Panitumumab AMG 954 20050203

DISTRIBUTION	DRAFT DATES
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CRF DEVELOPMENT MODEL

PRINTING

No. of Screening Packets:

No. of Casebooks:

No. of each extra form:

Casebook special instructions:

No. of QoLs: Assist

No. of booklets per binder:

QoL special instructions:

Number of subjects: 900

Number of sites: 200

Enrollment date:

CRO study?

Sponsor	Protocol Number
AMGEN Amgen Development Europe 240 Cambridge Science Park Cambridge, England CB4 0WD +44(0) 1223-420-305	**Panitumumab** **AMG 954 20050203**

CASE REPORT FORMS

PROTOCOL

A Randomized, Multicenter, Phase 3 Study to Compare the Efficacy of Panitumumab in Combination with Oxaliplatin/ 5-fluorouracil/ leucovorin to the Efficacy of Oxaliplatin/ 5-fluorouracil/ leucovorin Alone in Patients with Previously Untreated 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 4

6. **DO NOT RECORD SUBJECT INITIALS ON CRF**
7. Add comments to the General Comments CRF or "Specify" fields only

SUBJECT ELIGIBILITY CRITERIA WORKSHEET

All exceptions to eligibility criteria must be approved by Amgen prior to enrollment.

Inclusion Criteria

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

Code no.		Yes	No
101	Histologically or cytologically-confirmed adenocarcinoma of the colon or rectum in subjects who are presenting with metastatic disease	❑	❑
102	At least 1 uni-dimensionally measurable lesion of at least 20mm per modified RECIST guidelines (all sites of disease must be evaluated ≤ 28 days prior to randomization)	❑	❑
103	Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2	❑	❑
104	Paraffin-embedded tumor tissue from the primary tumor or metastasis available for central analyses of EGFr and biomarker testing	❑	❑
105	Man or woman ≥ 18 years of age	❑	❑

Hematologic function, as follows (≤ 7 days prior to randomization):

106	Absolute neutrophil count (ANC) ≥1.5 x 10^9/L	❑	❑
107	Platelet count ≥100 x 10^9/L	❑	❑
108	Hemoglobin ≥ 9 g/dL	❑	❑

Renal function, as follows (≤ 7 days prior to randomization):

109	Creatinine clearance, estimated with Cockcroft-Gault* ≥ 50ml/min	❑	❑

*Cockcroft-Gault:

$$\text{CrCl, estimated [ml/min]} = \left\{ \frac{(140 - \text{age[years]}) \times (\text{Lean body mass [kg]})}{(\text{Serum Creatinine [mg/dL]} \times 72)} \right\} \times 0.85 \text{ [for women]}$$

Hepatic function, as follows (≤ 7 days of randomization):

110	Aspartate aminotransferase (AST) ≤ 3 x ULN (if liver metastases ≤ 5 x ULN)	❑	❑
111	Alanine aminotransferase (ALT) ≤ 3 x ULN (if liver metastases ≤ 5 x ULN)	❑	❑
112	Total bilirubin ≤ 1.5 x ULN	❑	❑

SUBJECT ELIGIBILITY CRITERIA WORKSHEET

All exceptions to eligibility criteria must be approved by Amgen prior to enrollment.

Inclusion Criteria

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

Code no.		Yes	No
	Metabolic function, as follows (≤ 7 days prior to randomization):		
113	Magnesium ≥ lower limit of normal	❑	❑
114	Negative pregnancy test ≤ 72 hours prior to randomization (females of childbearing potential only)	❑	❑
115	Competent to comprehend, sign, and date an IEC/IRB-approved informed consent form	❑	❑
116	Life expectancy ≥ 3 months	❑	❑

SUBJECT ELIGIBILITY CRITERIA WORKSHEET

All exceptions to eligibility criteria must be approved by Amgen prior to enrollment.

Exclusion Criteria

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

Code no.		Yes	No
201	History or known presence of central nervous system (CNS) metastases	❑	❑
202	History of another primary cancer, except: Curatively treated in situ cervical cancer, or Curatively resected non-melanomal skin cancer, or Other primary solid tumor curatively treated with no known active disease present and no treatment administered for ≥ 5 years prior to randomization	❑	❑
203	Prior chemotherapy or systemic therapy for the treatment of metastatic colorectal carcinoma with the following exclusions: Subject may have received adjuvant fluropyrimidine-based chemotherapy if disease progression is documented at least 6 months after completion of chemotherapy, Subjects may have received prior fluropyrimidine therapy if administered solely for the purpose of radiosensitization	❑	❑
204	Prior oxaliplatin therapy	❑	❑
205	Prior anti-EGFr antibody therapy (eg, cetuximab) or treatment with small molecule EGFr inhibitors (eg, erlotinib)	❑	❑
206	Any investigational agent or therapy ≤ 30 days prior to randomization	❑	❑
207	Radiotherapy ≤ 14 days prior to randomization (subjects must have recovered from all radiotherapy related toxicities)	❑	❑
208	Known allergy or hypersensitivity to platinum-coating medications, 5-FU or leucovorin	❑	❑
209	Active infection requiring systemic treatment or any uncontrolled infection ≤ 14 days prior to randomization..	❑	❑
210	Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, cardiac arrhythmia) ≤ 1 year prior to randomization	❑	❑
211	History of interstitial lung disease (eg, pneumonitis or pulmonary fibrosis) or evidence of interstitial lung disease on baseline chest CT scan	❑	❑
212	Active inflammatory bowel disease or other bowel disease causing chronic diarrhea (defined as ≥ CTC grade 2, [CTCAE version 3.0])	❑	❑
213	Known positive tests for human immunodeficiency virus (HIV) infection, hepatitis C virus, acute or chronic active hepatitis B infection	❑	❑
214	Any co-morbid disease or condition that could increase the risk of toxicity, eg, dihydropyrimidine deficiency, significant ascites or pleural effusion	❑	❑

SUBJECT ELIGIBILITY CRITERIA WORKSHEET

All exceptions to eligibility criteria must be approved by Amgen prior to enrollment.

Exclusion Criteria

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

Code no.		Yes	No
215	Peripheral sensory neuropathy with functional impairment (≥ CTC grade 2 [CTCAE version 3.0] neuropathy, regardless of causality)	❑	❑
216	Any uncontrolled concurrent illness or history of any medical condition that may interfere with the interpretation of the study results	❑	❑
217	Major surgical procedure (requiring general anesthesia) ≤ 28 days or minor surgical procedure (excluding central venous catheter placement) ≤ 14 days prior to randomization. Subjects must have recovered from surgery related toxicities	❑	❑
218	Subject who is pregnant or breast feeding	❑	❑
219	Woman or man of childbearing potential not consenting to use adequate contraceptive precautions ie. double barrier contraceptive methods (eg diaphragm plus condom), or abstinence during the course of the study and for 6 months after the last study drug administration for women, and 1 month for men	❑	❑
220	Subject unwilling or unable to comply with study requirements	❑	❑
221	Previously randomized into this study protocol	❑	❑

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Equivalent Lab Units

Unit	Equivalents*												
10^{12}/L	T/L	10^6/uL	10^6/mm^3	10^6/cumm	10^6/cmm	10^6/mcl	Mill/uL	Mill/mm^3	Mill/cumm	Mill/cmm	Mill/mcl	/pL	
	N.B. Mill = Million, Mil, Mio												
10^9/L	G/L	GI/L	10^3/uL	10^3/mm^3	10^3/cumm	10^3/cmm	10^3/mcl	Thous/uL	Thous/mm^3	Thous/cumm	Thous/cmm	Thous/mcl	/nL
	N.B. Thous = Thousand, Thou, Tsnd, Ths, Th, K, k												
10^6/L	/uL	/mm^3	/cumm	/cmm	/mcl								
fL	um^3	U^3											
Fraction of 1	L/L	Ratio											
g/dL	gm/dL	Gms/dl	GM/DL										
g/L	gm/L	gms/L	GM/L										
mmol/L	mEq/L												
U/L	ukat/L	Units/L	UI/L	IU/L	MU/mL	MiU/mL	MIU/ml						

* This table lists the most common units and is not an exhaustive list of equivalent units.

SCREENING

Screening

DEMOGRAPHICS

Sex	Ethnic Group / Race *(enter one code)*				Date of Birth
	Code	Specify if "**88 Other**"			Day Month Year
0 ❑ M 1 ❑ F			**01** White or Caucasian **02** Black or African American **03** Hispanic or Latino **04** Asian *(e.g. 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

Was a separate Informed Consent signed for pharmacogenetics sample collection?

0 ❑ No 1 ❑ Yes

Date Pharmacogenetics Informed Consent Signed		
Day	Month	Year

RANDOMIZATION

Date of Randomization			Randomization Number	Treatment Arm ①	① **TREATMENT ARM CODES:**
Day	Month	Year			**01** Panitumumab + FOLFOX **02** FOLFOX alone

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:_____

_____

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

SCR

Screening
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		

HISTOLOGICAL TYPE FOR PRIMARY TUMOR

Histological type MUST correspond to the Primary Tumor Diagnosis

Histological Type ①	Differen-tiation ②	Histological Sub-Type ③	Specify if Histological Sub-Type is "***88 Other"***
1 8			

① HISTOLOGICAL TYPE CODES:
- **18** Adenocarcinoma

② DIFFERENTIATION CODES:
- **01** Well differentiated
- **02** Moderately differentiated
- **03** Poorly differentiated
- **04** Undifferentiated
- **99** Unknown

③ HISTOLOGICAL SUB-TYPE CODES:
- **00** No sub-type
- **01** Mucinous
- **02** Appendiceal
- **88** Other sub-type *(specify above)*
- **99** Unknown

MEDICAL & SURGICAL HISTORY

If the subject had prior surgery for colorectal cancer please record this on the 'Prior Surgery for Colorectal Cancer' CRF.

Does the subject have a known history of an abnormality, disease or surgery relating to any of the following systems?

0 ❑ No 1 ❑ Yes - If yes, list specific diagnosis or procedure below.

- **01** Special senses *(vision, hearing, olfaction and taste)*
- **02** Cardiovascular
- **03** Respiratory
- **04** Gastrointestinal
- **05** Hepatic / Biliary
- **06** Genitourinary / Reproductive
- **07** Renal
- **08** Endocrine / Metabolic
- **09** Musculoskeletal
- **10** Hematologic / Lymphatic
- **12** Dermatologic
- **13** Immunologic
- **50** Neurologic
- **51** Psychiatric
- **88** Other

Code *(as listed above)*	Diagnosis or Procedure *List one entry per line.*	Approximate Month and Year of Diagnosis or Procedure, if available Month Year	1 Continuing ✓	2 Resolved ✓

AMGEN Panitumumab
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Site No.

