AMGEN

Panitumumab AMG 954 20050203

DISTRIBUTION	DRAFT DATES	
CLINICAL STUDY MANAGER Fiona Sandeman Claire McPhie BIOSTATISTICS Mike Wolf Jun Wu CDM Jo Rosser Cheryl Garner Sarah Edgington Chizuru Hawker Emma Moore Julie Walker CDMGlobalLibraryRequests@amgen.com HEALTH ECONOMICS Jonh Lu	Recvd: 16Feb06 (Received mock-up, protocol, PE, etc.) v0.0.1: 27Feb06 v0.0.2: 09Mar06 v0.0.3: 28Mar06 v0.0.4: 18Apr06 v0.0.5: 03May06 v0.0.6: 15May06 v0.0.7: 18May06 FINAL: 02Jun06 Revision: Extra Pads v0.1 13Nov06 v0.2 15May07 v0.3 28Nov07 jdw pg 33.03_	
CRE DEVELOPME	ENT MODEL	

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

AMGEN

Amgen Development Europe 240 Cambridge Science Park Cambridge, England CB4 0WD +44(0) 1223-420-305 Protocol Number

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	JAN	2 0 0 4	

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

Site No.

Subject ID No.

2,1

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	e no.	Yes	No
101	Histologically or cytologically-confirmed adenocarcinoma of the colon or rectum in subjects who are presenting with metastatic disease	🖸	0
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)	🖸	0
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	🖸	0
105	Man or woman ≥ 18 years of age		
Hema 106 107 108	atologic function, as follows (≤ 7 days prior to randomization): Absolute neutrophil count (ANC) ≥1.5 x 10 ⁹ /L Platelet count ≥100 x 10 ⁹ /L Hemoglobin ≥ 9 g/dL		0
Rena	al function, as follows (≤ 7 days prior to randomization):		
109 Cr	Creatinine clearance, estimated with Cockcroft-Gault* ≥ 50ml/min		
Нера	tic function, as follows (≤ 7 days of randomization):		
110	Aspartate aminotransferase (AST) \leq 3 x ULN (if liver metastases \leq 5 x ULN)	🗖	
111	Alanine aminotransferase (ALT) \leq 3 x ULN (if liver metastases \leq 5 x ULN)	🗖	
112	Total bilirubin ≤ 1.5 x ULN	🗖	



Site No.

Subject ID No.

2,1

SUBJECT ELIGIBILITY CRITERIA WORKSHEET

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Inclusion Criteria

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

Site	No.

Subject ID No.

2,1

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

if any of the below questions are answered TES, then the subject SHOOLD NOT ENTER the study			ludy
Code	no.	Yes	No
201	History or known presence of central nervous system (CNS) metastases	. 🗖	۵
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 know 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, Subject may have received prior fluropyrimidine therapy if administered solely for the purpose of radiosensitization	S	0
204	Prior oxaliplatin therapy	. 🗖	۵
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	. 🗆	۵
207	Radiotherapy ≤ 14 days prior to randomization (subjects must have recovered from all radiotherapy related toxicities)	. 🗖	۵
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.	. 🗖	۵
210	Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, cardiac arrhythmia) ≤ 1 year prior to randomization	. 🗖	۵
211	History of interstitial lung disease (eg, pneumonitis or pulmonary fibrosis) or evidence of interstitial lung disease on baseline chest CT scan	.0	۵
212	Active inflammatory bowel disease or other bowel disease causing chronic diarrhea (defined as ≥ CTC grade 2, [CTCAE version 3.0])	. 🗖	٥
213	Known positive tests for human immunodeficiency virus (HIV) infection, hepatitis C virus, acute or chronic active hepatitis B infection	. 🗖	٥
214	Any co-morbid disease or condition that could increase the risk of toxicity, eg, dihydropyrimidine deficiency, significant ascites or pleural effusion	. 🗖	٥

Site No.

Subject ID No.

2,1

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) \leq 28 days or minor surgical procedure (excluding central venous catheter placement) \leq 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 precauti 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	🗖	



AMGEN Panitumumab AMG 954 20050203

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Equivalent Lab Units

Unit							Equiv	Equivalents*					
10¹²/L	T/L	10 ⁶ /uL	10 ⁶ /uL 10 ⁶ /mm ³	10 ⁶ /cumm 10 ⁶ /	cmm	10 ⁶ /mcl	Mill/uL	Mill/mm ³	106/mcl Mill/uL Mill/mm³ Mill/cumm	Mill/cmm	Mill/mcl	/br	
	N.B. M	ill = Milli	N.B. Mill = Million, Mil, Mio	oi									
10³/L	G/L	GI/L	10³/nL	10³/mm³	10³/cumm	10³/cmm	10³/mcl	Thous/uL	Thous/mm ³	10³/cumm 10³/cmm 10³/mcl Thous/uL Thous/mm³ Thous/cumm Thous/cmm Thous/mcl	Thous/cmm -	Thous/mcl	/nL
	N.B. T	hous = Tl	housand,	N.B. Thous = Thousand, Thou, Tsnd, Ths, Th, K, k	, Ths, Th,	ζ, k							
106/L	/nr	/mm³	/cnmm	/cmm	/mcl								
fL	_s mn	n ₃											
Fraction of 1	T/L	Ratio											
g/dL	gm/dL	gm/dL Gms/dl	GM/DL										
g/L	gm/L	gms/L	GM/L										
mmol/L	mEq/L												
U/L	ukat/L	ukat/L Units/L	NI/L	IU/L	MU/mL	MiU/mL MIU/ml	MIU/mI						

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

SCREENING

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

Screening **DEMOGRAPHICS**

		I	Ethnic G	roup / Race (enter one code)				Date of	Birth
Sex	Code	Specify if "88	Other"	01 White or Caucasian02 Black or African American		American Indian or Alaska Native	Day	Month	Year
₀□ M ₁□ F	ı			 03 Hispanic or Latino 04 Asian (e.g. Chinese, Bangladeshi, Indian, Pakistani) 05 Japanese 	08	Native Hawaiian or Other Pacific Islander Aborigine Other	I		

INFORMED CONSENT

Date	e Informed Co	nsent Signed
Day	Month	Year

Was a separate Inform	ned Consent signed for
pharmacogenetics	sample collection?
₀ □ No	₁ ☐ Yes

	Date Pharmac	
Day	Month	Year

RANDOMIZATION

	Date of Rando		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 <i>Eligibility Worksheet</i> :
Enter "999" if subject met Eligibility Criteria but did not enroll.
Comments:
Comments:
Comments:

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

Screening CANCER DIAGNOSIS

Primary Tumor Diagnosis ①	① PRIMARY TUMOR DIAGNOSIS CODE	 of Colorectal C	ancer Diagnosis Year	Date I	Metastatic Dis	ease Diagnosed Year
	1251 Colon cancer 1252 Rectal cancer					

HISTOLOGICAL TYPE FOR PRIMARY TUMOR Histological type MUST correspond to the Primary Tumor Diagnosis

Histolo Typ	oe	Differen- tiation	Histological Sub-Type	Specify if Histologi	ical Sub-Type is " 88 Other"
1	8	I			
		CAL TYPE CO	DDES:	 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?

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

02 03	Special senses (vision, hearing, olfaction and taste) Cardiovascular Respiratory Gastrointestinal	 05 Hepatic / Biliary 06 Genitourinary / Reproductive 07 Renal 08 Endocrine / Metabolic 09 Musculoskeletal 	12 D 13 In 50 N 51 P 88 O	nmu eurc sych	nologio logio liatrio	gic					
Code (as listed above)		nosis or Procedure one entry per line.	and	d Ye or	ear c Pro f ava	of D	iagı lure	nosi ,	n is	✓ Continuing	✓ Resolved
l				 		i					
i											
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								$oldsymbol{\perp}$	L		

10 Hematologic / Lymphatic

Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

Screening

PRIOR SURGERY FOR COLORECTAL CANCER

Were there any prior surgeries for colorectal cancer? ${}_{0}\square$ No ${}_{1}\square$ Yes - If yes, specify below.

	Year	_	_		_					Unknown Other (specify below)			
Date	Month		_		_					99 88 taging	Specify INTENT if "88 Other"		
										INTENT CODES: 01 Curative 05 Palliative 10 Diagnostic/Staging	ify INTEN		
+ .	Day	_	_		_					(m)	Spec		
Intent	©	_								and ecify below			
										Adrenal gland Spleen Skin Other (specify below)	Line #		
Description of Surgery	our gery									Lung parenchyma 51 Brain 69 Anus 84 Pleura or pleural wall 61 Esophagus 70 Ascites 85 Liver 62 Stomach 73 Retroperitoneum 86 Bone 63 Pancreas 74 Peritoneum 88 Chest wall 64 Small intestine 79 Gall bladder Pericardial effusion 65 Colon 81 Kidney Spinal cord 66 Rectum 82 Heart	Line # Specify SITE if "88 Other"		
Procedure Site Code(s) ②										CODES: © BODY SITE CODES: 00 Lymph node 13 01 Thyroid 17 pecify 20 Pharynx 30	Specify PROCEDURE if "88 Other"		
ø	#	1	2	က	4	2	9	7	∞	① PROCEDURE CODES: 01 Biopsy 02 Resection 88 Other (Specify below)	Line #		0 03

MMC 0E4 200E0202	Denituminash	Site No.	Subject ID No.
0 1			
C070C007 +C4 DMF	AMG 954 20050203	- - -	-

PRIOR THERAPY FOR NON-METASTATIC COLORECTAL CANCER

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

ion/	ar	_						
Progress	Year	_ 						
Date of Disease Progression/ Recurrence	Month	_ _					her"	
Date of	Day						is "88 Ot	
of Therapy	Year						Specify if TREATMENT SETTING is "88 Other"	
Date of Last Dose of Therapy	Month						fy if TREATMI	
Date c	Day						Specif	
of Therapy	Year							
Date of First Dose of Therapy	Month						Item #	
	Day							
Treat- ment Setting		_						
Type of ment ment Setting		_	_	_	_	_	"88 Other"	
Drug							Specify if TYPE OF THERAPY is "88 Other"	
ltem #		1	2	3	4	2	Item #	

① TYPE OF THERAPY CODES:	② TRE	© TREATMENT SETTING CODES:
01 Chemotherapy 05 Immunotherapy 13 Hormonal 14 Targeted biologics 15 Targeted small molecules 17 Chemoembolization 88 Other (Specify above)	90 04 88	Adjuvant Neo-adjuvant Other (Specify above)

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

Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

PRIOR THERAPY FOR NON-METASTATIC COLORECTAL CANCER Screening

Date of Disease Progression/ Year Recurrence Month Specify if TREATMENT SETTING is "88 Other" Day Date of Last Dose of Therapy Year Month Day Date of First Dose of Therapy Year Item # Month Day Treat-ment Setting Type of Therapy ⊕ Specify if TYPE OF THERAPY is "88 Other" Drug tem # tem # 3 2 2

① TYPE OF THERAPY CODES:	© TREATMENT SETTING CODES:
01 Chemotherapy 05 Immunotherapy 13 Hormonal 14 Targeted biologics 15 Targeted small molecules 17 Chemoembolization 88 Other (Specify above)	06 Adjuvant07 Neo-adjuvant88 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	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		SCR

Screening PRIOR RADIOTHERAPY FOR COLORECTAL CANCER

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

Line #	Body Site Code Record one per line	Area	Intent of Therapy ③	Day	Start I		Wo oz	Dov	Stop D		Did documented progression subsequently occur in this area?
	2			Day	Month	1	Year	Day	Month	Year	₀ No ✓ Yes ✓
1											I I
2											
3											1
4											1
5											1
6							1 1				1
7											1
8											1
9											1
10											
Line #	ŧ	Specify BODY SITE	if "88 Otl	ner"		Line #	Specify	/ INTEN	T OF RAD	IOTHERAPY	if "88 Other"

OTHER REGIONAL THERAPIES FOR COLORECTAL CANCER

Were any other regional therapies for colorectal cancer used? $_{_{0}}\square$ No $_{_{4}}\square$ Yes - If yes, specify below.

Line #	Regional Therapy	Body Site Code Record one per line	Area	Intent of Therapy		Start D	Date		Stop	Date	Did documented progression subsequently occur in this area?
		2			Day	Month	Year	Day	Month	Year	₀ No ✓ ¹ ₁ Yes ✓
1											
2											I I
3	i	i									1
Line #	Specif		NAL THERAP Other"	Y Line #	Spec	ify BODY S	SITE if "88 Othe	er" Lin	e# REG	pecify INTENT O	FOTHER Y if "88 Other"

① REC	GIONAL THERAPY CODES:
US	Padiofroguancy ablation

- Radiofrequency ablation Cryotherapy
- Chemoembolization
- Other (specify above)

3 INTENT OF THERAPY CODES:

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

- **② BODY SITE CODES:**
 - 00 Lymph node 01
 - Thyroid 02 Oral cavity
 - 03 Pharynx
 - Pelvis 08
 - 09
 - 10 Pleural effusion
 - 17 Pleura or pleural wall
 - **Breast**
 - 13 Lung parenchyma
 - 20 Liver
- 30 Bone

- 40 Chest wall
- Pericardial effusion 49
- 50 Spinal cord
- 51 Brain
- 61 Esophagus
- 62 Stomach
- 63 **Pancreas** 64 Small intestine
- 65 Colon
- 66 Rectum

- Anus
- Ascites
- Retroperitoneum
- Peritoneum
- 79 Gall bladder
- Kidney
- 82 Heart
- 84 Adrenal gland
- Spleen 85 Skin
- Other (specify above)

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

Screening VITAL SIGNS

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

ECOG PERFORMANCE STATUS

				Dat	:e					Performance Status
D	ay		Mon	th		Year				☑ ECOG ☐ KPS
① E	① ECOG PERFORMANCE STATUS CODES:									
0 F	ully a	ctive,	able	to ca	arry o	n all	pre-d	isea	ase p	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.									
	Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about > 50% of waking hours.									

ELECTROCARDIOGRAM

Day	Date Perf	ormed	Year		edure ode ①	Body Co	Site de ②	① PROCEDUR 13 Elec	RE CODE: trocardiogram (ECG))
				1	3	0	9	2 BODY SITE 09 Hear		
	Heart i		PR (msecs)			RS ecs)		QT (msecs)	QT _c (msecs)	
			Result Code ③	00		l nal, not	clinica	lly significant ignificant		
Result (requi	ired if abno	rmal):								



Screening PHYSICAL EXAMINATION

	Date of Exan	nination	Н	eight	Weight
Day	Month	Year		m 🖵 in	₁□ kg ₂□ lb
			1	2	1 02

		ject have any abnorm	al clinical fi	ndings relating to the	e following r	equired sites?	₀□ No ₁□	Yes - If yes,
		ngs below.						
SITE	CODES:							
(01 <u>I</u>	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04	Abdomen	08	Neurological	50	Extremities
, ا	02 (Cardiovascular	05 06	Musculoskeletal Skin	09 10	Genitourinary Breast / Chest	88	Other
	03	Respiratory	06 07	Lymph nodes	10	Rectal		
`		respiratory		a required assessme				
			muicate n	a required assessine	THE Was HOLE	ione.		
Code								
(as				Describe fin	dings			
listed				List one entry	per line.			
above)				•				
l								
Ι.								
l 1								
li								
l 1								
l ,								
Ι.								
l 1								

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

HEMATOLOGY

Screening

CHEMISTRY

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

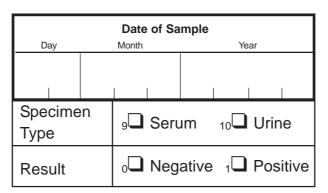
[Day	ı	Date Dr Month		Year	
	Test		Result		Unit	Specify if Other Unit
RBC				0 ⁶ /mm ³ 0 ¹² /L		
Не	emoglob	oin		4 Q	g/L g/dL nmol/L	
He	ematocr	it		15 C	% _/L rac of 1	
M	CV			8 G	L	
Pli	Platelets			9 1 10 1 88 0	0 ⁹ /L 0 ³ /mm ³	
W	вс			₁	0 ⁹ /L 0 ³ /mm ³	
	Neutro	phils		9 1 88 0	% 0º/L	
D I F	Lymph	nocytes		15 9 1 9 1 88 0	0º/L Other	
F E R E	Monod	cytes		9 1 88 0	0º/L Other	
N T I A	Eosino	ophils		9 1 88 0	0º/L Other	
L *	Basop	hils		9 1 88	0º/L Other	
	Granu	locytes		15 0 9 1 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1		

nd clinical sequelae on the	Date D				
Test	Result		Unit		Specifif Othe Unit
Sodium		1	¶ mEq/L ₈₈ □ C ¶ mmol/L	Other	
Potassium		1	】mEq/L ₈₈ □ C 】mmol/L	ther	
Chloride		1	】mEq/L ₈₈ □ C 】mmol/L	ther	
Bicarbonate (HCO ₃)		6	】mEq/L ₈₈ □ C 】mmol/L		
Total Protein		1] g/L ₈₈	Other	
Albumin		12	g/L ₈₈ C g/dL		
Calcium		6	l mg/dL ₈₈ □ C l mmol/L		
Magnesium		14	I mEq/L ₆ □ m I mg/L ₈₈ □ C I mg/dL		
Phosphorus		13	amg/dL ₈₈ □ C ammol/L	Other	
BUN		l -	☐ mg/dL ₈₈ ☐ C ☐ mmol/L	ther	
— — — OR — - Urea		1.0	☐ mg/dL ₈₈ ☐ C ☐ mmol/L	ther	
Creatinine			☐ mg/dL ₈₈ ☐ C ☐ umol/L	ther	
Uric Acid		13	ng/dL ₁₆ □ u nmol/L ₈₈ □ C		
Total Bilirubin		13	☐ mg/dL ₈₈ ☐ C		
Alk. Phos.		17	U/L ₈₈ C ukat/L	Other	
AST (SGOT)		17	U/L ₈₈ C ukat/L	ther	
ALT (SGPT)			U/L ₈₈ C ukat/L	Other	
LDH		1	U/L ₈₈ U C ukat/L	ther	
LDH	Local Labo	110			
Lower		Uppe	er		

Screening PREGNANCY TEST

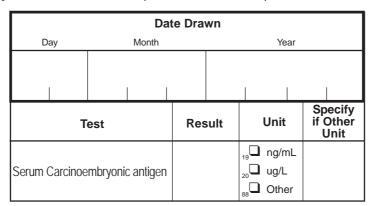
Is subject of child bearing potential? $_{0}\Box$ No $_{1}\Box$ Yes

Was pregnancy test performed? Do No Do Yes. If Yes, specify below



CEA

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



SITE OF BIOPSY FOR EGFr EVALUATION

Site of Biopsy	If '02-Metastatic' indicate Body Site	Specify BODY SITE if "88-Other"				
① SITE OF BIOPSY CODE: 01 Primary 02 Metastatic	 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 18 Kidney 18 Heart 18 Adrenal gland 18 Spleen 18 Skin 18 Other (specify above)				

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

BENIGN ABNORMALITIES

Does the subject have any benign conditions that may radiographically mimic metastatic disease? Does the subject have any benign conditions that may radiographically mimic metastatic disease? Does the subject have any benign conditions that may radiographically mimic metastatic disease? Does the subject have any benign conditions that may radiographically mimic metastatic disease?

0000	ily below.									
Line #	Condition ①	Lesion Site Code	Subsite					Details		
1										
2										
3										
4										
5										
6										
7										
8										
9	ı									
10										
11										
Line #	·	Specify C	CONDITION if "88 Othe	r"	Line #		,	Specify CONDITIO	N if "	'88 Other"
01 02 03 04 05 06 07 08	Benign live Benign bon Benign retr Benign GY Benign rens Post-traum Post-surgic	g lesions diastinal and r lesions ne lesions operitoneal a N lesions at lesions atic hemator ral, post proc ry fibrosis or	nas edural or post	2 LESION SIT 00 Lymph 01 Thyroid 02 Oral ca 03 Pharyn 08 Pelvis 09 Breast 10 Pleural 13 Lung pa 17 Pleura 20 Liver 30 Bone	node vity c	4 4 5 5 6 6 6	9 0 1 1 2 3 4 5 6	Chest wall Pericardial effusion Spinal cord Brain Esophagus Stomach Pancreas Small intestine Colon Rectum Anus	73 74 79 81	Peritoneum Gall bladder Kidney Heart Adrenal gland Spleen

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

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	[Day	Date of Pr	ocedure Year	Method of Assess- ment ①	Subsite Describe specific location	Lesion Site Code	Measurable Lesions (mm) (Longest Diameter) Must be unidimensionally measurable Dimensions (mm)	Was Lesion Previously Irradiated?	If lesion was previously irradiated has it subsequently had radiographically documented progression
01									Alls
02									graphica Iestion
03									nd radiog n-target
04								1	If lesion was irradiated but has not subsequently had radiographically determined progression, please record as a non-target lestion
05									subsequ
06								1	has not
07									ted but I
08								1	s irradia ned prog
09									sion wa. determi
10								1	If le
						n of rget			
1			ENT CODES: uted Tomograph	y (CT)	04 MRI (NMR) 23	Spiral Cor	mputed Tomography	(CT)	
00 01 02 03 08 09	ON SITE Lymph no Thyroid Oral cavit Pharynx Pelvis Breast Pleural ef	ty	13 Lung parer 17 Pleura or p 20 Liver 30 Bone 40 Chest wall 49 Pericardial 50 Spinal cord	leural wall effusion	61 Esophagus 62 Stomach 63 Pancreas 64 Small intestine 65 Colon	69 Anus 70 Ascite 73 Retrop 74 Peritor 79 Gall bl 81 Kidney 82 Heart	s 85 Speritoneum 86 Speritoneum 88 S	Adrenal gland Spleen Skin Other (specifi Subsite abovi	fy in

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

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?	٦∪	Yes - If	ves, specify	below
---	----	----------	--------------	-------

Lesion Note: Always maintain th same orde of lesion numbers	e	Date of Pr	ocedure Year	Method of Assess- ment ①	Subsite Describe specific location	Lesion Site Code	Longest Diameter (mm) (Record actual measurement if ≥ 5mm, otherwise record 5mm. For truly nonmeasurable lesions record 'NA'.)
11							
12		1 1					
13							
14							
15							
16							
17		1 1					
18							
19		1 1					
20							
03 04 ② LESI		CODES: e 13	d Tomography (CT)	25 . 51	Spiral Computed Tomography (CT) Bone Scan Brain 69 Anus	88 Other (al examination (specify below)
02 03 08 09	Thyroid Oral cavity Pharynx Pelvis Breast Pleural effu	17 20 30 40 49	Pleura or pleural v Liver Bone Chest wall Pericardial effusion Spinal cord	wall 61 62 63 64 on 65	Esophagus Stomach Pancreas Small intestine Colon Rectum 70 Ascites 73 Retroperitoneum 74 Peritoneum 79 Gall bladder Kidney Heart	85 Spl 86 Ski 88 Oth <i>above</i>)	een n ner (specify in subsite
Line	#			Specify if	f "88 Other" Method of Assessment		

TREATMENT PHASE

CYCLE 1

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , , ,
		C1D1

Cycle 1, Day 1

VITAL SIGNS

	Date		Blood Pressure	Heart Rate	Respiration	Temperature
Day	Month	Year	(mmHg)	(beats/minute)	(breaths/minute)	
			1			

BODY SURFACE AREA

Day	Date of Exam	nination Year	Weight ₁□ kg ₂□ lb	Body Surface Area

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Date Day Month Year							Performance Status ☑ ECOG ☐ KPS				
1	① ECOG PERFORMANCE STATUS CODES:										
0	Fully a	ctive	able	to car	ry on	all pr	e-dise	ease p	performance without restriction.		
1	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	2 Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about > 50% of waking hours.										
3											

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

- 5 0 d
- 5 Dead

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , ,
		C1D1

Cycle 1, Day 1 PHYSICAL EXAMINATION

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

Record any new linding or che	inge (wo	rseriirig) o	anca	istirig	miuni	<i>j</i> 011	uio r
Was a physical examination perfor	med? 。	□ No ₁□	l Yes				
		Date	of Exar	ninatio	on		
	Day	Mor	th		Yea	ır	

Does t	he subject have any abnorm	al clinical fi	indings relating to th	e following r	equired sites?	□ No □	Yes - If yes,			
describ	e findings below.		0 0	Ü	•	0 1	,			
SITE C	ODES:									
01 02 03	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other						
		Indicate if	a required assessm	ent was not d	done.					
Code (as listed above)	Describe findings List one entry per line.									

