Sponsor	Protocol Number
A 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	J A N	2 0 0 2

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

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

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 study*

Code no.		Yes	No
101	Pathologic diagnosis of colorectal adenocarcinoma (diagnostic tissue obtained by tissue biopsy) ..	❑	❑
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 3.1.1). 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	❑	❑
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 ≥ 1.5 x 10^9 cells/L and platelet count ≥ 100 x 10^9/L	❑	❑
111	Renal function, as follows: Creatinine < 2.0mg/dL	❑	❑
112	Hepatic function, as follows: AST ≤ 3 x ULN (≤5 x ULN if liver metastases), ALT ≤ 3 x ULN (≤5 x ULN if liver metastases) and bilirubin ≤ 2 ULN	❑	❑
113	Subject may have received prior radiotherapy (target lesions must not have been irradiated)	❑	❑
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	❑	❑

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SUBJECT ELIGIBILITY CRITERIA WORKSHEET
Exclusion Criteria

*If any of the below questions are answered **YES**, then the subject **SHOULD NOT ENTER** the study*

Code 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 opinion 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 molecules 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 considered as chemotherapy in this exclusion criterion)	❑	❑
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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THE FOLLOWING SECTIONS WILL BE AVAILABLE AS NEEDED IN INDIVIDUAL SHRINK-WRAPPED PACKS

SCREENING

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

AMENDMENT 2.0

SCR

Screening

DEMOGRAPHICS

Sex	**Ethnic Group / Race** *(enter one code)*			**Date of Birth**
	Code	*Specify if "***88 Other***"*	**ETHNIC GROUP / RACE CODES:**	Day Month Year
0 ❑ M 1 ❑ F			**01** White or Caucasian **02** Black or African American **03** Hispanic or Latino **04** Asian *(eg Chinese, Bangladeshi, Indian, Pakistani)* **05** Japanese **06** American Indian or Alaska Native **07** Native Hawaiian or Other Pacific Islander **08** Aborigine **88** Other	

INFORMED CONSENT

Date Informed Consent Signed		
Day	Month	Year

Protocol Amendment Number
2

RANDOMIZATION

Date of Randomization			**Randomization Number**	**Treatment group** ①
Day	Month	Year		

① **TREATMENT GROUP CODES**
01 ABX-EGF plus Best Supportive Care
02 Best Supportive Care

ELIGIBILITY CRITERIA

Did subject meet all eligibility criteria?

1 ❑ Yes 0 ❑ No - If No, please specify criteria number(s) from ***Eligibility Worksheet***:

Enter "999" *if subject met Eligibility Criteria but did not enroll.*

___ ___ ___ Comments:_____

_____

___ ___ ___ Comments:_____

_____

___ ___ ___ Comments:_____

_____

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Screening

MEDICAL & SURGICAL HISTORY

Does the subject have a known history of any of the following:

Code	Diagnosis	0 No ✓	1 Yes ✓	If yes, specify etiology	1 Continuing ✓	2 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					

Does the subject have a known history of any other major diagnosis? 0 ❑ No 1 ❑ Yes - If yes, list specific diagnosis below.

02 Cardiovascular	**05** Hepatic / Biliary	**09** Musculoskeletal	**13** Immunologic
03 Respiratory	**07** Renal	**10** Hematologic / Lymphatic	**88** Other
04 Gastrointestinal	**08** Endocrine / Metabolic	**11** Neurologic / Psychiatric	

Code *(as listed above)*	**Diagnosis** List one entry per line.	1 Continuing ✓	2 Resolved ✓

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

AMENDMENT 2.0

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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 biopsy)*

Pro-cedure Code ①	Description or Type	Intent Code ②	Date Day	Month	Year

① **PROCEDURE CODES:**

01	Biopsy	**88**	Other *(Specify below)*
02	Resection		

② **INTENT CODES:**

01	Curative	**99**	Unknown
05	Palliative	**88**	Other *(specify in General Comments)*
10	Diagnostic/Staging		

Specify **PROCEDURE** "**88** Other"

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

AMENDMENT 2.0

SCR

PRIOR CHEMOTHERAPY - First Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day Month Year	Date Last Administered Day Month Year	Name of Hospital
1							
2							
3							
4							
5							
6							
7							
8							
9							

① **FREQUENCY CODES:**
CI Continuous infusion
Q2WK Every 2 weeks
Q12H Every 12 hours
Q4WK Every 4 weeks
Q3WK Every 3 weeks
QMO Once a month
QD Once a day
OT Other *(specify below)*

② **DOSE STATUS CODES:**
01 Full intended dose
02 Dose reduction due to toxicity
03 Missed dose *(specify below)*
88 Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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

AMENDMENT 2.0

SCR

PRIOR CHEMOTHERAPY - First Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day	Date First Administered Month	Date First Administered Year	Date Last Administered Day	Date Last Administered Month	Date Last Administered Year	Name of Hospital
1											
2											
3											
4											
5											
6											
7											
8											
9											

① **FREQUENCY CODES:**

CI	Continuous infusion	**Q12H**	Every 12 hours	**Q3WK**	Every 3 weeks	**QD**	Once a day
Q2WK	Every 2 weeks	**Q4WK**	Every 4 weeks	**QMO**	Once a month	**OT**	Other *(specify below)*

② **DOSE STATUS CODES:**

01	Full intended dose	**03**	Missed dose *(specify below)*
02	Dose reduction due to toxicity	**88**	Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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

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SCR

PRIOR CHEMOTHERAPY - Second Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day	Date First Administered Month	Date First Administered Year	Date Last Administered Day	Date Last Administered Month	Date Last Administered Year	Name of Hospital
1											
2											
3											
4											
5											
6											
7											
8											
9											

① **FREQUENCY CODES:**

CI	Continuous infusion	**Q12H**	Every 12 hours	**Q3WK**	Every 3 weeks	**QD**	Once a day
Q2WK	Every 2 weeks	**Q4WK**	Every 4 weeks	**QMO**	Once a month	**OT**	Other *(specify below)*

② **DOSE STATUS CODES:**

01	Full intended dose	**03**	Missed dose *(specify below)*
02	Dose reduction due to toxicity	**88**	Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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

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PRIOR CHEMOTHERAPY - Second Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day	Date First Administered Month	Date First Administered Year	Date Last Administered Day	Date Last Administered Month	Date Last Administered Year	Name of Hospital
1											
2											
3											
4											
5											
6											
7											
8											
9											

① **FREQUENCY CODES:**

CI	Continuous infusion	**Q12H**	Every 12 hours	**Q3WK**	Every 3 weeks	**QD**	Once a day
Q2WK	Every 2 weeks	**Q4WK**	Every 4 weeks	**QMO**	Once a month	**OT**	Other *(specify below)*

② **DOSE STATUS CODES:**

01	Full intended dose	**03**	Missed dose *(specify below)*
02	Dose reduction due to toxicity	**88**	Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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

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PRIOR CHEMOTHERAPY - Third Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Did subject receive third line of treatment ? 0 ❑ No 1 ❑ Yes - If yes, specify below.

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day	Month	Year	Date Last Administered Day	Month	Year	Name of Hospital
1											
2											
3											
4											
5											
6											
7											
8											
9											

① **FREQUENCY CODES:**

CI	Continuous infusion	**Q12H**	Every 12 hours	**Q3WK**	Every 3 weeks	**QD**	Once a day
Q2WK	Every 2 weeks	**Q4WK**	Every 4 weeks	**QMO**	Once a month	**OT**	Other *(specify below)*

② **DOSE STATUS CODES:**

01	Full intended dose	**03**	Missed dose *(specify below)*
02	Dose reduction due to toxicity	**88**	Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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

AMENDMENT 2.0

SCR

PRIOR CHEMOTHERAPY - Third Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day	Date First Administered Month	Date First Administered Year	Date Last Administered Day	Date Last Administered Month	Date Last Administered Year	Name of Hospital
1											
2											
3											
4											
5											
6											
7											
8											
9											

① **FREQUENCY CODES:**

CI	Continuous infusion	**Q12H**	Every 12 hours	**Q3WK**	Every 3 weeks	**QD**	Once a day
Q2WK	Every 2 weeks	**Q4WK**	Every 4 weeks	**QMO**	Once a month	**OT**	Other *(specify below)*

② **DOSE STATUS CODES:**

01	Full intended dose	**03**	Missed dose *(specify below)*
02	Dose reduction due to toxicity	**88**	Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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Screening

RESPONSE TO PRIOR CHEMOTHERAPY REGIMENS

Line of Treatment ①	**Date of Scan Prior to Chemotherapy** Day / Month / Year	Best Response ②	**Date of Best Response** *(if CR, PR or SD)* Day / Month / Year	If Best Response was CR or PR was it confirmed? 66 **N/A** ✓ / 0 **No** ✓ / 1 **Yes** ✓	**Date of Disease Progression** Day / Month / Year

① **LINE OF TREATMENT CODES:**

- **01** 1st Line of treatment
- **02** 2nd Line of Treatment
- **03** 3rd Line of treatment

② **BEST RESPONSE CODES:**

- **CR** Complete Response
- **PR** Partial Response
- **SD** Stable Disease
- **PD** Progressive Disease

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Screening

PRIOR RADIOTHERAPY

Has the subject had prior radiotherapy? 0 ❑ No 1 ❑ Yes - If Yes, provide details below.

Specify Area	Date Course Started Day Month Year	Date Course Ended Day Month Year	Total Dose	Unit ①

① **UNIT CODE:**
GY Gray
cGY centi-Gray

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 First Administered Day Month Year	Date Last Administered Day Month 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 Treatment ①	Drug Name	Date First Administered Day Month Year	Date Last Administered Day Month Year
1				
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

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Tick when data checked. ☐

Screening

PHYSICAL EXAMINATION

Date of Examination			Weight
Day	Month	Year	❑ kg ❑ lb

Does the subject have any abnormal clinical findings relating to the following required sites? ❑ No ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate if a required assessment was not done.

Code *(as listed above)*	**Describe findings** *List one entry per line.*

For Amgen Use Only
Tick when data checked. ☐

Screening

VITAL SIGNS

Pulse should be resting

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

ECOG PERFORMANCE STATUS

Date of Assessment Day Month Year	**ECOG Performance Status** ①

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction.

1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work.

2 Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about > 50% of waking hours.