Subject ID No. 2 1

SCR

Screening

PRIOR SURGERY FOR COLORECTAL CANCER

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

Line #	Procedure Code ①	Site Code(s) ②	Description of Surgery	Intent Code ③	Date Day	Date Month	Date Year
1							
2							
3							
4							
5							
6							
7							
8							

① **PROCEDURE CODES:**
- **01** Biopsy
- **02** Resection
- **88** Other *(Specify below)*

② **BODY SITE CODES:**
- **00** Lymph node
- **01** Thyroid
- **02** Oral cavity
- **03** Pharynx
- **08** Pelvis
- **09** Breast
- **10** Pleural effusion
- **13** Lung parenchyma
- **17** Pleura or pleural wall
- **20** Liver
- **30** Bone
- **40** Chest wall
- **49** Pericardial effusion
- **50** Spinal cord
- **51** Brain
- **61** Esophagus
- **62** Stomach
- **63** Pancreas
- **64** Small intestine
- **65** Colon
- **66** Rectum
- **69** Anus
- **70** Ascites
- **73** Retroperitoneum
- **74** Peritoneum
- **79** Gall bladder
- **81** Kidney
- **82** Heart
- **84** Adrenal gland
- **85** Spleen
- **86** Skin
- **88** Other *(specify below)*

③ **INTENT CODES:**
- **01** Curative
- **05** Palliative
- **10** Diagnostic/Staging
- **99** Unknown
- **88** Other *(specify below)*

Line #	Specify **PROCEDURE** if "**88** Other"	Line #	Specify **SITE** if "**88** Other"	Line #	Specify **INTENT** if "**88** Other"

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SCR

Screening

PRIOR THERAPY FOR NON-METASTATIC COLORECTAL CANCER

Was any prior therapy given for non-metastatic colorectal cancer? 0 ❑ No 1 ❑ Yes - If yes, specify below.*

Item #	Drug	Type of Therapy ①	Treat-ment Setting ②	Date of First Dose of Therapy (Day / Month / Year)	Date of Last Dose of Therapy (Day / Month / Year)	Date of Disease Progression/ Recurrence (Day / Month / Year)
1						
2						
3						
4						
5						

Item #	Specify if **TYPE OF THERAPY** is "88 Other"	Item #	Specify if **TREATMENT SETTING** is "88 Other"

① TYPE OF THERAPY CODES:

- **01** Chemotherapy
- **05** Immunotherapy
- **13** Hormonal
- **14** Targeted biologics
- **15** Targeted small molecules
- **17** Chemoembolization
- **88** Other *(Specify above)*

② TREATMENT SETTING CODES:

- **06** Adjuvant
- **07** Neo-adjuvant
- **88** Other *(Specify above)*

**** If subject had more than one line of therapy for non-metastatic cancer, please record second line on next page.***

AMGEN Panitumumab
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Site No.

Subject ID No. 2 1

SCR

Screening

PRIOR THERAPY FOR NON-METASTATIC COLORECTAL CANCER

Item #	Drug	Type of Therapy ①	Treat-ment Setting ②	Date of First Dose of Therapy Day Month Year	Date of Last Dose of Therapy Day Month Year	Date of Disease Progression/ Recurrence Day Month Year
1						
2						
3						
4						
5						

Item #	Specify if **TYPE OF THERAPY** is "88 Other"	Item #	Specify if **TREATMENT SETTING** is "88 Other"

① TYPE OF THERAPY CODES:

- **01** Chemotherapy
- **05** Immunotherapy
- **13** Hormonal
- **14** Targeted biologics
- **15** Targeted small molecules
- **17** Chemoembolization
- **88** Other *(Specify above)*

② TREATMENT SETTING CODES:

- **06** Adjuvant
- **07** Neo-adjuvant
- **88** Other *(Specify above)*

If subject had more than two lines of therapy for non-metastatic cancer, please record on the extra page at the back of the CRF.

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

SCR

Screening

PRIOR RADIOTHERAPY FOR COLORECTAL CANCER

Was any prior radiotherapy for colorectal cancer used? 0❑ No 1❑ Yes - If yes, specify below.

Line #	Body Site Code *Record one per line* ②	Area	Intent of Therapy ③	Start Date Day	Start Date Month	Start Date Year	Stop Date Day	Stop Date Month	Stop Date Year	Did documented progression subsequently occur in this area? 0No ✓ 1Yes ✓
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

Line #	Specify **BODY SITE** if "88 Other"	Line #	Specify **INTENT OF RADIOTHERAPY** if "88 Other"

OTHER REGIONAL THERAPIES FOR COLORECTAL CANCER

Were any other regional therapies for colorectal cancer used? 0❑ No 1❑ Yes - If yes, specify below.

Line #	Regional Therapy ①	Body Site Code *Record one per line* ②	Area	Intent of Therapy ③	Start Date Day	Start Date Month	Start Date Year	Stop Date Day	Stop Date Month	Stop Date Year	Did documented progression subsequently occur in this area? 0No ✓ 1Yes ✓
1											
2											
3											

Line #	Specify **REGIONAL THERAPY** if "88 Other"	Line #	Specify **BODY SITE** if "88 Other"	Line #	Specify **INTENT OF OTHER REGIONAL THERAPY** if "88 Other"

① REGIONAL THERAPY CODES:

- **03** Radiofrequency ablation
- **04** Cryotherapy
- **05** Chemoembolization
- **88** Other *(specify above)*

③ INTENT OF THERAPY CODES:

- **01** Curative
- **05** Palliative
- **88** Other *(specify above)*
- **99** Unknown

② BODY SITE CODES:

- **00** Lymph node
- **01** Thyroid
- **02** Oral cavity
- **03** Pharynx
- **08** Pelvis
- **09** Breast
- **10** Pleural effusion
- **13** Lung parenchyma
- **17** Pleura or pleural wall
- **20** Liver
- **30** Bone
- **40** Chest wall
- **49** Pericardial effusion
- **50** Spinal cord
- **51** Brain
- **61** Esophagus
- **62** Stomach
- **63** Pancreas
- **64** Small intestine
- **65** Colon
- **66** Rectum
- **69** Anus
- **70** Ascites
- **73** Retroperitoneum
- **74** Peritoneum
- **79** Gall bladder
- **81** Kidney
- **82** Heart
- **84** Adrenal gland
- **85** Spleen
- **86** Skin
- **88** Other *(specify above)*

Screening

VITAL SIGNS

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

ECOG PERFORMANCE STATUS

Date (Day / Month / Year)	Performance Status ☑ ECOG ❑ KPS

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.

ELECTROCARDIOGRAM

Date Performed (Day / Month / Year)	Procedure Code ①	Body Site Code ②
	1 3	0 9

① **PROCEDURE CODE:**
13 Electrocardiogram (ECG)

② **BODY SITE CODE:**
09 Heart

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 *(required if abnormal)*: _____

_____

_____

_____

Screening

PHYSICAL EXAMINATION

Date of Examination			Height	Weight
Day	Month	Year	1 ❑ cm 2 ❑ in	1 ❑ kg 2 ❑ lb

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

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Screening

HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
RBC		1 ❑ /uL 2 ❑ $10^6/mm^3$ 3 ❑ $10^{12}/L$ 88 ❑ Other	
Hemoglobin		4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit		15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV		8 ❑ fL 88 ❑ Other	
Platelets		1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
WBC		1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
DIFFERENTIAL* Neutrophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
DIFFERENTIAL* Lymphocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
DIFFERENTIAL* Monocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
DIFFERENTIAL* Eosinophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
DIFFERENTIAL* Basophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
DIFFERENTIAL* Granulocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

CHEMISTRY

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

Screening

PREGNANCY TEST

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

Was pregnancy test performed? 0❑ No 1❑ Yes. If Yes, specify below

Date of Sample	
Day / Month / Year	
Specimen Type	9❑ Serum 10❑ Urine
Result	0❑ Negative 1❑ Positive

CEA

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn			
Day / Month / Year			
Test	**Result**	**Unit**	**Specify if Other Unit**
Serum Carcinoembryonic antigen		19❑ ng/mL 20❑ ug/L 88❑ Other	

SITE OF BIOPSY FOR EGFr EVALUATION

Site of Biopsy ①	**If '02-Metastatic' indicate Body Site** ②	Specify **BODY SITE** if "88-Other"

① **SITE OF BIOPSY CODE:**
- **01** Primary
- **02** Metastatic

② **BODY SITE CODES:**

00	Lymph node	**40**	Chest wall	**70**	Ascites
01	Thyroid	**49**	Pericardial effusion	**73**	Retroperitoneum
02	Oral cavity	**50**	Spinal cord	**74**	Peritoneum
03	Pharynx	**51**	Brain	**79**	Gall bladder
08	Pelvis	**61**	Esophagus	**81**	Kidney
09	Breast	**62**	Stomach	**82**	Heart
10	Pleural effusion	**63**	Pancreas	**84**	Adrenal gland
13	Lung parenchyma	**64**	Small intestine	**85**	Spleen
17	Pleura or pleural wall	**65**	Colon	**86**	Skin
20	Liver	**66**	Rectum	**88**	Other *(specify above)*
30	Bone	**69**	Anus		

Screening

BENIGN ABNORMALITIES

Does the subject have any benign conditions that may radiographically mimic metastatic disease? 0 ❑ No 1 ❑ Yes - If yes, specify below.

Line #	Condition ①	Lesion Site Code ②	Subsite	Details
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				

Line #	Specify **CONDITION** if "88 Other"	Line #	Specify **CONDITION** if "88 Other"

① **CONDITION CODES:**

- **01** Benign lung lesions
- **02** Benign mediastinal and hilar masses/nodules
- **03** Benign liver lesions
- **04** Benign bone lesions
- **05** Benign retroperitoneal abnormalities
- **06** Benign GYN lesions
- **07** Benign renal lesions
- **08** Post-traumatic hematomas
- **09** Post-surgical, post procedural or post inflammatory fibrosis or scarring
- **88** Other *(specify above)*

② **LESION SITE CODES:**

- **00** Lymph node
- **01** Thyroid
- **02** Oral cavity
- **03** Pharynx
- **08** Pelvis
- **09** Breast
- **10** Pleural effusion
- **13** Lung parenchyma
- **17** Pleura or pleural wall
- **20** Liver
- **30** Bone
- **40** Chest wall
- **49** Pericardial effusion
- **50** Spinal cord
- **51** Brain
- **61** Esophagus
- **62** Stomach
- **63** Pancreas
- **64** Small intestine
- **65** Colon
- **66** Rectum
- **69** Anus
- **70** Ascites
- **73** Retroperitoneum
- **74** Peritoneum
- **79** Gall bladder
- **81** Kidney
- **82** Heart
- **84** Adrenal gland
- **85** Spleen
- **86** Skin
- **88** Other *(specify above)*

Screening

TUMOR EVALUATION - TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

If any lesions were previously irradiated but have NOT had radiographically documented progression, please record these on the non-target lesion CRF

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day Month Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	**Measurable Lesions** *(mm)* *(Longest Diameter)* Must be unidimensionally measurable **Dimensions** *(mm)*	Was Lesion Previously Irradiated? 0 **No** ✓ 1 **Yes** ✓	If lesion was previously irradiated has it subsequently had radiographically documented progression 0 **No** ✓ 1 **Yes** ✓
01							*If lesion was irradiated but has not subsequently had radiographically determined progression, please record as a non-target lestion*
02							
03							
04							
05							
06							
07							
08							
09							
10							
				Sum of Target			

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

Screening

TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Were there any non-target lesions identified? 0 ❑ No 1 ❑ Yes - If yes, specify below

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day	Month	Year	**Method of Assessment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	**Longest Diameter** *(mm) (Record actual measurement if ≥ 5mm, otherwise record 5mm. For truly non-measurable lesions record 'NA'.)*
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

Line #	**Specify if "88 Other" Method of Assessment**

TREATMENT PHASE

CYCLE 1

Cycle 1, Day 1

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination (Day / Month / Year)	Weight ❑ 1 kg ❑ 2 lb	Body Surface Area (m^2)
/ /		___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

ECOG PERFORMANCE STATUS

Date (Day / Month / Year)	Performance Status ☑ ECOG ❑ KPS
/ /	

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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 1, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 1, Day 1

HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ $10^6/mm^3$ 3 ❑ $10^{12}/L$ 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

CHEMISTRY

Date Drawn Day Month Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C1D1

Cycle 1, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
1	:	:						

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C1

Cycle 1

CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CYCLE 2

Cycle 2, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		
				___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

Cycle 2, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 2, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 2, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C2D1

Cycle 2, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
2		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C2

Cycle 2

CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time *(24 hour clock)*	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 3

Cycle 3, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 3, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 3, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C3D1

Cycle 3, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C3D1

Cycle 3, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date Day Month Year	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume Administered of Panitumumab plus Saline Solution *(mL)*	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
3	:	:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C3

Cycle 3
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time *(24 hour clock)*	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 4

Cycle 4, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination		
Day	Month	Year

Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
	___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

Cycle 4, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 4, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 4, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C4D1

Cycle 4, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date Day Month Year	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume Administered of Panitumumab plus Saline Solution *(mL)*	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
4		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C4

Cycle 4
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

WEEK 8
ASSESSMENTS

Week 8
CEA

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn		
Day	Month	Year

Test	Result	Unit	Specify if Other Unit
Serum Carcinoembryonic antigen		19 ❑ ng/mL 20 ❑ ug/L 88 ❑ Other	

Week 8
TUMOR EVALUATION - TARGET LESIONS
CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day / Month / Year	Method of Assess-ment ①	Subsite *Describe specific location*	Lesion Site Code ②	Measurable Lesions * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable Dimensions *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ / 1 Yes ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						
					Sum of Target Lesions	

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

Week 8
TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone")* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ 1 **Yes** ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	**Specify if "88 Other" Method of Assessment**

Week 8

TUMOR RESPONSE

Date of Assessment (Day / Month / Year)	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions (0 No ✓ / 1 Yes ✓)	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

CYCLE 5

Cycle 5, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 5, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 5, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 5, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C5D1

Cycle 5, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date Day Month Year	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume Administered of Panitumumab plus Saline Solution *(mL)*	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
5		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C5

Cycle 5
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 6

Cycle 6, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		
				___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

Cycle 6, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 6, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C6D1

Cycle 6, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C6D1

Cycle 6, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
6		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C6

Cycle 6
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day Month Year	Start Time (24 hour clock)	Stop Date Day Month Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin				:		:			
2	1	Leucovorin	*l*-leucovorin 1 ❑ racemic *(dl-)* leucovorin 2 ❑			:		:			
3	1	5-FU Bolus			OTO	:		:			
4	1	5-FU Continuous Infusion			CI	:		:			
5	2	Leucovorin	*l*-leucovorin 1 ❑ racemic *(dl-)* leucovorin 2 ❑			:		:			
6	2	5-FU Bolus			OTO	:		:			
7	2	5-FU Continuous Infusion			CI	:		:			

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 7

Cycle 7, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area (m^2)
Day	Month	Year		
				___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 7, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 7, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 7, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C7D1

Cycle 7, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
7		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C7

Cycle 7
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time *(24 hour clock)*	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 8

Cycle 8, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination		
Day	Month	Year

Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
	___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

Cycle 8, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 8, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 8, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C8D1

Cycle 8, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
8		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C8

Cycle 8
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

WEEK 16
ASSESSMENTS

Week 16
CEA

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn		
Day	Month	Year

Test	Result	Unit	Specify if Other Unit
Serum Carcinoembryonic antigen		19 ❑ ng/mL 20 ❑ ug/L 88 ❑ Other	

Week 16
TUMOR EVALUATION - TARGET LESIONS
CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day / Month / Year	Method of Assess-ment ①	Subsite *Describe specific location*	Lesion Site Code ②	Measurable Lesions * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable Dimensions *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ / 1 Yes ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						
					Sum of Target Lesions	

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

Week 16
TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone")* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ 1 **Yes** ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

Week 16

TUMOR RESPONSE

Date of Assessment Day Month Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions 0 No ✓ 1 Yes ✓	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

CYCLE 9

Cycle 9, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 9, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 9, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 9, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C9D1

Cycle 9, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date Day Month Year	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume Administered of Panitumumab plus Saline Solution *(mL)*	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
9	:	:						

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C9

Cycle 9

CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time *(24 hour clock)*	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 10

Cycle 10, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination		
Day	Month	Year

Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
	___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

Cycle 10, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 10, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C10D1

Cycle 10, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C10D1

Cycle 10, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
10		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C10

Cycle 10
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day / Month / Year	Start Time *(24 hour clock)*	Stop Date Day / Month / Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin				:		:			
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑			:		:			
3	1	5-FU Bolus			OTO	:		:			
4	1	5-FU Continuous Infusion			CI	:		:			
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑			:		:			
6	2	5-FU Bolus			OTO	:		:			
7	2	5-FU Continuous Infusion			CI	:		:			

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 11

Cycle 11, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 11, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 11, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C11D1

Cycle 11, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C11D1

Cycle 11, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
11		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C11

Cycle 11

CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 12

Cycle 12, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination		
Day	Month	Year

Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
	___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

Cycle 12, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 12, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 12, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C12D1

Cycle 12, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
12		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C12

Cycle 12
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time *(24 hour clock)*	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

WEEK 24
ASSESSMENTS

Week 24

CEA

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn			
Day	Month	Year	
Test	**Result**	**Unit**	**Specify if Other Unit**
Serum Carcinoembryonic antigen		19 ❑ ng/mL 20 ❑ ug/L 88 ❑ Other	

Week 24
TUMOR EVALUATION - TARGET LESIONS
CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day / Month / Year	Method of Assess-ment ①	Subsite *Describe specific location*	Lesion Site Code ②	Measurable Lesions * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable **Dimensions** *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ / 1 Yes ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						
				Sum of Target Lesions		

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

W24

Week 24
TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 No ✓ 1 Yes ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone")* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ 1 Yes ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

Week 24

TUMOR RESPONSE

Date of Assessment Day Month Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions 0 No ✓ 1 Yes ✓	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

CYCLE 13

Cycle 13, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 13, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 13, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 13, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C13D1

Cycle 13, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
13		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C13

Cycle 13

CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 14

Cycle 14, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination		
Day	Month	Year

Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
	___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

Cycle 14, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 14, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 14, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C14D1

Cycle 14, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
14		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C14

Cycle 14
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 15

Cycle 15, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 15, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 15, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 15, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C15D1

Cycle 15, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time *(24 hour clock)*	Stop Time *(24 hour clock)*	Total Dose Administered *(mg)*	Total Volume Administered of Panitumumab plus Saline Solution *(mL)*	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
15		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C15

Cycle 15
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 16

Cycle 16, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination		
Day	Month	Year

Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
	___ . ___ ___

BSA Formula

$$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$$

Cycle 16, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 16, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 16, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C16D1

Cycle 16, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
16		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C16

Cycle 16

CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

WEEK 32
ASSESSMENTS

Week 32

CEA

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn		
Day	Month	Year

Test	Result	Unit	Specify if Other Unit
Serum Carcinoembryonic antigen		19 ❑ ng/mL 20 ❑ ug/L 88 ❑ Other	

Week 32
TUMOR EVALUATION - TARGET LESIONS
CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day / Month / Year	Method of Assess-ment ①	Subsite *Describe specific location*	Lesion Site Code ②	Measurable Lesions * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable Dimensions *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ / 1 Yes ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						
				Sum of Target Lesions		

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

Week 32
TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone"* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ 1 **Yes** ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

Week 32

TUMOR RESPONSE

Date of Assessment (Day / Month / Year)	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions (0 No ✓ / 1 Yes ✓)	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

CYCLE 17

Cycle 17, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area (m^2)
Day	Month	Year		___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 17, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 17, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 17, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C17D1

Cycle 17, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
17		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C17

Cycle 17
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 18

Cycle 18, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination		
Day	Month	Year

Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
	___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

Cycle 18, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 18, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 18, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C18D1

Cycle 18, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
18		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C18

Cycle 18
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 19

Cycle 19, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area (m^2)
Day	Month	Year		___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 19, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 19, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 19, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C19D1

Cycle 19, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
19		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C19

Cycle 19
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time *(24 hour clock)*	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 20

Cycle 20, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		
				___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

Cycle 20, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 20, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

C20D1

Cycle 20, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C20D1

Cycle 20, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
20	:	:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C20

Cycle 20
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

WEEK 40
ASSESSMENTS

Week 40

CEA

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn		
Day	Month	Year

Test	Result	Unit	Specify if Other Unit
Serum Carcinoembryonic antigen		19 ❑ ng/mL 20 ❑ ug/L 88 ❑ Other	

Week 40
TUMOR EVALUATION - TARGET LESIONS
CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day / Month / Year	Method of Assess-ment ①	Subsite *Describe specific location*	Lesion Site Code ②	Measurable Lesions * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable **Dimensions** *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ / 1 **Yes** ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						
					Sum of Target Lesions	

① METHOD OF ASSESSMENT CODES:

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② LESION SITE CODES:

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

Week 40
TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone"* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ 1 **Yes** ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

Week 40

TUMOR RESPONSE

Date of Assessment Day Month Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions 0 No ✓ 1 Yes ✓	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

CYCLE 21

Cycle 21, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area (m^2)
Day	Month	Year		
				___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle 21, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 21, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test	Result	Unit	Specify if Other Unit
RBC		1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin		4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit		15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV		8 ❑ fL 88 ❑ Other	
Platelets		1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC		1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL* Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test	Result	Unit	Specify if Other Unit
RBC		1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin		4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit		15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV		8 ❑ fL 88 ❑ Other	
Platelets		1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC		1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL* Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
DIFFERENTIAL* Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 21, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C21D1

Cycle 21, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
21		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C21

Cycle 21
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time *(24 hour clock)*	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	*2*	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 22

Cycle 22, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		
				___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

Cycle 22, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle 22, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle 22, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn (Day / Month / Year)

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C22D1

Cycle 22, Day 1

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
22		:	:					

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C22

Cycle 22
CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0 ❑ No 1 ❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time (24 hour clock)	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time (24 hour clock)	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	2	Leucovorin	*l*-leucovorin 1 ❑ / racemic *(dl-)* leucovorin 2 ❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0 ❑ No 1 ❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

END OF TREATMENT

END OF PANITUMUMAB TREATMENT

Subjects receiving FOLFOX alone do not need to complete this page

Enter the date the investigator decided to discontinue Panitumumab:

Date Investigator Decided to Discontinue Panitumumab		
Day	Month	Year

Enter PRIMARY reason for ending Panitumumab:

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 ①
07 Disease progression ①

Criteria Code	CRITERIA CODES:
	01 Radiographically determined disease progression **04** Non-Radiographically determined disease progression

09 Administrative decision ①
10 Lost to follow-up ①
11 Death ②
(Record cause of death on the Death Summary CRF and FAX completed Serious Adverse Event form to Amgen within one working day.)
12 Protocol-specified criteria ①

Criteria Code	CRITERIA CODES:
	52 Intervention toxicities *(not resolved within 6 weeks)*

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 Discontinued Panitumumab***
② *Record date of death as* ***Date Subject Discontinued Panitumumab***

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

_____

_____

END OF FOLFOX TREATMENT

Enter the date the investigator decided to discontinue all FOLFOX components:

Date Investigator Decided to Discontinue FOLFOX		
Day	Month	Year

Enter PRIMARY reason for ending FOLFOX:

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 ①
07 Disease progression ①

Criteria Code	CRITERIA CODES:
	01 Radiographically determined disease progression **04** Non-Radiographically determined disease progression