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

HEMATOLOGY Cycle 1, Day 1

CHEMISTRY

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

	If an	abnormal .	laboratory v Date Dra		resulted in clinic	al sequelae
	Day	١	Month	avvII	Year	
	Test		Result		Unit	Specify if Other Unit
RBC				2 Q	/uL 10 ⁶ /mm³ 10 ¹² /L Other	
Hemoglobin				12 6	g/L g/dL mmol/L Other	
Hematocrit				7	% L/L frac of 1 Other	
M	CV				fL Other	
Platelets				90100	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
WBC				9 10	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
	Neutro	ophils		15 9 88	% 10 ⁹ /L Other	
D	Lymph	nocytes			% 10 ⁹ /L Other	
F E R	E Monocytes			15 9 0	% 10º/L Other	
E N T I	Eosino	ophils		88	10 ⁹ /L Other	
L *	Basop	hils		88	10 ⁹ /L Other	
	Granu	locytes			% 10 ⁹ /L Other	

Day		Date D		ents Summary CRF. wn Year	
Test	:	Result		Unit	Specify if Other Unit
Sodium			1	mEq/L ₈₈ Other mmol/L	
Potassium			6	☐ mEq/L ₈₈ ☐ Other ☐ mmol/L	
Chloride			6	mEq/L ₈₈ Other mmol/L	
Bicarbonate	e (HCO ₃)		6	mEq/L ₈₈ Other mmol/L	
Total Protei	n		12	g/L 88 ☐ Other ☐ g/dL	
Albumin			12	☐ g/L 88☐ Other☐ g/dL	
Calcium			J ₆	mg/dL ₈₈ Other mmol/L	
Magnesium	l		14	□ mEq/L ₆ □ mmol/L □ mg/L ₈₈ □ Other □ mg/dL	
Phosphorus	3		13	☐ mg/dL ₈₈ ☐ Other☐ mmol/L	
BUN	OD		1.0	☐ mg/dL ₈₈ ☐ Other☐ mmol/L	
Urea	OR —		1 -	mg/dL ₈₈ Other mmol/L	
Creatinine				☐ mg/dL ₈₈ ☐ Other☐ umol/L	
Uric Acid			13	mg/dL ₁₆ umol/L umol/L other	
Total Bilirub	in		1	☐ mg/dL ₈₈ ☐ Other☐ umol/L	
Alk. Phos.				U/L 88 Other ukat/L	
AST (SGOT	Γ)		18	☐ U/L ₈₈ ☐ Other☐ ukat/L	
ALT (SGPT)		1	U/L ₈₈ U Other ukat/L	
LDH			1	U/L ₈₈ U Other ukat/L	
	LDH I	Local Labo	orat	ory Range	
Lower			Upp	per	

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

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danitumimah	Site No.	Subject ID No.
2	7	
MMC 064 20060203	·//	· ·
AINIG 734 20030203	_ _ _	
		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

	Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"		Package Lot Number	_
If "04 per protocol" is indicated for "Reason for	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code		n e	
Reason for Dose Change /	Reason for Dose Change / Dose Withheld		ON if "88 Other"	
Total Volume Administered of Panitumumab plus Saline Solution			SON FOR INFUSION INTERRUPTION if "88 Other"	
Total	Total Dose Administered (mg)		REASON FOR I	
	Stop Time (24 hour clock)		Specify REA	
Otto Timo	Start Time (24 hour clock)		σ	
	Year	- -	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date	Day Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cvcle		_	Was Infusion Interrupted ?	

INFUSION REACTION

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

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

protocol" is specified for "Reason for Dose Change", indicate code C_{1} Weight change Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reason Subject ID No. © "04 PER PROTOCOL" DOSE CHANGE CODES:
100 Weight change
386 Chemotherapy related hematologic dose limit
387 Chemotherapy related non-homotocic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date Month Day Site No. Start Time (24 hour clock) Year 04 Per protocol88 Other (specify below) Start Date **Cycle 1** Month Line # Day REASON FOR DOSE CHANGE CODES:
01 Adverse event 04 Per
02 Noncompliance 88 Oth
03 Dose administration error OTO OTO $\overline{\mathbf{c}}$ Freq. $\overline{\mathbf{c}}$ Actual Total Dose Administered Specify REASON FOR DOSE CHANGE "88 Other" (mg) **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

CYCLE 2

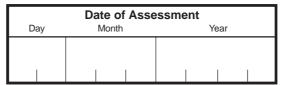


Cycle 2, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Exam Month	nination Year		Weight ₁☐ kg ₃☐ lb	Body Surface Area
			-	1 5 2	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		C2D1

Cycle 2, Day 1 **PHYSICAL EXAMINATION**

Record any new linding or cha	rige (wors	ening) oi ari exi	isting linding on the A	Adverse Events Summary CRF
Was a physical examination perform	med? $_{\scriptscriptstyle 0}$ $lacksquare$	No ₁☐ Yes		_
		Date of Exan	nination	
	Day	Month	Year	

	_							
Does	the su	bject have any abnorm	al clinical fi	ndings relating to th	e following re	equired sites?	₀ No ₁ U	Yes - If yes,
		ings below.						
SITE	CODES	:						
	01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04 05	Abdomen Musculoskeletal	08 09	Neurological Genitourinary	50 88	Extremities Other
	02	Cardiovascular	06	Skin	10	Breast / Chest	00	Other
	03	Respiratory	07	Lymph nodes	11	Rectal		
			Indicate if	a required assessm	ent was not d	one.		
Code								
(as				Describe fin				
listed				List one entry	per line.			
above)								
1								
<u>'</u>								
1								
,								
1								
,								

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C2D1

Cycle 2, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that were

Rec	ord Hema	tology resu	Its below tha	t were	taken on the pla	nned Day 1
	Day		Date Dra Month	awn	Year	
	,		-			
	Test		Result		Unit	Specify if Other Unit
				1	/uL	
RE	RC			$_{2}$	10 ⁶ /mm ³	
IXL				•	10 ¹² /L	
				88	Other	
					g/L	
Нє	emoglob	oin		12	g/dL	
				0	mmol/L	
					Other	
				15		
He	ematocr	it		5	L/L	
				,	frac of 1	
					Other	
NAC	CV			\square_8		
IVIV					Other	
					/uL	
				•	10 ⁹ /L	
Pla	atelets				10 ³ /mm ³	
				88	Other	
					/uL	
				•	10 ⁹ /L	
W	ВС				10 ³ /mm ³	
					Other	
				15		
	Neutro	nhile		-	10 ⁹ /L	
	rvound	priiis		88	Other	
				15		
D	Lymph	nocytes			10 ⁹ /L	
I F					Other	
F				15		
E	Monod	ov to c		-	10 ⁹ /L	
R E	IVIOLIOC	Lytes			Other	
N				15		
T	Eosino	ophils			10 ⁹ /L	
I A					Other	
L				15		
*	Booss	hile		•	10 ⁹ /L	
	Basop	iiiiS			Other	
				15		
	Granu	locytes		-	10 ⁹ /L	
		•		88	Other	

[Day	Date Dr Month	awn	Year	
		I		1	I
	Test	Result	U	nit	Specify if Othe Unit
RE	3C		10 ⁶ /r 2 10 ⁶ /r 3 10 ¹² / 88 Othe	L	
Не	emoglobin		4 g/L 12 g/dL 6 mmo 88 Othe	ol/L	
Не	ematocrit		15 % 5 L/L 7 frac 88 Othe	of 1	
M	CV		88 8 fL 80 Othe		
Pla	atelets		1 /uL 9 10°/L 10 10°/r 10 10°/r 88 Othe	nm³	
W	вс		1 /uL 9 10°/L 10 103/r 88 Othe	nm³	
	Neutrophils		9 10°/L 88 Othe		
D I F	Lymphocytes	3	9 10°/L 88 Othe		
F F E R E	Monocytes		$_{15}$ % $_{9}$ 10°/L $_{88}$ Other		
N T I	Eosinophils		9 10°/L 88 Othe		
A L *	Basophils		9 10°/L 88 Othe		
	Granulocytes	3	15 % 9 10 °/L □ Othe		

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

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

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

2.03

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C2D1

Cycle 2, Day 1 CHEMISTRY

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

Day Mo	Date Donth	rawn Year				
	1		1			
Test	Result	Unit	Specify if Other Unit			
dium		₁₁ □ mEq/L ₈₈ □ Oth ₆ □ mmol/L	ner			
tassium		mEq/L ₈₈ Oth	er			
lloride		nEq/L ₈₈ Oth mmol/L				
carbonate (HCO ₃)		mEq/L ₈₈ Oth				
tal Protein		₄ □ g/L ₈₈ □ Otl ₁₂ □ g/dL				
oumin		₄ □ g/L ₈₈ □ Oth				
ılcium		mg/dL 88 Oth				
agnesium		$_{11}$ mEq/L $_{6}$ mm $_{14}$ mg/L $_{88}$ Oth $_{13}$ mg/dL				
osphorus		13 — mg/dL ₈₈ □ Oth ₁₃ □ mmol/L	ner			
JN		ng/dL ₈₈ □ Oth	ner			
— — — OR — - ea		mg/dL ₈₈ Oth	ner			
eatinine		$_{13}$ mg/dL $_{88}$ Oth $_{16}$ umol/L	ner			
ic Acid		$_{13}$ mg/dL $_{16}$ um $_{6}$ mmol/L $_{88}$ Oth				
al Bilirubin		ng/dL ₈₈ Oth				
c. Phos.		17 U/L 88 Oth	ner			
ST (SGOT)		17 U/L 88 Oth	er			
T (SGPT)		17 U/L 88 Oth	ner			
Н		17 U/L 88 Oth	er			

nken on the actua		Date D					
Day	IVIU	onth	—		Y	'ear	
1	I	ı				ı	
Test		Result		ι	Jnit		Specify if Other Unit
Sodium			6	mEq/L	L L		
Potassium			6	mEq/L	/L		
Chloride			6	mEq/L mmol/	/L		
Bicarbonate	(HCO ₃)		6	mEq/L mmol/	/L		
Total Protein	ı		12	g/L g/dL			
Albumin			12	g/L g/dL			
Calcium			6	mg/dL mmol/	/L		
Magnesium			14	☐ mEq/L ☐ mg/L ☐ mg/dL	88	Other	
Phosphorus			1 -	☐ mg/dL☐ mmol/		Other	
BUN (or —		6	mg/dL mmol/	/L		
Urea			6	☐ mg/dL☐ mmol/	/L		
Creatinine			16	☐ mg/dL ☐ umol/l	L		
Uric Acid			6	☐ mg/dL ☐ mmol/	/L ₈₈	Other	
Total Bilirubi	n		1 -	☐ mg/dL ☐ umol/l		Other	
Alk. Phos.			1.,	❑ U/L ❑ ukat/L	00	Other	
AST (SGOT)			☐ U/L ☐ ukat/L		Other	
ALT (SGPT)			1	☐ U/L ☐ ukat/L		Other	
LDH				❑ U/L ❑ ukat/L		Other	
	LDH I	Local Labo	orat	ory Ran	ge		
Lower			Upp	er			

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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

	tocol" is Specify DOSE CHANGE/ teason for Specify DOSE CHANGE/ 9 / Dose WITHHELD DOSE if "88 Other"		Package Lot Number	
	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	r	
	Reason for lose Change ose Withhele	_	ION if "88 Othe	
	Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
	Total Dose Administered (mg)		REASON FOR	
	Stop Time (24 hour clock)		Specify	
	Start Time (24 hour clock)		S	
	Year	- - -	If infusion was interrupted provide the Reason for Infusion Interruption	_
	Date Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
	Cycle	2	Was If infusion Interrupted? time time (not in Ves	
Wh	ite & Yellow - An	ngen: <i>Blue</i>	e - CRA: White Caro	/ - Investiga

INFUSION REACTION

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

□ No □ Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code C_2 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 2 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin Continuous infusion One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ CI OTO Line # Line# 2 3 4 2 9

CYCLE 3

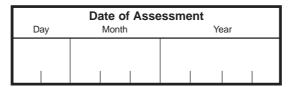


Cycle 3, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? D No D Yes



VITAL SIGNS

Date		Blood Pressure	Heart Rate	Respiration	Temperature	
Day Month Year		(mmHg)	(beats/minute)	(breaths/minute)		
			1			

BODY SURFACE AREA

	Date of Exar	nination	Weight	Body Surface Area
Day	Month	Year	│	(m ²)
			1 - 19 2 - 11	` ′

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Date						Performand		
[Day	Month			Year		₫ ECOG	☐ KPS
1	① ECOG PERFORMANCE STATUS CODES:							
0	0 Fully active, able to carry on all pre-disease performance without restriction.							
1	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		atory and ca	•			,	nable to carry out rs.	any work
2	Canah	Canable of only limited colf care, confined to had at about more than E00/ of						

- 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

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , ,
		C3D1

Cycle 3, Day 1 PHYSICAL EXAMINATION

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

Record any new linding or cha	rige (wors	eriirig) oi ari ex	isung ililaling on the A	adverse Everils Summary CRI
Was a physical examination perform	ned? $_{\scriptscriptstyle 0}$ $lacksquare$	No ₁☐ Yes		_
		Date of Exan	nination	
	Day	Month	Year	
				1

Does descri	the su	ubject have any abnorm	al clinical f	indings relating to the	e following r	equired sites?	No 1	Yes - If yes,
SITE (04 05 06 07 Indicate if	Abdomen Musculoskeletal Skin Lymph nodes a required assessme	08 09 10 11 ent was not c	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
Code (as listed above)				Describe fin List one entry				

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID	O No.
	2,1, , ,	

C3D1

Cycle 3, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that were

Rec	ord Hema	tology resu	Its below tha	t were	taken on the pla	nned Day 1
	Day		Date Dra Month	awn	Year	
	,		-			
	Test		Result		Unit	Specify if Other Unit
				1	/uL	
RE	RC			$_{2}$	10 ⁶ /mm ³	
IXL				•	10 ¹² /L	
				88	Other	
					g/L	
Нє	emoglob	oin		12	g/dL	
				0	mmol/L	
					Other	
				15		
He	ematocr	it		5	L/L	
				,	frac of 1	
					Other	
NAC	CV			\square_8		
IVIV					Other	
					/uL	
				•	10 ⁹ /L	
Pla	atelets				10 ³ /mm ³	
				88	Other	
					/uL	
				•	10 ⁹ /L	
W	ВС				10 ³ /mm ³	
					Other	
				15		
	Neutro	nhile		-	10 ⁹ /L	
	rvouire	priiis		88	Other	
				15		
D	Lymph	nocytes			10 ⁹ /L	
I F					Other	
F				15		
E	Monod	ov to c		-	10 ⁹ /L	
R E	IVIOLIOC	Lytes			Other	
N				15		
T	Eosino	ophils			10 ⁹ /L	
I A					Other	
L				15		
*	Booss	hile		•	10 ⁹ /L	
	Basop	iiiiS			Other	
				15		
	Granu	locytes		-	10 ⁹ /L	
		•		88	Other	

[Day	Date Dr Month	awn Ye	ar
		I		1 1
	Test	Result	Unit	Specify if Othe Unit
RE	3C		106/mm³ 1012/L 88 Other	
Не	emoglobin		4 g/L 12 g/dL 6 mmol/L 88 Other	
Не	ematocrit		15 % 5 L/L 7 frac of 1 88 Other	
M	CV		88 fL 8 Other	
Pla	atelets		10°/L 10°/L 10°/mm³ 88 Other	
W	вс		1 /uL 9 10°/L 10 10°/mm³ 88 Other	
	Neutrophils		15	
D I F	Lymphocytes	3	15	
F E R E	Monocytes		15	
N T I	Eosinophils		15	
A L *	Basophils		15	
	Granulocytes	3	15 % 9 10 9/L 88 Other	

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

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

Blue - CRA; White Card - Investigator

3.03

AMGEN	Panitumumab
AMG 954 2	0050203

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								
Day	Мо	Date D onth	Prawn Year					
Test		Result	Specif Unit if Othe Unit					
Sodium			mEq/L 88 Other 6 mmol/L					
Potassium			mEq/L 88 Other 6 mmol/L					
Chloride			mEq/L ₈₈ Other					
Bicarbonate	(HCO ₃)		mEq/L ₈₈ Other					
Total Proteir	ı		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL					
Albumin			4 g/L 88 Other 12 g/dL					
Calcium			mg/dL 88 Other 6 mmol/L					
Magnesium			11 mEq/L 6 mmol/L 14 mg/L 88 Other 13 mg/dL					
Phosphorus			mg/dL 88 Other Other					
BUN	OR — -		mg/dL ₈₈ Other Other					
Urea			$_{13}$ \square mg/dL $_{88}$ \square Other $_{6}$ \square mmol/L					
Creatinine			ng/dL 88 Other to the last of					
Uric Acid			$\begin{array}{c} \label{eq:mgdl} \text{13} \ \square \ \text{mg/dL} \ \text{16} \ \square \ \text{umol/L} \\ \ \ _{6} \ \square \ \text{mmol/L} \ \text{88} \ \square \ \text{Other} \end{array}$					
Total Bilirub	in		ng/dL 88 Other labeled umol/L					
Alk. Phos.			U/L 88 Other labeled the label					
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 L	ocal Labo	oratory Range					
Lower			Upper					

If chemotherapy aken on the actua			for	delay or			
Day	Мс	onth	ıı av	VII	`	Year	
Test		Result		l	Jnit		Specify if Other Unit
Sodium			6	mEq/l mmol/	L L		
Potassium			6	mEq/l	/L		
Chloride			6	mEq/l	/L		
Bicarbonate	e (HCO ₃)		6	mEq/l	/L		
Total Proteir	า		12	g/L g/dL			
Albumin			12	g/L g/dL	00		
Calcium			6	mg/dl	/L		
Magnesium			14	」 mEq/l ☐ mg/L ☐ mg/dl		mmol/L Other	
Phosphorus	3		1	☐ mg/dl ☐ mmol		Other	
BUN	OR — -		1.0_	mg/dl	00	Other	
Urea	OK		1	mg/dl mmol		Other	
Creatinine			l _	mg/dl umol/		Other	
Uric Acid			1.0	mg/dl mmol			
Total Bilirub	in		1	mg/dl umol/		Other	
Alk. Phos.			1	Ū U/L Ū ukat/L		Other	
AST (SGOT	<u>-</u>)		1	U/L ukat/l		Other	
ALT (SGPT)		1	U/L ukat/l		Other	
LDH			1	Ū U/L Ū ukat/l		Other	
	LDH	Local Labo	orat	ory Ran	ge		
Lower			Upp	er			

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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 Day Month Year Was If infusion was interupted? Was If infusion was interupted? Was If infusion was interupted? Was Information of administration interupted? If infusion interupted? Was If infusion was interupted? Was Infusion was interupted? Was If infusion was interupted? Withheld ", indicate for "Reason for "If "04 per protocol" is a family and indicated for "Reason for "If "04 per protocol" is a family and indicated for "Reason for "If "04 per protocol" is a family and indicated for "Reason for "If "04 per protocol" is a family and indicated for "Reason for "If "04 per protocol" is a family and indicated for "Reason for "If "04 per protocol" is a family and indicate
--

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code \mathcal{E} Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 3 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line# 2 3 4 2 9

CYCLE 4

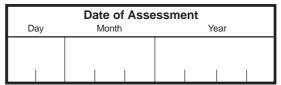


Cycle 4, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Date Day Month Year		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature	
			1			

BODY SURFACE AREA

	Date of Exan	nination	Weight	Body Surface Area
Day	Month	Year	kg 2 lb	(m ²)
			1 - 1.9 2 - 1.2	, ,
l				
				•

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , ,
		C4D1

Cycle 4, Day 1 PHYSICAL EXAMINATION

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

rigo (word	orning) or arr ox	isting infamig on the i	laverse Everne Carminary Or l				
Was a physical examination performed? ₀☐ No ₁☐ Yes							
	Date of Exar	nination					
Day	Month	Year					
	med? ₀□	med? ₀☐ No ₁☐ Yes Date of Exam	Date of Examination				

Does the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites?								
0	CODES 01 02 03	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory	04 05 06 07 Indicate if	Abdomen Musculoskeletal Skin Lymph nodes a required assessm	08 09 10 11 ent was not d	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
Code (as listed above)				Describe fir List one entry				