PREGNANCY TEST

Is subject of child bearing potential? 0❑ No 1❑ Yes

If Yes, specify below

Date of Sample Day Month Year	**Time of Sample** *(24 hour clock)*
	:

Specimen Type	10❑ Urine	9❑ Serum
Result	0❑ Negative	1❑ Positive

For Amgen Use Only
Tick when data checked. ☐

Screening

ELECTROCARDIOGRAM

Date Performed Day Month Year	Procedure Code ①	Body Site Code ②	① **PROCEDURE CODES:** **13** Electrocardiogram (ECG) ② **BODY SITE CODES:** **09** Heart
	1 3	0 9	

Heart Rate *(cycles/minute)*	PR *(msecs)*	QRS *(msecs)*	QT *(msecs)*	QT_C *(msecs)*

Result Code ③	③ **RESULT CODES:**
	00 Normal **02** Abnormal, not clinically significant **03** Abnormal, clinically significant

Result: If clinically significant abnormality, specify _____

_____

_____

_____

CANCER DIAGNOSIS

Primary Tumor Diagnosis ①	① **PRIMARY TUMOR DIAGNOSIS CODE**	Date of Colorectal Cancer Diagnosis Day Month Year	Date Metastatic Disease Diagnosed Day Month Year
	1251 Colon cancer **1252** Rectal cancer		

For Amgen Use Only
Tick when data checked. ☐

Screening

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Other" Method of Assessment**

For Amgen Use Only
Tick when data checked. ☐

Screening

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11					___ ___ ___
12					___ ___ ___
13					___ ___ ___
14					___ ___ ___
15					___ ___ ___
16					___ ___ ___
				Sum of Non-Target Lesions	___ ___ ___

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
04	MRI (NMR)	**88**	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

TREATMENT PHASE

WEEKS 1 - 8

Week 1

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 1

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 findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 3

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)* ①	Specify if Skin Toxicity is "01 Nail Changes"	① 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)* ②	Specify if Type of Skin Lesion is "88 Other"	② TYPE OF SKIN LESION CODES: **00** None; **01** Pustular; **02** Vesicular; **04** Macular; **05** Papular; **07** Dry flaking; **08** Desquamation (sloughing); **09** Comedones; **10** Cysts; **88** Other *(specify)*

Total % BSA Affected ③	③ TOTAL % BSA CODES: **04** > 50% BSA; **05** ≤ 50% BSA	Location ④ *(list all that apply)*	Specify if Location is "88 Other"	④ LOCATION CODES: **09** Face; **10** Trunk; **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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 3

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use 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)

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For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W1-W3

Weeks 1-3
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ / 2 °F ✓)	Weight (1 ☐ kg / 2 ☐ lb)
1		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	:	/				
3		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	:	/				

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

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For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W5-W7

Weeks 5-7
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ / 2 °F ✓)	Weight (1 ☐ kg / 2 ☐ lb)
5		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	:	/				
7		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W1-W7

Weeks 1-7
INVESTIGATIONAL PRODUCT ADMINISTRATION

Subjects receiving BSC will not receive Investigational Product Administration, please score through the page

Study Week	Date Day / Month / Year	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume *(mL)*	Reason for Dose Change ①	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code ②	If Reason for Dose Change is "88 Other", please specify
1		:	:					
3		:	:					
5		:	:					
7		:	:					

If subject did not complete investigational product administration, provide any additional relevant information:

_____

_____

_____

① **DOSE CHANGE CODES:**

01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(Specify above)*

② **"04 Per protocol" DOSE CHANGE CODES:**

100 Weight change
118 Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject
120 Skin infection requiring systemic IV antibiotic or IV antifungal treatment
121 Need for surgical debridement
122 Any skin-related serious adverse event
200 Dose reinstated
201 Dose increase *(after reinstatement)*

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

Weeks 1-7
INVESTIGATIONAL PRODUCT LOT NUMBER

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

For Amgen Use Only
Tick when data checked. ☐

Week 5

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 5

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 findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 5

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 5

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 7

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)* ①	Specify if Skin Toxicity is "01 Nail Changes"	① 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)* ②	Specify if Type of Skin Lesion is "88 Other"	② TYPE OF SKIN LESION CODES: 00 None; 01 Pustular; 02 Vesicular; 04 Macular; 05 Papular; 07 Dry flaking; 08 Desquamation (sloughing); 09 Comedones; 10 Cysts; 88 Other *(specify)*

Total % BSA Affected ③	③ TOTAL % BSA CODES: 04 > 50% BSA; 05 ≤ 50% BSA	Location ④ *(list all that apply)*	Specify if Location is "88 Other"	④ LOCATION CODES: 09 Face; 10 Trunk; 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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 7

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 8

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment**

For Amgen Use Only
Tick when data checked. ☐

Week 8

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						___ ___ ___
12						___ ___ ___
13						___ ___ ___
14						___ ___ ___
15						___ ___ ___
16						___ ___ ___
					Sum of Non-Target Lesions	___ ___ ___

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

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

Week 8

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①
8				

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
Tick when data checked. ☐

Weeks 1-8 PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ①	Malignant Cell? 0No✓ 1Yes✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE: **32** Surgical
	3 2			

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE: **16** Biopsy
	1 6			

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE: 33 Colonoscopy; 34 Sigmoidoscopy; 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**
01 Abdomen; **02** Brain; **03** Breast; **04** Bone; **05** Chest; **06** Eye; **07** Gastrointestinal tract; **08** Head; **09** Heart; **10** Kidney; **11** Liver; **12** Lung; **13** Pleura; **14** Pelvic site; **15** Retroperitoneum; **16** Skin; **17** Total body; **18** Thorax; **19** Extremity(ies); **23** Neck; **88** Other *(Specify above)*

For Amgen Use Only
Tick when data checked. ☐

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

WEEKS 9 - 16

Week 9

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 9

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 findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 9

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
   (Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 9

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**	② **SUBJECT PERCEPTION CODES:**
A **B** **C** **D**	**01** Not at all **03** Moderate **05** Intolerable **02** A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

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

Week 11

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:**	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:**
	04 > 50% BSA **05** ≤ 50% BSA			**09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 11

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all
02 A little
03 Moderate
04 Very much
05 Intolerable

For Amgen Use 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. ☐

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

AMENDMENT 2.0

W9-W11

Weeks 9-11
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ / 2 °F ✓)	Weight (1 ☐ kg / 2 ☐ lb)
9		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	:	/				
11		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W13-W15

Weeks 13-15
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ 2 °F ✓)	Weight (1 ☐ kg 2 ☐ lb)
13		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	:	/				
15		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	:	/				

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

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For Amgen Use Only
Tick when data checked.

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

AMENDMENT 2.0

W9-W15

Weeks 9-15
INVESTIGATIONAL PRODUCT ADMINISTRATION

Subjects receiving BSC will not receive Investigational Product Administration, please score through the page

Study Week	Date: Day / Month / Year	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume *(mL)*	Reason for Dose Change ①	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code ②	If Reason for Dose Change is "88 Other", please specify
9		:	:					
11		:	:					
13		:	:					
15		:	:					

If subject did not complete investigational product administration, provide any additional relevant information:

_____

_____

_____

① **DOSE CHANGE CODES:**

01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(Specify above)*

② **"04 Per protocol" DOSE CHANGE CODES:**

100 Weight change
118 Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject
120 Skin infection requiring systemic IV antibiotic or IV antifungal treatment
121 Need for surgical debridement
122 Any skin-related serious adverse event
200 Dose reinstated
201 Dose increase *(after reinstatement)*

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

Weeks 9-15

INVESTIGATIONAL PRODUCT LOT NUMBER

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

For Amgen Use Only
Tick when data checked. ☐

Week 12

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions***(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

For Amgen Use Only
Tick when data checked. ☐

Week 12

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 No ✓ 1 Yes ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

Week 13

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 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

Does the subject have any abnormal clinical findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 13

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 15

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 15

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 16

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

For Amgen Use Only
Tick when data checked. ☐

Week 16

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

Weeks 12-16

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①
12				
16				

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
Tick when data checked. ☐

Weeks 9-16 PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ①	Malignant Cell? 0No✓ 1Yes✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE:
	3 2			**32** Surgical

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE:
	1 6			**16** Biopsy

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE:
					33 Colonoscopy 34 Sigmoidoscopy 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**																	
	01 Abdomen	**02** Brain	**03** Breast	**04** Bone	**05** Chest	**06** Eye	**07** Gastrointestinal tract	**08** Head	**09** Heart	**10** Kidney	**11** Liver	**12** Lung	**13** Pleura	**14** Pelvic site	**15** Retroperitoneum	**16** Skin	**17** Total body	**18** Thorax	**19** Extremity(ies)	**23** Neck	**88** Other *(Specify above)*

For Amgen Use Only
Tick when data checked. ☐

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

WEEKS 17 - 24

Week 17

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 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

Does the subject have any abnormal clinical findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status** ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 17

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)* ①	Specify if Skin Toxicity is "01 Nail Changes"	① 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)* ②	Specify if Type of Skin Lesion is "88 Other"	② TYPE OF SKIN LESION CODES: 00 None; 01 Pustular; 02 Vesicular; 04 Macular; 05 Papular; 07 Dry flaking; 08 Desquamation (sloughing); 09 Comedones; 10 Cysts; 88 Other *(specify)*

Total % BSA Affected ③	③ TOTAL % BSA CODES: 04 > 50% BSA; 05 ≤ 50% BSA	Location ④ *(list all that apply)*	Specify if Location is "88 Other"	④ LOCATION CODES: 09 Face; 10 Trunk; 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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 17

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 19

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **01** Pustular **02** Vesicular **04** Macular **05** Papular **07** Dry flaking **08** Desquamation (sloughing) **09** Comedones **10** Cysts **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 19

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use 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. ☐

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

AMENDMENT 2.0

W17-W19

Weeks 17-19
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ 2 °F ✓)	Weight (1 ☐ kg 2 ☐ lb)
17		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	:	/				
19		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W21-W23

Weeks 21-23
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ 2 °F ✓)	Weight (1 ☐ kg 2 ☐ lb)
21		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	:	/				
23		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

A ABX-EGF 20020408	Site No.	Subject ID No. 11	Subject Initials

AMENDMENT 2.0

W17-W23

Weeks 17-23
INVESTIGATIONAL PRODUCT ADMINISTRATION

Subjects receiving BSC will not receive Investigational Product Administration, please score through the page

Study Week	Date (Day / Month / Year)	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume *(mL)*	Reason for Dose Change ①	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code ②	If Reason for Dose Change is "88 Other", please specify
17		:	:					
19		:	:					
21		:	:					
23		:	:					

If subject did not complete investigational product administration, provide any additional relevant information:

_____

_____

_____

① **DOSE CHANGE CODES:**

01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(Specify above)*

② **"04 Per protocol" DOSE CHANGE CODES:**

100 Weight change
118 Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject
120 Skin infection requiring systemic IV antibiotic or IV antifungal treatment
121 Need for surgical debridement
122 Any skin-related serious adverse event
200 Dose reinstated
201 Dose increase *(after reinstatement)*

Weeks 17-23

INVESTIGATIONAL PRODUCT LOT NUMBER

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

For Amgen Use Only
Tick when data checked. ☐

Week 21

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 21

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 findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 21

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)* ①	Specify if Skin Toxicity is "01 Nail Changes"	① 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)* ②	Specify if Type of Skin Lesion is "88 Other"	② TYPE OF SKIN LESION CODES: 00 None; 01 Pustular; 02 Vesicular; 04 Macular; 05 Papular; 07 Dry flaking; 08 Desquamation (sloughing); 09 Comedones; 10 Cysts; 88 Other *(specify)*