09 Administrative decision ①
10 Lost to follow-up ①
11 Death ②
(Record cause of death on the Death Summary CRF and FAX completed Serious Adverse Event form to Amgen within one working day.)
12 Protocol-specified criteria ①

Criteria Code	CRITERIA CODES:
	52 Intervention toxicities *(not resolved within 6 weeks)*

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 Discontinued FOLFOX***
② *Record date of death as* ***Date Subject Discontinued FOLFOX***

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

_____

_____

SAFETY FOLLOW-UP

Safety Follow-Up

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

WEIGHT

Date of Examination			Weight 1 ❑ kg 2 ❑ lb
Day	Month	Year	

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Safety Follow-Up

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Safety Follow-Up

HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ $10^6/mm^3$ 3 ❑ $10^{12}/L$ 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

CHEMISTRY

Date Drawn Day Month Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

Safety Follow-Up

PREGNANCY TEST

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

Was pregnancy test performed? 0❑ No 1❑ Yes. If Yes, specify below

Date of Sample	
Day / Month / Year	
Specimen Type	9❑ Serum 10❑ Urine
Result	0❑ Negative 1❑ Positive

CEA

Did subject do a CEA assessment? *(Only necessary for subjects who have ended treatment for reasons other than radiographically documented progressive disease and have not had a specified tumor evaluation completed within the previous 8 weeks)* 0❑ No 1❑ Yes

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn			
Day / Month / Year			
Test	**Result**	**Unit**	**Specify if Other Unit**
Serum Carcinoembryonic antigen		19❑ ng/mL 20❑ ug/L 88❑ Other	

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

FUP

Safety Follow-Up
TUMOR EVALUATION - TARGET LESIONS
CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Was a Tumor Evaluation done? *(Only necessary for subjects who have ended treatment for reasons other than radiographically documented progressive disease and have not had a specified tumour evaluation completed within the previous 8 weeks.)* 0 ❑ No 1 ❑ Yes

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day / Month / Year	Method of Assess-ment ①	Subsite *Describe specific location*	Lesion Site Code ②	Measurable Lesions * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable Dimensions *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ / 1 Yes ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						

Sum of Target Lesions

① METHOD OF ASSESSMENT CODES:

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② LESION SITE CODES:

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

FUP

Safety Follow-Up
TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day Month Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone"* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ 1 **Yes** ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

Safety Follow-Up

TUMOR RESPONSE

Date of Assessment (Day / Month / Year)	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions (0 No ✓ / 1 Yes ✓)	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

SAFETY FOLLOW-UP VISIT

SAFETY FOLLOW-UP VISIT

If subject has any ongoing medically significant adverse events considered related to the investigational product by the investigator or the sponsor, please follow until resolved or considered stable.

Did subject complete any safety follow-up assessments? 0 ❑ No 1 ❑ Yes - *If Yes, record the date the safety follow-up was completed and do not record a reason code. If No, record the date of the subject's last assessment (unless the subject died, in which case record the date of death) and enter the primary reason code for why no safety follow-up assessments were done.*

Date Subject Completed Last Safety Follow-Up Assessment OR Date of Last Study Assessment		
Day	Month	Year

If subject did not do any safety follow-up assessments, enter PRIMARY reason code:

Enter Code:

CODES:

02 Ineligibility determined ①
05 Adverse event ① *(FAX this form to Amgen)*
06 Consent withdrawn ①
09 Administrative decision ①
10 Lost to follow-up ①
11 Death ②
(Record cause of death on the Death Summary CRF and FAX completed Serious Adverse Event form to Amgen within one working day.)
12 Protocol Specified Criteria ①

Criteria Code	**CRITERIA CODES:**
	40 Deterioration of condition *(If possible please try to confirm radiographically, however this is not necessary if the subject was withdrawn from treatment due to radiographically determined disease progression)*

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

① *Record date of last assessment*
② *Record date of death*

If subject did not complete any safety follow-up assessments, provide any additional relevant information:

_____

_____

CLINICAL EVENTS

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

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

Line #	Medication *Record one per line*	✓ Prophylaxis	Category ①	Indication	Dose	Unit ②	Route ③	Freq. ④	Date FIRST Taken Day	Month	Year	Date LAST Taken Day	Month	Year	*Check if medication continuing at End of Safety Follow Up* ✓
1															
2															
3															
4															
5															
6															
7															
8															

① CATEGORY CODES:

- **01** Steroids or narcotics given for treatment related skin/nail toxicity
- **02** Infusion reaction
- **03** Antibiotic/Antifungal for the treatment of skin/nail infection
- **04** Anti-emetic
- **66** Not applicable

② UNIT CODES:

AMP	Ampule	**MG**	Milligram
CAP	Capsule	**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)*
MEQ	Milliequivalent		

③ ROUTE CODES:

ET	Endotracheal tube	**OP**	Ophthalmic
GT	Gastrostomy	**PO**	Oral
IA	Intra-arterial	**PR**	Rectal
ID	Intradermal	**PV**	Vaginal
IH	Inhaled	**SC**	Subcutaneous
IM	Intramuscular	**SL**	Sublingual
IP	Intraperitoneal	**TD**	Transdermal
IT	Intrathecal	**TP**	Topical
IV	Intravenous	**OT**	Other *(specify below)*

④ FREQUENCY CODES:

BIW	Twice a week	**QD**	Once a day
CI	Continuous infusion	**QIW**	4 times a week
HS	At bedtime	**QMO**	Once a month
OTO	One time only	**QOD**	Every other day
PRN	As needed	**QWK**	Every week
Q2WK	Every 2 weeks	**TIW**	3 times a week
Q3WK	Every 3 weeks	**OT**	Other *(specify below)*
Q4WK	Every 4 weeks		

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

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

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*	✓ Prophylaxis	Category ①	Indication	Dose	Unit ②	Route ③	Freq. ④	*Check if medication continued from previous Con Med form* ✓	Date FIRST Taken Day	Month	Year	Date LAST Taken Day	Month	Year	*Check if medication continuing at End of Safety Follow Up* ✓
1																
2																
3																
4																
5																
6																
7																
8																

① CATEGORY CODES:

- **01** Steroids or narcotics given for treatment related skin/nail toxicity
- **02** Infusion reaction
- **03** Antibiotic/Antifungal for the treatment of skin/nail infection
- **04** Anti-emetic
- **66** Not applicable

② UNIT CODES:

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

③ ROUTE CODES:

- **ET** Endotracheal tube
- **GT** Gastrostomy
- **IA** Intra-arterial
- **ID** Intradermal
- **IH** Inhaled
- **IM** Intramuscular
- **IP** Intraperitoneal
- **IT** Intrathecal
- **IV** Intravenous
- **OP** Ophthalmic
- **PO** Oral
- **PR** Rectal
- **PV** Vaginal
- **SC** Subcutaneous
- **SL** Sublingual
- **TD** Transdermal
- **TP** Topical
- **OT** Other *(specify below)*

④ FREQUENCY CODES:

- **BIW** Twice a week
- **CI** Continuous infusion
- **HS** At bedtime
- **OTO** One time only
- **PRN** As needed
- **Q2WK** Every 2 weeks
- **Q3WK** Every 3 weeks
- **Q4WK** Every 4 weeks
- **QD** Once a day
- **QIW** 4 times a week
- **QMO** Once a month
- **QOD** Every other day
- **QWK** Every week
- **TIW** 3 times a week
- **OT** Other *(specify below)*

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

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

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*	✓ Prophylaxis	Category ①	Indication	Dose	Unit ②	Route ③	Freq. ④	*Check if medication continued from previous Con Med form* ✓	Date FIRST Taken Day	Month	Year	Date LAST Taken Day	Month	Year	*Check if medication continuing at End of Safety Follow Up* ✓
1																
2																
3																
4																
5																
6																
7																
8																

① CATEGORY CODES:

- **01** Steroids or narcotics given for treatment related skin/nail toxicity
- **02** Infusion reaction
- **03** Antibiotic/Antifungal for the treatment of skin/nail infection
- **04** Anti-emetic
- **66** Not applicable

② UNIT CODES:

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

③ ROUTE CODES:

- **ET** Endotracheal tube
- **GT** Gastrostomy
- **IA** Intra-arterial
- **ID** Intradermal
- **IH** Inhaled
- **IM** Intramuscular
- **IP** Intraperitoneal
- **IT** Intrathecal
- **IV** Intravenous
- **OP** Ophthalmic
- **PO** Oral
- **PR** Rectal
- **PV** Vaginal
- **SC** Subcutaneous
- **SL** Sublingual
- **TD** Transdermal
- **TP** Topical
- **OT** Other *(specify below)*

④ FREQUENCY CODES:

- **BIW** Twice a week
- **CI** Continuous infusion
- **HS** At bedtime
- **OTO** One time only
- **PRN** As needed
- **Q2WK** Every 2 weeks
- **Q3WK** Every 3 weeks
- **Q4WK** Every 4 weeks
- **QD** Once a day
- **QIW** 4 times a week
- **QMO** Once a month
- **QOD** Every other day
- **QWK** Every week
- **TIW** 3 times a week
- **OT** Other *(specify below)*

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

Adverse Events Summary Instructions

1. Record all adverse events as specified in 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 worsening 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.

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

AE1

ADVERSE EVENTS SUMMARY

Has the subject had any Adverse Events? 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 first dose of Panitumumab or FOLFOX? 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 Safety Follow Up ✓	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 Panitumumab? 0 No ✓ 1 Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by Chemotherapy? 0 No ✓ 1 Yes ✓	Action Taken for This Event *(record all that apply)* 01 No action taken 02 Panitumumab dose altered 03 Medication taken 04 Hospitalized / Prolonged hospitalization 05 Removed from study 06 Panitumumab discontinued 07 Transfusion performed 70 Panitumumab infusion interrupted 80 Chemotherapy dose discontinued 81 Chemotherapy dose altered 82 Chemotherapy dose delayed 88 Other *(specify below)*	** Serious? 0 No ✓ 1 Yes ✓
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																

*** * 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

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

AE2

ADVERSE EVENTS SUMMARY

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 first dose of Panitumumab or FOLFOX? 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 Safety Follow Up ✓	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 Panitumumab? 0 No ✓ 1 Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by Chemotherapy? 0 No ✓ 1 Yes ✓	Action Taken for This Event (record all that apply) 01 No action taken 02 Panitumumab dose altered 03 Medication taken 04 Hospitalized / Prolonged hospitalization 05 Removed from study 06 Panitumumab discontinued 07 Transfusion performed 70 Panitumumab infusion interrupted 80 Chemotherapy dose discontinued 81 Chemotherapy dose altered 82 Chemotherapy dose delayed 88 Other (specify below)	** Serious? 0 No ✓ 1 Yes ✓
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	

*** * 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

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

AE3

ADVERSE EVENTS SUMMARY

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 first dose of Panitumumab or FOLFOX? 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 Safety Follow Up ✓	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 Panitumumab? 0 No ✓ 1 Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by Chemotherapy? 0 No ✓ 1 Yes ✓	Action Taken for This Event (record all that apply) 01 No action taken 02 Panitumumab dose altered 03 Medication taken 04 Hospitalized / Prolonged hospitalization 05 Removed from study 06 Panitumumab discontinued 07 Transfusion performed 70 Panitumumab infusion interrupted 80 Chemotherapy dose discontinued 81 Chemotherapy dose altered 82 Chemotherapy dose delayed 88 Other (specify below)	** Serious? 0 No ✓ 1 Yes ✓
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	

*** * 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

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

HOSP

HOSPITAL UTILIZATIONS

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

Has the subject had any hospitalizations from time of signing informed consent through to end of safety follow up visit? 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 Safety Follow Up ✓	Primary Reason for Admission: Reason Code ①	Primary Reason for Admission: Specify if "88 Other"	Unit in Hospital ②	Did the subject visit the emergency department before being admitted? 0 No ✓ / 1 Yes ✓	Reason for discharge ③

① REASON CODES:

- **02** Adverse event
- **04** Respite care
- **05** Normal clinical practice
- **40** RBC transfusion
- **41** Platelet transfusion
- **50** Chemotherapy
- **88** Other

② UNIT IN HOSPITAL CODES:

- **01** ICU (Intensive care unit (includes any cardiac care unit)
- **03** General Ward
- **07** Monitored Bed

③ REASON FOR DISCHARGE CODES:

- **01** Improvement in condition
- **02** End of respite care
- **03** Normal clinical practice
- **04** Admission to palliative care
- **05** Death
- **88** Other

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

PROC

PROCEDURES

Has the subject had any additional procedures during the study? 0 ❑ No 1 ❑ Yes - If Yes, provide details below.