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	_
	2,1, , , , , , ,	

C4D1

Cycle 4, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that were

Rec	ord Hemat	ology resu	Its below tha	t were	taken on the pla	anned Day 1
	Day	1	Date Dra Month	awn	Year	
						,
	Test		Result		Unit	Specify if Other Unit
RE	3C			2 a	/uL 1 10 ⁶ /mm ³ 1 10 ¹² /L I Other	
Не	emoglob	in		4 12 6	g/L g/dL mmol/L Other	
Не	ematocri	t		15 5		
М	CV			8	fL Other	
Pla	atelets			9 0	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
W	вс			10	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
	Neutro	phils		88	l 10º/L l Other	
D I F	Lymph	ocytes		•	% 10º/L Other	
F E R E	Monoc	ytes		88	l 10º/L l Other	
N T I A	Eosino	phils			% 10º/L Other	
L *	Basopl	nils		88	l 10º/L l Other	
	Granul	ocytes		-	% 10º/L Other	

[Day	Date Dr Month	Yea	r
_	Test	Result	Unit	Specify if Other
		1333313	/uL	Unit
RF	3C		2 10 ⁶ /mm ³	
			3 10 ¹² /L 88 Other	
			88 Other	
Н	emoglobin		12 g/dL	
110	moglobin		6 mmol/L	
			88 Other	
			15	
He	ematocrit		5 - L/L 7 - frac of 1	
			88 Other	
M	CV		₈ □ fL	
			88 Other	
			₁ □ /uL ₂ □ 10º/L	
Pla	atelets		9 10 / L 10 10 10 / mm ³	
			88 Other	
			₁☐ /uL	
۱۸/	ВС		₉ 10°/L	
VV	ьс		10 ³ /mm ³ 88 Other	
			88 Strict	
			9 10°/L	
	Neutrophils		88 Other	
			15 %	
D I	Lymphocyte	es	9 10 ⁹ /L Other	
F			88 Other	
F E			15 9 10°/L	
R E	Monocytes		88 Other	
N			15 %	
T I	Eosinophils		9 10°/L	
Α			88 Other	
L *			15 70°/L	
	Basophils		88 Other	
			₁₅ %	
	Granulocyte	es	₉ 10°/L	
	all cases, please		88 Other	

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

AMGEN	Panitumumab
AMG 954 2	0050203

1	Site No.	Subject ID No.	
		2,1, , , , , , ,	

C4D1

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 Chei		Its below th					•
Day	Mo	Date D	raw	n	Ye	ar	
							0
Test		Result		U	nit		Specify if Other Unit
			11	l mEq/L	₈₈ 🗆 C	Other	
Sodium			0	mmol/L			
Datassium			l	l mEq/L	00	ther	
Potassium			1 0	mmol/L			
Chloride			1	mEq/L)ther	
Chloride			10	mmol/L			
Bicarbonate	(HCO.)		l	mEq/L	00	other	
Diodroonato	(11003)		1 0	mmol/L)thor	
Total Protein	1		1	g/L	88	Jinei	
	-			g/dL g/L)ther	
Albumin			1	l g/L l g/dL	88	MIEI	
				mg/dL		Other	
Calcium			1	l mmol/l		Julion	
			<u> </u>	mEq/L		nmol/L	
Magnesium			1	l mg/L	•		
			1	l mg/dL			
Phosphorus				mg/dL		Other	
				l mmol/l			
BUN			I	l mg/dL		Other	
	or —-			mmol/l		- — -	
Urea			1	l mg/dL		Other	
			-	mmol/l			
Creatinine				l mg/dL		Other	
			1.4	l umol/L			
Uric Acid			1	l mg/dL			
			-	mmol/l			
Total Bilirubi	n		1 -	l mg/dL l umol/L		uner	
Alla Diana			1.0	l U/L		Other	
Alk. Phos.			l	l ukat/L	88	Juici	
AST (SGOT	`\		1.4	l U/L	O)ther	
A31 (3001	,			l ukat/L			
ALT (SGPT)			1.0	l U/L		Other	
, LI (501 I)			l	l ukat/L			
LDH			1.0	l U/L		ther	
			l	l ukat/L			
	LDH I	Local Labo	orato	ry Rang	e		
Lower			Uppe	r			

aken on the actua		Date D					
Day	Mo	onth	\neg		Y	ear	
1	1	1		1		t	1
Test		Result		U	Jnit		Specify if Other Unit
Sodium			6	mEq/L mmol/l	L		
Potassium			6	mEq/L	L L		
Chloride			6	mEq/L mmol/	L_		
Bicarbonate	HCO ₃		6	mEq/L mmol/	L		
Total Protein	1		12	□ g/L □ g/dL			
Albumin			12	g/L g/dL			I
Calcium			6	mg/dL mmol/	/L		
Magnesium			14	☐ mEq/L ☐ mg/L ☐ mg/dL			
Phosphorus	i		6	☐ mg/dL ☐ mmol/	L_		
BUN	or — -		6	mg/dL mmol/	′L		
Urea			6	☐ mg/dL☐ mmol/	L		
Creatinine			16	☐ mg/dL ☐ umol/L	L		
Uric Acid			6	☐ mg/dL ☐ mmol/	/L ₈₈	Other	
Total Bilirubi	n		16	☐ mg/dL ☐ umol/l	L		
Alk. Phos.			18	☐ U/L ☐ ukat/L	•		
AST (SGOT)		18	☐ U/L ☐ ukat/L	-		
ALT (SGPT)			18	U/L ukat/L	-		
LDH			18	Ū U/L Ū ukat/L	-	Other	
	LDH I	Local Labo			ge		
Lower		1	Upp	er			

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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

If "04 per protocol" is indicated for "Reason for Dose Change Jose Withheld", indicate code		Package Lot Number	_
If "04 per production of the product	_	ner"	
Reason for Dose Change / Dose Withheld	_	FION if "88 Oth	
Total Volume Administered of Panitumumab plus Saline Solution		ASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify RE/	
Start Time (24 hour clock)	:	S	
Year		If infusion was interrupted provide the Reason for Infusion Interruption	
Date Month		If infusion was inter- upted provide the total time of administration (not including interrup- tions)	
Day	_		
Cycle	4	Was Infusion Interrupted?	

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

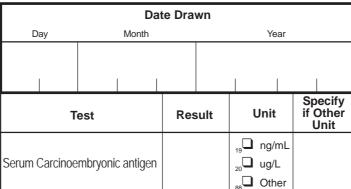
protocol" is specified for "Reason for Dose Change", indicate code 9 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 4 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin Continuous infusion One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ CI 0T0 Line # Line# 2 3 4 2 9

WEEK 8 ASSESSMENTS

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		[2,1, , , , , , , ,]
		W8

Week 8 CEA

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



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 Date of Procedure Method of Assess ment					f ess- ent	Subsite Describe specific location							ion te de	(L	Long unid m	asura esio (mm, est Dia Must b imensi easura	Was Interventiona Therapy Performed On This Lesion Since the Last Assessment					
	Day	Mon	th		Ye	ar												Di	ime	nsior	is (mm)		1 √ !
01																		_					
02																					1		
03																					1		
04							l												ı		I		
05							1												ı		ı		
06						<u> </u>																	
07						<u> </u>															1		
08						<u> </u>																	
09																					1		
10																							
10														3	Sum of Ta	_				1	<u> </u>		
_	HOD OF Conventi		_					y (CT)		04	MR	I (NMR)	23	Spi	iral Computed	Tom	ogra	aphy	(CT	Γ)			
00 L 01 7 02 0 03 F 08 F 09 E	ON SITE Lymph no Thyroid Oral cavit Pharynx Pelvis Breast Pleural et	ode ty		17 20 30 40 (Pleu Live Bon Che Peri	ira o r e st w caro	or pl vall dial	chyma leural v	wall	51 61 62 63 64 65 66	Si Pi Si C	rain sophagus somach ancreas mall intestine olon ectum	69 70 73 74 79 83	0 3 4 9	Anus Ascites Retroperitone Peritoneum Gall bladder Kidney Heart	eum		85 86 88	Sple Skir Oth	er (sp	gland pecify in bove)		

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

	Site No.			
////	Ollo 140.			
			2	1
////.		1	-	ı

Subject ID No.

W8

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							Meth of Asse me	f ess- nt	Descr	Subsi ibe speci	te fic location	S	sion ite ode 2	Les	ew ions	Lo Dia	onge: amete (mm)	er*	Resi (Re if bo code "04	mor bonse ecord dy site is NOT Bone"	Interve The Perfo On Les Sino	entional rapy ormed This sion e the ast sment?	
11			1	1			ı	1	1							l		 		ı	1		I		
12																		 							
13																		 							_ _ _ _
14																		 							
15																		! 							! ! !
16																		 			1				
17																		 		l					- -
18			1	1														 		l	1				_ _ _
19			1															 		l					
20			1					1										 		l	1				
① METH 01 2 03 0 04	X-Ra Conv	y entic	nal							hy (CT))		oiral Compone Scan	outed Tome	ograp	hy (0	CT)					aminati fy belo			
2 LESIO 00 L 01 T 02 C 03 F 08 F 09 E 10 F	Jympi Thyro Oral o Phary Pelvis Breas Pleura DR R	h noo id avity nx id al effo	de usio	n E C	OD	17 20 30 40 49 50	Ple Live Bor Che Per Spi	ura er ne est rical	or p wall		wall on	61 62 63 64 65 66	Brain Esopha Stomac Pancrea Small ir Colon Rectum	n as itestine	70 73 74 79 81	Re Pe	scites etrope eritone all bla idney eart	eriton eum idder		85 86 88	SI SI SI O		gland pecify above)		
CR SD	Com	plete	res	poi									disease /aluate					Not a	pplica Done	able					

Line #	Specify if "88 Other" Method of Assessment

^{*} 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'.

Week 8

TUMOR RESPONSE

Date of Assessment Day Month Year				Overall Target Lesion Response Code ①	Non-Ta	II Existing rget Lesion nse Code ②	No	esions Yes	Overall Tumor Response Code	
① OVERALI	 TARGET LESIO	DN	2 OVER	ALL EX	ISTING NON-TARGET	3 OVEF	 RALL TUMOR	R RESP	ONSE CO	DDES:
CR Com PR Part SD Stab PD Proc UE Una NA Not	SE CODES: uplete response al response le disease pressive disease ble to evaluate applicable done		CR SD PD UE NA ND	Comple Stable of Progress		CR PR SD PD UE ND	Complete re Partial respo Stable disea Progressive Unable to ev Not done	onse ase disease		

	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL		OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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-	Progressive Disease (PD)
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)	

CYCLE 5

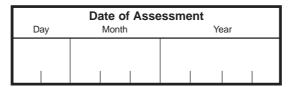


Cycle 5, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? D No D Yes



VITAL SIGNS

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

BODY SURFACE AREA

	Date of Exar	nination	Weight	Body Surface Area
Day	Month	Year	l lb kg ₂□ lb	(m²)
			1 - 19 2 - 10	, ,

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Date									се	Status			
Day Month			Year		9	Z EC	OG		☐ KPS				
1	ECOG	PERF	ORM	IANC	E STA	TUS	COD	ES:					
0	Fully a	active,	able	to car	ry on	all pr	e-dise	ease p	erfo	mance	witho	ut r	restriction.
1	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		latory a								e to ca	rry out	t an	ny work

- 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

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

Cycle 5, Day 1 **PHYSICAL EXAMINATION**

Record any new finding or cha	nge (wors	sening) of an ex	isting finaling on the <i>i</i>	Adverse Events Summary CRF
Was a physical examination perform	med? ₀□	l No ₁☐ Yes		_
		Date of Exar	nination	
	Day	Month	Year	

_									
D	oes	the su	ıbject have any abnorm	nal clinical fi	indings relating to th	e following re	equired sites?	ONO 1	Yes - If yes,
			lings below.						
S		ODES	:						
	0)1	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04	Abdomen	08	Neurological	50	Extremities
)2	Cardiovascular	05 06	Musculoskeletal Skin	09 10	Genitourinary Breast / Chest	88	Other
		3	Respiratory	06 07	Lymph nodes	10	Rectal		
	•		respiratory		a required assessme				
_				muicale n	a required assessing	ent was not u	one.		
	ode								
(as				Describe fin				
	ted				List one entry	per line.			
ab	ove)								
_									
<u> </u>									
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_									
<u> </u>									
	I								
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	ı								
\vdash									
	1								

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C5D1

Cycle 5, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that were

Rec	ord Hema	tology resu			taken on the plai	nned Day 1
	Day	1	Date Dra Month	awn	Year	
	Test		Result		Unit	Specify if Other Unit
					l /uL	
RE	3C			_	10 ⁶ /mm ³	
				_	10 ¹² /L	
					Other	
					g/L	
He	emoglob	oin			g/dL	
					mmol/L	
					Other	
				15		
He	ematocr	it			L/L	
				'	frac of 1	
					Other	
M	CV			-	Other	
					/uL	
					10 ⁹ /L	
Pla	atelets				10 ³ /mm ³	
					Other	
					/uL	
					10 ⁹ /L	
WI	ВС				10 ³ /mm ³	
					Other	
				15		
					10 ⁹ /L	
	Neutro	ophils			Other	
				15	%	
D	Lymph	nocytes			10 ⁹ /L	
I F	, .	•		88	Other	
F				15		
Е	Manag	n too		_	10 ⁹ /L	
R E	Mono	cytes			Other	
N				15		
T	Eosino	ophils			10 ⁹ /L	
I A					Other	
L *				15		
*	Basop	hils		_	10 ⁹ /L	
	Базор				Other	
				15		
	Granu	locytes			10 ⁹ /L	
				88	Other	

[Day	Date Dr Month	awn	S Summary CRF. sulfs below that were taken on e chemo admin page). Year			
		ı		1 1	1		
Test		Result		Unit	Specify if Othe Unit		
RE	3C		3 10	0 ⁶ /mm ³			
Не	emoglobin		4 g 12 g 6 m	g/dL nmol/L			
He	ematocrit		l '				
M	CV		88 III 88				
Pla	atelets		10 / 10 10 10 10 10 10 10 10 10 10 10 10 10	uL			
WBC			₁ / (
	Neutrophils		9 10 88 0	D ⁹ /L			
DIFFERENTIAL*	Lymphocytes		9 10 88 0	0º/L Other			
	Monocytes		9 10 88 0	0°/L Other			
	Eosinophils		9 10 88 0	0º/L Other			
	Basophils		15 9 9 10 88 0	0°/L Other			
	Granulocytes		15 9 9 10				

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

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

Blue - CRA; White Card - Investigator 6.03

AMGEN	Panitumumab
AMG 954 2	0050203

Sit	e No.	Subject ID No.								
	I I	2	1,	ı	ı	ı	1	1	ı	

C5D1

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								
Day Mo			Date D)rawn Year				
,		<u></u>						
	Test		Result		Uni	it		Specify if Other Unit
Sodiu	m			6	mEq/L ₈₈ mmol/L			
Potass	sium			6	mEq/L ₈₈ mmol/L	,		
Chlori	de				mEq/L ₈₈			
Bicarb	onate	(HCO ₃)			mEq/L ₈₈			
Total F	Protein			12] g/L 88			
Album	nin			12] g/L ₈₈			
Calciu	ım			6	mg/dL 88			
Magne	Magnesium			14 13] mEq/L ₆] mg/L ₈₈] mg/dL	, Q 0	ther	
Phosp	ohorus			I	mg/dL ₈₈ mmol/L	, Q 0	ther	
BUN	(OR — -		_6_	mg/dL ₈₈	- —		
Urea)K		l'~_	mg/dL ₈₈ mmol/L	, □ 0	ther	
Creati	nine			1 -	mg/dL ₈₈ umol/L	, u o	ther	
Uric A	.cid	_		1,0	mg/dL ₁₆ mmol/L ₈₈	,		
Total E	Total Bilirubin			1 -	mg/dL ₈₈ umol/L	, _ o	ther	
Alk. P	Alk. Phos.			₁₇ □ U/L ₈₈ □ Other ₁₈ □ ukat/L				
AST (SGOT))		1	〕 U/L ₈₈ 〕 ukat/L	, u o	ther	
ALT (S	SGPT)			1	〕 U/L ₈₈ 〕 ukat/L	, u o	ther	
LDH				1	U/L 88 ukat/L	, u o	ther	
		LDH I	Local Labo	rato	ry Range			
Lower				Uppe	er			

If chemotherapy was delayed record the Chemistry results below that were aken on the actual Day 1 (record reason for delay on the chemo admin page).									
Day	Mo		wn		'ear				
			_				'~ !s.		
Test		Result			Jnit		Specify if Other Unit		
Sodium			6	☐ mEq/l☐ mmol/	L L				
Potassium			I _	☐ mEq/l☐ mmol/		Other			
Chloride			6	☐ mEq/l☐ mmol/	/L				
Bicarbonate	HCO ₃)		6	☐ mEq/l☐ mmol/	/L				
Total Proteir	า	_	12	□ g/L □ g/dL					
Albumin			12	☐ g/L ☐ g/dL					
Calcium			6	☐ mg/dl☐ mmol	/L				
Magnesium		14	☐ mEq/l☐ mg/L☐ mg/dl						
Phosphorus	;		13	☐ mg/dL☐ mmol	□ ₈₈ □	Other			
BUN			13	☐ mg/dl☐ mmol/		Other			
Urea	OR —		13	☐ mg/dl	88	Other			
Creatinine			16	☐ mg/dl☐ umol/	L				
Uric Acid			1	☐ mg/dl ☐ mmol					
Total Bilirubi	in		13	☐ mg/dL☐ umol/	L ₈₈ L				
Alk. Phos.			1	U/L ukat/L		Other			
AST (SGOT			17	□ U/L □ ukat/l		Other			
ALT (SGPT))		17	U/L ukat/l	88	Other			
LDH			17	☐ U/L ☐ ukat/l	88	Other			
LDH Local Laboratory Range									

Upper

Lower

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

C5D1Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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

ol" is Specify DOSE CHANGE/ Dose WITHHELD DOSE if "88 Other"		Package Lot Number	
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	u .	
Reason for Jose Change Jose Withhel	_	ION if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)	:	S	
Year	_ _ _	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Day	_		
Cycle	2	Was Infusion Interrupted? ONo Yes	

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Year Other" Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. C $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

CYCLE 6

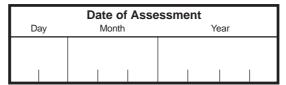


Cycle 6, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Date of Examination Day Month Year			Weight	Body Surface Area
			1 - 19 2 - 11	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

AMGEN Panitumumab	Site No.		Subject ID No.	
AMG 954 20050203		2,1,		
				C6D1

Cycle 6, Day 1 **PHYSICAL EXAMINATION**

Record any new finding or cha	nge (wors	sening) of an ex	isting finding on the <i>i</i>	Adverse Events Summary CRF		
Was a physical examination perform	med? $_{_{0}}\square$	l No ₁☐ Yes		_		
Date of Examination						
	Day	Month	Year			

Does the subject have any abnormal clinical findings relating to the following required sites? Does the subject have any abnormal clinical findings relating to the following required sites?										
describ	e findings below.		0 0	Ü	•	0 1	,			
SITE C	ODES:									
01 02 03	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other						
	Indicate if a required assessment was not done.									
Code (as listed above)	Describe findings List one entry per line.									