Total % BSA Affected ③	③ TOTAL % BSA CODES: 04 > 50% BSA; 05 ≤ 50% BSA	Location ④ *(list all that apply)*	Specify if Location is "88 Other"	④ LOCATION CODES: 09 Face; 10 Trunk; 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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 21

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 23

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)* ①	Specify if Skin Toxicity is "01 Nail Changes"	① 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)* ②	Specify if Type of Skin Lesion is "88 Other"	② TYPE OF SKIN LESION CODES: **00** None; **01** Pustular; **02** Vesicular; **04** Macular; **05** Papular; **07** Dry flaking; **08** Desquamation (sloughing); **09** Comedones; **10** Cysts; **88** Other *(specify)*

Total % BSA Affected ③	③ TOTAL % BSA CODES: **04** > 50% BSA; **05** ≤ 50% BSA	Location ④ *(list all that apply)*	Specify if Location is "88 Other"	④ LOCATION CODES: **09** Face; **10** Trunk; **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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 23

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 24

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00 Lymph nodes	**40** Chest	**60** Gastrointestinal	**86** Skin
10 Pulmonary	**50** Central nervous system	**70** Abdomen	**88** Other *(specify in subsite above)*
20 Liver	**55** Head	**75** Pelvic Site	
30 Bone	**56** Neck	**85** 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 Assessment

For Amgen Use Only
Tick when data checked. ☐

Week 24

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

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

Week 24

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①
24				

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
Tick when data checked. ☐

Weeks 17-24 PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ①	Malignant Cell? 0No✓ 1Yes✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE:
	3 2			**32** Surgical

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE:
	1 6			**16** Biopsy

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE:
					33 Colonoscopy 34 Sigmoidoscopy 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**																	
01 Abdomen	**02** Brain	**03** Breast	**04** Bone	**05** Chest	**06** Eye	**07** Gastrointestinal tract	**08** Head	**09** Heart	**10** Kidney	**11** Liver	**12** Lung	**13** Pleura	**14** Pelvic site	**15** Retroperitoneum	**16** Skin	**17** Total body	**18** Thorax	**19** Extremity(ies)	**23** Neck	**88** Other *(Specify above)*

For Amgen Use Only
Tick when data checked. ☐

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

WEEKS 25 - 32

Week 25

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 25

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 findings relating to the following required sites? $_{0}$❑ No $_{1}$❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 25

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)* ①	Specify if Skin Toxicity is "01 Nail Changes"	① 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)* ②	Specify if Type of Skin Lesion is "88 Other"	② TYPE OF SKIN LESION CODES: 00 None; 01 Pustular; 02 Vesicular; 04 Macular; 05 Papular; 07 Dry flaking; 08 Desquamation (sloughing); 09 Comedones; 10 Cysts; 88 Other *(specify)*

Total % BSA Affected ③	③ TOTAL % BSA CODES: 04 > 50% BSA; 05 ≤ 50% BSA	Location ④ *(list all that apply)*	Specify if Location is "88 Other"	④ LOCATION CODES: 09 Face; 10 Trunk; 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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 25

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all
02 A little
03 Moderate
04 Very much
05 Intolerable

For Amgen Use Only
Tick when data checked. ☐

Week 27

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:**	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:**
	04 > 50% BSA **05** ≤ 50% BSA			**09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 27

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use 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)

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Tick when data checked.

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

AMENDMENT 2.0

W25-W27

Weeks 25-27
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ 2 °F ✓)	Weight (1 ❑ kg 2 ❑ lb)
25		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	:	/				
27		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W29-W31

Weeks 29-31
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ 2 °F ✓)	Weight (1 ☐ kg 2 ☐ lb)
29		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	:	/				
31		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

A ABX-EGF 20020408	Site No.	Subject ID No. 11	Subject Initials

AMENDMENT 2.0

W25-W31

Weeks 25-31
INVESTIGATIONAL PRODUCT ADMINISTRATION

Subjects receiving BSC will not receive Investigational Product Administration, please score through the page

Study Week	Date (Day / Month / Year)	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume *(mL)*	Reason for Dose Change ①	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code ②	If Reason for Dose Change is "88 Other", please specify
25		:	:					
27		:	:					
29		:	:					
31		:	:					

If subject did not complete investigational product administration, provide any additional relevant information:

_____

_____

_____

① **DOSE CHANGE CODES:**

01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(Specify above)*

② **"04 Per protocol" DOSE CHANGE CODES:**

100 Weight change
118 Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject
120 Skin infection requiring systemic IV antibiotic or IV antifungal treatment
121 Need for surgical debridement
122 Any skin-related serious adverse event
200 Dose reinstated
201 Dose increase *(after reinstatement)*

Weeks 25-31

INVESTIGATIONAL PRODUCT LOT NUMBER

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

For Amgen Use Only
Tick when data checked. ☐

Week 29

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 29

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 findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 29

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 29

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 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

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"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 31

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 32

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

For Amgen Use Only
Tick when data checked. ☐

Week 32

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

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

Week 32

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①
32				

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
Tick when data checked. ☐

Weeks 25-32 PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ①	Malignant Cell? 0No✓ 1Yes✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE:
	3 2			**32** Surgical

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE:
	1 6			**16** Biopsy

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE:
					33 Colonoscopy 34 Sigmoidoscopy 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**

01 Abdomen	**05** Chest	**09** Heart	**13** Pleura	**17** Total body	**88** Other *(Specify above)*
02 Brain	**06** Eye	**10** Kidney	**14** Pelvic site	**18** Thorax	
03 Breast	**07** Gastrointestinal tract	**11** Liver	**15** Retroperitoneum	**19** Extremity(ies)	
04 Bone	**08** Head	**12** Lung	**16** Skin	**23** Neck	

For Amgen Use Only
Tick when data checked. ☐

WEEKS 33 - 40

Week 33

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 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

Does the subject have any abnormal clinical findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 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

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"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **01** Pustular **02** Vesicular **04** Macular **05** Papular **07** Dry flaking **08** Desquamation (sloughing) **09** Comedones **10** Cysts **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 33

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 35

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **01** Pustular **02** Vesicular **04** Macular **05** Papular **07** Dry flaking **08** Desquamation (sloughing) **09** Comedones **10** Cysts **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 35

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use 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)

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For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W33-W35

Weeks 33-35
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ 2 °F ✓)	Weight (1 ☐ kg 2 ☐ lb)
33		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	:	/				
35		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W37-W39

Weeks 37-39
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ 2 °F ✓)	Weight (1 ☐ kg 2 ☐ lb)
37		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	:	/				
39		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

A **ABX-EGF 20020408**	Site No.	Subject ID No. 11	Subject Initials

AMENDMENT 2.0

W33-W39

Weeks 33-39
INVESTIGATIONAL PRODUCT ADMINISTRATION

Subjects receiving BSC will not receive Investigational Product Administration, please score through the page

Study Week	Date (Day / Month / Year)	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume *(mL)*	Reason for Dose Change ①	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code ②	If Reason for Dose Change is "88 Other", please specify
33		:	:					
35		:	:					
37		:	:					
39		:	:					

If subject did not complete investigational product administration, provide any additional relevant information:

_____

_____

_____

① DOSE CHANGE CODES:

- **01** Adverse event
- **02** Noncompliance
- **03** Dose administration error
- **04** Per protocol
- **88** Other *(Specify above)*

② "04 Per protocol" DOSE CHANGE CODES:

- **100** Weight change
- **118** Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject
- **120** Skin infection requiring systemic IV antibiotic or IV antifungal treatment
- **121** Need for surgical debridement
- **122** Any skin-related serious adverse event
- **200** Dose reinstated
- **201** Dose increase *(after reinstatement)*

Weeks 33-39

INVESTIGATIONAL PRODUCT LOT NUMBER

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

For Amgen Use Only
Tick when data checked. ☐

Week 37

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 37

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 findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 37

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **01** Pustular **02** Vesicular **04** Macular **05** Papular **07** Dry flaking **08** Desquamation (sloughing) **09** Comedones **10** Cysts **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 37

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 39

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)* ①	Specify if Skin Toxicity is "01 Nail Changes"	① 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)* ②	Specify if Type of Skin Lesion is "88 Other"	② TYPE OF SKIN LESION CODES: 00 None; 01 Pustular; 02 Vesicular; 04 Macular; 05 Papular; 07 Dry flaking; 08 Desquamation (sloughing); 09 Comedones; 10 Cysts; 88 Other *(specify)*

Total % BSA Affected ③	③ TOTAL % BSA CODES: 04 > 50% BSA; 05 ≤ 50% BSA	Location ④ *(list all that apply)*	Specify if Location is "88 Other"	④ LOCATION CODES: 09 Face; 10 Trunk; 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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 39

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 40

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

For Amgen Use Only
Tick when data checked. ☐

Week 40

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

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

Week 40

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①
40				

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
Tick when data checked. ☐

Weeks 33-40
PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ①	Malignant Cell? 0No✓ 1Yes✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE:
	3 2			**32** Surgical

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE:
	1 6			**16** Biopsy

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE:
					33 Colonoscopy 34 Sigmoidoscopy 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**

01 Abdomen	**05** Chest	**09** Heart	**13** Pleura	**17** Total body	**88** Other *(Specify above)*
02 Brain	**06** Eye	**10** Kidney	**14** Pelvic site	**18** Thorax	
03 Breast	**07** Gastrointestinal tract	**11** Liver	**15** Retroperitoneum	**19** Extremity(ies)	
04 Bone	**08** Head	**12** Lung	**16** Skin	**23** Neck	

For Amgen Use Only
Tick when data checked. ☐

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

WEEKS 41 - 48

Week 41

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 41

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 findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 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

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"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 41

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 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.