Line #	Date of Procedure (Day / Month / Year)	Procedure Code ①	If Procedure code = "30 or 31", were there any malignant cells? 0 No ✓ / 1 Yes ✓	Body Site Code ②	Description/Findings
1					
2					
3					
4					
5					
6					
7					
8					

① PROCEDURE CODES:

30	Paracentesis	**33**	Colonoscopy
31	Thoracentesis	**34**	Sigmoidoscopy
32	Surgical	**88**	Other *(specify below)*

② BODY SITE CODES:

00	Lymph node	**10**	Pleural effusion	**49**	Pericardial effusion	**64**	Small intestine	**74**	Peritoneum	**86**	Skin
01	Thyroid	**13**	Lung parenchyma	**50**	Spinal cord	**65**	Colon	**79**	Gall bladder	**88**	Other *(specify above)*
02	Oral cavity	**17**	Pleura or pleural wall	**51**	Brain	**66**	Rectum	**81**	Kidney		
03	Pharynx	**20**	Liver	**61**	Esophagus	**69**	Anus	**82**	Heart		
08	Pelvis	**30**	Bone	**62**	Stomach	**70**	Ascites	**84**	Adrenal gland		
09	Breast	**40**	Chest wall	**63**	Pancreas	**73**	Retroperitoneum	**85**	Spleen		

Line #	Specify **PROCEDURE** if "**88** Other"	Line #	Specify **BODY SITE** if "**88** Other"

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

INTHER

INTERVENTIONAL THERAPY FOR METASTASES

Line #	Procedure Code ①	Specify Procedure if "88 Other"	Results of Procedure ②	Body Site Code ③	Date Started Day Month Year	Date Ended Day Month Year	If Procedure is '08 - Radiotherapy' Specify Dose	If Procedure is '08 - Radiotherapy' Specify Unit ④	If Procedure is '08 - Radiotherapy' Specify Intent ⑤	Lesion Numbers Affected *Record lesion number from tumor evaluation page*
1										
2										
3										
4										
5										

Line #	Specify **BODY SITE** if "88 Other"	Line #	Specify **INTENT** if "88 Other"

① **PROCEDURE CODES:**
- **03** Radiofrequency ablation
- **04** Cryotherapy
- **07** Surgery
- **08** Radiotherapy
- **88** Other *(specify above)*

② **RESULTS OF PROCEDURE CODES:**
- **00** No removal/reduction
- **09** Partial removal/reduction
- **10** Complete removal/reduction

③ **BODY SITE CODES:**
- **00** Lymph node
- **01** Thyroid
- **02** Oral cavity
- **03** Pharynx
- **08** Pelvis
- **09** Breast
- **10** Pleural effusion
- **13** Lung parenchyma
- **17** Pleura or pleural wall
- **20** Liver
- **30** Bone
- **40** Chest wall
- **49** Pericardial effusion
- **50** Spinal cord
- **51** Brain
- **61** Esophagus
- **62** Stomach
- **63** Pancreas
- **64** Small intestine
- **65** Colon
- **66** Rectum
- **69** Anus
- **70** Ascites
- **73** Retroperitoneum
- **74** Peritoneum
- **79** Gall bladder
- **81** Kidney
- **82** Heart
- **84** Adrenal gland
- **85** Spleen
- **86** Skin
- **88** Other *(specify above)*

④ **UNIT CODES:**
- **GY** Gray
- **cGY** centi-Gray

⑤ **INTENT CODES:**
- **05** Palliation
- **88** Other *(specify above)*

POST INTERVENTION TUMOR EVALUATION

Post Intervention

TUMOR EVALUATION - TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

If any lesions were previously irradiated but have NOT had radiographically documented progression, please record these on the non-target lesion CRF

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day / Month / Year	Method of Assess-ment ①	Subsite *Describe specific location*	Lesion Site Code ②	Measurable Lesions *(mm)* *(Longest Diameter)* Must be unidimensionally measurable **Dimensions** *(mm)*	Was interventional therapy performed on this lesion? 0 **No** ✓ / 1 **Yes** ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						
				Sum of Target Lesions		

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

Post Intervention
TUMOR EVALUATION - NON-TARGET LESIONS
CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Were there any non-target lesions identified? 0 ❑ No 1 ❑ Yes - If yes, specify below

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	**Longest Diameter** *(mm) (Record actual measurement if ≥ 5mm, otherwise record 5mm.For truly non-measurable lesions record 'NA')*	Was Interventional Therapy Performed on This Lesion? 0 **No** ✓ / 1 **Yes** ✓
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

① **METHOD OF ASSESSMENT CODES:**

01 X-ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

Line #	Specify **METHOD OF ASSESSMENT** if "88 Other"

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: _____

_____

_____

_____

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: _____

_____

_____

_____

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: _____

DEATH SUMMARY

DEATH SUMMARY

Complete Death Summary CRF for any death that occurs from randomization up to 30 days after the last dose of Panitumumab or FOLFOX

Death occurring within 30 days after the last dose of Panitumumab or FOLFOX, or at any time if considered possibly related to Panitumumab, must be reported to Amgen immediately.

Date of Death		
Day	Month	Year

Did subject die during the study? 0❑ No 1❑ Yes - If Yes, specify below.

Primary Cause of Death	**PRIMARY CAUSE OF DEATH CODES:**	Specify **PRIMARY CAUSE OF DEATH** if "88 Other"
	07 Disease progression **88** Other *(specify)*	

INVESTIGATOR VERIFICATION

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

ADDITIONAL ASSESSMENTS FOR SUBJECTS DISCONTINUING PRIOR TO DISEASE PROGRESSION

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

AFUP

___ Weeks After Previous On-Study Tumor Evaluation

HOSPITAL UTILIZATIONS

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

Has the subject had any hospitalizations during this 8 week period?' 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 Safety Follow Up ✓	Primary Reason for Admission: Reason Code ①	Primary Reason for Admission: Specify if "88 Other"	Unit in Hospital ②	Did the subject visit the emergency department before being admitted? 0 No ✓ / 1 Yes ✓	Reason for discharge ③

① **REASON CODES:**

02 Adverse event
04 Respite care
05 Normal clinical practice
40 RBC transfusion
41 Platelet transfusion
50 Chemotherapy
88 Other

② **UNIT IN HOSPITAL CODES:**

01 ICU (Intensive care unit (includes any cardiac care unit)
03 General Ward
07 Monitored Bed

③ **REASON FOR DISCHARGE CODES:**

01 Improvement in condition
02 End of respite care
03 Normal clinical practice
04 Admission to palliative care
05 Death
88 Other

____ Weeks After Previous On-Study Tumor Evaluation

TUMOR EVALUATION - TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Was a Tumor Evaluation done? 0 ❑ No 1 ❑ Yes

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	**Measurable Lesions** * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable **Dimensions** *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ / 1 **Yes** ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						

Sum of Target Lesions

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

____ Weeks After Previous On-Study Tumor Evaluation *AFUP*

TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 No ✓ 1 Yes ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone")* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ 1 Yes ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

____ Weeks After Previous On-Study Tumor Evaluation

TUMOR RESPONSE

Date of Assessment Day Month Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions 0 No ✓ 1 Yes ✓	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

END OF RADIOGRAPHIC FOLLOW-UP

Only complete if the subject discontinued prior to disease progression confirmed by radiographic assessment

Did subject complete the additional radiographic assessments until disease progression was confirmed? 0 ❑ No 1 ❑ Yes - *If No, record the date the last radiographic assessment was completed, or if no additional radiographic assessments were performed, record the date the decision was made not to perform additional radiographic assessments. Also record the primary reason code why additional assessments were not performed.*

Date Subject Completed Last Additional Radiographic Assessment OR Date of Decision Not to Perform any Additional Radiographic Assessments		
Day	Month	Year

If subject did not complete additional radiographic assessments until disease progression was confirmed, enter PRIMARY reason code:

Enter Code: ____

CODES:

05 Adverse event ①
06 Consent withdrawn ①
13 Subject request ①
07 Disease progression ①

Criteria Code	CRITERIA CODES:
	04 Non-radiographically determined disease progression

09 Administrative decision ①
10 Lost to follow-up ①
11 Death ②
(Record cause of death on the Death Summary CRF and FAX completed Serious Adverse Event form to Amgen within one working day.)
12 Protocol Specified Criteria ①

Criteria Code	CRITERIA CODES:
	40 Deterioration of condition

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

① *Record date of last additional radiographic assessment or date of decision not to perform additional radiographic assessments*
② *Record date of death*

If subject did not complete additional radiographic assessments until disease progression was confirmed, provide any additional relevant information:

_____

_____

SURVIVAL STATUS

Month 3
SURVIVAL STATUS

To be collected every 3 months following the last Panitumumab or FOLFOX administration.

If subject discontinued study treatment prior to disease progression ensure subject is followed for disease progression (per modified RECIST) every 8 weeks.

Date of Last Contact		
Day	Month	Year

Status of Subject ①	① **STATUS OF SUBJECT CODES:**
	0 Dead* **1** Alive **2** Lost to Follow-up * ***Record Date and Cause of Death***

If status is Dead (0), specify:

Date of Death			Principal Cause of Death ②	② **PRINCIPAL CAUSE OF DEATH CODES:**
Day	Month	Year		**01** Disease progression **88** Other (*specify*)_____

For all subject statuses (0,1 or 2), specify:
Since the last assessment has the subject received any treatment for colorectal cancer?

Anti Tumor Treatment Given for Colorectal Cancer ③	③ **ANTI TUMOR TREATMENT GIVEN FOR COLORECTAL CANCER CODES:**	
	00 None	**10** Other Anti VEGF unspecified
	11 Panitumumab	**16** Oxaliplatin
	12 Cetuximab	**17** Irinotecan
	13 Other EGFr moAb	**18** Fluoropyrimidine
	14 Other EGFr small molecule	**99** Not known
	15 Bevacizumab	**88** Other *(specify)* _____

Month 6
SURVIVAL STATUS

To be collected every 3 months following the last Panitumumab or FOLFOX administration.

If subject discontinued study treatment prior to disease progression ensure subject is followed for disease progression (per modified RECIST) every 8 weeks.