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C6D1

Cycle 6, Day 1

HEMATOLOGY

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

If chamother and was delayed record the Hamatology results below that were

Record Hematology results below that were taken on the planned Day 1							
	Day	1	Date Dra Month	awn	Year		
						,	
	Test		Result		Unit	Specify if Other Unit	
RE	3C			2 a	/uL 1 10 ⁶ /mm ³ 1 10 ¹² /L I Other		
Hemoglobin		in		4 12 6	g/L g/dL mmol/L Other		
Hematocrit		t		15 5			
MCV				8	fL Other		
Platelets			9 0	/uL 10 ⁹ /L 10 ³ /mm ³ Other			
WBC				10	/uL 10 ⁹ /L 10 ³ /mm ³ Other		
	Neutro	phils		88	l 10º/L l Other		
D I F	Lymph	ocytes		•	% 10º/L Other		
F E R E	Monoc	ytes		88	l 10º/L l Other		
NTIAL*	Eosino	phils			% 10º/L Other		
	Basopl	nils		88	l 10º/L l Other		
	Granul	ocytes		-	% 10º/L Other		

Day		Date Dr Month	awn	Year
	Test	Result	Un	Specification if Other Unit
RI	BC		1 /uL 2 106/m 3 10 ¹² /L 88 Other	nm³
He	emoglobin		$_{4}$ $_{2}$ $_{3}$ $_{2}$ $_{3}$ $_{4}$ $_{2}$ $_{3}$ $_{4}$ $_{5}$ $_{6}$ $_{6}$ $_{6}$ $_{6}$ $_{6}$ $_{7}$ $_{8}$ $_{8}$ $_{6}$ Othe	
Не	ematocrit		15 % 5 L/L 7 frac co	of 1
M	CV		8☐ fL 8☐ Othe	r
Platelets			1 /uL 9 10°/L 10 10°/m 88 Other	
WBC			109/L 109/L 1009/L 1009/M	
	Neutrophils	;	15 % 9 □ 10	r
D I	Lymphocyte	es	15 % 9 10 10 10 Other	r
F E R E N T I A	Monocytes		₁₅ □ % ₉ □ 10 ⁹ /L ₈₈ □ Other	r
	Eosinophils	3	₁₅ % ₉ 10 °/L ₈₈ Other	r
L *	Basophils		15 % ₉ □ 10 °/L ₈₈ □ Other	r
	Granulocyto	es	15 % 9 10 10 10 Other	r

AMGEN	Panitumumab
AMG 954 2	0050203

Site N	0.	;	Subject	t ID N	0.			
	_ 2	1, ,	1	1	ı	ı	ı	

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								
Day	<u>-</u>	Mc	Date D	Drawn Year			ar	
-								
	Test		Result		Uı	nit		Specify if Other Unit
Sodiu	m 			6	mEq/L mmol/L			
Potass	sium			6	mEq/L mmol/L	-		
Chloric	de			6	mEq/L mmol/L	-		
Bicarb	onate	(HCO ₃)		6	mEq/L mmol/L	-		
Total F	Protein			12	g/L g/dL			
Album	nin			12	g/L g/dL			
Calciu	ım			6	mg/dL mmol/L			
Magne	esium			14 13	☐ mEq/L ☐ mg/L ☐ mg/dL	88 Q C	Other	
Phosp	horus			1	☐ mg/dL ☐ mmol/L)ther	
BUN	(OR — -		6	mg/dL mmol/L	<u>-</u> _		
Urea)K		1.0_	☐ mg/dL ☐ mmol/L	00)ther	
Creati	nine				☐ mg/dL ☐ umol/L		other	
Uric A	cid	_		1,0	☐ mg/dL ☐ mmol/L	10		
Total E	Bilirubir	1		13	mg/dL umol/L	0 🗖		
Alk. Pl	hos.			17	U/L ukat/L		Other	
AST (SGOT)	1		17	U/L ukat/L	₈₈ D O	ther	
ALT (S	3GPT)			1	U/L ukat/L	88 C	Other	
LDH				1	U/L ukat/L	88 0	ther	
		LDH I	Local Labo	orato	ory Rang	е		
Lower				Uppe	er			

Day	Mo	Date Drawn onth Year						
Day	1410	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			oui			
1	1	1		I	1			
Test		Result		Unit		Specify if Other Unit		
Sodium			mEq/	00	Other			
Potassium			nEq. □ mmo	I/L				
Chloride			nEq. □ mmo	I/L				
Bicarbonate	e (HCO ₃)		mEq.	I/L				
Total Protei	n		₄ □ g/L ₁₂ □ g/dL					
Albumin			₄ □ g/L ₁₂ □ g/dL					
Calcium			mg/d	I/L				
Magnesium	ı		mEq/ mg/L mg/d mg/d					
Phosphorus	3		ng/d mg/d mmo	00	Other			
BUN	0.0		ng/d a mmo	00	Other			
Urea	OR —		mg/d	00	Other			
Creatinine			ng/d 13 mg/d 16 umol	L 88 J	Other			
Uric Acid			13 mg/d 6 mmo	L 16				
Total Bilirub	in		mg/d	L 88 J				
Alk. Phos.			17 U/L 18 ukat/	88	Other			
AST (SGOT	Γ)		17 U/L 18 ukat/		Other			
ALT (SGPT)		17 U/L 18 ukat/	88	Other			
LDH			17 U/L 18 ukat/		Other			

LDH Local Laboratory Range

Upper

Lower

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

C₆D₁ Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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

sol" is Specify DOSE CHANGE/ Bose WITHHELD DOSE if "88 Other" te code		Package Lot Number	-
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code		ויי	
Reason for Jose Change Jose Withhel	_	10N if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution (mL)		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Vear		If infusion was interrupted provide the Reason for Infusion Interruption	_
Date Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	9	Was If Infusion rup Interrupted? tin (no	

INFUSION REACTION

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

protocol" is specified for "Reason for Dose Change", indicate code 90 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 6 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. C $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line# 2 3 4 2 9

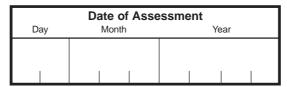
CYCLE 7



Cycle 7, Day 1

SKIN TOXICITY ASSESSMENT

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



VITAL SIGNS

Date Day Month Year		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature	
			1			

BODY SURFACE AREA

	Date of Exan	nination	Weight	Body Surface Area
Day	Month	Year	kg 2 lb	(m²)
			1 32	` ´
l .				
				•

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Г			Date	.				Performano		
	Day	Mont	h		Υ	ear		ॼ ECOG	☐ KPS	
	1	1								
① ECOG PERFORMANCE STATUS CODES:										
0	Fully a	ctive, able	to car	ry on	all pr	e-dise	ease p	erformance withou	t restriction.	
1								ambulatory and at thousework or offi		
2	2 Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about > 50% of waking hours.									
3		le of only l	imited	self-c	are, o	confin	ed to I	oed or chair more t	han 50% of	

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

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		C7D1

Cycle 7, Day 1 PHYSICAL EXAMINATION

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

rige (wors	eriirig) or arr ex	isting infamig on the 7	Adverse Everils Summary Civi
med? $_{\scriptscriptstyle 0}$	No ₁☐ Yes		_
	Date of Exar		
Day	Month	Year	
	med? ₀□	med? ₀☐ No ₁☐ Yes Date of Exar	Date of Examination

	ribe 1	subject have any abnorm findings below.	al clinical fi	ndings relating to th	e following re	equired sites?	No 1	Yes - If yes,
	01 02 03	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory	04 05 06 07 Indicate if	Abdomen Musculoskeletal Skin Lymph nodes a required assessm	08 09 10 11 ent was not d	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
Code (as	:			Describe fin	dinas			
listed above				List one entry				

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	_
	2,1, , , , , , ,	

C7D1

Cycle 7, Day 1

HEMATOLOGY

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

Rec	ord Hematology	results	below tha	t were		anned Day 1
	Day	Mor	Date Dra	awn	Year	
		1				
	Test	F	Result		Unit	Specify if Other Unit
RE	3.0			2	/uL 10 ⁶ /mm³	
					10 ¹² /L Other	
Нє	emoglobin			12 6	g/L g/dL mmol/L Other	
Нє	ematocrit			15 5		
М	CV			8	Other fL Other	
DI	atelets			1 9	/uL 10 ⁹ /L	
Гю				88	10³/mm³ Other	
W	вс			9 10	10 ⁹ /L 10 ³ /mm ³ Other	
	Neutrophil	5		9 🗖	% 10 ⁹ /L Other	
D	Lymphocy	es			% 10 ⁹ /L Other	
FER	Monocytes	3		15 0		
ENTIAL*	Eosinophils				% 10 ⁹ /L Other	
	Basophils			88	10 ⁹ /L Other	
	Granulocy	tes		-	% 10 ⁹ /L Other	

Day		Date Dr Month	awn	Year		
		1		1 1	1	
	Test	Result		Unit	Specify if Othe Unit	
RBC			3 1	0 ⁶ /mm ³		
Hemoglobin			4 9	g/dL nmol/L		
Hematocrit			15 c	%		
M	CV		88 8 f	L		
Platelets			''			
			₁			
	Neutrophils		15 9 1 9 1 1 88 0	0 ⁹ /L		
D I F	Lymphocytes		9 1 88	% 0º/L Other		
r F E R E	Monocytes		9 1 88 0	0º/L Other		
N T I A	Eosinophils		9 1 88 0	0º/L Other		
L *	Basophils		9 1 88 0	0º/L Other		
	Granulocytes		₁₅ 0 9			

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

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

Blue - CRA; White Card - Investigator

8.03

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C7D1

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						
Day	Mc	Date Donth	rav	wn	Year	
Test		Result		U	nit	Specify if Other Unit
Sodium			١	☐ mEq/L ☐ mmol/L	88 Other	
Potassium			l · · _	mEq/L mmol/L	88 Other	
Chloride			1	☐ mEq/L ☐ mmol/L	88 Other	
Bicarbonate	(HCO ₃)			☐ mEq/L ☐ mmol/L	88 Other	
Total Proteir	1		12	□ g/dL	₈₈ Other	
Albumin			12	□ g/dL	88 Other	
Calcium		6	mmol/l			
Magnesium			14		6 mmol/L 88 Other	
Phosphorus			13		88 Other	
BUN			13		88 Other	
Urea	OR — -		-	mg/dL mmol/L	Other	
Creatinine			13		88 Other	
Uric Acid			١.٠		umol/L 88 Other	
Total Bilirubi	n		1 -	☐ mg/dL ☐ umol/L	88 Other	
Alk. Phos.	Alk. Phos.			U/L ukat/L	₈₈ Other	
AST (SGOT			l	U/L ukat/L	88 Other	
ALT (SGPT))			U/L ukat/L	88 Other	
LDH			l	U/L ukat/L	88 Other	
	LDH I	ocal Labo	rat	ory Rang	e	
Lower Upper						

If chemotherapy was delayed record the Chemistry results below that were aken on the actual Day 1 (record reason for delay on the chemo admin page).							
Day	Mc	Date Donth	rav	wn	Year		
Test		Result		U	Init		Specify if Other Unit
Sodium			6	mmol/L			
Potassium			6	mmol/l			
Chloride			6	mmol/l			
Bicarbonate	; (HCO ₃)		6	mmol/l			
Total Proteir	า		12	□ g/dL	88 Otl		
Albumin			12	□ g/dL	88 Oth		
Calcium			6	mmol/			
Magnesium		14		. ₆ □ mn ₈₈ □ Oth			
Phosphorus	;		13		88 Oth	ner	
BUN	OR — -		13 [6	mg/dL	. ₈₈ □ Oth L	_	
Urea			6	mmol/			
Creatinine			1	☐ mg/dL ☐ umol/L	. ₈₈ □ Oth -	ner	
Uric Acid			1.0		. ₁₆ um L ₈₈ Otł	- 1	
Total Bilirubi	in		13		88 Oth		
Alk. Phos.			17		88 Oth	ner	
AST (SGOT	-)		1	□ U/L □ ukat/L	88 🖵 Oth	ner	
ALT (SGPT))		17		88 Oth	ner	
LDH				□ U/L □ ukat/L	₈₈ D Oth	ner	
	LDH I	Local Labo	orat	ory Rang	је		
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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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

otocol" is Specify DOSE CHANGE/ ge/ Dose WITHHELD DOSE if "88 Other"	_	Package Lot Number	- - - -
If "04 per prindicated for " Dose Chang Withheld", inc	_		
Reason for Dose Change / Dose Withheld	_	ON if "88 Othe	
Total Volume Administered of Panitumumab plus Saline Solution		INFUSION INTERRUPTI	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		s	
Year		If infusion wa interrupted provide the Reason for Infusion Interruption	_
Date Month		fusion was inter- d provide the total of administration ncluding interrup- tions)	
Cycle	7		
	Date Start Time Stop Time Stop Time Day Month Year Solution Day Total Volume Administered of Start Time Stop Time (mg) Total Volume Administered of Panitumumab plus Saline Solution Administered of Panitumumab plus Saline Solution (mL) Total Volume Administered of Dose Change / Dose / D	Date Start Time Stop Time Stop Time Day Month Year Date Stop Time Stop Time Stop Time C24 hour clock) Start Time Stop Time C24 hour clock) Stop Time C34 hour clock) Stop Time C4 hour clock) Start Time C4 hour clock) Stop Time C5 hour clock) Stop	Day Month Year Start Time Stop Time Catholic Cat

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 7 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line# 2 3 4 2 9

CYCLE 8

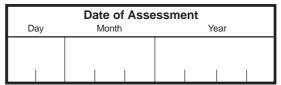


Cycle 8, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Exam Month	nination Year	Weight	Body Surface Area
			1 32	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

AMGEN Panitumumab	Site No.	Subject ID No.			
AMG 954 20050203		2,1, , , , , , ,			
		C8D1			

Cycle 8, Day 1 **PHYSICAL EXAMINATION**

Record any new finding or cha	nge (wors	ening) of an ex	isting finding on the A	Adverse Events Summary CRF
Was a physical examination perform	med? $_{\scriptscriptstyle 0}$ $lacksquare$	No ₁☐ Yes		_
Date of Examination				
	Day	Month	Year	

_									
D	Does the subject have any abnormal clinical findings relating to the following required sites? On No 1 Yes - If yes, describe findings below.								
S		ODES	:						
	0)1	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04	Abdomen	08	Neurological	50	Extremities
)2	Cardiovascular	05 06	Musculoskeletal Skin	09 10	Genitourinary Breast / Chest	88	Other
)3	Respiratory	06 07	Lymph nodes	10	Rectal		
	•		respiratory		a required assessme				
_				muicale n	a required assessing	ent was not u	one.		
	ode								
(as				Describe fin				
	ted				List one entry	per line.			
ab	ove)								
_									
<u> </u>									
	ı								
_									
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_									
	ı								
\vdash									
	1								

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C8D1

Cycle 8, Day 1

HEMATOLOGY

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

If chamother and was delayed record the Hamatology results below that were

Rec	ord Hematol	ogy resu			taken on the pla	nned Day 1
	Day		Date Dra Month	awn	Year	
	<u>, </u>		-			
	Test		Result		Unit	Specify if Other Unit
				•	/uL	
RE	3C			-	10 ⁶ /mm ³	
				•	10 ¹² /L	
					Other	
					g/L	
He	emoglobin	ı			g/dL	
	J			U	mmol/L	
					Other	
				15		
He	ematocrit			-	L/L	
				,	frac of 1	
					Other	
М	CV			80		
					Other	
					/uL	
DI.	-4-1-4-			•	10 ⁹ /L	
Pi	atelets				10 ³ /mm ³	
					Other	
					/uL	
147				•	10 ⁹ /L	
VV	ВС				10 ³ /mm ³	
					Other	
				15		
	Neutrop	hils			10 ⁹ /L	
				88	Other	
				15		
D I	Lympho	cytes		•	10 ⁹ /L	
F					Other	
F				15		
E R	Monocyt	tes		-	10°/L	
E					Other	
N				15		
T I	Eosinop	hils			10 ⁹ /L	
Α					Other	
L *				15		
*	Basophi	ls		•	10 ⁹ /L	
	_ 200piii	-			Other	
				15		
	Granulo	cytes			10 ⁹ /L	
				88	Other	

[Day	Date Dr Month	awn	Year	
		1		1 1	1
	Test	Result		Unit	Specify if Othe Unit
RE	3C		3 1	0 ⁶ /mm ³	
Не	emoglobin		4 9	g/dL nmol/L	
Не	ematocrit		15 c	%	
M	CV		88 8 f	L	
Pla	atelets		''		
W	вс		₁		
	Neutrophils		15 9 1 9 1 1 88 0	0 ⁹ /L	
D I F	Lymphocytes		9 1 88	% 0º/L Other	
r F E R E	Monocytes		9 1 88 0	0º/L Other	
N T I A	Eosinophils		9 1 88 0	0º/L Other	
L *	Basophils		9 1 88 0	0º/L Other	
	Granulocytes		₁₅ 0 9		

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

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

Blue - CRA; White Card - Investigator

9.03

AMGEN	Panitumumab
AMG 954 2	0050203

Site N	0.	;	Subject	t ID N	0.			
	_ 2	1, ,	1	1	ı	ı	ı	

Cycle 8, Day 1 CHEMISTRY

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

Day Mo	Date D	awn Year									
Bay Mic	JIIIII	real									
	1										
Test	Result	Unit	Specify if Other Unit								
Sodium		mEq/L 88 Other 6 mmol/L									
Potassium		mEq/L ₈₈ Other of mmol/L									
Chloride		mEq/L ₈₈ Other of mmol/L									
Bicarbonate (HCO ₃)		mEq/L ₈₈ Other									
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL									
Albumin		₄ g/L ₈₈ Other ₁₂ g/dL									
Calcium		mg/dL 88 Other 6 mmol/L									
Magnesium		mEq/L 6 mmol/L 14 mg/L 88 Other 13 mg/dL									
Phosphorus		ng/dL 88 ☐ Other 6 ☐ mmol/L									
BUN OR		mg/dL 88 Other 6 mmol/L									
Urea		mg/dL 88 Other 6 mmol/L									
Creatinine		mg/dL 88 Other									
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other									
Total Bilirubin		ng/dL 88 ☐ Other of the other o									
Alk. Phos.		17 U/L 88 Other									
AST (SGOT)		17 U/L 88 Other									
ALT (SGPT)		17 U/L 88 Other									
	1										
LDH		17 U/L 88 Other									

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

C8D1

Day			ate D				⁄ear		
Test		Re	sult		l		if	oecify Other	
Sodium				1	mEq/l	00	Other		<u>Unit</u>
Potassium				6	mEq/	/L			
Chloride				6	mEq/	/L			
Bicarbonate	e (HCO ₃)			6	mEq/ mmol	/L			
Total Proteir	n			12	g/L g/dL				
Albumin				12	g/L g/dL				
Calcium				6	mg/dl	I/L			
Magnesium				14	☐ mEq/l☐ mg/L☐ mg/dl☐				
Phosphorus	3			1	☐ mg/dl ☐ mmol		Other		
BUN	OP —				☐ mg/dl ☐ mmol		Other		
Urea	OR —			١.٠	☐ mg/dl ☐ mmol	00	Other		
Creatinine				1	☐ mg/dl☐ umol/		Other		
Uric Acid				1 -	☐ mg/dl ☐ mmol				
Total Bilirub	in			1	☐ mg/dl ☐ umol/		Other		
Alk. Phos.				1	☑ U/L ☑ ukat/l		Other		
AST (SGOT	Γ)			1	□ U/L □ ukat/l		Other		
ALT (SGPT)			1	U/L ukat/l		Other		
LDH				1	□ U/L □ ukat/l	00	Other		
	LDH I	Local	Labo	rat	ory Ran	ge			
Lower				Upp	er				

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

C8D1 Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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

sason for Specify DOSE CHANGE/ 1 Dose WITHHELD DOSE if "88 Other"		Package Lot Number	-
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	,,	
Reason for Dose Change / Dose Withheld	_	10N if "88 Othe	
Total Volume Administered of Panitumumab plus Saline Solution		ASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify RE/	
Start Time (24 hour clock)		S	
Year	_ _ _	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date Month	If infusion was interrupted provide the total time of administration (not including interruptions)		
Day	_		
Cycle	∞	Was Infusion Interrupted? °No Yes	

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

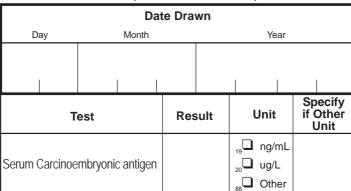
protocol" is specified for "Reason for Dose Change", indicate code Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 8 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin Continuous infusion One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ CI OTO Line # Line# 2 3 4 2 9

WEEK 16 ASSESSMENTS

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		14/16

Week 16 CEA

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



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	D	Pate of F	Proc		i re Year		Method of Assess- ment	Subsite Describe specific location	Lesion Site Code	Measurable Lesions * (mm) (Longest Diameter) Must be unidimensionally measurable Dimensions (mm)	Was Interventional Therapy Performed On This Lesion Since the Last Assessment?
01		1 1		ı	1	1					1
02											
03											
04											! ! !
05											1 1 1
06											
07											1 1 1
08					1						
09											I I I
10											1
								Sum of 1 Le	arget sions		
1	HOD OF						y (CT)	04 MRI (NMR) 23 Spiral Compute	d Tomogra	phy (CT)	
Description Site Codes: Ou Lymph node Out Thyroid Out Cavity Out Cavity								51 Brain 69 Anus 61 Esophagus 70 Ascites 62 Stomach 73 Retroperitor 63 Pancreas 74 Peritoneum 64 Small intestine 79 Gall bladder 65 Colon 81 Kidney 66 Rectum 82 Heart	neum 8	Adrenal gland Spleen Skin 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'.

Site N	0.		
ı	ı	ı	

Subject ID No.

2,1

W16

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	e r	D		of flont		oce	dur	'e		Meth of Asse mer	ss- nt	Desci	Subsite ibe specific loc	ation	Lesi Site Coc	e de	Lesi	ew ions 'Yes	Lo Dia	onges amete (mm)	st er*	Resp (Re if boo code "04"	mor ponse cord dy site is NOT Bone"	Interv The Perf On Le Sind	entional erapy ormed This sion ce the ast ssment?
11			1				ı	ı	1						1					ı	ı		ı		
12																									
13																									
14																		 							
15																									- - - -
16							[1		1								
17							1								1								1		
18															1		1				1				
19							1		1						1		i !				1				 - -
20									1											I			<u> </u>		_ _ _
03	X-Ra	ıy /entid	onal							ny (CT)			oiral Computed one Scan	Tomo	graphy	y (C	CT)	6(8)				aminati ify belo			
© LESION SITE CODES: 00 Lymph node 13 Lung paren 01 Thyroid 17 Pleura or pl 02 Oral cavity 20 Liver 03 Pharynx 30 Bone 08 Pelvis 40 Chest wall 09 Breast 49 Pericardial 10 Pleural effusion 50 Spinal cord								leural wall 61 Esophagus 62 Stomach 63 Pancreas 64 Small intestine effusion 65 Colon			е	 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) 													
CR SD	Com	plete	e res	spo									disease valuate					Not a		able					

Line #	Specify if "88 Other" Method of Assessment	

^{*} 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'.