Skin Toxicity *(list all that apply)* ①	Specify if Skin Toxicity is "01 Nail Changes"	① 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)* ②	Specify if Type of Skin Lesion is "88 Other"	② TYPE OF SKIN LESION CODES: 00 None; 01 Pustular; 02 Vesicular; 04 Macular; 05 Papular; 07 Dry flaking; 08 Desquamation (sloughing); 09 Comedones; 10 Cysts; 88 Other *(specify)*

Total % BSA Affected ③	③ TOTAL % BSA CODES: 04 > 50% BSA; 05 ≤ 50% BSA	Location ④ *(list all that apply)*	Specify if Location is "88 Other"	④ LOCATION CODES: 09 Face; 10 Trunk; 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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 43

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use 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. ☐

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

AMENDMENT 2.0

W41-W43

Weeks 41-43
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ / 2 °F ✓)	Weight (1 ☐ kg / 2 ☐ lb)
41		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	:	/				
43		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

W45-W47

Weeks 45-47
ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ 2 °F ✓)	Weight (1 ☐ kg 2 ☐ lb)
45		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	:	/				
47		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	:	/				

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

For Amgen Use Only
Tick when data checked. ☐

A **ABX-EGF 20020408**	Site No.	Subject ID No. 11	Subject Initials

AMENDMENT 2.0

W41-W47

Weeks 41-47
INVESTIGATIONAL PRODUCT ADMINISTRATION

Subjects receiving BSC will not receive Investigational Product Administration, please score through the page

Study Week	Date (Day / Month / Year)	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume *(mL)*	Reason for Dose Change ①	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code ②	If Reason for Dose Change is "88 Other", please specify
41		:	:					
43		:	:					
45		:	:					
47		:	:					

If subject did not complete investigational product administration, provide any additional relevant information:

_____

_____

_____

① **DOSE CHANGE CODES:**

- **01** Adverse event
- **02** Noncompliance
- **03** Dose administration error
- **04** Per protocol
- **88** Other *(Specify above)*

② **"04 Per protocol" DOSE CHANGE CODES:**

- **100** Weight change
- **118** Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject
- **120** Skin infection requiring systemic IV antibiotic or IV antifungal treatment
- **121** Need for surgical debridement
- **122** Any skin-related serious adverse event
- **200** Dose reinstated
- **201** Dose increase *(after reinstatement)*

Weeks 41-47

INVESTIGATIONAL PRODUCT LOT NUMBER

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

For Amgen Use Only
Tick when data checked. ☐

Week 45

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

Week 45

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 findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status** ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

Week 45

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 45

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all
02 A little
03 Moderate
04 Very much
05 Intolerable

For Amgen Use Only
Tick when data checked. ☐

Week 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

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"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:**	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:**
	04 > 50% BSA **05** ≤ 50% BSA			**09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

Week 47

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week 48

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

For Amgen Use Only
Tick when data checked. ☐

Week 48

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

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

Week 48

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①
48				

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
Tick when data checked. ☐

Weeks 41-48 PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ①	Malignant Cell? 0No✓ 1Yes✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE:
	3 2			**32** Surgical

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE:
	1 6			**16** Biopsy

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE:
					33 Colonoscopy 34 Sigmoidoscopy 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**

01 Abdomen	**05** Chest	**09** Heart	**13** Pleura	**17** Total body	**88** Other *(Specify above)*
02 Brain	**06** Eye	**10** Kidney	**14** Pelvic site	**18** Thorax	
03 Breast	**07** Gastrointestinal tract	**11** Liver	**15** Retroperitoneum	**19** Extremity(ies)	
04 Bone	**08** Head	**12** Lung	**16** Skin	**23** Neck	

For Amgen Use Only
Tick when data checked. ☐

WEEKS 49 - PD

Week ____

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

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

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

Does the subject have any abnormal clinical findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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

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 **Yes** ✓ *Enter corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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

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

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 Yes ✓ *Enter corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use 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)

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Tick when data checked. ☐

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

AMENDMENT 2.0

Weeks _____

ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ / 2 °F ✓)	Weight (1 ❑ kg / 2 ❑ lb)
		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	:	/				
		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	:	/				

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

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For Amgen Use Only
Tick when data checked.

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

AMENDMENT 2.0

Weeks _____

ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 (1 °C ✓ / 2 °F ✓)	Weight (1 ❑ kg / 2 ❑ lb)
		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	:	/				
		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	:	/				

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

v2.0 30Jun04camb

For Amgen Use Only
Tick when data checked.

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

AMENDMENT 2.0

Weeks _____

ABX-EGF INFUSION VITAL SIGNS and WEIGHT

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 1 °C ✓ 2 °F ✓	Weight 1 ❑ kg 2 ❑ lb
		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	:	/				
		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	:	/				

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

For Amgen Use Only
Tick when data checked.

A **ABX-EGF 20020408**	Site No.	Subject ID No. 11	Subject Initials

AMENDMENT 2.0

Weeks _____

INVESTIGATIONAL PRODUCT ADMINISTRATION

Subjects receiving BSC will not receive Investigational Product Administration, please score through the page

Study Week	Date Day Month Year	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume *(mL)*	Reason for Dose Change ①	If "04 Per protocol" is indicated for "Reason for Dose Change", indicate code ②	If Reason for Dose Change is "88 Other", please specify
		:	:					
		:	:					
		:	:					
		:	:					
		:	:					
		:	:					

If subject did not complete investigational product administration, provide any additional relevant information:

_____

_____

_____

① **DOSE CHANGE CODES:**

01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(Specify above)*

② **"04 Per protocol" DOSE CHANGE CODES:**

100 Weight change
118 Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject
120 Skin infection requiring systemic IV antibiotic or IV antifungal treatment
121 Need for surgical debridement
122 Any skin-related serious adverse event
200 Dose reinstated
201 Dose increase *(after reinstatement)*

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

Weeks _____

INVESTIGATIONAL PRODUCT LOT NUMBER

Study Week	ABX-EGF Package Lot Number	ABX-EGF Package Lot Number

For Amgen Use Only
Tick when data checked. ☐

Week ____

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

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

Does the subject have any abnormal clinical findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:**	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:**
	04 > 50% BSA **05** ≤ 50% BSA			**09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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 **Yes** ✓ *Enter corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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 **Yes** ✓ *Enter corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**
A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**
01 Not at all **03** Moderate **05** Intolerable
02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week ____

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

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

Does the subject have any abnormal clinical findings relating to the following required sites? 0 ❑ No 1 ❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate 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 Status ①
Day	Month	Year	

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair
5 Dead

For Amgen Use Only
Tick when data checked. ☐

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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 **Yes** ✓ *Enter corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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 **Yes** ✓ *Enter corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

Week ____

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				____ ____ ____
02				____ ____ ____
03				____ ____ ____
04				____ ____ ____
05				____ ____ ____
06				____ ____ ____
07				____ ____ ____
08				____ ____ ____
09				____ ____ ____
10				____ ____ ____
			Sum of Target Lesions	____ ____ ____

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

For Amgen Use Only
Tick when data checked. ☐

Week ____

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

Week ____

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

Weeks _____
PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure Day Month Year	Procedure ①	Malignant Cell? 0No ✓ 1Yes ✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure Day Month Year	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE: **32** Surgical
	3 2			

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure Day Month Year	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE: **16** Biopsy
	1 6			

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure Day Month Year	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE: 33 Colonoscopy 34 Sigmoidoscopy 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**
01 Abdomen, **02** Brain, **03** Breast, **04** Bone, **05** Chest, **06** Eye, **07** Gastrointestinal tract, **08** Head, **09** Heart, **10** Kidney, **11** Liver, **12** Lung, **13** Pleura, **14** Pelvic site, **15** Retroperitoneum, **16** Skin, **17** Total body, **18** Thorax, **19** Extremity(ies), **23** Neck, **88** Other *(Specify above)*

For Amgen Use Only
Tick when data checked. ☐

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

END OF TREATMENT

End of Treatment

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

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

AMENDMENT 2.0

EOT

END OF TREATMENT

Date Subject Ended Treatment Phase		
Day	Month	Year

Enter PRIMARY reason for ending Treatment Phase:

Enter Code: ☐

CODES:

02 Ineligibility determined ①
03 Protocol deviation ①
04 Noncompliance ①
05 Adverse event ① *(FAX this form to Amgen)*
06 Consent withdrawn ①
13 Subject request
07 Disease progression ①
09 Administrative decision ①
10 Lost to follow-up ①
11 Death ②
(Enter cause of death on Adverse Events Summary CRF and FAX completed Serious Adverse Event form to Amgen within one working day.)
12 Protocol specified criteria ①

Criteria Code	**CRITERIA CODES:**
	118 Symptomatic skin-related toxicity requiring narcotics, systemic steroids, or felt to be intolerable by subject **120** Skin infection requiring systemic IV antibiotic or antifungal treatment **121** Need for surgical debridement **122** Any skin-related serious adverse event

14 Pregnancy ① *(complete Pregnancy Notification Worksheet)*
88 Other ①

① *Record date the decision was made to end the treatment phase as* ***Date Subject Ended Treatment Phase***
② *Record date of death as* ***Date Subject Ended Treatment Phase***

Please provide any additional relevant information on the PRIMARY reason for ending treatment phase:

_____

_____

_____

For Amgen Use Only
Tick when data checked. ☐

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

SAFETY FOLLOW-UP

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)*

Safety Follow-up

HEALTH RESOURCE UTILIZATION QUESTIONNAIRE

Date of Assessment		
Day	Month	Year

I would like to ask you a few questions about any additional visits (not required by the trial) that you may have made to a doctor or an outpatient facility in the last four weeks

1. Emergency Room Visits
Number of emergency room visits ☐

2. Therapy Visits
Number of therapy (mental health) visits ☐

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 ☐

For Amgen Use Only
Tick when data checked. ☐

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

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

AMENDMENT 2.0

FUP

Safety Follow-up
VITAL SIGNS

Pulse should be resting

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

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 findings relating to the following required sites? 0❑ No 1❑ Yes - If yes, describe findings below.

01 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck
02 Cardiovascular
03 Pulmonary
04 Abdomen
05 Musculoskeletal
06 Skin
07 Lymph nodes
08 Neurological
09 Genitourinary
10 Breast / Chest
11 Rectal
88 Other

Indicate if a required assessment was not done.

Code *(as listed above)*	**Describe findings** *List one entry per line.*

ECOG PERFORMANCE STATUS

Date of Assessment Day Month Year	**ECOG Performance Status** ①

① **ECOG PERFORMANCE STATUS CODES:**

0 Fully active, able to carry on all pre-disease performance without restriction.
1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, ie, light housework or office work.
2 Ambulatory and capable of all self-care, but unable to carry 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 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.
5 Dead

For Amgen Use Only
Tick when data checked. ☐

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

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

AMENDMENT 2.0

FUP

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? 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"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:**	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:**
	04 > 50% BSA **05** ≤ 50% BSA			**09** Face **10** Trunk **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. Was crusting present? 0 ❑ No 1 ❑ Yes

3. Since the last assessment, did the rash cause pain? 0 ❑ No 1 ❑ Yes

4. Since the last assessment, did the rash cause itching? 0 ❑ No 1 ❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? 0 ❑ No 1 ❑ Yes
(Record on Concomitant Medications CRF)

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?

0 ❑ No 1 ❑ Yes - If yes, provide date.

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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

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 corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

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Tick when data checked. ☐

Safety Follow-up

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				___ ___ ___
02				___ ___ ___
03				___ ___ ___
04				___ ___ ___
05				___ ___ ___
06				___ ___ ___
07				___ ___ ___
08				___ ___ ___
09				___ ___ ___
10				___ ___ ___
			Sum of Target Lesions	___ ___ ___

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

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Safety Follow-up

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 No ✓ 1 Yes ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

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Safety Follow-up

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

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

AMENDMENT 2.0

FUP

Safety Follow-up PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ①	Malignant Cell? 0No✓ 1Yes✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE:
	3 2			**32** Surgical

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE:
	1 6			**16** Biopsy

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE:
					33 Colonoscopy 34 Sigmoidoscopy 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**																			
01 Abdomen	**02** Brain	**03** Breast	**04** Bone	**05** Chest	**06** Eye	**07** Gastrointestinal tract	**08** Head	**09** Heart	**10** Kidney	**11** Liver	**12** Lung	**13** Pleura	**14** Pelvic site	**15** Retroperitoneum	**16** Skin	**17** Total body	**18** Thorax	**19** Extremity(ies)	**23** Neck	**88** Other *(Specify above)*

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CLINICAL EVENTS

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

AMENDMENT 2.0

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.