Date of Last Contact		
Day	Month	Year

Status of Subject ①	① **STATUS OF SUBJECT CODES:**
	0 Dead* **1** Alive **2** Lost to Follow-up * ***Record Date and Cause of Death***

If status is Dead (0), specify:

Date of Death			Principal Cause of Death ②	② **PRINCIPAL CAUSE OF DEATH CODES:**
Day	Month	Year		**01** Disease progression **88** Other (*specify*)_____

For all subject statuses (0,1 or 2), specify:
Since the last assessment has the subject received any treatment for colorectal cancer?

Anti Tumor Treatment Given for Colorectal Cancer ③	③ **ANTI TUMOR TREATMENT GIVEN FOR COLORECTAL CANCER CODES:**	
	00 None	**10** Other Anti VEGF unspecified
	11 Panitumumab	**16** Oxaliplatin
	12 Cetuximab	**17** Irinotecan
	13 Other EGFr moAb	**18** Fluoropyrimidine
	14 Other EGFr small molecule	**99** Not known
	15 Bevacizumab	**88** Other *(specify)* _____

Month 9
SURVIVAL STATUS

To be collected every 3 months following the last Panitumumab or FOLFOX administration.

If subject discontinued study treatment prior to disease progression ensure subject is followed for disease progression (per modified RECIST) every 8 weeks.

Date of Last Contact		
Day	Month	Year

Status of Subject ①	① **STATUS OF SUBJECT CODES:**
	0 Dead* **1** Alive **2** Lost to Follow-up * ***Record Date and Cause of Death***

If status is Dead (0), specify:

Date of Death			Principal Cause of Death ②	② **PRINCIPAL CAUSE OF DEATH CODES:**
Day	Month	Year		**01** Disease progression **88** Other (*specify*)_____

For all subject statuses (0,1 or 2), specify:
Since the last assessment has the subject received any treatment for colorectal cancer?

Anti Tumor Treatment Given for Colorectal Cancer ③	③ **ANTI TUMOR TREATMENT GIVEN FOR COLORECTAL CANCER CODES:**	
	00 None	**10** Other Anti VEGF unspecified
	11 Panitumumab	**16** Oxaliplatin
	12 Cetuximab	**17** Irinotecan
	13 Other EGFr moAb	**18** Fluoropyrimidine
	14 Other EGFr small molecule	**99** Not known
	15 Bevacizumab	**88** Other *(specify)* _____

Month 12
SURVIVAL STATUS

To be collected every 3 months following the last Panitumumab or FOLFOX administration.

If subject discontinued study treatment prior to disease progression ensure subject is followed for disease progression (per modified RECIST) every 8 weeks.

Date of Last Contact		
Day	Month	Year

Status of Subject ①	① **STATUS OF SUBJECT CODES:**
	0 Dead* **1** Alive **2** Lost to Follow-up * ***Record Date and Cause of Death***

If status is Dead (0), specify:

Date of Death			Principal Cause of Death ②	② **PRINCIPAL CAUSE OF DEATH CODES:**
Day	Month	Year		**01** Disease progression **88** Other (*specify*)_____

For all subject statuses (0,1 or 2), specify:
Since the last assessment has the subject received any treatment for colorectal cancer?

Anti Tumor Treatment Given for Colorectal Cancer ③	③ **ANTI TUMOR TREATMENT GIVEN FOR COLORECTAL CANCER CODES:**	
	00 None	**10** Other Anti VEGF unspecified
	11 Panitumumab	**16** Oxaliplatin
	12 Cetuximab	**17** Irinotecan
	13 Other EGFr moAb	**18** Fluoropyrimidine
	14 Other EGFr small molecule	**99** Not known
	15 Bevacizumab	**88** Other *(specify)* _____

Month 15
SURVIVAL STATUS

To be collected every 3 months following the last Panitumumab or FOLFOX administration.

If subject discontinued study treatment prior to disease progression ensure subject is followed for disease progression (per modified RECIST) every 8 weeks.

Date of Last Contact		
Day	Month	Year

Status of Subject ①	① **STATUS OF SUBJECT CODES:**
	0 Dead* **1** Alive **2** Lost to Follow-up * ***Record Date and Cause of Death***

If status is Dead (0), specify:

Date of Death			Principal Cause of Death ②	② **PRINCIPAL CAUSE OF DEATH CODES:**
Day	Month	Year		**01** Disease progression **88** Other (*specify*)_____

For all subject statuses (0,1 or 2), specify:
Since the last assessment has the subject received any treatment for colorectal cancer?

Anti Tumor Treatment Given for Colorectal Cancer ③	③ **ANTI TUMOR TREATMENT GIVEN FOR COLORECTAL CANCER CODES:**	
	00 None	**10** Other Anti VEGF unspecified
	11 Panitumumab	**16** Oxaliplatin
	12 Cetuximab	**17** Irinotecan
	13 Other EGFr moAb	**18** Fluoropyrimidine
	14 Other EGFr small molecule	**99** Not known
	15 Bevacizumab	**88** Other *(specify)* _____

Month 18
SURVIVAL STATUS

To be collected every 3 months following the last Panitumumab or FOLFOX administration.

If subject discontinued study treatment prior to disease progression ensure subject is followed for disease progression (per modified RECIST) every 8 weeks.

Date of Last Contact		
Day	Month	Year

Status of Subject ①	① **STATUS OF SUBJECT CODES:**
	0 Dead* **1** Alive **2** Lost to Follow-up * ***Record Date and Cause of Death***

If status is Dead (0), specify:

Date of Death			Principal Cause of Death ②	② **PRINCIPAL CAUSE OF DEATH CODES:**
Day	Month	Year		**01** Disease progression **88** Other (*specify*)_____

For all subject statuses (0,1 or 2), specify:
Since the last assessment has the subject received any treatment for colorectal cancer?

Anti Tumor Treatment Given for Colorectal Cancer ③	③ **ANTI TUMOR TREATMENT GIVEN FOR COLORECTAL CANCER CODES:**	
	00 None	**10** Other Anti VEGF unspecified
	11 Panitumumab	**16** Oxaliplatin
	12 Cetuximab	**17** Irinotecan
	13 Other EGFr moAb	**18** Fluoropyrimidine
	14 Other EGFr small molecule	**99** Not known
	15 Bevacizumab	**88** Other *(specify)* _____

EXTRA FORMS

MEDICAL & SURGICAL HISTORY

01 Special senses *(vision, hearing, olfaction and taste)*
02 Cardiovascular
03 Respiratory
04 Gastrointestinal
05 Hepatic / Biliary
06 Genitourinary / Reproductive
07 Renal
08 Endocrine / Metabolic
09 Musculoskeletal
10 Hematologic / Lymphatic
12 Dermatologic
13 Immunologic
50 Neurologic
51 Psychiatric
88 Other

Code *(as listed above)*	**Diagnosis or Procedure** *List one entry per line.*	**Approximate Date of Diagnosis or Procedure, if available** Month	Year	[1] **Continuing** ✓	[2] **Resolved** ✓

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 21

SCR

Screening

PRIOR THERAPY FOR NON-METASTATIC COLORECTAL CANCER

Item #	Drug	Type of Therapy ①	Treat-ment Setting ②	Date of First Dose of Therapy (Day / Month / Year)	Date of Last Dose of Therapy (Day / Month / Year)	Date of Disease Progression/ Recurrence (Day / Month / Year)
1						
2						
3						
4						
5						

Item #	Specify if **TYPE OF THERAPY** is "88 Other"	Item #	Specify if **TREATMENT SETTING** is "88 Other"

① **TYPE OF THERAPY CODES:**

- **01** Chemotherapy
- **05** Immunotherapy
- **13** Hormonal
- **14** Targeted biologics
- **15** Targeted small molecules
- **17** Chemoembolization
- **88** Other *(Specify above)*

② **TREATMENT SETTING CODES:**

- **06** Adjuvant
- **07** Neo-adjuvant
- **88** Other *(Specify above)*

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

PROC

PROCEDURES

Line #	Date of Procedure (Day / Month / Year)	Procedure Code ①	If Procedure code = "30 or 31", were there any malignant cells? (0 No ✓ / 1 Yes ✓)	Body Site Code ②	Description/Findings
1					
2					
3					
4					
5					
6					
7					
8					

① PROCEDURE CODES:

30	Paracentesis	**33**	Colonoscopy
31	Thoracentesis	**34**	Sigmoidoscopy
32	Surgical	**88**	Other *(specify below)*

② BODY SITE CODES:

00	Lymph node	**10**	Pleural effusion	**49**	Pericardial effusion	**64**	Small intestine	**74**	Peritoneum	**86**	Skin
01	Thyroid	**13**	Lung parenchyma	**50**	Spinal cord	**65**	Colon	**79**	Gall bladder	**88**	Other *(specify above)*
02	Oral cavity	**17**	Pleura or pleural wall	**51**	Brain	**66**	Rectum	**81**	Kidney		
03	Pharynx	**20**	Liver	**61**	Esophagus	**69**	Anus	**82**	Heart		
08	Pelvis	**30**	Bone	**62**	Stomach	**70**	Ascites	**84**	Adrenal gland		
09	Breast	**40**	Chest wall	**63**	Pancreas	**73**	Retroperitoneum	**85**	Spleen		

Line #	Specify **PROCEDURE** if "**88** Other"	Line #	Specify **BODY SITE** if "**88** Other"

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

INTHER

INTERVENTIONAL THERAPY FOR METASTASES

Line #	Procedure Code ①	Specify Procedure if "88 Other"	Results of Procedure ②	Body Site Code ③	Date Started Day Month Year	Date Ended Day Month Year	If Procedure is '08 - Radiotherapy' Specify Dose	If Procedure is '08 - Radiotherapy' Specify Unit ④	If Procedure is '08 - Radiotherapy' Specify Intent ⑤	Lesion Numbers Affected *Record lesion number from tumor evaluation page*
1										
2										
3										
4										
5										

Line #	Specify **BODY SITE** if "88 Other"	Line #	Specify **INTENT** if "88 Other"

① PROCEDURE CODES:
- **03** Radiofrequency ablation
- **04** Cryotherapy
- **07** Surgery
- **08** Radiotherapy
- **88** Other *(specify above)*

② RESULTS OF PROCEDURE CODES:
- **00** No removal/reduction
- **09** Partial removal/reduction
- **10** Complete removal/reduction

③ BODY SITE CODES:
- **00** Lymph node
- **01** Thyroid
- **02** Oral cavity
- **03** Pharynx
- **08** Pelvis
- **09** Breast
- **10** Pleural effusion
- **13** Lung parenchyma
- **17** Pleura or pleural wall
- **20** Liver
- **30** Bone
- **40** Chest wall
- **49** Pericardial effusion
- **50** Spinal cord
- **51** Brain
- **61** Esophagus
- **62** Stomach
- **63** Pancreas
- **64** Small intestine
- **65** Colon
- **66** Rectum
- **69** Anus
- **70** Ascites
- **73** Retroperitoneum
- **74** Peritoneum
- **79** Gall bladder
- **81** Kidney
- **82** Heart
- **84** Adrenal gland
- **85** Spleen
- **86** Skin
- **88** Other *(specify above)*

④ UNIT CODES:
- **05** Palliation
- **88** Other *(specify above)*

Unscheduled

TUMOR EVALUATION - TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	**Measurable Lesions** * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable **Dimensions** *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ / 1 **Yes** ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						
					Sum of Target Lesions	

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

UNSCHED

Unscheduled
TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone"* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ 1 **Yes** ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

Unscheduled

TUMOR RESPONSE

Date of Assessment Day Month Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions 0 No ✓ 1 Yes ✓	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

PROGRESSING NON-TARGET LESIONS AT LEAST 10MM AT TIME OF PROGRESSION

Only complete this form if an Overall Tumor Response of 'Disease Progression' has been determined solely by the progression of Non-Target Lesions

Record the Non-Target Lesion numbers for those lesions that have demonstrated progression										

The sum of these lesions should be entered for each time point that tumor evaluations were performed throughout the study. The sum should just be of the lesions that have been identified as progressing and should correlate to the measurements of these lesions recorded at each assessment.