Week 16

TUMOR RESPONSE

Day	Date of Assess	s ment Year	Overall Target Lesion Response Code ①			Overall Tumor Response Code
RESPO	ALL TARGET LESION ONSE CODES: complete response rartial response ratiale disease rogressive disease rapplicable to evaluate lot applicable lot done	LESION RESI CR Comple SD Stable PD Progres		OVERALL TUMOR CR Complete re PR Partial respo SD Stable disea PD Progressive UE Unable to ev ND Not done	esponse onse use disease	ODES:

	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL	011100110110	OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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 nontarget 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-	Progressive Disease (PD)			
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)				

CYCLE 9

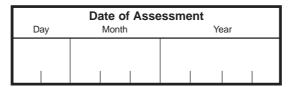


Cycle 9, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? Dan No



VITAL SIGNS

Day	Date Day Month Year		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

	Date of Exan	nination	Weight	Body Surface Area
Day	Month	Year	kg 2 lb	(m²)
			1 32	` ´
l .				
				•

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Day	Date Month	Performance Status ECOG KPS			
0 Fully a	ECOG PERFORMANCE STATUS CODES: Fully active, able to carry on all pre-disease performance without restriction. Restricted in physically strenuous activity, but ambulatory and able to carry				

- 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

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		C9D1

Cycle 9, Day 1 PHYSICAL EXAMINATION

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

record any new infaming or ona	ngo (word	crimg, or arr ox	isting imanig on the r
Was a physical examination perform	med? ₀□	No ₁☐ Yes	
		Date of Exan	nination
	Day	Month	Year

descri	Does the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites?							
	CODES: D1 Head, I Throat D2 Cardiov Respira	Ears, Eyes, Nose, (HEENT) / Neck ascular itory	06 07	Abdomen Musculoskeletal Skin Lymph nodes a required assessme	08 09 10 11 ent was not de	Neurological Genitourinary Breast / Chest Rectal one.	50 88	Extremities Other
Code (as listed above)				Describe fin <i>List one entry</i>				

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C9D1

Cycle 9, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that were

Rec	ord Hema	tology resu	Its below tha	t were	taken on the pla	nned Day 1
	Day		Date Dra Month	awn	Year	
	,		-			
	Test		Result		Unit	Specify if Other Unit
				1	/uL	
RE	RC			$_{2}$	10 ⁶ /mm ³	
IXL				•	10 ¹² /L	
				88	Other	
					g/L	
Нє	emoglob	oin		12	g/dL	
				0	mmol/L	
					Other	
				15		
He	ematocr	it		5	L/L	
Hematocht				,	frac of 1	
					Other	
NAC	?\/			\square_8		
MCV					Other	
					/uL	
				•	10 ⁹ /L	
Pla	atelets				10 ³ /mm ³	
				88	Other	
					/uL	
				•	10 ⁹ /L	
W	ВС				10 ³ /mm ³	
					Other	
				15		
	Neutro	nhile		-	10 ⁹ /L	
	rvound	priiis		88	Other	
				15		
D	Lymph	nocytes			10 ⁹ /L	
I F					Other	
F				15		
E	Monod	ov to c		-	10 ⁹ /L	
R E	IVIOLIOC	Lytes			Other	
N T I A				15		
	Eosino	ophils			10 ⁹ /L	
					Other	
L				15		
*	Booss	hile		•	10 ⁹ /L	
	Basop	iiiiS			Other	
				15		
	Granu	locytes		-	10 ⁹ /L	
				88	Other	

[Day	Month	Yea	ar
				Specif
	Test	Result	Unit	if Othe Unit
			₁☐ /uL	
RE	3C		₂ 10 ⁶ /mm ³	
			₃ 10 ¹² /L	
			88 Other	
			₄ □ g/L	
Не	emoglobin		₁₂ g/dL	
	Ü		₆ ☐ mmol/L	
			88 Other	
			15_ %	
Не	ematocrit		5_ L/L	
			₇ frac of 1	
			88 Other	
М	CV		8 fL	
			88 Other	
Platelets			₁☐ /uL	
			₉ 🖵 10 ⁹ /L	
Pla	atelets		₁₀ 10 ³ /mm ³	
			88 Other	
			₁☐ /uL	
			₉ — 10 ⁹ /L	
VV	ВС		10 ³ /mm ³	
	T		88 Other	
			15 %	
	Neutrophils		₉ 10 ⁹ /L	
			88 Other	
			15 %	
D I	Lymphocyte	es	₉ 10°/L	
F			88 Other	
F			15 %	
E R	Monocytes		₉ 10 ⁹ /L	
E			88 Other	
N			15 %	
T I	Eosinophils		9 10°/L	
Α			88 Other	
L *			15 %	
•	Basophils		9 10°/L	
			88 Other	
			15 %	
	Granulocyte	es	9 10°/L	
	all cases, please		88 Other	

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

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , ,	ı

C9D1

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							
Day	Mo	Date D	raw	n	Ye	ar	
							0
Test		Result		U	nit		Specify if Other Unit
			11	l mEq/L	₈₈ 🗆 C	Other	
Sodium			0	mmol/L			
Datassium			l	l mEq/L	00	ther	
Potassium			1 0	mmol/L			
Chloride			1	mEq/L)ther	
Chloride			10	mmol/L			
Bicarbonate	(HCO.)		l	mEq/L	00	other	
Diodroonato	(11003)		1 0	mmol/L)thor	
Total Protein	1		1	g/L	88	Jinei	
	-			g/dL g/L)ther	
Albumin			1	l g/L l g/dL	88	MIEI	
				mg/dL		Other	
Calcium			1	l mmol/l		Julion	
			<u> </u>	mEq/L		nmol/L	
Magnesium			1	l mg/L	•		
			1	l mg/dL			
Phosphorus				mg/dL		Other	
				l mmol/l			
BUN			I	l mg/dL		Other	
	or —-			mmol/l		- — -	
Urea			1	l mg/dL		Other	
			-	mmol/l			
Creatinine				l mg/dL		Other	
			1.4	l umol/L			
Uric Acid			1	l mg/dL			
			-	mmol/l			
Total Bilirubi	n		1 -	l mg/dL l umol/L		uner	
All. Dhan			1.0	l U/L		Other	
Alk. Phos.			l	l ukat/L	88	Juici	
AST (SGOT	`\		1.4	l U/L	O)ther	
A31 (3GO1	,			l ukat/L			
ALT (SGPT)			1.0	l U/L		Other	
, LI (501 I)			l	l ukat/L			
LDH			1.0	l U/L		ther	
			l	l ukat/L			
	LDH I	Local Labo	orato	ry Rang	e		
Lower			Uppe	r			

If chemotherapy was delayed record the Chemistry results below that were aken on the actual Day 1 (record reason for delay on the chemo admin page).						
Day	Mc	Date D	ra	wn	Year	
			ı			Specify
Test		Result		Ur	nit 	Specify if Other Unit
o "			l	_ `	88 Other	
Sodium			10	mmol/L	□ <u>~</u>	
Potassium			l	」 mEq/L _{ 〕 mmol/L	38 Other	
			1 0		Other	
Chloride			1	mmol/L	38 -	
			l	_ `	38 Other	
Bicarbonate	(HCO ₃)		1 0	mmol/L		
Total Protein					88 Other	
TUIAIT TUIGII.				g/dL	□ Othor	
Albumin				」 g/L ॄ 」 g/dL	₈₈ Other	
			1		88 Other	
Calcium				☐ mmol/L		
			-		₆ □ mmol/L	
Magnesium			14	mg/L	Other	
				mg/dL		
Phosphorus			1	⅃ mg/dL ॄ ⅃ mmol/L	88 Other	
5111			-		Other	
BUN			-	☐ mmol/L		
— — — (Urea	or —	<u> </u>	1_0		— — — − ₈₈ □ Other	$\vdash - \dashv$
Ulta			1	☐ mmol/L		
Creatinine			Ť		Other	
0100			1	umol/L	36	
Uric Acid			13	mg/dL ,	16 umol/L	
					88 Other	
Total Bilirubir	1				₈₈ Other	
			1.0	umol/L		
Alk. Phos.			1		88 Other	
- :			-	ukat/L	□ Othor	
AST (SGOT))			J U/L ॄ J ukat/L	38 ☐ Other	
ALT (SGPT)			1.0		88 Other	
ALI (001.,			1	ukat/L	38 -	
LDH					Other	
			1	ukat/L		
	LDH I	Local Labo	orat	tory Range)	
Lauran			I Inc.			

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

C9D1Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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

col" is Specify DOSE CHANGE/ 4 Dose WITHHELD DOSE if "88 Other"		Package Lot Number	
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code			
Reason for Jose Change Jose Withhel	_	10N if "88 Othe	
Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		σ	
Year	- - -	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date v Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	o	Was If in Infusion ruption time time time time time time time (not only only only only only only only only	

INFUSION REACTION

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

protocol" is specified for "Reason for Dose Change", indicate code Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year 04 Per protocol88 Other (specify below) Start Date Cycle 9 Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. C $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin Continuous infusion One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ CI OTO Line # Line# 2 3 4 2 9

CYCLE 10

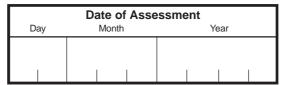


Cycle 10, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Examination Day Month Year		Weight	Body Surface Area
			1 - 19 2 - 11	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}



Cycle 10, Day 1 PHYSICAL EXAMINATION

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

rige (wors	eriirig) or arr ex	isting infamig on the 7	Adverse Everils Summary Civi
med? $_{\scriptscriptstyle 0}$	No ₁☐ Yes		_
	Date of Exar	nination	
Day	Month	Year	
	med? ₀□	med? ₀☐ No ₁☐ Yes Date of Exar	Date of Examination

descri	be find	bject have any abnorm ings below.	al clinical fi	ndings relating to th	e following re	equired sites?	ONO 1	Yes - If yes,
	CODES 01 02 03	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory	04 05 06 07 Indicate if	Abdomen Musculoskeletal Skin Lymph nodes a required assessm	08 09 10 11 ent was not d	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
Code (as listed above)				Describe fir List one entry				

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C10D1

Cycle 10, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record that Hamatology results below that were

Rec	ord Hema	tology resu			taken on the pla	nned Day 1
Date Drawn Day Month Year						
	Test		Result		Unit	Specify if Other Unit
					l /uL	
RE	3C			-	10 ⁶ /mm ³	
				-	l 10 ¹² /L	
					Other	
					lg/L lg/dL	
He	emoglob	oin			mmol/L	
				•	l Other	
				88		
Ца	mataar	:4			l L/L	
пе	matocr	IL		•	frac of 1	
				,	Other	
	2) (l fL	
M	√ک			88	Other	
				1	l /uL	
				•	l 10º/L	
Pla	atelets				10 ³ /mm ³	
					Other	
					l /uL	
				•	l 10 ⁹ /L	
VVI	ВС				1 10 ³ /mm ³	
					Other	
				15		
	Neutro	phils			1 10°/L	
				88	Other	
D	ما مدمد ا				1 70 1 10 ⁹ /L	
- 1	Суттрг	nocytes			Other	
F F					l %	
E					l 10º/L	
R	Monod	cytes		•	Other	
E N					l %	
T I A L	Eosino	ophils		9	l 10º/L	
		•			Other	
				15		
	Basop	hile		•	10 ⁹ /L	
	υαδυρ	oillo			Other	
				15		
	Granu	locytes		•	l 10 ⁹ /L	
				88	Other	

Day		Date Drawn Month		Year	
	Test	Result		Unit	Specif if Othe Unit
				/uL	
RE	3C			10 ⁶ /mm ³ 10 ¹² /L	
				Other	
			88		
				g/dL	
He	emoglobin		I	mmol/L	
			"	Other	
			15		
Не	ematocrit		5		
			7	frac of 1	
				Other	
M	CV		_ ₈ _		
171				Other	
			10		
DI	atelets		"	10º/L	
П	alelels			10 ³ /mm ³	
			00	Other	
				/uL 10 ⁹ /L	
W	ВС			10 ³ /mm ³	
				Other	
			88	%	
				10º/L	
	Neutrophils			Other	
			15		
D	Lymphocytes	5	1	10 ⁹ /L	
I				Other	
F F			15	%	
Е	Monocytos		о — е	10 ⁹ /L	
R E	Monocytes		100	Other	
N			15	%	
T I	Eosinophils		"	10º/L	
Α				Other	
L *			15		
	Basophils		"	10º/L Other	
				%	
	0		15	70 10 ⁹ /L	
	Granulocytes	5	ľ	Other	
* In	all cases, please re		00		

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

AMGEN	Panitumumab
AMG 954 2	0050203

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.

If chemotherapy was delayed record the Chemistry results below that were

Record the Chemistry results below that were taken on the planned Day 1							
Day		Date D				ear	
2,		715.				7G.	
Test		Result			Jnit		Specify if Other Unit
Sodium				☐ mEq/L ☐ mmol/l		Other	
Potassium			6	mEq/L mmol/l	L		
Chloride			6	☐ mEq/L ☐ mmol/l	L		
Bicarbonate	(HCO ₃)		6	mEq/L mmol/l	L		
Total Protein	1		12	⊒ g/L ⊒ g/dL			
Albumin			12	g/L g/dL			
Calcium			6	mg/dL mmol/	/L		
Magnesium			14	☐ mEq/L ☐ mg/L ☐ mg/dL	88		
Phosphorus	i	_	13	mg/dL mmol/	. 88	Other	_
BUN			13	☐ mg/dL☐ mmol/		Other	
Urea	OR — -		13	mg/dL mmol/	88	Other	
Creatinine			13	☐ mg/dL☐ umol/L	. Less 1	Other	
Uric Acid			13	☐ mg/dL☐ mmol/	. ₁₆ L		
Total Bilirubi	n		13	☐ mg/dL ☐ umol/L	. ₈₈ .		
Alk. Phos.			17	U/L ukat/L	88	Other	
AST (SGOT)		17	□ U/L □ ukat/L	₈₈ □ (Other	
ALT (SGPT)			1	☐ U/L ☐ ukat/L		Other	
LDH			1	□ U/L □ ukat/L		Other	
	LDH I	Local Labo	orat	ory Rang	ge		
Lower			Upp	er			

aken on the actua Day		Date D			Year	. 5
		1		1		
Test		Result		Un	it	Specify if Other Unit
Sodium			l _	mEq/L ₈₈	Other	
Potassium			1	mEq/L ₈₈	Other	
Chloride			l _	mEq/L ₈₈	Other	
Bicarbonate	e (HCO ₃)			mEq/L ₈₈ mmol/L	Other	
Total Protein	n			☐ g/L 8i	Other	
Albumin			1 '	☐ g/L 88 ☐ g/dL	Other	
Calcium			1	mg/dL 8	₈ Other	
Magnesium			14	☐ mEq/L _e ☐ mg/L ₈₈ ☐ mg/dL	_s □ mmol/L ₃□ Other	
Phosphorus	3		13	mg/dL 81	Other	
BUN			13	☐ mg/dL ₈₈ ☐ mmol/L	Other	
Urea	OR —		13	mg/dL 88	Other	
Creatinine			13	mg/dL 88	Other	
Uric Acid			13	mg/dL 16		
Total Bilirub	in		13	☐ mg/dL 88		
Alk. Phos.			17	U/L 8 ukat/L	₈ □ Other	
AST (SGOT	Γ)		17	U/L 88	Other	
ALT (SGPT)		17	U/L 88	Other	
LDH			17	U/L 88	Other	
	LDH I	Local Labo		ory Range		1
Lower			Upp			

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danitumumah	Site No.	Subject ID No.
_	7	
AMC 054 200E0203		7
AING 734 20030203		
		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

If "04 per protocol" is specify DOSE CHANGE/ indicated for "Reason for Dose Change / Dose WITHHELD DOSE if "88 Other" Withheld", indicate code		Package Lot Number	- - - -
Reason for Dose Change Dose Withhelc	_	ON if "88 Other"	
Total Volume Administered of Panitumumab plus Saline Solution (mL)		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR I	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)			
Year	- - -	If infusion was interrupted provide the Reason for Infusion Interruption	
Date Day Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	10	Was Infusion Interrupted?	

INFUSION REACTION

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

protocol" is specified for "Reason for Dose Change", indicate code Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year 04 Per protocol88 Other (specify below) Cycle 10 Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO 010 If chemotherapy was administered, was it delayed? ₀□ No Freq. C $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

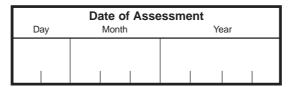
CYCLE 11



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? D No D Yes



VITAL SIGNS

	Date	•	Blood Pressure	Heart Rate	Respiration	Temperature
Day	Day Month Year		(mmHg) (beats/minute)	(breaths/minute)		
			1			

BODY SURFACE AREA

	Date of Exar	nination	Weight	Body Surface Area
Day	Month	Year	│	(m ²)
			1 - 19 2 - 11	` ′

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Da	ıy	Date Month Year			Performance ECOG	ce Status			
-	OG PER	_		-				- uf - u : : isl	
l	•			•			•	erformance withou ambulatory and al	
								t housework or off	
	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.								

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

or chair. 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	as a physical examination performed? $_{\scriptscriptstyle 0}$ No $_{\scriptscriptstyle 1}$ Yes	
	Date of Examination Day Month Year	
descril	scribe findings below.	Yes - If yes,
0		Extremities Other
Code (as listed above)	Describe findings List one entry per line.	

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	_
	2,1, , , , , , ,	

C11D1

Cycle 11, Day 1

HEMATOLOGY

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

If chamother and was delayed record the Hamatology results below that were

Record Hematology results below that were taken on the planned Day 1							
	Day	1	Date Dra Month	awn	Year		
		1					
	Test		Result		Unit	Specify if Other Unit	
RBC				2 Q	/uL 10 ⁶ /mm ³ 10 ¹² /L Other		
Hemoglobin				12	g/L g/dL mmol/L Other		
Hematocrit				7	% L/L frac of 1 Other		
M	CV				fL Other		
Platelets				900000000000000000000000000000000000000	/uL 10 ⁹ /L 10 ³ /mm ³ Other		
W	вс			10	/uL 10 ⁹ /L 10 ³ /mm ³ Other		
	Neutro	phils		88	10 ⁹ /L Other		
D I F	Lymphocytes				10 ⁹ /L Other		
F E R E	Monoc	eytes		88	10 ⁹ /L Other		
N T I A	Eosino	phils		88	10º/L Other		
L *	Basop	hils			10º/L Other		
	Granulocytes			-	% 10 ⁹ /L Other		

[Day Month		awn Year	r
		1		ı
	Test	Result	Unit	Specify if Othe Unit
RE	BC .		1 /uL 2 10 ⁶ /mm ³ 3 10 ¹² /L 88 Other	
Не	emoglobin		4 g/L 12 g/dL 6 mmol/L 88 Other	
Не	ematocrit		15 % 5 L/L 7 frac of 1 88 Other	
M	CV		88 — 5 ins. 8	
Pla	atelets		1 /uL 9 10 ⁹ /L 10 10 ³ /mm ³ 88 Other	
W	вс		1 /uL 9 10 ⁹ /L 10 10 ³ /mm ³ 88 Other	
	Neutrophils		15 % ₉ □ 10 ⁹ /L ₈₈ □ Other	
D I	Lymphocytes	6	15	
F F E R E	Monocytes		15	
N T I A	Eosinophils		15	
L *	Basophils		15	
	Granulocytes	6	15 % 9 □ 10 ⁹ /L 88 □ Other	

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

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

Blue - CRA; White Card - Investigator 13.03

AMGEN	Panitumumab
AMG 954 2	0050203

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				
Day	Mon	Date D	Drawn Year	
54,		101	1.55	
Test		Result	Unit	
Sodium			mEq/L 88 Other	
Potassium			mEq/L ₈₈ Other mmol/L	
Chloride			mEq/L 88 Other 6 mmol/L	
Bicarbonate (H	CO ₃)		mEq/L ₈₈ Other	
Total Protein			₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL	
Albumin			4 g/L 88 Other 12 g/dL	
Calcium			mg/dL ₈₈ Other of the other other of the other other of the other other of the other	
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 — — — OR			ng/dL 88 Other mmol/L	
Urea			ng/dL 88 ☐ Other 6 ☐ mmol/L	
Creatinine			₁₃ □ mg/dL ₈₈ □ Other ₁₆ □ umol/L	
Uric Acid			$_{13}$ \square mg/dL $_{16}$ \square umol/L $_{6}$ \square mmol/L $_{88}$ \square Other	
Total Bilirubin			13 mg/dL 88 Other	
Alk. Phos.			17 U/L 88 Other	
AST (SGOT)			17 U/L 88 Other 18 ukat/L	
ALT (SGPT)			U/L 88 Other 18 ukat/L	
LDH			U/L 88 Other 18 ukat/L	
	LDH Lo	ocal Labo	oratory Range	
Lower		1	Upper	

aken on the actua		Date D				, .
Day	Мо	onth			Year	
	l ,	1		1		
			<u> </u>			Specify
Test	:	Result		Un	it	if Other
			-	mEq/L 8	□ Other	Unit
Sodium			1	mmol/L	8 - 0	
			ļ -	mEq/L _{8:}	□ Other	
Potassium			1	■ meq/L ₈ ; ■ mmol/L	8 0 0 110.	
			10	mmoi/L mEq/L	□ Other	
Chloride			1	■ mEq/L ₈ ; ■ mmol/L	8 Unie	
OTHER.			10		Other	
Bicarbonate	(HCO.)		1	mEq/L ₈₈	8 Utilei	
Dicarbonas	; (11003/		10	mmol/L	- Other	
Total Proteir	_		_	_	Other	
TUtar i Tuton	.1			J g/dL	—	
Albumin			1 '	g /L 8	8 Other	
Albumin			1	g/dL	_	
O - Latinop				mg/dL 8	38 Other	
Calcium			-	mmol/L	_	
			1		6 mmol/L	
Magnesium			1	mg/L ₈	8 Other	
			110	mg/dL	Othor	
Phosphorus	;		1.0_	mg/dL ₈	8 Utriei	
			10	mmol/L	□ a	
BUN			1 -	mg/dL 8	8 Other	
	or —		1-0-	mmol/L		<u> </u>
Urea			1.0	mg/dL 8	8 Other	
			_	mmol/L		
Creatinine			1 -	mg/dL 8	₈ Other	
			1.0	umol/L	_	
Uric Acid			1		₆ □ umol/L	
			-	mmol/L ₈		
Total Bilirub	in		1 -	mg/dL 8	8 Other	
			16	umol/L		
Alk. Phos.			17	1 U/L 8	Other	
			18	ukat/L		
AST (SGOT	Γ)		17	1 U/L 8	Other	
,	,		1	ukat/L		
ALT (SGPT))	_	1.4	1 U/L ₈	_s Other	
, , , , , ,	<i>'</i>			ukat/L		
LDH			1	1 U/L 8	。 Other	
LDI.			1	ukat/L	8	
	LDH I	Local Labo		ory Range		

Upper

Lower

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danitumimah	Site No.	Subject ID No.
7	7	
AMG 954 20050203	- - -	
		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

ol" is Specify DOSE CHANGE/ Dose WITHHELD DOSE if "88 Other" e code		Package Lot Number	- - -
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	9		
Reason for Jose Change Jose Withhel	_	ION if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution (mL)		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mq)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Voar		If infusion was interrupted provide the Reason for Infusion Interruption	_
Date		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	7	Was If in Indusion rupt time time time time time time time tim	

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code C11 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year 04 Per protocol88 Other (specify below) Start Date Cycle 11 Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO 010 If chemotherapy was administered, was it delayed? □ No Freq. C $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

CYCLE 12

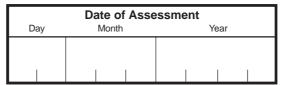


Cycle 12, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Exam Month	nination Year	Weight	Body Surface Area
			1 - 19 2 - 11	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

Cycle 12, Day 1 PHYSICAL EXAMINATION

Record any new finding or cha	inge (wors	sening) of an ex	isting finding on the <i>i</i>	Adverse Events S	ummary CRF
Was a physical examination perform	med? ₀□	l No ₁☐ Yes			
		Date of Exan	nination	1	
	Day	Month	Year]	
Does the subject have any abnormal clinical findings relating to the following required sites? 0 No 1 Yes - If y					

Does the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites?								
	CODES 01 02 03	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory	04 05 06 07 Indicate if	Abdomen Musculoskeletal Skin Lymph nodes a required assessm	08 09 10 11 ent was not d	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
Code (as listed above)				Describe fir List one entry				