Were any concomitant medications used from enrollment to End of Safety Follow-Up? 0 ❑ No 1 ❑ Yes - If yes, specify below.

Line #	Medication *Record one per line*	✓ Prophylaxis	Indication	Dose	Unit ①	Route ②	Freq. ③	Date FIRST Taken Day Month Year	Date LAST Taken Day Month Year	*Check if medication continuing at End of Study* ✓
1										
2										
3										
4										
5										
6										
7										

① UNIT CODES:

AMP	Ampule	**MEQ**	Milliequivalent
CAP	Capsule	**MG**	Milligram
CC	Cubic centimeter	**ML**	Milliliter (cc)
GM	Gram	**TAB**	Tablet
GR	Grain	**TBS**	Tablespoon
GTT	Drop	**TSP**	Teaspoon
IU	International unit	**U**	Unit
MCG	Microgram	**OT**	Other **Specify below*

② ROUTE CODES:

DL	Intraduodenal	**IT**	Intrathecal	**SC**	Subcutaneous
ET	Endotracheal tube	**IV**	Intravenous	**SL**	Sublingual
GT	Gastrostomy	**JI**	Joint injection	**TD**	Transdermal
IA	Intra-arterial	**NG**	Nasogastric tube	**TP**	Topical
ID	Intradermal	**OP**	Ophthalmic	**OT**	Other**Specify below*
IH	Inhaled	**PO**	Oral		
IM	Intramuscular	**PR**	Rectal		
IP	Intraperitoneal	**PV**	Vaginal		

③ FREQUENCY CODES:

BID	Twice a day	**Q2WK**	Every 2 weeks	**QIW**	4 times a week
BIW	Twice a week	**Q3WK**	Every 3 weeks	**QMO**	Once a month
CI	Continuous infusion	**Q4WK**	Every 4 weeks	**QOD**	Every other day
HS	At bedtime	**Q4H**	Every 4 hours	**QWK**	Every week
OTO	One time only	**Q6H**	Every 6 hours	**STAT**	Immediately
PRN	As needed	**Q8H**	Every 8 hours	**TID**	3 times a day
QH	Every hour	**QD**	Once a day	**TIW**	3 times a week
Q12H	Every 12 hours	**QID**	4 times a day	**OT**	Other**Specify below*

Line #	Specify **UNIT** "OT Other"	Line #	Specify **ROUTE** "OT Other"	Line #	Specify **FREQUENCY** "OT Other"

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

AMENDMENT 2.0

CM2

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.

Line #	Medication *Record one per line*	*Check if medication continued from previous Con Med form* ✓	✓ Prophylaxis	Indication	Dose	Unit ①	Route ②	Freq. ③	Date FIRST Taken Day Month Year	Date LAST Taken Day Month Year	*Check if medication continuing at End of Study* ✓
1											
2											
3											
4											
5											
6											
7											

① UNIT CODES:

AMP	Ampule	**MEQ**	Milliequivalent
CAP	Capsule	**MG**	Milligram
CC	Cubic centimeter	**ML**	Milliliter (cc)
GM	Gram	**TAB**	Tablet
GR	Grain	**TBS**	Tablespoon
GTT	Drop	**TSP**	Teaspoon
IU	International unit	**U**	Unit
MCG	Microgram	**OT**	Other **Specify below*

② ROUTE CODES:

DL	Intraduodenal	**IT**	Intrathecal	**SC**	Subcutaneous
ET	Endotracheal tube	**IV**	Intravenous	**SL**	Sublingual
GT	Gastrostomy	**JI**	Joint injection	**TD**	Transdermal
IA	Intra-arterial	**NG**	Nasogastric tube	**TP**	Topical
ID	Intradermal	**OP**	Ophthalmic	**OT**	Other**Specify below*
IH	Inhaled	**PO**	Oral		
IM	Intramuscular	**PR**	Rectal		
IP	Intraperitoneal	**PV**	Vaginal		

③ FREQUENCY CODES:

BID	Twice a day	**Q2WK**	Every 2 weeks	**QIW**	4 times a week
BIW	Twice a week	**Q3WK**	Every 3 weeks	**QMO**	Once a month
CI	Continuous infusion	**Q4WK**	Every 4 weeks	**QOD**	Every other day
HS	At bedtime	**Q4H**	Every 4 hours	**QWK**	Every week
OTO	One time only	**Q6H**	Every 6 hours	**STAT**	Immediately
PRN	As needed	**Q8H**	Every 8 hours	**TID**	3 times a day
QH	Every hour	**QD**	Once a day	**TIW**	3 times a week
Q12H	Every 12 hours	**QID**	4 times a day	**OT**	Other**Specify below*

Line #	Specify **UNIT** "OT Other"	Line #	Specify **ROUTE** "OT Other"	Line #	Specify **FREQUENCY** "OT Other"

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

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Tick when data checked.

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

AMENDMENT 2.0

CM3

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.

Line #	Medication *Record one per line*	*Check if medication continued from previous Con Med form* ✓	Prophylaxis ✓	Indication	Dose	Unit ①	Route ②	Freq. ③	Date FIRST Taken Day Month Year	Date LAST Taken Day Month Year	*Check if medication continuing at End of Study* ✓
1											
2											
3											
4											
5											
6											
7											

① UNIT CODES:

AMP	Ampule	**MEQ**	Milliequivalent
CAP	Capsule	**MG**	Milligram
CC	Cubic centimeter	**ML**	Milliliter (cc)
GM	Gram	**TAB**	Tablet
GR	Grain	**TBS**	Tablespoon
GTT	Drop	**TSP**	Teaspoon
IU	International unit	**U**	Unit
MCG	Microgram	**OT**	Other **Specify below*

② ROUTE CODES:

DL	Intraduodenal	**IT**	Intrathecal	**SC**	Subcutaneous
ET	Endotracheal tube	**IV**	Intravenous	**SL**	Sublingual
GT	Gastrostomy	**JI**	Joint injection	**TD**	Transdermal
IA	Intra-arterial	**NG**	Nasogastric tube	**TP**	Topical
ID	Intradermal	**OP**	Ophthalmic	**OT**	Other* *Specify below*
IH	Inhaled	**PO**	Oral		
IM	Intramuscular	**PR**	Rectal		
IP	Intraperitoneal	**PV**	Vaginal		

③ FREQUENCY CODES:

BID	Twice a day	**Q2WK**	Every 2 weeks	**QIW**	4 times a week
BIW	Twice a week	**Q3WK**	Every 3 weeks	**QMO**	Once a month
CI	Continuous infusion	**Q4WK**	Every 4 weeks	**QOD**	Every other day
HS	At bedtime	**Q4H**	Every 4 hours	**QWK**	Every week
OTO	One time only	**Q6H**	Every 6 hours	**STAT**	Immediately
PRN	As needed	**Q8H**	Every 8 hours	**TID**	3 times a day
QH	Every hour	**QD**	Once a day	**TIW**	3 times a week
Q12H	Every 12 hours	**QID**	4 times a day	**OT**	Other* *Specify below*

Line #	Specify **UNIT** "OT Other"	Line #	Specify **ROUTE** "OT Other"	Line #	Specify **FREQUENCY** "OT Other"

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

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

AMENDMENT 2.0

CM4

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.

Line #	Medication *Record one per line*	*Check if medication continued from previous Con Med form* ✓	Prophylaxis ✓	Indication	Dose	Unit ①	Route ②	Freq. ③	Date FIRST Taken Day Month Year	Date LAST Taken Day Month Year	*Check if medication continuing at End of Study* ✓
1											
2											
3											
4											
5											
6											
7											

① UNIT CODES:

AMP	Ampule	**MEQ**	Milliequivalent
CAP	Capsule	**MG**	Milligram
CC	Cubic centimeter	**ML**	Milliliter (cc)
GM	Gram	**TAB**	Tablet
GR	Grain	**TBS**	Tablespoon
GTT	Drop	**TSP**	Teaspoon
IU	International unit	**U**	Unit
MCG	Microgram	**OT**	Other **Specify below*

② ROUTE CODES:

DL	Intraduodenal	**IT**	Intrathecal	**SC**	Subcutaneous
ET	Endotracheal tube	**IV**	Intravenous	**SL**	Sublingual
GT	Gastrostomy	**JI**	Joint injection	**TD**	Transdermal
IA	Intra-arterial	**NG**	Nasogastric tube	**TP**	Topical
ID	Intradermal	**OP**	Ophthalmic	**OT**	Other**Specify below*
IH	Inhaled	**PO**	Oral		
IM	Intramuscular	**PR**	Rectal		
IP	Intraperitoneal	**PV**	Vaginal		

③ FREQUENCY CODES:

BID	Twice a day	**Q2WK**	Every 2 weeks	**QIW**	4 times a week
BIW	Twice a week	**Q3WK**	Every 3 weeks	**QMO**	Once a month
CI	Continuous infusion	**Q4WK**	Every 4 weeks	**QOD**	Every other day
HS	At bedtime	**Q4H**	Every 4 hours	**QWK**	Every week
OTO	One time only	**Q6H**	Every 6 hours	**STAT**	Immediately
PRN	As needed	**Q8H**	Every 8 hours	**TID**	3 times a day
QH	Every hour	**QD**	Once a day	**TIW**	3 times a week
Q12H	Every 12 hours	**QID**	4 times a day	**OT**	Other**Specify below*

Line #	Specify **UNIT** "OT Other"	Line #	Specify **ROUTE** "OT Other"	Line #	Specify **FREQUENCY** "OT Other"

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

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

AMENDMENT 2.0

CM5

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.