Week	**Date** Day	Month	Year	**Sum of Non-Target Lesions Identified to Have Progressed**

EXTRA PADS

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

HOSP

HOSPITAL UTILIZATIONS

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

Date of Admission (Day / Month / Year)	Date of Discharge (Day / Month / Year)	Check if not discharged at End of Safety Follow Up ✓	Primary Reason for Admission — Reason Code ①	Primary Reason for Admission — Specify if "88 Other"	Unit in Hospital ②	Did the subject visit the emergency department before being admitted? 0 No ✓ / 1 Yes ✓	Reason for discharge ③

① REASON CODES:

- **02** Adverse event
- **04** Respite care
- **05** Normal clinical practice
- **40** RBC transfusion
- **41** Platelet transfusion
- **50** Chemotherapy
- **88** Other

② UNIT IN HOSPITAL CODES:

- **01** ICU (Intensive care unit (includes any cardiac care unit)
- **03** General Ward
- **07** Monitored Bed

③ REASON FOR DISCHARGE CODES:

- **01** Improvement in condition
- **02** End of respite care
- **03** Normal clinical practice
- **04** Admission to palliative care
- **05** Death
- **88** Other

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

AFUP

____ Weeks After Previous On-Study Tumor Evaluation
HOSPITAL UTILIZATIONS

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

Has the subject had any hospitalizations during this 8 week period?' 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 Safety Follow Up ✓	Primary Reason for Admission: Reason Code ①	Primary Reason for Admission: Specify if "88 Other"	Unit in Hospital ②	Did the subject visit the emergency department before being admitted? 0No ✓ / 1Yes ✓	Reason for discharge ③

① **REASON CODES:**

02 Adverse event
04 Respite care
05 Normal clinical practice
40 RBC transfusion
41 Platelet transfusion
50 Chemotherapy
88 Other

② **UNIT IN HOSPITAL CODES:**

01 ICU (Intensive care unit (includes any cardiac care unit)
03 General Ward
07 Monitored Bed

③ **REASON FOR DISCHARGE CODES:**

01 Improvement in condition
02 End of respite care
03 Normal clinical practice
04 Admission to palliative care
05 Death
88 Other

____ Weeks After Previous On-Study Tumor Evaluation

TUMOR EVALUATION - TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Was a Tumor Evaluation done? 0 ❑ No 1 ❑ Yes

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	**Measurable Lesions** * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable **Dimensions** *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ / 1 **Yes** ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						

Sum of Target Lesions

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node	**13** Lung parenchyma	**51** Brain	**69** Anus	**84** Adrenal gland
01 Thyroid	**17** Pleura or pleural wall	**61** Esophagus	**70** Ascites	**85** Spleen
02 Oral cavity	**20** Liver	**62** Stomach	**73** Retroperitoneum	**86** Skin
03 Pharynx	**30** Bone	**63** Pancreas	**74** Peritoneum	**88** Other *(specify in subsite above)*
08 Pelvis	**40** Chest wall	**64** Small intestine	**79** Gall bladder	
09 Breast	**49** Pericardial effusion	**65** Colon	**81** Kidney	
10 Pleural effusion	**50** Spinal cord	**66** Rectum	**82** Heart	

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

AFUP

____ Weeks After Previous On-Study Tumor Evaluation
TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 No ✓ 1 Yes ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone"* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ 1 Yes ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

____ Weeks After Previous On-Study Tumor Evaluation

TUMOR RESPONSE

Date of Assessment Day Month Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions 0 No ✓ 1 Yes ✓	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

Month ___

SURVIVAL STATUS

To be collected every 3 months following the last Panitumumab or FOLFOX administration.

If subject discontinued study treatment prior to disease progression ensure subject is followed for disease progression (per modified RECIST) every 8 weeks.

Date of Last Contact		
Day	Month	Year

Status of Subject ①	① **STATUS OF SUBJECT CODES:**
	0 Dead* **1** Alive **2** Lost to Follow-up * ***Record Date and Cause of Death***

If status is Dead (0), specify:

Date of Death			Principal Cause of Death ②	② **PRINCIPAL CAUSE OF DEATH CODES:**
Day	Month	Year		**01** Disease progression **88** Other (*specify*)_____

For all subject statuses (0,1 or 2), specify:
Since the last assessment has the subject received any treatment for colorectal cancer?

Anti Tumor Treatment Given for Colorectal Cancer ③	③ **ANTI TUMOR TREATMENT GIVEN FOR COLORECTAL CANCER CODES:**	
	00 None	**10** Other Anti VEGF unspecified
	11 Panitumumab	**16** Oxaliplatin
	12 Cetuximab	**17** Irinotecan
	13 Other EGFr moAb	**18** Fluoropyrimidine
	14 Other EGFr small molecule	**99** Not known
	15 Bevacizumab	**88** Other *(specify)* _____

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

CM

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	Category ①	Indication	Dose	Unit ②	Route ③	Freq. ④	*Check if medication continued from previous Con Med form* ✓	Date FIRST Taken Day	Month	Year	Date LAST Taken Day	Month	Year	*Check if medication continuing at End of Safety Follow Up* ✓
1																
2																
3																
4																
5																
6																
7																
8																

① CATEGORY CODES:

- **01** Steroids or narcotics given for treatment related skin/nail toxicity
- **02** Infusion reaction
- **03** Antibiotic/Antifungal for the treatment of skin/nail infection
- **04** Anti-emetic
- **66** Not applicable

② UNIT CODES:

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

③ ROUTE CODES:

- **ET** Endotracheal tube
- **GT** Gastrostomy
- **IA** Intra-arterial
- **ID** Intradermal
- **IH** Inhaled
- **IM** Intramuscular
- **IP** Intraperitoneal
- **IT** Intrathecal
- **IV** Intravenous
- **OP** Ophthalmic
- **PO** Oral
- **PR** Rectal
- **PV** Vaginal
- **SC** Subcutaneous
- **SL** Sublingual
- **TD** Transdermal
- **TP** Topical
- **OT** Other *(specify below)*

④ FREQUENCY CODES:

- **BIW** Twice a week
- **CI** Continuous infusion
- **HS** At bedtime
- **OTO** One time only
- **PRN** As needed
- **Q2WK** Every 2 weeks
- **Q3WK** Every 3 weeks
- **Q4WK** Every 4 weeks
- **QD** Once a day
- **QIW** 4 times a week
- **QMO** Once a month
- **QOD** Every other day
- **QWK** Every week
- **TIW** 3 times a week
- **OT** Other *(specify below)*

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

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

AE

ADVERSE EVENTS SUMMARY

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 first dose of Panitumumab or FOLFOX? 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 Safety Follow Up ✓	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 Panitumumab? 0 No ✓ 1 Yes ✓	Relationship Is there a reasonable possibility that the event may have been caused by Chemotherapy? 0 No ✓ 1 Yes ✓	Action Taken for This Event (record all that apply)	** Serious? 0 No ✓ 1 Yes ✓
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	

01 No action taken
02 Panitumumab dose altered
03 Medication taken
04 Hospitalized / Prolonged hospitalization
05 Removed from study
06 Panitumumab discontinued
07 Transfusion performed
70 Panitumumab infusion interrupted
80 Chemotherapy dose discontinued
81 Chemotherapy dose altered
82 Chemotherapy dose delayed
88 Other *(specify below)*

*** * 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

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: _____

_____

_____

_____

Cycle ____, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn
Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle ____, Day 1

CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn

Day | Month | Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

Cycle ___, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn (Day / Month / Year)

	Test	Result	Unit	Specify if Other Unit
	RBC		1 ❑ /uL 2 ❑ $10^6/mm^3$ 3 ❑ $10^{12}/L$ 88 ❑ Other	
	Hemoglobin		4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
	Hematocrit		15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
	MCV		8 ❑ fL 88 ❑ Other	
	Platelets		1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
	WBC		1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle ___, Day 1

CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn

Day | Month | Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

Week ___
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn (Day / Month / Year)

	Test	Result	Unit	Specify if Other Unit
	RBC		1 ❑ /uL 2 ❑ $10^6/mm^3$ 3 ❑ $10^{12}/L$ 88 ❑ Other	
	Hemoglobin		4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
	Hematocrit		15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
	MCV		8 ❑ fL 88 ❑ Other	
	Platelets		1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
	WBC		1 ❑ /uL 9 ❑ $10^9/L$ 10 ❑ $10^3/mm^3$ 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ $10^9/L$ 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Week ___

CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn

Day | Month | Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

CYCLE 23 TO PROGRESSIVE DISEASE NON-RADIOGRAPHIC ASSESSMENTS

CYCLE __

Cycle ___, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

ECOG PERFORMANCE STATUS

Date			Performance Status ☑ ECOG ❑ KPS
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 more than 50% of waking hours.

4 Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair.

5 Dead

Cycle ___, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle ____, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle ____, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn — Day | Month | Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn — Day | Month | Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C__

Cycle ____

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
	:	:						

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C__

Cycle ____

CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0❑ No 1❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day Month Year	Start Time *(24 hour clock)*	Stop Date Day Month Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin					:		:		
2	1	Leucovorin	*l*-leucovorin 1❑ racemic *(dl-)* leucovorin 2❑				:		:		
3	1	5-FU Bolus			OTO		:		:		
4	1	5-FU Continuous Infusion			CI		:		:		
5	*2*	Leucovorin	*l*-leucovorin 1❑ racemic *(dl-)* leucovorin 2❑				:		:		
6	2	5-FU Bolus			OTO		:		:		
7	2	5-FU Continuous Infusion			CI		:		:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0❑ No 1❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

Cycle ___, Day 1

SKIN TOXICITY ASSESSMENT

If skin toxicity was present, record all details on the Adverse Events Summary CRF

Was the subject assessed for skin toxicity? 0 ❑ No 1 ❑ Yes

Date of Assessment		
Day	Month	Year

VITAL SIGNS

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

BODY SURFACE AREA

Date of Examination			Weight 1 ❑ kg 2 ❑ lb	Body Surface Area *(m^2)*
Day	Month	Year		
				___ . ___ ___

BSA Formula

$BSA\ (m^2) = ([Height\ (cm) \times Weight\ (kg)] / 3600)^{½}$

Cycle ____, Day 1

PHYSICAL EXAMINATION

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

Was a physical examination performed? 0 ❑ No 1 ❑ Yes

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.

SITE CODES:

01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	**04**	Abdomen	**08**	Neurological	**50**	Extremities
02	Cardiovascular	**05**	Musculoskeletal	**09**	Genitourinary	**88**	Other
03	Respiratory	**06**	Skin	**10**	Breast / Chest		
		07	Lymph nodes	**11**	Rectal		

Indicate if a required assessment was not done.