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subje	ect ID No.	_
	2,1, , ,		

C12D1

Cycle 12, Day 1

HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequence in the charge of the complete and the charge of the c

Rec	ord Hema	tology resu	Date Dra		taken on the pla	nned Day 1		
	Day Month Year							
	Test		Result		Unit	Specify if Other Unit		
RE	BC			2 Q	/uL 10 ⁶ /mm ³ 10 ¹² /L Other			
He	emoglob	in		12 6	g/L g/dL mmol/L Other			
Нє	ematocr	it		15 5 7				
M	CV			 	fL Other			
Pla	atelets			0 9 10	/uL 10 ⁹ /L 10 ³ /mm ³ Other			
W	вс			10 10 88	10 ⁹ /L 10 ³ /mm ³ Other			
	Neutro	ophils		88	10 ⁹ /L Other			
D I F	Lymph	nocytes		15 9 88	% 10 ⁹ /L Other			
F E R	Monod	cytes			10 ⁹ /L Other			
E N T I A L *	Eosino	ophils			10 ⁹ /L Other			
	Basop	hils		88	10 ⁹ /L Other			
	Granulocytes				% 10º/L Other			

	Day	Date Dr. Month	vents Summary C logy results below that v y on the chemo admin pa awn Year	
	Test	Result	Unit	Specify if Othe Unit
			₁ /uL ₂ 10 ⁶ /mm ³	
RBC			_	
			3 10 ¹² /L	
			88 Other	
			4 ☐ g/L	
Н	emoglobin		12 g/dL	
			6 mmol/L	
			88 Other	
			15 %	
Н	ematocrit		5 L/L	
			₇ frac of 1	
			88 Other	
NΛ	CV		₈ f L	
IVI			88 Other	
			₁☐ /uL	
			₉ 🗖 10º/L	
Pl	atelets		₁₀ 10³/mm³	
			88 Other	
			₁☐ /uL	
			₉ 1 0 ⁹ /L	
W	BC		10 ³ /mm ³	
			Other	
			₁₅ □ %	
			10 ⁹ /L	
	Neutrophils		88 Other	
			15 %	
D	Lymphagyta	00	15 70 9 10°/L	
I	Lymphocyte	50	Other	
F			88 Strict	
F E			15 70 10°/L	
R	Monocytes		9 Other	
Е			88 Strie	
N			15 % 10°/L	
T I	Eosinophils			
Α			00	
L *			15 W	
•	Basophils		₉ 10 ⁹ /L	
			88 Other	
			15 %	
	Granulocyte	es	₉ \bigcap 10°/L	
			88 Other	

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

AMGEN	Panitumumab
AMG 954 2	0050203

Site I	No.			Sı	ubject	1 DI	Vo.
		1	2,1				

C12D1

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 resu			ned Day 1		Day 1 (record reason	e Chemistry results below for delay on the chemo ac	
Day Mo	Date D	rawn Year		Day	Date D Month	rawn Year	
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Spec if Oth Uni
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L	
Potassium		mEq/L ₈₈ Other of the		Potassium		mEq/L 88 Other 6 mmol/L	
Chloride		mEq/L ₈₈ Other mmol/L		Chloride		mEq/L ₈₈ Other of mmol/L	
Bicarbonate (HCO ₃)		mEq/L ₈₈ Other mmol/L		Bicarbonate (HCO ₃)	mEq/L ₈₈ Other mmol/L	
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL	
Albumin		4 g/L 88 Other 12 g/dL		Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL	
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L	
Magnesium		11 mEq/L 6 mmol/L 14 mg/L 88 Other 13 mg/dL	-	Magnesium		11 mEq/L 6 mmol/l 14 mg/L 88 Other 13 mg/dL	
Phosphorus		mg/dL ₈₈ Other of the other		Phosphorus		mg/dL ₈₈ Other of mmol/L	
BUN 		mg/dL 88 Other 6 mmol/L		BUN	R — — —	mg/dL 88 Other 6 mmol/L	
Urea		mg/dL 88 Other 6 mmol/L		Urea		mg/dL 88 Other 6 mmol/L	
Creatinine		mg/dL 88 Other of the other othe		Creatinine		mg/dL 88 Other of the other othe	
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		ng/dL 16 umol/L umol/L 0ther	
Total Bilirubin		mg/dL 88 Other other umol/L		Total Bilirubin		mg/dL ₈₈ Other other umol/L	
Alk. Phos.		U/L 88 Other 0 Other 18 Ukat/L		Alk. Phos.		U/L 88 Other 0 Other 18 Ukat/L	
AST (SGOT)		U/L 88 Other ukat/L		AST (SGOT)		U/L 88 Other ukat/L	
ALT (SGPT)		U/L 88 Other 0 Other 18 ukat/L		ALT (SGPT)		U/L 88 Other labeled ukat/L	
LDH		₁₇ U/L ₈₈ Other ₁₈ ukat/L		LDH		U/L 88 Other ukat/L	
LDH	Local Labo	oratory Range			LDH Local Labo	oratory Range	
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danitum mash	Site No.	Subject ID No.
┕	7	
AMC 05/1 2005020	·//.	7
AINO 734 20030203		
		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

son for Specify DOSE CHANGE/ Ison for Specify DOSE CHANGE/ Dose WITHHELD DOSE if "88 Other"		Package Lot Number	
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	(*)	
Reason for Jose Change Ose Withhel	_	10N if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Year		If infusion was interrupted provide the Reason for Infusion Interruption	
Date y Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	12	Was If in Infusion ruptic time time (not No Yes	

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code C12 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year 04 Per protocol88 Other (specify below) Cycle 12 Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO 010 If chemotherapy was administered, was it delayed? □ No Freq. C $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

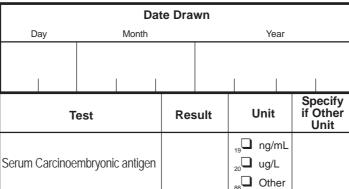
WEEK 24 ASSESSMENTS



Week 24

CEA

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



W24

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	C	ate of Pr	ocedure		Method of Assess- ment	Subsite Describe specific location	Lesion Site Code	Measurable Lesions * (mm) (Longest Diameter) Must be unidimensionally measurable	Was Interventional Therapy Performed On This Lesion Since the Last Assessment?
	Day	Month	Year					Dimensions (mm)	₀No ⊥₁Yes ✓ ⊥ ✓
01									
02									
03									
04									
05									
06									
07									
08									
09									
10									
	<u> </u>					Sum of T Les	arget sions		
			IENT CODE	-	/ (CT)	04 MRI (NMR) 23 Spiral Computed	d Tomogra	phy (CT)	
00 01 02 03 08 09	ON SITE Lymph no Thyroid Oral cavir Pharynx Pelvis Breast Pleural er	ty	13 Lung p 17 Pleura 20 Liver 30 Bone 40 Chest 49 Perica 50 Spinal	wall	eural wall	51 Brain 69 Anus 61 Esophagus 70 Ascites 62 Stomach 73 Retroperiton 63 Pancreas 74 Peritoneum 64 Small intestine 79 Gall bladder 65 Colon 81 Kidney 66 Rectum 82 Heart	eum 8 8	4 Adrenal gland5 Spleen6 Skin8 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'.

Site	No.		
1	1	1	

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

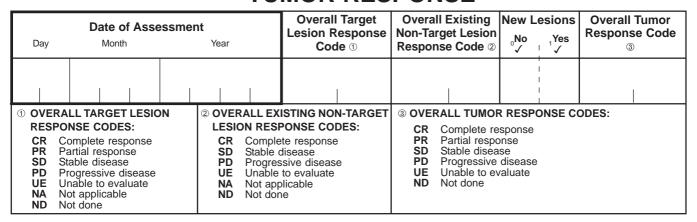
Lesion Note: Always maintain the same order of lesion numbers	1	Pate of Pro	ocedure Year		Method of Assess- ment	Subsite Describe specific locat	Lesion Site Code	New Lesions	Longest Diameter* (mm)	Tumor Response (Record if body site code is NOT "04 Bone"	Was Interventional Therapy Performed On This Lesion Since the Last Assessment?
11		1 1		1				1	1 1		
12								1			
13		1 1		ı							
14								1 1			
15											
16								1			
17								1			
18								1 1			
19								1			1
20								1			
01 X 03 (METHOD OF ASSESSMENT CODES: 01 X-Ray 03 Conventional Computed Tomography (CT) 04 MRI (NMR) 23 Spiral Computed Tomography (CT) 25 Bone Scan 88 Other (specify below)										
00 L 01 T 02 C 03 P 08 P 09 B 10 P	ymph no hyroid Oral cavit Pharynx Pelvis Breast Pleural ef	у	20 Liver30 Bone40 Ches49 Peric50 Spina	a or p t wall ardial	leural wall effusion	51 Brain61 Esophagus62 Stomach63 Pancreas64 Small intestine65 Colon66 Rectum	74 P	scites etroperitone eritoneum all bladder idney	85 Sp eum 86 SI 88 O	drenal gland bleen kin ther (specify a ubsite above)	
CR (e response	_0.			ressive disease ble to evaluate		NA Not a			

Specify if "88 Other" Method of Assessment

^{*} 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'.

W24

Week 24 TUMOR RESPONSE



TUMOR RESPONSE INSTRUCTIONS								
OVERALL	OVERALL		OVERALL					
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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-	Progressive Disease (PD)								
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)									

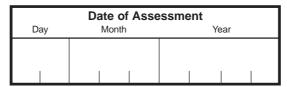
CYCLE 13



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? D No D Yes



VITAL SIGNS

Day	Date Day Month Year		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature	
			1				

BODY SURFACE AREA

	Date of Exan		l	Weight	Body Surface Area
Day	Month	Year		kg alb	(m²)
			П	1 5 2	. ,
					•

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Day	Date Month	Performand ECOG	ce Status				
	1 1	1 1	ı				
© ECOG PERFORMANCE STATUS CODES: D Fully active, able to carry on all pre-disease performance without restriction.							
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.							
I	2 Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about > 50% of waking hours.						

- or chair.
- 5 Dead

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

C13D1

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? $_{_{0}}\square$ No $_{_{1}}\square$ Yes

			Data of Francis		1				
		_	Date of Exami						
		Day	Month	Year	1				
descri	the subject have any abnormatibe findings below.	l clinical fi	ndings relating to	the following requi	red sites?	No 1	Yes - If yes,		
(CODES: 11 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck 12 Cardiovascular 13 Respiratory	04 05 06 07 Indicate if	Abdomen Musculoskeletal Skin Lymph nodes a required assess	09 Ge 10 Br	eurological enitourinary east / Chest ectal	50 88	Extremities Other		
Code (as listed	Describe findings								
above)			LIST ONE EN	ry per iirie.					

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.	Subject ID No.	_
	2,1, , , , , , ,	

C13D1

Cycle 13, Day 1

HEMATOLOGY

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

If chamother and was delayed record the Hamatology results below that were

Red	ord Hemat	tology resu			taken on the pla	anned Day 1
	Day	1	Date Dra Month	awn	Year	
		1				
	Test		Result		Unit	Specify if Other Unit
RBC			2 Q	/uL 10 ⁶ /mm ³ 10 ¹² /L Other		
Hemoglobin			12	g/L g/dL mmol/L Other		
Hematocrit		t		7	% L/L frac of 1 Other	
M	CV				fL Other	
Platelets				900000000000000000000000000000000000000	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
WBC				10	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
	Neutro	phils		88	10 ⁹ /L Other	
D I F	Lymph	ocytes			10 ⁹ /L Other	
F E R E	Monoc	eytes		88	10 ⁹ /L Other	
N T I A	Eosinophils			88	10º/L Other	
L *	Basop	hils			10º/L Other	
	Granul	locytes		-	% 10 ⁹ /L Other	

Day I		Date Drawn Month		Year		
Test		Result		Unit	Specify if Othe Unit	
RBC			3 1	0 ⁶ /mm ³		
Hemoglobin			4 9	g/dL nmol/L		
Hematocrit			15 c	%		
M	CV		88 8 f	L		
Platelets			''			
WBC			₁			
	Neutrophils		15 9 1 9 1 1 88 0	0 ⁹ /L		
D I F	Lymphocytes		9 1 88	% 0º/L Other		
r F E R E	Monocytes		9 1 88 0	0º/L Other		
N T I A	Eosinophils		9 1 88 0	0º/L Other		
L *	Basophils		9 1 88 0	0º/L Other		
	Granulocytes		₁₅ 0 9			

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

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

Blue - CRA; White Card - Investigator 16.03

AMGEN	Panitumumab
AMG 954 20	0050203

,,,,	Site I	۷o.				Su	bject	ID N	10.
			1	2,1	l				

C13D1

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 th	nat were taken on the plann	ned Day 1			e Chemistry results below I for delay on the chemo ad		
Day	Date D Month	rawn Year		Day	rawn Year	i wn Year		
Day	WOTH	Teal		Day	Month	Teal		
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Specific Other Unit	
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L		
Potassium		mEq/L ₈₈ Other of mmol/L		Potassium		mEq/L ₈₈ Other of mmol/L		
Chloride		mEq/L ₈₈ Other of mmol/L		Chloride		mEq/L ₈₈ Other of mmol/L		
Bicarbonate (HC	(O ₃)	mEq/L ₈₈ Other of mmol/L		Bicarbonate (F	HCO ₃)	mEq/L ₈₈ Other of mmol/L		
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		
Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL		Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL		
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L		
Magnesium		$\begin{array}{cccccccccccccccccccccccccccccccccccc$	-	Magnesium		$\begin{vmatrix} 1 & \text{mEq/L} & 6 \\ 1 & \text{mg/L} & 88 \\ 1 & \text{mg/dL} \end{vmatrix}$ mg/dL	-	
Phosphorus		mg/dL 88 Other 6 mmol/L		Phosphorus		mg/dL ₈₈ Other ₆ mmol/L		
BUN		mg/dL ₈₈ Other ₆ mmol/L		BUN	,	mg/dL 88 Other 6 mmol/L		
OR Urea		ng/dL 88 Other mmol/L		— — — OF Urea	x — — — —	ng/dL 88 Other 6 mmol/L		
Creatinine		mg/dL ₈₈ Other other umol/L		Creatinine		mg/dL ₈₈ Other other umol/L		
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		mg/dL 16 umol/L 0 umo		
Total Bilirubin		mg/dL 88 Other of the other othe		Total Bilirubin		mg/dL 88 Other of the other othe		
Alk. Phos.		U/L 88 Other 0 Other 18 Ukat/L		Alk. Phos.		U/L 88 Other 0 Other 18 Ukat/L		
AST (SGOT)		U/L 88 Other 18 ukat/L		AST (SGOT)		17 U/L 88 Other 18 ukat/L		
ALT (SGPT)		U/L 88 Other 18 ukat/L		ALT (SGPT)		U/L 88 Other 18 ukat/L		
LDH		U/L 88 Other ukat/L		LDH		U/L 88 Other ukat/L		
I	_DH Local Labo	oratory Range			LDH Local Labo	oratory Range		
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danitumumah	Site No.	Subject ID No.
_	7	
AMC 95/ 20050203		
AND 734 20030203		
		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

tocol" is Specify DOSE CHANGE/ Reason for Specify DOSE CHANGE/ e) Lose WITHHELD DOSE if "88 Other"		Package Lot Number	_
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	" ,	
Reason for lose Change ose Withhele	_	I ON if "88 Othel	
Total Volume Administered of Panitumumab plus Saline Solution	p Time Dose Panitumimab plus Saline Dose Withheld Our clock) (mg) (mL) (ml) (ml) (ml) (ml) (ml) (ml)		
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		σ	
Year	- - -	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date Day Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	13	Was Inferrupted? No Ves	

INFUSION REACTION

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

protocol" is specified for "Reason for Dose Change", indicate code C13 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reason Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 13 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

CYCLE 14

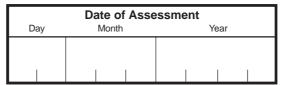


Cycle 14, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Exam Month	nination Year	Weight	Body Surface Area
			1 - 19 2 - 11	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}



Cycle 14, Day 1
PHYSICAL EXAMINATION

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

Record any new finding or cha	inge (wors	ening) of an ex	isting tinaing on the <i>i</i>	Adverse Events Summary CRF	
Was a physical examination perform	med? ₀□	No ₁☐ Yes		_	
	Date of Examination				
	Day	Month	Year		

Does descri	the su	ubject have any abnorm	al clinical f	indings relating to the	e following r	equired sites?	No 1	Yes - If yes,
SITE (04 05 06 07 Indicate if	Abdomen Musculoskeletal Skin Lymph nodes a required assessme	08 09 10 11 ent was not c	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
Code (as listed above)				Describe fin List one entry				

AMGEN	Panitumumab
AMG 954 20	0050203

 Site No.		Sub	ject	ID No	0.			
1 1 1	2,1	ı	1	1	1	1	1	

C14D1

Cycle 14, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that warren

Rec	ord Hema	tology resu			taken on the plai	nned Day 1
	Day	1	Date Dra Month	awn	Year	
	Test		Result	Unit		Specify if Other Unit
					l /uL	
RE	3C			_	10 ⁶ /mm ³	
			_	10 ¹² /L		
					Other	
				g/L		
Hemoglobin				g/dL		
				mmol/L		
					Other	
Hematocrit			15			
				L/L		
			'	frac of 1		
					Other	
MCV			-	Other		
					/uL	
					10 ⁹ /L	
Pla	atelets				10 ³ /mm ³	
					Other	
					/uL	
					10 ⁹ /L	
WI	ВС				10 ³ /mm ³	
					Other	
				15		
					10 ⁹ /L	
	Neutro	ophils			Other	
				15	%	
D	Lymph	nocytes			10 ⁹ /L	
I F	, .	•		88	Other	
F				15		
Е	Manag	n too			10 ⁹ /L	
R E	Mono	cytes			Other	
N				15		
T	Eosino	ophils			10 ⁹ /L	
I A					Other	
L *				15		
*	Basop	hils		_	10 ⁹ /L	
	Базор				Other	
				15		
	Granu	locytes			10 ⁹ /L	
				88	Other	

[Day	Date Dr Month	Year	
		1 1		Specif
	Test	Result	Unit	if Othe Unit
RBC			₁☐ /uL	
RE	3C		2 10 ⁶ /mm ³	
			3 10¹²/L	
			88 Other	
			₄ □ g/L ₁₂ □ g/dL	
Hemoglobin			12 g/dL 6 mmol/L	
			<u>"</u>	
			88 Other	
			15 70 5 L/L	
H	ematocrit		5 —	
			88 Other	
			88 — 5 M S	
M	CV		8 Other	
			58 1	
			° □ 109/L	
Pl	atelets		10 ³ /mm ³	
			88 Other	
			1 dL	
			₉ 10 ⁹ /L	
W	BC		10 ³ /mm ³	
			88 Other	
			₁₅ %	
	Moutrophila		₉ 1 0 ⁹ /L	
	Neutrophils		88 Other	
			15 %	
D	Lymphocyte	es	₉ 10°/L	
I F			88 Other	
F			15 %	
E R	Monocytes		₉ 10 ⁹ /L	
K E			88 Other	
N			15 %	
T I	Eosinophils		9 10°/L	
Α			88 Other	
L *			₁₅ □ % ₉ □ 10 ⁹ /L	
	Basophils		<u>"</u>	
			00	
	0		₁₅	
	Granulocyte	es		
* 1	all cases, please		00	

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

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.		Subj	ect II	O No.
	2,1,	1		

C14D1

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 res	ults below th	nat were taken on the plann	ned Day 1			e Chemistry results below for delay on the chemo ac	
Day N	Date D	rawn Year		Day	Date D Month	rawn Year	
Day	ionun	Teal		Day	WOTHT	Teal	
	1		1 L		1 1		ı
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Spec if Oth Uni
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L	
Potassium		mEq/L ₈₈ Other of mmol/L		Potassium		mEq/L ₈₈ Other of mmol/L	
Chloride		mEq/L ₈₈ Other mmol/L		Chloride		mEq/L ₈₈ Other mmol/L	
Bicarbonate (HCO ₃))	mEq/L ₈₈ Other of the medical		Bicarbonate (l	HCO ₃)	mEq/L ₈₈ Other of the modern	
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL	
Albumin		4 g/L 88 Other 12 g/dL		Albumin		4 g/L 88 Other 12 g/dL	
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L	
Magnesium		$_{11}$ mEq/L $_{6}$ mmol/L $_{14}$ mg/L $_{88}$ Other $_{13}$ mg/dL	-	Magnesium		mEq/L 6 mmol/l mg/L 88 Other mg/dL	-
Phosphorus		mg/dL ₈₈ Other 6 mmol/L		Phosphorus		mg/dL ₈₈ Other 6 mmol/L	
BUN		mg/dL 88 Other 6 mmol/L		BUN	D	mg/dL ₈₈ Other 6 mmol/L	
— — — OR — Urea		mg/dL 88 Other 6 mmol/L		— — — O Urea		mg/dL ₈₈ Other 6 mmol/L	
Creatinine		mg/dL 88 Other of the other othe		Creatinine		mg/dL ₈₈ Other other umol/L	
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		ng/dL 16 umol/L umol/L 0 mmol/L 88 Other	
Total Bilirubin		mg/dL 88 Other umol/L		Total Bilirubin		mg/dL 88 Other umol/L	
Alk. Phos.		U/L 88 Other 18 ukat/L		Alk. Phos.		U/L 88 Other 0 Other 18 Ukat/L	
AST (SGOT)		U/L 88 Other ukat/L		AST (SGOT)		U/L 88 Other ukat/L	
ALT (SGPT)		U/L 88 Other ukat/L		ALT (SGPT)		U/L 88 Other ukat/L	
LDH		U/L 88 Other ukat/L		LDH		U/L 88 Other 0 Other 18 Ukat/L	
LDH	Local Labo	pratory Range			LDH Local Labo	oratory Range	
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

deminimized NEOND	Site No.	Subject ID No.
_ a	7	
ANAC 054 20050203	·// <i>/</i>	7
AINIG 734 20030203		
		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

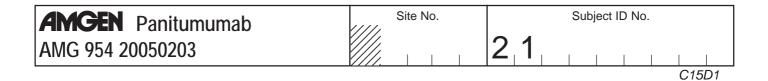
If "04 per protocol" is Specify DOSE CHANGE/ indicated for "Reason for Dose Change / Dose WITHHELD DOSE if "88 Other" Withheld", indicate code		Package Lot Number	- - - -
If "04 per indicated fo Dose Cha Withheld",	_	er"	
Reason for Dose Change / Dose Withheld	_	ION if "88 Oth	
Total Volume Administered of Panitumumab plus Saline Solution (mL)		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Year		If infusion was interrupted provide the Reason for Infusion Interruption	
Date Day Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	14	Was Infusion Interrupted?	