Line #	Medication *Record one per line*	*Check if medication continued from previous Con Med form* ✓	Prophylaxis ✓	Indication	Dose	Unit ①	Route ②	Freq. ③	Date FIRST Taken Day Month Year	Date LAST Taken Day Month Year	*Check if medication continuing at End of Study* ✓
1											
2											
3											
4											
5											
6											
7											

① UNIT CODES:

AMP	Ampule	**MEQ**	Milliequivalent
CAP	Capsule	**MG**	Milligram
CC	Cubic centimeter	**ML**	Milliliter (cc)
GM	Gram	**TAB**	Tablet
GR	Grain	**TBS**	Tablespoon
GTT	Drop	**TSP**	Teaspoon
IU	International unit	**U**	Unit
MCG	Microgram	**OT**	Other **Specify below*

② ROUTE CODES:

DL	Intraduodenal	**IT**	Intrathecal	**SC**	Subcutaneous
ET	Endotracheal tube	**IV**	Intravenous	**SL**	Sublingual
GT	Gastrostomy	**JI**	Joint injection	**TD**	Transdermal
IA	Intra-arterial	**NG**	Nasogastric tube	**TP**	Topical
ID	Intradermal	**OP**	Ophthalmic	**OT**	Other**Specify below*
IH	Inhaled	**PO**	Oral		
IM	Intramuscular	**PR**	Rectal		
IP	Intraperitoneal	**PV**	Vaginal		

③ FREQUENCY CODES:

BID	Twice a day	**Q2WK**	Every 2 weeks	**QIW**	4 times a week
BIW	Twice a week	**Q3WK**	Every 3 weeks	**QMO**	Once a month
CI	Continuous infusion	**Q4WK**	Every 4 weeks	**QOD**	Every other day
HS	At bedtime	**Q4H**	Every 4 hours	**QWK**	Every week
OTO	One time only	**Q6H**	Every 6 hours	**STAT**	Immediately
PRN	As needed	**Q8H**	Every 8 hours	**TID**	3 times a day
QH	Every hour	**QD**	Once a day	**TIW**	3 times a week
Q12H	Every 12 hours	**QID**	4 times a day	**OT**	Other**Specify below*

Line #	Specify **UNIT** "OT Other"	Line #	Specify **ROUTE** "OT Other"	Line #	Specify **FREQUENCY** "OT Other"

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Adverse Events Summary Instructions

1. Record all adverse events occurring after the first dose of investigational product whether considered related to investigational product or not. If changes in baseline condition are to be collected from an earlier time point (eg, after informed consent has 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.

3. Each adverse event / medical concept must be listed on a separate line. For example, nausea and vomiting are two separate events and should be recorded on two separate lines. Muscle and joint aches should also be recorded on two separate lines. Diagnoses or syndromes should be recorded rather than signs or symptoms. For example, congestive heart failure should be reported instead of individual symptoms of shortness of breath, tachycardia and dependent edema.

4. Do not record unconfirmed diagnoses using “rule out, presumed or possible”, instead record signs or symptoms.

5. 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.”

6. 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.

7. “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”.

8. “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.

9. 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.

10. For serious adverse events (SAEs), data entered on the Adverse Events Summary CRF must be consistent with that provided on the SAER form, including amendments.

v2.0 30Jun04camb

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Tick when data checked. ☐

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

AMENDMENT 2.0

AE1

ADVERSE EVENTS SUMMARY

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

Were there any AEs up to End of Study? $_0$☐ No $_1$☐ Yes - If yes, specify below.

Line #	Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s) *List one per line*	Did event start before randomization? $_0$No ✓ $_1$Yes ✓	Date Started Day Month Year	Date Ended, Changed in Severity or Resulted in Death Day Month Year	*Check if event continuing at End of Study* ✓	Intermittent ✓	Severity *(use CTCAE Grading Scale)* *Record one code* 01 02 03 04* 05	*If CTCAE Grade 04, did the event place the subject at immediate risk of death? $_0$No ✓ $_1$Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by investigational product? $_0$No ✓ $_1$Yes ✓	Action Taken for This Event *(record all that apply)* 01 No action taken 02 Investigational product dose altered 03 Medication taken 04 Hospitalized/Prolonged hospitalization 05 Removed from study 06 Investigational product discontinued 07 Transfusion performed 88 Other *Specify below	* Serious ? $_0$No ✓ $_1$Yes ✓
1											
2											
3											
4											
5											
6											
7											
8											

**** Criteria for Serious Adverse Event:**

Serious adverse event includes any event that (is):

- fatal
- life threatening (places subject at immediate risk of death)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability / incapacity
- a congenital anomaly / birth defect
- other significant medical hazard

If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day.

Line #	Specify if "88 Other" Action Taken

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

v2.0 30Jun04camb

For Amgen Use Only
Tick when data checked.

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

AMENDMENT 2.0

AE2

ADVERSE EVENTS SUMMARY

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

Line #	Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s) *List one per line*	*Check if event continued from previous AE form* ✓	Did event start before random-ization? 0 No 1 Yes ✓	Date Started Day	Month	Year	Date Ended, Changed in Severity or Resulted in Death Day	Month	Year	*Check if event continuing at End of Study* ✓	Intermittent ✓	Severity *(use CTCAE Grading Scale)* *Record one code* 01 02 03 04* 05	*If CTCAE Grade 04, did the event place the subject at immediate risk of death? 0 No ✓ 1 Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by investigational product? 0 No ✓ 1 Yes ✓	Action Taken for This Event *(record all that apply)* 01 No action taken 02 Investigational product dose altered 03 Medication taken 04 Hospitalized/Prolonged hospitalization 05 Removed from study 06 Investigational product discontinued 07 Transfusion performed 88 Other *Specify below	* Serious ? 0 No ✓ 1 Yes ✓
1																
2																
3																
4																
5																
6																
7																
8																

**** Criteria for Serious Adverse Event:**

Serious adverse event includes any event that (is):

- fatal
- life threatening (places subject at immediate risk of death)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability / incapacity
- a congenital anomaly / birth defect
- other significant medical hazard

If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day.

Line #	Specify if "88 Other" Action Taken

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

v2.0 30Jun04camb

For Amgen Use Only
Tick when data checked.

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

AMENDMENT 2.0

AE3

ADVERSE EVENTS SUMMARY

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

Line #	Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s) *List one per line*	*Check if event continued from previous AE form* ✓	Did event start before random-ization? 0 No 1 Yes ✓	Date Started Day	Month	Year	Date Ended, Changed in Severity or Resulted in Death Day	Month	Year	*Check if event continuing at End of Study* ✓	Intermittent ✓	Severity *(use CTCAE Grading Scale)* *Record one code* 01 02 03 04* 05	*If CTCAE Grade 04, did the event place the subject at immediate risk of death? 0 No ✓ 1 Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by investigational product? 0 No ✓ 1 Yes ✓	Action Taken for This Event *(record all that apply)* 01 No action taken 02 Investigational product dose altered 03 Medication taken 04 Hospitalized/Prolonged hospitalization 05 Removed from study 06 Investigational product discontinued 07 Transfusion performed 88 Other *Specify below	* Serious ? 0 No ✓ 1 Yes ✓
1																
2																
3																
4																
5																
6																
7																
8																

**** Criteria for Serious Adverse Event:**

Serious adverse event includes any event that (is):

- fatal
- life threatening (places subject at immediate risk of death)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability / incapacity
- a congenital anomaly / birth defect
- other significant medical hazard

If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day.

Line #	Specify if "88 Other" Action Taken

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

v2.0 30Jun04camb

For Amgen Use Only
Tick when data checked.

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

AMENDMENT 2.0

AE4

ADVERSE EVENTS SUMMARY

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

Line #	Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s) *List one per line*	*Check if event continued from previous AE form* ✓	Did event start before random-ization? 0 No 1 Yes ✓	Date Started Day / Month / Year	Date Ended, Changed in Severity or Resulted in Death Day / Month / Year	*Check if event continuing at End of Study* ✓	Intermittent ✓	Severity *(use CTCAE Grading Scale)* *Record one code* 01 02 03 04* 05	*If CTCAE Grade 04, did the event place the subject at immediate risk of death? 0 No 1 Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by investigational product? 0 No 1 Yes ✓	Action Taken for This Event *(record all that apply)* 01 No action taken 02 Investigational product dose altered 03 Medication taken 04 Hospitalized/Prolonged hospitalization 05 Removed from study 06 Investigational product discontinued 07 Transfusion performed 88 Other *Specify below	* Serious ? 0 No 1 Yes ✓
1												
2												
3												
4												
5												
6												
7												
8												

**** Criteria for Serious Adverse Event:**

Serious adverse event includes any event that (is):

- fatal
- life threatening (places subject at immediate risk of death)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability / incapacity
- a congenital anomaly / birth defect
- other significant medical hazard

If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day.

Line #	Specify if "88 Other" Action Taken

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

v2.0 30Jun04camb

For Amgen Use Only
Tick when data checked.

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

AMENDMENT 2.0

AE5

ADVERSE EVENTS SUMMARY

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

Line #	Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s) *List one per line*	*Check if event continued from previous AE form* ✓	Did event start before random-ization? 0 No 1 Yes ✓	Date Started Day	Month	Year	Date Ended, Changed in Severity or Resulted in Death Day	Month	Year	*Check if event continuing at End of Study* ✓	Intermittent ✓	Severity *(use CTCAE Grading Scale)* *Record one code* 01 02 03 04* 05	*If CTCAE Grade 04, did the event place the subject at immediate risk of death? 0 No ✓ 1 Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by investigational product? 0 No ✓ 1 Yes ✓	Action Taken for This Event *(record all that apply)* 01 No action taken 02 Investigational product dose altered 03 Medication taken 04 Hospitalized/Prolonged hospitalization 05 Removed from study 06 Investigational product discontinued 07 Transfusion performed 88 Other *Specify below	* Serious ? 0 No ✓ 1 Yes ✓
1																
2																
3																
4																
5																
6																
7																
8																

**** Criteria for Serious Adverse Event:**

Serious adverse event includes any event that (is):

- fatal
- life threatening (places subject at immediate risk of death)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability / incapacity
- a congenital anomaly / birth defect
- other significant medical hazard

If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day.

Line #	Specify if "88 Other" Action Taken

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

10.05

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Tick when data checked. ☐

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

AMENDMENT 2.0

RAT

RADIOTHERAPY

Has the subject had radiotherapy during the treatment phase? 0 ☐ No 1 ☐ Yes - If Yes, provide details below.

Body Site Code ①	Subsite *Describe specific location*	Date Course Started Day	Month	Year	Date Course Ended Day	Month	Year	Total Dose	Unit ①

① **LESION SITE CODES:**

00 Lymph nodes	**40** Chest	**60** Gastrointestinal	**86** Skin
10 Pulmonary	**50** Central nervous system	**70** Abdomen	**88** Other *(specify in subsite above)*
20 Liver	**55** Head	**75** Pelvic Site	
30 Bone	**56** Neck	**85** Spleen	

① **UNIT CODE:**

GY Gray
cGY centi-Gray

TRANSFUSIONS

Were there any transfusions from Screening to Safety Follow-Up? 0❑ No 1❑ Yes - If yes, specify below.

Date Day Month Year	**Type of Blood Product** ① **Code** *(enter one code)*	**Specify if "88 Other"**

① **BLOOD PRODUCT CODES:**

01	Platelets	**05**	White blood cells
02	Packed red blood cells	**07**	Peripheral Blood Progenitor Cells (PBPC)
03	Whole blood	**08**	Bone marrow
04	Fresh frozen plasma	**88**	Other *(specify above)*

For Amgen Use Only
Tick when data checked. ☐

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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? $_{0}$❑ No $_{1}$❑ Yes - If yes, specify below.

Date of Admission Day Month Year	**Date of Discharge** Day Month Year	*Check if not discharged at End of Study* ✓	**Primary Reason for Admission** *Enter primary reason code* **Reason Code** ①	 **Specify if "88 Other"**

① **REASON CODES:**
02 Adverse event **03** Procedure not specified in protocol **88** Other

For Amgen Use Only
Tick when data checked. ☐

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

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? $_0$❑ No $_1$❑ Yes - If Yes, provide details below.

