report												

А	////	Site No.		Subjec	t ID No.			\exists	Subject Initials
ABX-EGF 20020408		1 1 1	1,1		ı	1			1 1
AMENDMENT 2.0				•					CMNTX

Record any additional relevant information which cannot be captured elsewhere in the casebook.

	Date Informatio		Refers to CRF page no.(s)	
Day	Month	Year		
			•	
Details	:			
	Date Informatio		Refers to CRF page no.(s)	
Day	Month	Year	+	
l ,				
D-1-11-				
Details	·			
	Date Informatio	n Polatos To	T	
Day	Month	Year	Refers to CRF page no.(s)	
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Details				
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Α	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , , ,	
AMENDMENT 2.0			TEX

Week ____ TUMOR EVALUATION - TARGET LESIONS

Date of Procedure											
Day	Month	Year									

Lesion Note: Always maintain the same order of lesion numbers	Lesion Site Code	Subsite Describe specific location	Method of Assessment	Measurable Lesions(mm) Must be unidimensionally measurable Dimensions (mm)				
01			ı					
02								
03								
04								
05								
06								
07								
08								
09								
10								
		Sum	of Target Lesions					

00 Lymp	50 s 55	Chest Chest Central nervous system Head Neck	75	Gastrointestinal Abdomen Pelvic Site Spleen		Skin Other (specify in subsite above)	METHOD OF ASSESSMENT: 1 X-Ray 3 Conventional Computed Tomography (CT) 4 Magnetic Resonance Imaging (MRI) 3 Spiral Computed Tomography (CT) 8 Other (specify below)
Line #				Specify if "88	Othe	r" Method of Asse	ssment

For Amgen Use	e Only
Tick when	
data checked	

Д										////	S	Site N	Ю.					S	Sub	oject II	D No).			Su	bjec	t Ini	itials
ABX-EGF 20020408											1.1.																	
MEN							_			////																	TE	X
													W	ee	k _		_											
		_		N/I	<u> </u>	D		=\	/ A		ΙΛ	T 1.	~		NIC	.		- A F		~ E			:01/	~ N	10			
		•	U	IVI	U													ΑΓ sites					SIC	JIN	3			
oolon								Cui			<i>-</i>	un (1 100	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		110	1	_		T		Meas	urah	le I e	sior	ns (r	 mm
Lesion te: Always aintain the		Dat	e of	Pro	ced	lure	è		5	ody Site				Subs						od of	1	ew ions	1	st be	unidin easura	ensi		
me order of lesion numbers	Davi			41-		V				ode ①		D	escrib	e sped	cific Ic	ocati	on	Assessment			1336331116111							
	Day		Mon	ın		Ye	ear														√	√						
11			l																			1						_
12																						 						
			<u></u>																		\vdash	 						_
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00 Ly	mph r	ode		E3:) C										rointes	tina	al			Skin	,	., .		.,	
10 Pt 20 Li ¹ 30 Bt	ver	ary					5) C 5 H 6 N	ead	al ner	vous	syst	em		7	75	Abdo Pelvio Splee	c Site				88	Othe a	r (spe bove)		sub	site	
METH)F /	\SS	FS	SM	FN																						
01 >													23 S	lagnet piral C other (Compu	uted	Tomo	Imagin ograph	ıg (ıy (MRI) CT)								
Line #											Spe	cify	if "88	Oth	er" N	Viet	nod (of Ass	ses	ssmer	nt							

Δ	Site No.	Subject ID No.	Subject Initials
ABX-EGF 20020408		1,1, , , , , , ,	
AMENDMENT 2.0			IER

Independent Eligibility Review PRIOR THERAPY FAILURE

Date of Review										
Day	Month	Year								

Is the subject confirmed to have developed progressive disease or relapsed while on or after prior chemotherapy as per the Independent Eligibility Review Committee?

₀ □ No - If no, specify below ₁ □ Yes

_	criteria Code licate all that app		Specify if "88 Other"
① CRITE	RIA CODES:	02 L 03 S	ack of radiographic progression ast chemotherapy failure > 6 months subject did not receive or fail protocol defined pre-study chemotherapy regimen other (Specify above)

Signature of Independent Eligibility Review Committee Chairperson	Day	Date Sig Month	jned Year

For Amgen Use	e Only
Tick when	
data checked.	