INFUSION REACTION

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

protocol" is specified for "Reason for Dose Change", indicate code C14 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 14 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO 010 If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

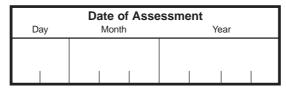
CYCLE 15



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? D No D Yes



VITAL SIGNS

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

BODY SURFACE AREA

	Date of Exan	nination	Weight	Body Surface Area
Day	Month	Year	kg 2 lb	(m²)
			1 32	` ´
l .				
				•

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Day	Date Pay Month Year			Performand ECOG	ce Status
	1 1				
	PERFORMANC			erformance withou	ut restriction.
				ambulatory and all thousework or off	
I	latory and capabl ies. Up and abou		,	nable to carry out rs.	any work
	ole of only limited g hours.	self-care, co	onfined to	ped or chair more	than 50% of

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

C15D

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 perfor	med? 。	No ₁□ Yes				
		Date of Examination					
		Day	Day Month Year				
descri	the subject have any abnorma pe findings below.	l clinical f	indings relating t	to the following r	equired sites?	₀□ No ₁□	Yes - If yes,
	 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory 	04 05 06 07	Abdomen Musculoskeletal Skin Lymph nodes	08 09 10 11	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
	•	Indicate it	a required asses	ssment was not o	done.		
Code (as listed				e findings ntry per line.			

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.				_			
	2.1	l l	1	1	1	ı	

C15D1

Cycle 15, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that warren

Record Hematology results below that were taken on the planned Day 1						
	Day	1	Date Dra Month	awn	Year	
	Test		Result		Unit	Specify if Other Unit
					l /uL	
RF	RBC			_	10 ⁶ /mm ³	
RBC				10 ¹² /L		
					Other	
					g/L	
He	emoglob	oin			g/dL	
					mmol/L	
					Other	
				15		
He	ematocr	it			L/L	
				,	frac of 1	
				88	Other	
M	CV			-	Other	
					/uL	
					10 ⁹ /L	
Pla	atelets				10³/mm³	
					Other	
					/uL	
					10 ⁹ /L	
W	ВС				10 ³ /mm ³	
					Other	
				15		
					10 ⁹ /L	
	Neutro	ophils		_	Other	
				15		
D	Lymph	nocytes			10 ⁹ /L	
I		, , , , ,		88	Other	
F F				15		
Е				\square_{ϱ}	10 ⁹ /L	
R E	Mono	cytes			Other	
N				15		
T	Eosino	ophils			10 ⁹ /L	
I A	Eosinophils				Other	
L				15		
*	Bacan	hile			10 ⁹ /L	
	Basop	n IIIS			Other	
				15		
	Granu	locytes			10 ⁹ /L	
		-		88	Other	

[Day	Month	rawn Yea	ar
		<u> </u>		Specif
	Test	Result	Unit	if Othe Unit
			₁☐ /uL	
RE	3C		₂ 10 ⁶ /mm ³	
			₃ 10 ¹² /L	
			88 Other	
			4 □ g/L	
Не	emoglobin		12 g/dL	
Hemoglobin			6 mmol/L	
			88 Other	
			15 %	
He	ematocrit		5 L/L	
			frac of 1	
			88 Other	
M	CV		8 Other	
			₈₈ Other	
			1 70L □ 10º/L	
Pla	atelets		9 10 /L 10 ³ /mm ³	
rialeiels				
			88 Other	
			1 702 9 109/L	
WBC			$_{10}^{9}$ 10 ³ /mm ³	
			88 Other	
			15 %	
			9 10%L	
	Neutrophils		88 Other	
			₁₅ %	
D	Lymphocyte	es	9 10º/L	
I			88 Other	
F F			15 %	
Ē	.		₉ 🖵 10 ⁹ /L	
R E	Monocytes		₈₈ Other	
Г N			₁₅ □ %	
Т	Eosinophils		₉ 10 ⁹ /L	
I A			88 Other	
L			₁₅ %	
*	Bacanhila		₉ 10 ⁹ /L	
	Basophils		88 Other	
			15 %	
	Granulocyte	es	₉ 10 ⁹ /L	
			88 Other	

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

AMGEN	Panitumumab
AMG 954 20	0050203

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	2,1,_	2,1, ,	2,1, , ,	2,1, , , ,

C15D1

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 th	nat were taken on the plann	ned Day 1			e Chemistry results below I for delay on the chemo ad	
Day	Date D Month	rawn Year		Day	Date D Month	Prawn Year	
Day	WOTH	Teal		Day	WOTHT	Teal	
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Specific Other Unit
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L	
Potassium		mEq/L ₈₈ Other of mmol/L		Potassium		mEq/L ₈₈ Other of mmol/L	
Chloride		mEq/L ₈₈ Other of mmol/L		Chloride		mEq/L ₈₈ Other of mmol/L	
Bicarbonate (HC	(O ₃)	mEq/L ₈₈ Other of mmol/L		Bicarbonate (F	HCO ₃)	mEq/L ₈₈ Other of mmol/L	
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL	
Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL		Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL	
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L	
Magnesium		$\begin{array}{cccccccccccccccccccccccccccccccccccc$	-	Magnesium		$\begin{vmatrix} 1 & \text{mEq/L} & 6 \\ 1 & \text{mg/L} & 88 \\ 1 & \text{mg/dL} \end{vmatrix}$ mg/dL	-
Phosphorus		mg/dL 88 Other 6 mmol/L		Phosphorus		mg/dL ₈₈ Other ₆ mmol/L	
BUN		mg/dL ₈₈ Other ₆ mmol/L		BUN	,	mg/dL 88 Other 6 mmol/L	
OR Urea		ng/dL 88 Other mmol/L		— — — OF Urea	x — — — —	ng/dL 88 Other 6 mmol/L	
Creatinine		mg/dL ₈₈ Other other umol/L		Creatinine		mg/dL ₈₈ Other other umol/L	
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		mg/dL 16 umol/L 0 umo	
Total Bilirubin		mg/dL 88 Other of the other othe		Total Bilirubin		mg/dL 88 Other of the other othe	
Alk. Phos.		U/L 88 Other 0 Other 18 Ukat/L		Alk. Phos.		U/L 88 Other 0 Other 0 Other	
AST (SGOT)		U/L 88 Other 18 ukat/L		AST (SGOT)		17 U/L 88 Other 18 ukat/L	
ALT (SGPT)		U/L 88 Other 18 ukat/L		ALT (SGPT)		U/L 88 Other 18 ukat/L	
LDH		U/L 88 Other ukat/L		LDH		U/L 88 Other ukat/L	
I	_DH Local Labo	oratory Range			LDH Local Labo	oratory Range	
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danitumumah	Site No.	Subject ID No.
	7	
AMG 954 20050203	_ _ _	7
	-	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

ason for Specify DOSE CHANGE/ ason for Specify DOSE CHANGE/ ason for Specify DOSE if "88 Other" are code		Package Lot Number	
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	n,	
Reason for Jose Change Jose Withhel	_	10N if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Year	- -	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date y Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	15	Was If in Infusion ruptication interrupted? time time (not yes)	

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code C15 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reason Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 15 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO 010 If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

CYCLE 16

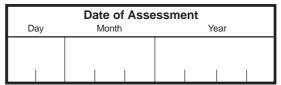


Cycle 16, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Day Month Year		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Exam Month	nination Year	Weight	Body Surface Area
			1 32	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

Cycle 16, Day 1

PHYSICAL EXAMINATION

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

Record any new finding or cha	nge (wors	ening) of an ex	isting finding on the A	Adverse Events Summary CRF
Was a physical examination perform	med? ₀□	No ₁☐ Yes		_
		Date of Exar	nination	
	Day	Month	Year	

	_							
Does	the su	bject have any abnorm	al clinical fi	ndings relating to th	e following re	equired sites?	₀ No ₁ U	Yes - If yes,
		ings below.						
SITE	CODES	:		A.L. I.				
	01	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck	04 05	Abdomen Musculoskeletal	08 09	Neurological Genitourinary	50 88	Extremities Other
	02	Cardiovascular	06	Skin	10	Breast / Chest	00	Other
	03	Respiratory	07	Lymph nodes	11	Rectal		
			Indicate if	a required assessm	ent was not d	one.		
Code								
(as				Describe fin				
listed				List one entry	per line.			
above)								
1								
<u>'</u>								
1								
,								
1								
,								

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.	Subject ID No.	_
	2,1, , , , , , ,	

C16D1

Cycle 16, Day 1

HEMATOLOGY

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

If chamother and was delayed record the Hamatology results below that were

Rec	ord Hemat	ology resu	Its below tha	t were	taken on the pl	anned Day 1		
	Day	1	Date Drawn Month Year					
Test		Result	Unit		Specify if Other Unit			
RBC				2 a	/uL 1 10 ⁶ /mm³ 1 10 ¹² /L			
Hemoglobin				4 12 6	Other g/L g/dL mmol/L Other			
Hematocrit				15 5				
M	CV			8	fL Other			
Platelets				9 0	/uL 10º/L 10³/mm³ Other			
WBC				10	/uL 10 ⁹ /L 10 ³ /mm ³ Other			
	Neutrophils			-	% 10 ⁹ /L Other			
D I	Lymphocytes			•	% 10 ⁹ /L Other			
F F E R E N T I A L *	Monoc	ytes		88	l 10º/L l Other			
	Eosinophils			88	l 10º/L l Other			
	Basophils			88	l 10º/L l Other			
	Granul	ocytes		-	% 10º/L Other			

[Day	Date Dr Month	awn	Year		
		1		1 1	1	
	Test	Result		Unit	Specify if Othe Unit	
RE	3C		3 1 1	0 ⁶ /mm ³		
Не	emoglobin		4 g	g/dL nmol/L		
Не	ematocrit		15 %	%		
M	CV		88 fl	L		
Pla	atelets					
WBC			₁			
	Neutrophils		9 10 88 0	0º/L		
D I F	Lymphocytes		9 1 88 0	% 0º/L Other		
F F E R E	Monocytes		15 9 9 10 88 0	0 ⁹ /L		
N T I A	Eosinophils		9 10 88 0	0º/L Other		
A L *	Basophils		15 % 9 10 88 0	0º/L Other		
	Granulocytes		15 9 9			

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

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

Blue - CRA; White Card - Investigator 19.03

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.		Sub	oject I	D N	0.
	2,1,				

C16D1

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 res	ults below tl	nat were taken on the plann	ned Day 1	If chemotherapy was delayed record the Chemistry results below that w taken on the actual Day 1 (record reason for delay on the chemo admin p Date Drawn									
Day N	Date D	rawn Year		Day	Date D Month	Prawn Year							
Day	Юпип	Teal		Day	WOTH	Teal							
	1				1 1		ſ						
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Speci if Oth Unit						
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L							
Potassium		mEq/L ₈₈ Other of mmol/L		Potassium		mEq/L ₈₈ Other of mmol/L							
Chloride		mEq/L ₈₈ Other of mmol/L		Chloride		mEq/L ₈₈ Other of mmol/L							
Bicarbonate (HCO ₃))	mEq/L ₈₈ Other of mmol/L		Bicarbonate ((HCO ₃)	mEq/L ₈₈ Other mmol/L							
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL							
Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL		Albumin		$_{4}$ g/L $_{88}$ Other $_{12}$ g/dL							
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L							
Magnesium		111 mEq/L 6 mmol/L 14 mg/L 88 Other 13 mg/dL	-	Magnesium		mEq/L 6 mmol/L mg/L 88 Other mg/dL	_						
Phosphorus		mg/dL 88 Other 6 mmol/L		Phosphorus		ng/dL 88 ☐ Other 6 ☐ mmol/L							
BUN		mg/dL ₈₈ Other 6 mmol/L		BUN	\D	mg/dL ₈₈ Other 6 mmol/L							
— — — OR — Urea		ng/dL 88 Other 6 mmol/L		Urea	OR — — — —	ng/dL 88 Other 6 mmol/L							
Creatinine		mg/dL ₈₈ Other other umol/L		Creatinine		mg/dL ₈₈ Other ₁₆ umol/L							
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other							
Total Bilirubin		mg/dL 88 Other of the other othe		Total Bilirubin	1	ng/dL 88 ☐ Other when the other are umol/L							
Alk. Phos.		U/L 88 Other labeled Other labeled Other		Alk. Phos.		$_{17}$ U/L $_{88}$ Other $_{18}$ ukat/L							
AST (SGOT)		U/L 88 Other labeled U/L 000 Other		AST (SGOT)		U/L 88 Other 18 ukat/L							
ALT (SGPT)		U/L 88 Other ukat/L		ALT (SGPT)		U/L 88 Other ukat/L							
LDH		U/L 88 Other ukat/L		LDH		U/L 88 Other ukat/L							
LDH	Local Labo	oratory Range			LDH Local Lab	oratory Range							
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danifuminash	Site No.	Subject ID No.
	7/	
AMG 954 20050203	- - -	-
		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

sol" is Specify DOSE CHANGE/ Bose WITHHELD DOSE if "88 Other" te code		Package Lot Number	
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	'n	
Reason for Jose Change Ose Withhel	_	ION if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Year	_ _ _	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date Day Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	16	Was Infusion Interrupted? (1)	

INFUSION REACTION

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

7	3		4								Site No.			Subjec	Subject ID No.	
₹ ₹	1G 95	AMG 954 20050203	Ω								_	_	2	_	_	_
							ડ	Cycle 16	9							C16
Jid Si	ubject r	CHEI	CHEMOTHERAPY ADM herapy? O No D Yes If yes, please enter	RAI s If yes	JY AL	MIN Inter deta	INISTRA details below:	RATI ow:	NO	INISTRATION - FOLFOX Regimen details below:	X	Regir	nen			
Line	Study	Drug Name	Drug Type	Ac	Actual Total Dose Administered	Freq.		Start Date	ate	Start Time (24 hour		Stop Date	Jate	Stop Time (24 hour	Reason for Dose Change	If "04 Per protocol" is specified for "Reason for Dose Change",
					(mg)		Day	Month	Year	clock)	Day	Month	Year	clock)	©	indicate code
1	_	Oxaliplatin						_	_		_	_	_		_	_
2	1	Leucovorin	/leucovorin 1 racemic (dl-) 2 leucovorin 2				_	_			_	_ _	_		_	_
3	1	5-FU Bolus				ОТО	_	_	_ _ _	••	_	_ _	_ _ _		_	_
4	_	5-FU Continuous Infusion				5					_					_
5	2	Leucovorin	/Heucovorin 1 racemic (d/-) 2 leucovorin 2													_
9	2	5-FU Bolus				ОТО	_	_	_ _ _		. <u>-</u>	<u> </u>	_		_	_
_	7	5-FU Continuous Infusion				5	_				_	_				
Ē 50 ⊝	FREQUEN CI Cont OTO One	© FREQUENCY CODES: CI Continuous infusion OTO One time only	© REASC 01 Ad 02 No 03 Do	Adverse event Noncompliance Dose administra	 REASON FOR DOSE CHANGE 10 Adverse event 02 Noncompliance 03 Dose administration error 	COD 94 88	ES: Per pro Other (ES: Per protocol Other (specify below)	(MC	© "04 100 386 387	14	"04 PER PROTOCOL 100 Weight change 386 Chemotherapy re 387 Chemotherapy re	" DOSE CHA elated hemato	PER PROTOCOL" DOSE CHANGE CODES: Weight change Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity	ting toxicity limiting tox	doity
Line #	#	Specify REASON	Specify REASON FOR DOSE CHANGE "88	3, 3DN	38 Other"		Line #	#	0,	Specify REASON FOR DOSE CHANGE "88	SON FOR	DOSE (SHANGE "8	8 Other"		
					CHEMO		TER.	APY	THERAPY DELAY	ΑY						
		If chemotherapy was administered, was it delayed? $_{\circ}\Box$	was administered	d, was	it delayed	oN □° SI	☐ ≻	es If yes,	please er	₁□ Yes If yes, please enter reason code:	:ope:					
		Reason for Delay		REASO	©REASON CODES:	7				Spe	Specify REASON	88, NOS	3 Other"			
				230 230 316 11 24	Protocol specified adverse event Protocol specified lab value Intervendal therapy for metastases	fied lab val	e even ue metasta	ases								
				- 1	Otner (specify)											

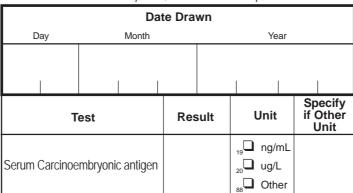
WEEK 32 ASSESSMENTS

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		W32

Week 32

CEA

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



Week 32
TUMOR EVALUATION - TARGET LESIONS
CT or MRI of the Chest, Abdomen, Pelvis and all other sites of disease

Was Interventional Therapy Performed Measurable Lesion Note: Always Lesions * Method On This Lesion **Subsite** (mm) of maintain Lesion (Longest Diameter) Must be **Date of Procedure** Site Assess-Describe specific location the same Since the order of lesion Code ment Last unidimensionally 1 2 Assessment? measurable numbers _₀No ₁,Yes Day Dimensions (mm) Month Year 01 02 03 04 05 06 07 08 09 10 **Sum of Target** Lesions

METHOD OF ASSESS O3 Conventional Cor	SMENT CODES: nputed Tomography (CT)	04 MRI (NMR)	23 Spiral Computed Tomo	ography (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 Brain61 Esophagus62 Stomach63 Pancreas64 Small intestine65 Colon66 Rectum	 69 Anus 70 Ascites 73 Retroperitoneum 74 Peritoneum 79 Gall bladder 81 Kidney 82 Heart 	84 Adrenal gland85 Spleen86 Skin88 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'.

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.		Subjec	t ID N	0.			
	2 1	1 1	ı	ı	ı	ı	

W32

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	Da		ate Mo	of		осе		re		Method of Assess- ment	Des	scrib	Subsite ne specific location		esio Site Code ②	e	Ne Lesi ₀No	ons		onge amet (mm)	er*	Res (R if bo	mor ponse ecord idy site is NOT Bone"	Interve The Perfo On Les Sino La Assess	rapy ormed This sion ee the ast sment?
11			ı	1			1	1	1								 			ı	1		1		
12																	 								
13																	 								
14																	 								
15																	 			1					
16																	 								
17																	 								
18																	 			1					
19																	 								
20																	 			1	I				!
① METH 01 〉 03 ① 04 M	K-Ray Conve	/ entio	nal							hy (CT)			ral Computed Tom ne Scan	ogra	aphy	(CT	T)			hysica ther (s					
② LESIC 00 Ly 01 T 02 O 03 P 08 P 09 B 10 P	ymph hyroi ral ca haryr elvis reast leura	nod d avity nx l	le usio	n		17 20 30 40 49 50	Ple Liv Boo Ch Per Spi	eura er ne est rica	or p	effusion	6; 6; 6; 6;	1 2 3 4 5	Brain Esophagus Stomach Pancreas Small intestine Colon Rectum		74	Asc Ret Per Gal Kid	cites trope ritone Il bla ney	riton eum dder	eum	84 85 86 88	5 S 6 S 8 O	pleen kin ther <i>(</i> s	gland specify above)		
CR (SD S	Comp Stable	lete e dise	res eas	por e	nse					PD Prog UE Una	ble to	eva	aluate				ND I	Not a	one						

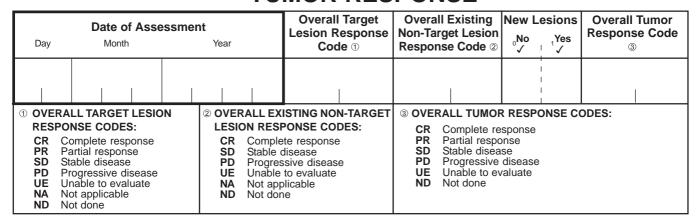
Line #	Specify if "88 Other" Method of Assessment

^{*} 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'.

W32

Week 32 TUMOR RESPONSE



	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL		OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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
1			

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

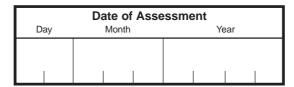
EVALUATION OF OVERALL EXISTING NON-TARGET LESION RESPONSE					
Individual Lesion Responses	Overall Non-Target Lesion Responses				
All Non-Target Lesions have an individual response of CR	Complete Response (CR)				
Does not qualifying for CR or PD as defined above and below, respectively	Stable Disease (SD)				
Unequivocal progression of existing Non-	Progressive Disease (PD)				
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)					

CYCLE 17



Cycle 17, Day 1 SKIN TOXICITY ASSESSMENT

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



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

	Date of Exan	nination	Weight	Body Surface Area
Day	Month	Year	kg 2 lb	(m²)
			1 32	` ´
l .				
				•

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Date			Performance Status		
	Day	Month	Year		☑ ECOG ☐ KPS
L					
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	2 Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about > 50% of waking hours.				
3	Canah	le of only limite	d self-care confir	ned to I	hed or chair more than 50% of

- 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

	100014	any non mang or one	ingo (moi	(3011111g) 01 all 01	oung mianig	011 1110 1	1010100 =1	onic Gamin	.,, 0, .,
Was	a phys	ical examination perfor	med? ₀	No ₁☐ Yes					
			Day	Date of Examination Day Month Year			1		
			Day	World	l ear				
descril	Does the subject have any abnormal clinical findings relating to the following required sites? ₀ No ₁ Yes - If yes, describe findings below.								
0)2	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory	04 05 06 07	Abdomen Musculoskeletal Skin Lymph nodes	08 09 10 11	Ge Br	eurological enitourinary east / Chest	50 88	Extremities Other
03 Respiratory 07 Lymph nodes 11 Rectal Indicate if a required assessment was not done.									
Code (as listed above) Describe findings List one entry per line.									