Line #	Therapy	Start Date Day Month Year	Stop Date Day Month Year	*Check if continuing at End of Study* ✓
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				

For Amgen Use Only
Tick when data checked. ☐

END OF STUDY

END OF STUDY

Did subject complete the end of study? $_0$❑ No $_1$❑ Yes

Completing the end of study is defined as completing the Safety Follow-Up

Date Subject Ended Study		
Day	Month	Year

If subject did not complete end of study, enter PRIMARY reason for ending study:

Enter Code:

CODES:

02 Ineligibility determined ①
03 Protocol deviation ①
04 Noncompliance ①
05 Adverse event ① *(FAX this form to Amgen)*
06 Consent withdrawn ①
07 Disease progression ①
09 Administrative decision ①
10 Lost to follow-up ①
11 Death ②
(Enter cause of death on Adverse Events Summary CRF and FAX completed Serious Adverse Event form to Amgen within one working day.)
14 Pregnancy ① *(complete Pregnancy Notification Worksheet)*
88 Other ①

① *Record date of last on-study contact as* ***Date Subject Ended Study***
② *Record date of death as* ***Date Subject Ended Study***

If subject did not complete the end of study, provide any additional relevant information:

_____

_____

_____

For Amgen Use Only
Tick when data checked. ☐

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

For Amgen Use Only
Tick when data checked. ☐

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

GENERAL COMMENTS

GENERAL COMMENTS

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

Was there any additional information? 0❑ No 1❑ Yes - If yes, specify below.

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

For Amgen Use Only
Tick when data checked. ☐

GENERAL COMMENTS

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

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

For Amgen Use Only
Tick when data checked. ☐

GENERAL COMMENTS

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

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

For Amgen Use Only
Tick when data checked. ☐

GENERAL COMMENTS

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

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

For Amgen Use Only
Tick when data checked. ☐

GENERAL COMMENTS

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

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

For Amgen Use Only
Tick when data checked. ☐

LONG TERM FOLLOW-UP

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.

Long Term Follow-up Status

MONTH 3

Was Long Term Follow-up performed? $_{0}$❑ No $_{1}$❑ Yes - If yes, specify below

Date of Assessment		
Day	Month	Year

Subject Status ①	① SUBJECT STATUS CODES	Specify if Subject Status is "88 Other"
	01 Alive **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)*	

Tumor Response ②	Date of Disease Progression Day Month Year	Date of Death or Last Contact if Lost to Follow-Up Day Month Year

② **TUMOR RESPONSE CODES**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

Signature of Principal Investigator	Date Signed Day Month Year

For Amgen Use 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.

Long Term Follow-up Status

MONTH 6

Was Long Term Follow-up performed? 0❑ No 1❑ Yes - If yes, specify below

Date of Assessment		
Day	Month	Year

Subject Status ①	① SUBJECT STATUS CODES	Specify if Subject Status is "88 Other"
	01 Alive **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)*	

Tumor Response ②	Date of Disease Progression Day Month Year	Date of Death or Last Contact if Lost to Follow-Up Day Month Year

② **TUMOR RESPONSE CODES**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

Signature of Principal Investigator	Date Signed Day Month Year

For Amgen Use 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.

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

AMENDMENT 2.0

FUPM9

Long Term Follow-up Status

MONTH 9

Was Long Term Follow-up performed? $_{0}$❑ No $_{1}$❑ Yes - If yes, specify below

Date of Assessment		
Day	Month	Year

Subject Status ①	① SUBJECT STATUS CODES	Specify if Subject Status is "88 Other"
	01 Alive **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)*	

Tumor Response ②	Date of Disease Progression Day Month Year	Date of Death or Last Contact if Lost to Follow-Up Day Month Year

② **TUMOR RESPONSE CODES**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

Signature of Principal Investigator	Date Signed Day Month Year

For Amgen Use Only
Tick when data checked. ☐

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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.

Long Term Follow-up Status

MONTH 12

Was Long Term Follow-up performed? $_{0}$❑ No $_{1}$❑ Yes - If yes, specify below

Date of Assessment		
Day	Month	Year

Subject Status ①	① SUBJECT STATUS CODES	Specify if Subject Status is "88 Other"
	01 Alive **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)*	

Tumor Response ②	Date of Disease Progression Day Month Year	Date of Death or Last Contact if Lost to Follow-Up Day Month Year

② **TUMOR RESPONSE CODES**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

Signature of Principal Investigator	Date Signed Day Month Year

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Tick when data checked. ☐

EXTRA FORMS

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

AMENDMENT 2.0

SCR

Screening

DEMOGRAPHICS

Sex	Ethnic Group / Race *(enter one code)*			Date of Birth
	Code	*Specify if "***88 Other***"*	**ETHNIC GROUP / RACE CODES:**	Day Month Year
0 ❑ M 1 ❑ F			**01** White or Caucasian **02** Black or African American **03** Hispanic or Latino **04** Asian *(eg Chinese, Bangladeshi, Indian, Pakistani)* **05** Japanese **06** American Indian or Alaska Native **07** Native Hawaiian or Other Pacific Islander **08** Aborigine **88** Other	

INFORMED CONSENT

Date Informed Consent Signed Day Month Year	Protocol Amendment Number
	2

RANDOMIZATION

Date of Randomization Day Month Year	Randomization Number	Treatment group ①

① **TREATMENT GROUP CODES**
01 ABX-EGF plus Best Supportive Care
02 Best Supportive Care

ELIGIBILITY CRITERIA

Did subject meet all eligibility criteria?

1 ❑ Yes 0 ❑ No - If No, please specify criteria number(s) from ***Eligibility Worksheet***:

Enter "999" *if subject met Eligibility Criteria but did not enroll.*

___ ___ ___ Comments:_____

_____

___ ___ ___ Comments:_____

_____

___ ___ ___ Comments:_____

_____

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Tick when data checked. ☐

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Screening

MEDICAL & SURGICAL HISTORY

(continued)

02 Cardiovascular
03 Respiratory
04 Gastrointestinal
05 Hepatic / Biliary
07 Renal
08 Endocrine / Metabolic
09 Musculoskeletal
10 Hematologic / Lymphatic
11 Neurologic / Psychiatric
88 Other

Code *(as listed above)*	**Diagnosis** List one entry per line	1 ↙ **Continuing**	2 ↙ **Resolved**

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Tick when data checked. ☐

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Tick when data checked.

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

AMENDMENT 2.0

SCR

PRIOR CHEMOTHERAPY - First Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day	Month	Year	Date Last Administered Day	Month	Year	Name of Hospital
1											
2											
3											
4											
5											
6											
7											
8											
9											

① **FREQUENCY CODES:**
CI Continuous infusion
Q2WK Every 2 weeks
Q12H Every 12 hours
Q4WK Every 4 weeks
Q3WK Every 3 weeks
QMO Once a month
QD Once a day
OT Other *(specify below)*

② **DOSE STATUS CODES:**
01 Full intended dose
02 Dose reduction due to toxicity
03 Missed dose *(specify below)*
88 Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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

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Tick when data checked.

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

AMENDMENT 2.0

SCR

PRIOR CHEMOTHERAPY - Second Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day	Date First Administered Month	Date First Administered Year	Date Last Administered Day	Date Last Administered Month	Date Last Administered Year	Name of Hospital
1											
2											
3											
4											
5											
6											
7											
8											
9											

① **FREQUENCY CODES:**

CI	Continuous infusion	**Q12H**	Every 12 hours	**Q3WK**	Every 3 weeks	**QD**	Once a day
Q2WK	Every 2 weeks	**Q4WK**	Every 4 weeks	**QMO**	Once a month	**OT**	Other *(specify below)*

② **DOSE STATUS CODES:**

01	Full intended dose	**03**	Missed dose *(specify below)*
02	Dose reduction due to toxicity	**88**	Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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

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Tick when data checked.

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

AMENDMENT 2.0

SCR

PRIOR CHEMOTHERAPY - Third Line of Treatment

Please record prior chemotherapy for metastatic cancer

Regimen Name:

Line #	Agent Name	Dose *(mg/m²)*	Freq ①	Dose Status ②	Date First Administered Day	Date First Administered Month	Date First Administered Year	Date Last Administered Day	Date Last Administered Month	Date Last Administered Year	Name of Hospital
1											
2											
3											
4											
5											
6											
7											
8											
9											

① **FREQUENCY CODES:**
CI Continuous infusion
Q2WK Every 2 weeks
Q12H Every 12 hours
Q4WK Every 4 weeks
Q3WK Every 3 weeks
QMO Once a month
QD Once a day
OT Other *(specify below)*

② **DOSE STATUS CODES:**
01 Full intended dose
02 Dose reduction due to toxicity
03 Missed dose *(specify below)*
88 Other *(specify below)*

Line #	Specify **Reason for Chemotherapy Dose Change "03 Missed Dose"**	Line #	Specify **Reason for Chemotherapy Dose Change "88 Other"**	Line #	Specify **Frequency "OT Other"**	Line #	Specify **Frequency "OT Other"**

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

0.06_

Screening

PRIOR ADJUVANT CHEMOTHERAPY

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

PRIOR ANTI-TUMOR THERAPY

Line #	Line of Treatment ①	Drug Name	Date First Administered Day Month Year	Date Last Administered Day Month Year
1				
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

For Amgen Use Only
Tick when data checked. ☐

Screening

PRIOR ADJUVANT CHEMOTHERAPY

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

PRIOR ANTI-TUMOR THERAPY

Line #	Line of Treatment ①	Drug Name	Date First Administered Day Month Year	Date Last Administered Day Month Year
1				
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

For Amgen Use Only
Tick when data checked. ☐

Week ____

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				____ ____ ____
02				____ ____ ____
03				____ ____ ____
04				____ ____ ____
05				____ ____ ____
06				____ ____ ____
07				____ ____ ____
08				____ ____ ____
09				____ ____ ____
10				____ ____ ____
			Sum of Target Lesions	____ ____ ____

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

For Amgen Use Only
Tick when data checked. ☐

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Week ____

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						____ ____ ____
12						____ ____ ____
13						____ ____ ____
14						____ ____ ____
15						____ ____ ____
16						____ ____ ____
					Sum of Non-Target Lesions	____ ____ ____

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

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

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

ADTAX

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 **Yes** ✓ *Enter corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

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

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)* ①	**Specify if Skin Toxicity is "01 Nail Changes"**	① **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)* ②	**Specify if Type of Skin Lesion is "88 Other"**	② **TYPE OF SKIN LESION CODES:** **00** None **07** Dry flaking **01** Pustular **08** Desquamation (sloughing) **02** Vesicular **09** Comedones **04** Macular **10** Cysts **05** Papular **88** Other *(specify)*

Total % BSA Affected ③	③ **TOTAL % BSA CODES:** **04** > 50% BSA **05** ≤ 50% BSA	Location ④ *(list all that apply)*	**Specify if Location is "88 Other"**	④ **LOCATION CODES:** **09** Face **10** Trunk **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. Was crusting present? $_{0}$❑ No $_{1}$❑ Yes

3. Since the last assessment, did the rash cause pain? $_{0}$❑ No $_{1}$❑ Yes

4. Since the last assessment, did the rash cause itching? $_{0}$❑ No $_{1}$❑ Yes

5. Since the last assessment, did the rash require treatment with narcotics? $_{0}$❑ No $_{1}$❑ Yes
(Record on Concomitant Medications CRF)

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?