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

Cycle ____, Day 1
HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record Hematology results below that were taken on the planned Day 1

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

If chemotherapy was delayed record the Hematology results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn Day Month Year

Test		Result	Unit	Specify if Other Unit
RBC			1 ❑ /uL 2 ❑ 10^6/mm^3 3 ❑ 10^{12}/L 88 ❑ Other	
Hemoglobin			4 ❑ g/L 12 ❑ g/dL 6 ❑ mmol/L 88 ❑ Other	
Hematocrit			15 ❑ % 5 ❑ L/L 7 ❑ frac of 1 88 ❑ Other	
MCV			8 ❑ fL 88 ❑ Other	
Platelets			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
WBC			1 ❑ /uL 9 ❑ 10^9/L 10 ❑ 10^3/mm^3 88 ❑ Other	
DIFFERENTIAL*	Neutrophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Lymphocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Monocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Eosinophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Basophils		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	
	Granulocytes		15 ❑ % 9 ❑ 10^9/L 88 ❑ Other	

**** In all cases, please record data used to determine ANC at your site.***

Cycle ____, Day 1
CHEMISTRY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Record the Chemistry results below that were taken on the planned Day 1

Date Drawn — Day | Month | Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

If chemotherapy was delayed record the Chemistry results below that were taken on the actual Day 1 (record reason for delay on the chemo admin page).

Date Drawn — Day | Month | Year

Test	Result	Unit	Specify if Other Unit
Sodium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Potassium		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Chloride		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Bicarbonate (HCO_3)		11 ❑ mEq/L 88 ❑ Other 6 ❑ mmol/L	
Total Protein		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Albumin		4 ❑ g/L 88 ❑ Other 12 ❑ g/dL	
Calcium		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Magnesium		11 ❑ mEq/L 6 ❑ mmol/L 14 ❑ mg/L 88 ❑ Other 13 ❑ mg/dL	
Phosphorus		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
BUN		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
OR			
Urea		13 ❑ mg/dL 88 ❑ Other 6 ❑ mmol/L	
Creatinine		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Uric Acid		13 ❑ mg/dL 16 ❑ umol/L 6 ❑ mmol/L 88 ❑ Other	
Total Bilirubin		13 ❑ mg/dL 88 ❑ Other 16 ❑ umol/L	
Alk. Phos.		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
AST (SGOT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
ALT (SGPT)		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	
LDH		17 ❑ U/L 88 ❑ Other 18 ❑ ukat/L	

LDH Local Laboratory Range	
Lower	Upper

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① **DOSE CHANGE CODES:**

01 Adverse Events **03** Dose administration error **41** Dose reinstated **88** Other (*specify*)
02 Noncompliance **04** Per protocol **42** Dose increase

② **"04 PER PROTOCOL" DOSE CHANGE CODES:**

100 Weight change

DOSE WITHHELD CODES

① **DOSE WITHHELD CODES:**

01 Adverse Events **02** Noncompliance **03** Dose administration error **04** Per protocol **88** Other (*specify*)

② **"04 PER PROTOCOL" DOSE WITHHELD CODES:**

113 Skin- or nail-related toxicity **114** Non-skin- or nail-related toxicity

REASON FOR INTERRUPTION

③ **REASON FOR INTERRUPTION CODES:**

01 Adverse event **50** IV occluded **88** Other (*specify*)

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C__

Cycle ____

PANITUMUMAB ADMINISTRATION/WITHHELD DOSES

Subjects receiving FOLFOX alone do not need to complete this page

If subject received Panitumumab please complete all relevant fields. If subject did not receive Panitumumab please record the date they should have received the infusion, record a 'zero' dose and record the reason for withholding the dose

ADMINISTRATION DETAILS

Cycle	Date (Day / Month / Year)	Start Time (24 hour clock)	Stop Time (24 hour clock)	Total Dose Administered (mg)	Total Volume Administered of Panitumumab plus Saline Solution (mL)	Reason for Dose Change / Dose Withheld ①	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code ②	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
	:	:						

Was Infusion Interrupted? 0 No ✓ 1 Yes ✓	If infusion was interrupted provide the total time of administration (not including interruptions)	If infusion was interrupted provide the Reason for Infusion Interruption ③	Specify **REASON FOR INFUSION INTERRUPTION** if "88 Other"	**Package Lot Number**
	:			

INFUSION REACTION

Did the subject experience an infusion reaction (according to the CTCAE guidelines) due to the panitumumab administration?

0 ❑ No 1 ❑ Yes If yes, record all details on the Adverse Events Summary CRF

AMGEN Panitumumab
AMG 954 20050203

Site No.

Subject ID No. 2 1

C__

Cycle ____

CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen

Did subject receive chemotherapy? 0❑ No 1❑ Yes If yes, please enter details below:

Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered *(mg)*	Freq. ①	Start Date Day	Start Date Month	Start Date Year	Start Time *(24 hour clock)*	Stop Date Day	Stop Date Month	Stop Date Year	Stop Time *(24 hour clock)*	Reason for Dose Change ②	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code ③
1	1	Oxaliplatin							:				:		
2	1	Leucovorin	*l*-leucovorin 1❑ racemic *(dl-)* leucovorin 2❑						:				:		
3	1	5-FU Bolus			OTO				:				:		
4	1	5-FU Continuous Infusion			CI				:				:		
5	*2*	Leucovorin	*l*-leucovorin 1❑ racemic *(dl-)* leucovorin 2❑						:				:		
6	2	5-FU Bolus			OTO				:				:		
7	2	5-FU Continuous Infusion			CI				:				:		

① **FREQUENCY CODES:**
CI Continuous infusion
OTO One time only

② **REASON FOR DOSE CHANGE CODES:**
01 Adverse event
02 Noncompliance
03 Dose administration error
04 Per protocol
88 Other *(specify below)*

③ **"04 PER PROTOCOL" DOSE CHANGE CODES:**
100 Weight change
386 Chemotherapy related hematologic dose limiting toxicity
387 Chemotherapy related non-hematologic dose limiting toxicity

Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"	Line #	Specify **REASON FOR DOSE CHANGE** "88 Other"

CHEMOTHERAPY DELAY

If chemotherapy was administered, was it delayed? 0❑ No 1❑ Yes If yes, please enter reason code:

Reason for Delay *(record all that apply)* ①	①**REASON CODES:**	Specify **REASON** "88 Other"
	229 Protocol specified adverse event **230** Protocol specified lab value **316** Interventional therapy for metastases **88** Other (*specify*)	

CYCLE 23 TO PROGRESSIVE DISEASE RADIOGRAPHIC ASSESSMENTS

WEEK __

Week ____

CEA

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae on the Adverse Events Summary CRF.

Date Drawn		
Day	Month	Year

Test	Result	Unit	Specify if Other Unit
Serum Carcinoembryonic antigen		19 ❑ ng/mL 20 ❑ ug/L 88 ❑ Other	

Week ____

TUMOR EVALUATION - TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure Day / Month / Year	Method of Assess-ment ①	Subsite *Describe specific location*	Lesion Site Code ②	Measurable Lesions * *(mm)* *(Longest Diameter)* Must be unidimensionally measurable Dimensions *(mm)*	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ / 1 Yes ✓
01						
02						
03						
04						
05						
06						
07						
08						
09						
10						
					Sum of Target Lesions	

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT) **04** MRI (NMR) **23** Spiral Computed Tomography (CT)

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'.***

Week ____

TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 **No** ✓ 1 **Yes** ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone")* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 **No** ✓ 1 **Yes** ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment

Week ____

TUMOR RESPONSE

Date of Assessment (Day / Month / Year)	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	New Lesions (0 No ✓ / 1 Yes ✓)	Overall Tumor Response Code ③

① OVERALL TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

② OVERALL EXISTING NON-TARGET LESION RESPONSE CODES:

- **CR** Complete response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **NA** Not applicable
- **ND** Not done

③ OVERALL TUMOR RESPONSE CODES:

- **CR** Complete response
- **PR** Partial response
- **SD** Stable disease
- **PD** Progressive disease
- **UE** Unable to evaluate
- **ND** Not done

TUMOR RESPONSE INSTRUCTIONS

OVERALL TARGET LESIONS	OVERALL NON-TARGET LESIONS	NEW LESIONS	OVERALL RESPONSE
CR	CR	No	CR
CR	SD	No	PR
CR	UE/ND	No	UE
PR	Non-PD/NA**	No	PR
PR	UE/ND	No	UE
SD	Non-PD/NA**	No	SD
SD	UE/ND	No	UE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD+
Any	Any	Yes	PD
UE	Non-PD/NA**	No	UE
ND	Non-PD/NA**	No	UE
NA*	SD	No	SD
NA*	CR	No	CR

NA* = No target lesions identified at baseline

NA** = No non-target lesions identified at baseline

+ = If the Overall Tumor Response code is 'PD' solely based on the progression of the non-target lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section

EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE

Individual Lesion Responses	Overall Non-Target Lesion Responses
All Non-Target Lesions have an individual response of **CR**	Complete Response (**CR**)
Does not qualifying for **CR** or **PD** as defined above and below, respectively	Stable Disease (**SD**)
Unequivocal progression of existing Non-Target Lesions (if the Overall Tumor Response code is '**PD**' solely based on the progression of Non-Target Lesions, please fill in the 'Progressing Non-Target Lesions at Least 10mm at time of Progression' page in the 'Extra Forms' section)	Progressive Disease (**PD**)

Screening

TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day / Month / Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	**Longest Diameter** *(mm) (Record actual measurement if ≥ 5mm, otherwise record 5mm. For truly non-measurable lesions record 'NA'.)*
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

① **METHOD OF ASSESSMENT CODES:**

03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast
10 Pleural effusion
13 Lung parenchyma
17 Pleura or pleural wall
20 Liver
30 Bone
40 Chest wall
49 Pericardial effusion
50 Spinal cord
51 Brain
61 Esophagus
62 Stomach
63 Pancreas
64 Small intestine
65 Colon
66 Rectum
69 Anus
70 Ascites
73 Retroperitoneum
74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

Line #	**Specify if "88 Other" Method of Assessment**

AMGEN Panitumumab AMG 954 20050203	Site No.	Subject ID No. 2 1

Week ____

W__

TUMOR EVALUATION - NON-TARGET LESIONS

CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease; or whole body bone scan

Lesion Note: Always maintain the same order of lesion numbers	**Date of Procedure** Day Month Year	**Method of Assess-ment** ①	**Subsite** *Describe specific location*	**Lesion Site Code** ②	New Lesions 0 No ✓ 1 Yes ✓	**Longest Diameter*** *(mm)*	Tumor Response *(Record if body site code is NOT "04 Bone"* ③	Was Interventional Therapy Performed On This Lesion Since the Last Assessment? 0 No ✓ 1 Yes ✓
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

① **METHOD OF ASSESSMENT CODES:**

01 X-Ray
03 Conventional Computed Tomography (CT)
04 MRI (NMR)
23 Spiral Computed Tomography (CT)
25 Bone Scan
60 Physical Examination
88 Other *(specify below)*

② **LESION SITE CODES:**

00 Lymph node
01 Thyroid
02 Oral cavity
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74 Peritoneum
79 Gall bladder
81 Kidney
82 Heart
84 Adrenal gland
85 Spleen
86 Skin
88 Other *(specify in subsite above)*

③ **TUMOR REPONSE CODES:**

CR Complete response
SD Stable disease
PD Progressive disease
UE Unable to evaluate
NA Not applicable
ND Not Done

**** If a lesion has decreased in size to < 5mm, record 5mm, otherwise record actual size. If a lesion has disappeared, please record '0'. If a lesion is truly non-measurable record 'NA'.***

Line #	Specify if "88 Other" Method of Assessment