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

Date		
Day	Month	Year

For Amgen Use Only
Tick when data checked. ☐

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

AMENDMENT 2.0

ADTAX

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 **Yes** ✓ *Enter corresponding 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 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 Perception ②

① **PHOTO-BASED CODING SCALE CODES:**

A **B** **C** **D**

② **SUBJECT PERCEPTION CODES:**

01 Not at all **03** Moderate **05** Intolerable

02 A little **04** Very much

For Amgen Use Only
Tick when data checked. ☐

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

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
Tick when data checked. ☐

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

OVERALL DISEASE RESPONSE

Tumor response to be determined using Modified RECIST criteria

Study Week	Date Day	Month	Year	Tumor Response Code ①

① **TUMOR RESPONSE CODE:**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

For Amgen Use Only
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DISTRIBUTION: *White & Yellow* - Amgen; *Blue* - CRA*; White Card* - Investigator

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

AMENDMENT 2.0 *PRX*

Week ____

PROCEDURES

CYTOLOGY

Was any cytology performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ①	Malignant Cell? 0No✓ 1Yes✓	Body Site ④	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:_____

_____

SURGICAL

Were any surgical procedures performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ②	Body Site Code ④	Specify if Body Site is "88 Other"	② PROCEDURE CODE:
	3 2			**32** Surgical

Findings:_____

_____

BIOPSY

Was biopsy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure Code ③	Body Site Code ④	Specify if Body Site is "88 Other"	③ PROCEDURE CODE:
	1 6			**16** Biopsy

Findings:_____

_____

ENDOSCOPY

Was endoscopy performed? 0❑ No 1❑ Yes - If yes, specify below.

Date of Procedure (Day / Month / Year)	Procedure ⑤	Body Site ④	Specify if Procedure Code is "88 Other"	Specify if Body Site is "88 Other"	⑤ PROCEDURE CODE:
					33 Colonoscopy 34 Sigmoidoscopy 88 Other *(Specify)*

Findings:_____

_____

④ **BODY SITE CODES:**

01 Abdomen	**05** Chest	**09** Heart	**13** Pleura	**17** Total body	**88** Other *(Specify above)*
02 Brain	**06** Eye	**10** Kidney	**14** Pelvic site	**18** Thorax	
03 Breast	**07** Gastrointestinal tract	**11** Liver	**15** Retroperitoneum	**19** Extremity(ies)	
04 Bone	**08** Head	**12** Lung	**16** Skin	**23** Neck	

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Tick when data checked. ☐

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

Long Term Follow-up Status

MONTH ☐

Was Long Term Follow-up performed? 0❑ No 1❑ Yes - If yes, specify below

Date of Assessment		
Day	Month	Year

Subject Status ①	① SUBJECT STATUS CODES	Specify if Subject Status is "88 Other"
	01 Alive **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)*	

Tumor Response ②	Date of Disease Progression			Date of Death or Last Contact if Lost to Follow-Up		
	Day	Month	Year	Day	Month	Year

② **TUMOR RESPONSE CODES**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

Signature of Principal Investigator	Date Signed		
	Day	Month	Year

For Amgen Use 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.

Long Term Follow-up Status

MONTH ☐

Was Long Term Follow-up performed? 0❑ No 1❑ Yes - If yes, specify below

Date of Assessment		
Day	Month	Year

Subject Status ①	① SUBJECT STATUS CODES	Specify if Subject Status is "88 Other"
	01 Alive **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)*	

Tumor Response ②	Date of Disease Progression			Date of Death or Last Contact if Lost to Follow-Up		
	Day	Month	Year	Day	Month	Year

② **TUMOR RESPONSE CODES**

CR	Complete Response	**SD**	Stable Disease
PD	Progressive Disease	**UE**	Unable to evaluate
PR	Partial Response		

Signature of Principal Investigator	Date Signed		
	Day	Month	Year

For Amgen Use 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.

EXTRA PADS OF PAGES

For Amgen Use Only
Tick when data checked. ☐

A **ABX-EGF 20020408**	Site No.	Subject ID No. 11	Subject Initials

AMENDMENT 2.0

CMX

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.

Line #	Medication *Record one per line*	✓ Prophylaxis	Indication	Dose	Unit ①	Route ②	Freq. ③	Date FIRST Taken Day Month Year	Date LAST Taken Day Month Year	*Check if medication continuing at End of Study* ✓
1										
2										
3										
4										
5										
6										
7										

① UNIT CODES:

AMP	Ampule	**MEQ**	Milliequivalent
CAP	Capsule	**MG**	Milligram
CC	Cubic centimeter	**ML**	Milliliter (cc)
GM	Gram	**TAB**	Tablet
GR	Grain	**TBS**	Tablespoon
GTT	Drop	**TSP**	Teaspoon
IU	International unit	**U**	Unit
MCG	Microgram	**OT**	Other **Specify below*

② ROUTE CODES:

DL	Intraduodenal	**IT**	Intrathecal	**SC**	Subcutaneous
ET	Endotracheal tube	**IV**	Intravenous	**SL**	Sublingual
GT	Gastrostomy	**JI**	Joint injection	**TD**	Transdermal
IA	Intra-arterial	**NG**	Nasogastric tube	**TP**	Topical
ID	Intradermal	**OP**	Ophthalmic	**OT**	Other**Specify below*
IH	Inhaled	**PO**	Oral		
IM	Intramuscular	**PR**	Rectal		
IP	Intraperitoneal	**PV**	Vaginal		

③ FREQUENCY CODES:

BID	Twice a day	**Q2WK**	Every 2 weeks	**QIW**	4 times a week
BIW	Twice a week	**Q3WK**	Every 3 weeks	**QMO**	Once a month
CI	Continuous infusion	**Q4WK**	Every 4 weeks	**QOD**	Every other day
HS	At bedtime	**Q4H**	Every 4 hours	**QWK**	Every week
OTO	One time only	**Q6H**	Every 6 hours	**STAT**	Immediately
PRN	As needed	**Q8H**	Every 8 hours	**TID**	3 times a day
QH	Every hour	**QD**	Once a day	**TIW**	3 times a week
Q12H	Every 12 hours	**QID**	4 times a day	**OT**	Other**Specify below*

Line #	Specify **UNIT** "OT Other"	Line #	Specify **ROUTE** "OT Other"	Line #	Specify **FREQUENCY** "OT Other"

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

AMENDMENT 2.0

AEX

ADVERSE EVENTS SUMMARY

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

Line #	**Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s)** *List one per line*	*Check if event continued from previous AE form* ✓	Did event start before random-ization ? 0 **No** ✓ 1 **Yes** ✓	**Date Started** Day Month Year	**Date Ended, Changed in Severity or Resulted in Death** Day Month Year	*Check if event continuing at End of Study* ✓	**Intermittent** ✓	Severity *(use CTCAE Grading Scale)* *Record one code* **01 02 03 04* 05**	*If CTCAE Grade 04, did the event place the subject at immediate risk of death? 0 **No** ✓ 1 **Yes** ✓	Relationship Is there a reasonable possibility that the event may have been caused by investigational product? 0 **No** ✓ 1 **Yes** ✓	**Action Taken for This Event** *(record all that apply)* 01 No action taken 02 Investigational product dose altered 03 Medication taken 04 Hospitalized/Prolonged hospitalization 05 Removed from study 06 Investigational product discontinued 07 Transfusion performed 88 Other **Specify below*	* Serious ? 0 No ✓ 1 Yes ✓
1												
2												
3												
4												
5												
6												
7												
8												

**** Criteria for Serious Adverse Event:**

Serious adverse event includes any event that (is):

- fatal
- life threatening (places subject at immediate risk of death)
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability / incapacity
- a congenital anomaly / birth defect
- other significant medical hazard

If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day.

Line #	Specify if "88 Other" Action Taken

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

10.0_

GENERAL COMMENTS

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

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

Date Information Relates To Day Month Year	**Refers to CRF page no.(s)**

Details: _____

_____

_____

_____

For Amgen Use Only
Tick when data checked. ☐

Week ____

TUMOR EVALUATION - TARGET LESIONS

Date of Procedure		
Day	Month	Year

Lesion Note: Always maintain the same order of lesion numbers	**Lesion Site Code** ①	**Subsite** *Describe specific location*	**Method of Assessment** ②	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable* **Dimensions** *(mm)*
01				____ ____ ____
02				____ ____ ____
03				____ ____ ____
04				____ ____ ____
05				____ ____ ____
06				____ ____ ____
07				____ ____ ____
08				____ ____ ____
09				____ ____ ____
10				____ ____ ____
			Sum of Target Lesions	____ ____ ____

① LESION SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver			**75**	Pelvic Site		
30	Bone	**55**	Head	**85**	Spleen		
		56	Neck				

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 Assessment

For Amgen Use Only
Tick when data checked. ☐

Week ___

TUMOR EVALUATION - NON-TARGET LESIONS

Please record all other lesions and sites of disease.

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day Month Year	Body Site Code ①	Subsite *Describe specific location*	Method of Assessment ②	New Lesions 0 No ✓ 1 Yes ✓	**Measurable Lesions** *(mm)* *Must be unidimensionally measurable.* **Dimensions** *(mm)*
11						___ ___ ___
12						___ ___ ___
13						___ ___ ___
14						___ ___ ___
15						___ ___ ___
16						___ ___ ___
					Sum of Non-Target Lesions	___ ___ ___

① BODY SITE CODES:

00	Lymph nodes	**40**	Chest	**60**	Gastrointestinal	**86**	Skin
10	Pulmonary	**50**	Central nervous system	**70**	Abdomen	**88**	Other *(specify in subsite above)*
20	Liver	**55**	Head	**75**	Pelvic Site		
30	Bone	**56**	Neck	**85**	Spleen		

② METHOD OF ASSESSMENT CODES:

01	X-Ray	**04**	Magnetic Resonance Imaging (MRI)
03	Conventional Computed Tomography (CT)	**23**	Spiral Computed Tomography (CT)
		88	Other *(specify below)*

Line #	Specify if "88 Other" Method of Assessment

For Amgen Use Only
Tick when data checked. ☐

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

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 *(Indicate all that apply)* ①	**Specify if "88 Other"**

① **CRITERIA CODES:**

01 Lack of radiographic progression
02 Last chemotherapy failure > 6 months
03 Subject did not receive or fail protocol defined pre-study chemotherapy regimen
88 Other *(Specify above)*

Signature of Independent Eligibility Review Committee Chairperson	**Date Signed** Day / Month / Year

For Amgen Use Only
Tick when data checked. ☐