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	_
	2,1, , , , , , ,	

C17D1

Cycle 17, Day 1
HEMATOLOGY
If an abnormal laboratory value resulted in clinical sequelae, record clinical sequelae, record

Red	ord Hematology re		t were taken on the pla	nned Day 1	
	Date Drawn Day Month Year				
	Test	Result	Unit	Specify if Other Unit	
			₁☐ /uL	0	
RE	3C		₂ 10 ⁶ /mm ³		
1 ()			₃ 10 ¹² /L		
			Other		
			4 g/L □ g/dl		
He	emoglobin		₁₂ □ g/dL ₆ □ mmol/L		
			6 Other		
			88 Strict		
На	ematocrit		5 L/L		
110	matocnt		frac of 1		
			Other		
1.//	CV		₈ u fL		
IVIV			88 Other		
			₁ uL		
DI	atalata		₉ 10°/L		
Pla	atelets		10 ³ /mm ³		
			Other		
			₁ີ /uL ₉ ີ 10º/L		
W	ВС		₁₀ 10 ³ /mm ³		
•			Other		
			88 Sinoi		
			9 10°/L		
	Neutrophils		88 Other		
			15 %		
D	Lymphocytes		₉ 1 0 ⁹ /L		
I F			88 Other		
F			15_ %		
E	Monocytes		₉ 10 ⁹ /L		
R Mor	Wienledytee		88 Other		
Ν			15 %		
T I A L	Eosinophils		₉ 10°/L		
			0ther		
			15 → 78		
	Basophils		9 Other		
			15 %		
	Granulocytes		9 10°/L		
			88 Other		

	<i>the actual Day T (recol</i> Day	Date Dr Month	vents Summary CF plogy results below that w ny on the chemo admin pad awn Year	ye <i>).</i>
	Juy	World	1001	
	Test	Result	Unit	Specify if Other Unit
			₁☐ /uL	
RI	3C		₂ 10 ⁶ /mm ³	
1 (1	30		₃ 10 ¹² /L	
			88 Other	
			₄ □ g/L	
Не	emoglobin		₁₂ g/dL	
	3 - 1		₆ mmol/L	
			88 Other	
			15 %	
Не	ematocrit		₅ L/L	
			₇ frac of 1	
			88 Other	
NA	CV		₈ fL	
IVI	O V		88 Other	
			₁☐ /uL	
			₉ 10 ⁹ /L	
PI	atelets		₁₀ 10 ³ /mm ³	
			88 Other	
			₁☐ /uL	
			₉ 1 0 ⁹ /L	
W	BC		10 ³ /mm ³	
			88 Other	
			15 %	
	Navitranhila		₉ 1 0 ⁹ /L	
	Neutrophils		88 Other	
			15 %	
D	Lymphocytes		₉ 1 0°/L	
l F			88 Other	
F			15 %	
Ε	Managartas		₉ 1 0 ⁹ /L	
R E N T	Monocytes		88 Other	
			15 %	
	Eosinophils		₉ 10 ⁹ /L	
I A			88 Other	
L *			₁₅ %	
	Paganhila		₉ 10 ⁹ /L	
	Basophils		88 Other	
			15 %	
	Granulocytes		₉ 10 ⁹ /L	
	l ' ' '		88 Other	

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

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

Blue - CRA; White Card - Investigator 21.03

AMGEN	Panitumumab
AMG 954 2	0050203

 Site N	٧o.		Sı	ubject	1 DI	Ι٥.
1		2,1				

C17D1

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 res	ults below tl	nat were taken on the plann	ned Day 1			ne Chemistry results below n for delay on the chemo ac		
Day N	Date D		/n Year		Date D Month	Date Drawn onth Year		
Day	Юпип	Teal		Day	WOTH	Teal		
	1				1 1		ſ	
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Speci if Oth Unit	
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L		
Potassium		mEq/L ₈₈ Other of mmol/L		Potassium		mEq/L ₈₈ Other of mmol/L		
Chloride		mEq/L ₈₈ Other of mmol/L		Chloride		mEq/L ₈₈ Other of mmol/L		
Bicarbonate (HCO ₃))	mEq/L ₈₈ Other of mmol/L		Bicarbonate ((HCO ₃)	mEq/L ₈₈ Other mmol/L		
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL		
Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL		Albumin		$_{4}$ g/L $_{88}$ Other $_{12}$ g/dL		
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L		
Magnesium		111 mEq/L 6 mmol/L 14 mg/L 88 Other 13 mg/dL	-	Magnesium		mEq/L 6 mmol/L mg/L 88 Other mg/dL	_	
Phosphorus		mg/dL 88 Other 6 mmol/L		Phosphorus		ng/dL 88 ☐ Other 6 ☐ mmol/L		
BUN		mg/dL ₈₈ Other 6 mmol/L		BUN	\D	mg/dL ₈₈ Other 6 mmol/L		
— — — OR — Urea		ng/dL 88 Other 6 mmol/L		Urea	OR — — — —	ng/dL 88 Other 6 mmol/L		
Creatinine		mg/dL ₈₈ Other other umol/L		Creatinine		mg/dL ₈₈ Other ₁₆ umol/L		
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		
Total Bilirubin		mg/dL 88 Other of the other othe		Total Bilirubin	1	ng/dL 88 ☐ Other when the other are umol/L		
Alk. Phos.		U/L 88 Other labeled Other labeled Other		Alk. Phos.		$_{17}$ U/L $_{88}$ Other $_{18}$ ukat/L		
AST (SGOT)		U/L 88 Other labeled U/L 000 Other		AST (SGOT)		U/L 88 Other 18 ukat/L		
ALT (SGPT)		U/L 88 Other ukat/L		ALT (SGPT)		U/L 88 Other ukat/L		
LDH		U/L 88 Other ukat/L		LDH		U/L 88 Other ukat/L		
LDH	Local Labo	oratory Range			LDH Local Lab	oratory Range		
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danitumumah	Site No.	Subject ID No.
AMG 954 20050203	_ _ _	7
		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

on for Specify DOSE CHANGE/ son for Specify DOSE (if "88 Other" code		Package Lot Number	
f "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	u	
Reason for Jose Change Jose Withheld	_	I ON if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Year		If infusion was interrupted provide the Reason for Infusion Interruption	_
Dat e Day Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	17	Was Infusion rull Interrupted? (I	

INFUSION REACTION

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

□ No □ Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code C17 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year 04 Per protocol88 Other (specify below) Start Date Cycle 17 Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO 010 If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

CYCLE 18

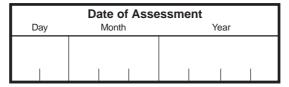


Cycle 18, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Examination Month Year		Weight ₁☐ kg ₂☐ lb	Body Surface Area (m²)
			1 02	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

C18D1

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 perfo	ormed? ₀□	No ₁☐ Yes				
		Day	Date of Exan Month	nination Year			
descrii SITE C	the subject have any abnormable findings below. CODES: 1 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory	04 05 06 07	Abdomen Musculoskeletal Skin Lymph nodes	08 09 10 11	Neurological Genitourinary Breast / Chest Rectal	0 No 1 □	Yes - If yes, Extremities Other
		Indicate if	a required asses	ssment was not	done.		
Code (as listed above)				e findings ntry per line.			

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subje	ect ID No.
	2,1, , ,	1 1 1 1

C18D1

Cycle 18, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that warren

Rec	ord Hema	tology resu			taken on the plai	nned Day 1
	Day	1	Date Dra Month	awn	Year	
	Test		Result		Unit	Specify if Other Unit
					l /uL	
RE	3C			_	10 ⁶ /mm ³	
					10 ¹² /L	
					Other	
					g/L	
He	emoglob	oin			g/dL	
					mmol/L	
					Other	
				15		
He	ematocr	it			L/L	
				,	frac of 1	
				88	Other	
M	CV			-	Other	
					/uL	
					10 ⁹ /L	
Pla	atelets				10³/mm³	
1 latelets					Other	
					/uL	
					10 ⁹ /L	
W	ВС				10 ³ /mm ³	
					Other	
				15		
					10 ⁹ /L	
	Neutro	ophils		_	Other	
				15		
D	Lymph	nocytes			10 ⁹ /L	
I		, , , , ,		88	Other	
F F				15		
Е				\square_{ϱ}	10 ⁹ /L	
R E	Mono	cytes			Other	
N				15		
T Eosino	ophils			10 ⁹ /L		
I A					Other	
L				15		
*	Bacan	hile			10 ⁹ /L	
	Basop	n IIIS			Other	
				15		
	Granu	locytes			10 ⁹ /L	
Grandiocyte		-		88	Other	

Day I		Date Di Month		ary CRF. ythat were taken on Imin page). Year
		1 1		1 1
	Test	Result	Unit	Specify if Other Unit
RI	3C		106/mm 106/mm 1012/L 1012/L	3
Н	emoglobin		$_{4}$ g/L $_{12}$ g/dL $_{6}$ mmol/L $_{88}$ Other	
Н	ematocrit		15 % 5 L/L 7 frac of 88 Other	1
М	CV		8 Glass	
Pl	atelets		1 /uL 9 10°/L 10 10³/mm 10 Other	3
W	вс		10 /uL 9 109/L 10 103/mm 88 Other	3
	Neutrophils		15 % 9 □ 10 ⁹ /L 88 □ Other	
D I F	Lymphocyte	s	15 % 9 □ 10 ⁹ /L 88 □ Other	
F E R E	Monocytes		15 % 9 □ 10 ⁹ /L 88 □ Other	
N T I A	Eosinophils		15 % 9 □ 10 °/L 88 □ Other	
L *	Basophils		15 % 9 □ 10 °/L 88 □ Other	
	Granulocyte	s	15 % 9 □ 10 ⁹ /L 88 □ Other	

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.		Su	bject	ID N	lo.
	2,1				

C18D1

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 Chemistr	y results below th	nat were taken on the plann	ned Day 1			e Chemistry results below I for delay on the chemo ac	
Day	Date D Month	rawn Year		Day	Date D Month	rawn Year	
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Spec if Oth Uni
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L	
Potassium		mEq/L ₈₈ Other of the other		Potassium		mEq/L 88 Other 6 mmol/L	
Chloride		mEq/L ₈₈ Other mmol/L		Chloride		mEq/L 88 Other 6 mmol/L	
Bicarbonate (H0	CO ₃)	mEq/L ₈₈ Other mmol/L		Bicarbonate	(HCO ₃)	mEq/L 88 Other 6 mmol/L	
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL	
Albumin		4 g/L 88 Other 12 g/dL		Albumin		₄ g/L ₈₈ Other ₁₂ g/dL	
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L	
Magnesium		$_{11}$ mEq/L $_{6}$ mmol/L $_{14}$ mg/L $_{88}$ Other $_{13}$ mg/dL	-	Magnesium		11 mEq/L 6 mmol/l 14 mg/L 88 Other 13 mg/dL	
Phosphorus		mg/dL ₈₈ Other of the other		Phosphorus		mg/dL ₈₈ Other 6 mmol/L	
BUN OR		mg/dL 88 Other 6 mmol/L		BUN	DR — — — —	mg/dL 88 Other 6 mmol/L	
Urea		mg/dL 88 Other 6 mmol/L		Urea		mg/dL 88 Other 6 mmol/L	
Creatinine		mg/dL 88 Other umol/L		Creatinine		mg/dL 88 Other of the other othe	
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		mg/dL 16 umol/L mmol/L ₈₈ Other	
Total Bilirubin		mg/dL 88 Other other umol/L		Total Bilirubir	1	mg/dL 88 Other other umol/L	
Alk. Phos.		U/L 88 Other ukat/L		Alk. Phos.		U/L 88 Other ukat/L	
AST (SGOT)		U/L 88 Other ukat/L		AST (SGOT)		U/L 88 Other ukat/L	
ALT (SGPT)		U/L 88 Other ukat/L		ALT (SGPT)		U/L 88 Other ukat/L	
LDH		U/L 88 Other 0 Other 18 Ukat/L		LDH		U/L 88 Other ukat/L	
	LDH Local Labo	oratory Range			LDH Local Labo	oratory Range	
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

GNOEN Don't many	Site No.	Subject ID No.
AMG 954 20050203	_ _ _	7
		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

14/1-									
Cycle	Date		Start Time	Stop Time	Total Dose Administered	Total Volume Administered of Panitumumab plus Saline Solution	Reason for Dose Change / Dose Withheld	Reason for If "04 per protocol" is Dose Change / indicated for "Reason for Dose Withheld	or Specify DOSE CHANGE/ WITHHELD DOSE if "88 Other"
a, . A ~	Day Month	Year	(z4 nour ciock)			(mL)	①	Withheld", indicate co	
egger: Blue							_	_	
Was Infusion Interrupted?	If infusion was inter- rupted provide the total time of administration	If infusion was interrupted provide the Reason for		Specify I	REASON FOR I	Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	ON if "88 Other"		Package Lot Number
No Yes		Infusion Interruption ®							
		_							-

INFUSION REACTION

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

D No D Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code C18 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reason Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 18 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line# 2 3 4 2 9

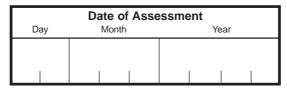
CYCLE 19



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? D No D Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

	Date of Exar	nination	Weight	Body Surface Area
Day	Month	Year	l lb kg ₂□ lb	(m²)
			1 - 19 2 - 10	, ,

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

Date Day Month Year							·	Performand ECOG	ce Status	
	_									
	① ECOG PERFORMANCE STATUS CODES:									
		_	_				_			
0	Fully a	ctive, able	to car	ry on	all pr	e-dise	ase p	erformance withou	it restriction.	
1								ambulatory and alt housework or off		
2		atory and es. Up and						nable to carry out	any work	
3		le of only hours.	imited	self-c	are, o	confin	ed to l	ped or chair more	than 50% of	
1	Compl	ataly disak	Nod C	annot	corr	, out	nv co	If care. Totally con-	finad to had	

or chair. Dead

CIBD

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 perfor	med? ₀	No ₁ Yes				
			Date of Exar	mination			
		Day	Month	Year			
		24,	· · · · · · · · · · · · · · · · · · ·	100.			
descrii SITE (the subject have any abnormalities findings below. CODES: 1 Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular	04 05 06	Abdomen Musculoskeletal Skin	to the following ro	equired sites? Neurological Genitourinary Breast / Chest	₀ No ₁ □	Yes - If yes, Extremities Other
	Respiratory	07	Lymph nodes	11	Rectal		
	1	Indicate if a	a required asses	ssment was not d	lone.		
Code							
(as listed above)				e findings entry per line.			

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	_
	2,1, , , , , , ,	

C19D1

Cycle 19, Day 1

HEMATOLOGY

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

If chamother and was delayed record the Hamatology results below that were

Record Hematology resu		ology resu	Its below tha	t were	taken on the pla	anned Day 1
	Day	1	Date Dra Month	awn	Year	
						,
	Test		Result		Unit	Specify if Other Unit
RE	3C			2 a	/uL 1 10 ⁶ /mm ³ 1 10 ¹² /L I Other	
Не	emoglob	in		4 12 6	g/L g/dL mmol/L Other	
Не	ematocri	t		15 5		
М	CV			8	fL Other	
Pla	atelets			9 0	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
W	вс			10	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
	Neutro	phils		88	l 10º/L l Other	
D I F	Lymph	ocytes		•	% 10º/L Other	
F E R E	Monoc	ytes		88	l 10º/L l Other	
N T I A	Eosino	phils			% 10º/L Other	
L *	Basopl	nils		88	l 10º/L l Other	
	Granul	ocytes		-	% 10º/L Other	

[Day	Date Dra Month	awn Year	r
		1		ı
	Test	Result	Unit	Specify if Othe Unit
RE	BC .		1 /uL 2 10 ⁶ /mm ³ 3 10 ¹² /L 88 Other	
Не	emoglobin		4 g/L 12 g/dL 6 mmol/L 88 Other	
Не	ematocrit		15 % 5 L/L 7 frac of 1 88 Other	
M	CV		88 — 5 ins. 8	
Pla	atelets		1 /uL 9 10 ⁹ /L 10 10 ³ /mm ³ 88 Other	
W	вс		1 /uL 9 10 ⁹ /L 10 10 ³ /mm ³ 88 Other	
	Neutrophils		15 % ₉ □ 10 ⁹ /L ₈₈ □ Other	
D I	Lymphocytes	6	15	
F F E R E	Monocytes		15	
N T I A	Eosinophils		15	
L *	Basophils		15	
	Granulocytes	6	15 % 9 □ 10 ⁹ /L 88 □ Other	

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

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

Blue - CRA; White Card - Investigator 23.03

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.				Subj	ect IE	No.	
	2	1	ı	ı	I	ı	ı

C19D1

Cycle 19, Day 1 CHEMISTRY

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

	,	value resulted in clinical . nat were taken on the plann	,
Day	Date D Month	rawn Year	
	1 1		
Test	Result	Unit	Specify if Other Unit
Sodium		mEq/L 88 Other 6 mmol/L	
Potassium		mEq/L ₈₈ Other mmol/L	
Chloride		mEq/L ₈₈ Other mmol/L	
Bicarbonate (H	ICO ₃)	mEq/L ₈₈ Other	
Total Protein		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL	
Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL	
Calcium		mg/dL 88 Other 6 mmol/L	
Magnesium		mEq/L ₆ mmol/L mg/L ₈₈ Other mg/dL	
Phosphorus		mg/dL 88 Other 6 mmol/L	
BUN		mg/dL 88 Other 6 mmol/L	
— — — OF Urea	(– – – –	mg/dL 88 Other 6 mmol/L	
Creatinine		ng/dL 88 ☐ Other umol/L	
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other	
Total Bilirubin		ng/dL 88 ☐ Other umol/L	
Alk. Phos.		17 U/L 88 Other	
AST (SGOT)		17 U/L 88 □ Other 18 □ ukat/L	
ALT (SGPT)		17 U/L 88 Other	
LDH		17 U/L 88 Other	
	LDH Local Labo		
Lower		Upper	

ord clinical sequ If chemotherapy Taken on the actua	was delaye	d reco	ord th	e C	hemistry	results	below	
Date Drawn Day Month Year								
Day	1410	// IU1				10	aı	
		ı			I			
Test	:	Res	sult		ι	Jnit		Specify if Other Unit
Sodium				1	mEq/L mmol/	00	Other	O.I.I.
Potassium				11	mEq/l mmol/	- 88	Other	
Chloride				11	mEq/l mmol/	- 88	Other	
Bicarbonate	e (HCO ₃)			11	mEq/l mmol/		Other	
Total Protei	Ü			4	⊒ mmo// ⊒ g/L ⊒ g/dL		Other	
Albumin				4	3 g/dL 3 g/L 3 g/dL	88	Other	
Calcium				13	■ g/aL ■ mg/dL ■ mmol/		Other	
Magnesium	l			11	mEq/L mg/L mg/dl	- G r r r r r r r r r r r r r r r r r r		
Phosphorus	3			13	☐ mg/dL☐ mmol/		Other	
BUN	O D			13	mg/dL mmol/		Other	
Urea	OR —			1.0	☐ mg/dL☐ mmol/	00	Other	
Creatinine				16	☐ mg/dL ☐ umol/l	-		
Uric Acid				1	☐ mg/dL ☐ mmol/			
Total Bilirub	in			1	☐ mg/dL ☐ umol/l		Other	
Alk. Phos.				17	U/L ukat/L	88	Other	
AST (SGOT	Γ)			1	U/L ukat/L		Other	
ALT (SGPT)			17	U/L ukat/L	88	Other	
LDH				17	U/L ukat/L	₈₈ □ (Other	
	LDHI	ocal	Labo	orat	ory Ran	ne		

Upper

Lower

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danifuminash	Site No.	Subject ID No.
AMG 954 20050203	- - -	
	-	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

otocol" is Specify DOSE CHANGE/ Reason for Specify DOSE CHANGE/ ge / Dose WITHHELD DOSE if "88 Other"		Package Lot Number	- - - -
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_		
Reason for Dose Change / Dose Withheld ①	_	I ON if "88 Othe	
Total Volume Administered of Panitumumab plus Saline Solution		ASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify RE/	
Start Time (24 hour clock)	:	S	
Year		If infusion was interrupted provide the Reason for Infusion Interruption	_
Date Day Month		If infusion was inter- upted provide the total time of administration (not including interrup- tions)	
Cycle	19	Was Infusion rull Interrupted? (f	

INFUSION REACTION

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

D No D Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code C19 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reason Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 19 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

CYCLE 20

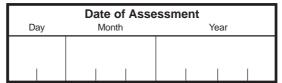


Cycle 20, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Date Day Month Year		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature	
			1			

BODY SURFACE AREA

Day	Date of Exam Month	nination Year	Weight	Body Surface Area
			1 - 19 2 - 11	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

Cycle 20, Day 1 PHYSICAL EXAMINATION

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

	,	• •	σ,	0			•
Was	a physical examination perfor	med? ₀	No ₁□ Yes				
			Date of Exan	nination			
		Day	Month	Year			
	the subject have any abnorma	l clinical f	indings relating t	o the following r	equired sites?	ONO 1	Yes - If yes,
SITE	CODES:						
	Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory	04 05 06 07	Abdomen Musculoskeletal Skin Lymph nodes	08 09 10 11	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
		Indicate it	a required asses	ssment was not d	done.		
Code (as listed				e findings ntry per line.			

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.		Subject	ID N	0.		_
	2,1	1 1	1	1		

C20D1

Cycle 20, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that were

Rec	ord Hema	tology resu	Its below tha	t were	taken on the pla	nned Day 1
	Day		Date Dra Month	awn	Year	
	,		-			
Test			Result	Unit		Specify if Other Unit
				1	/uL	
DE	RC			$_{2}$	10 ⁶ /mm ³	
RBC			•	10 ¹² /L		
				88	Other	
					g/L	
Нє	emoglob	oin		12	g/dL	
				0	mmol/L	
					Other	
				15		
He	ematocr	it		5	L/L	
				,	frac of 1	
					Other	
NAC	CV			\square_8		
IVIV					Other	
					/uL	
				•	10 ⁹ /L	
Pla	atelets				10 ³ /mm ³	
				88	Other	
					/uL	
				•	10 ⁹ /L	
W	ВС				10 ³ /mm ³	
					Other	
				15		
	Neutro	nhile		-	10 ⁹ /L	
	rvound	priiis		88	Other	
				15		
D	Lymph	nocytes			10 ⁹ /L	
I F					Other	
F				15		
E	Monod	ov to c		-	10 ⁹ /L	
R E	IVIOLIOC	Lytes			Other	
N				15		
T I A L	Eosino	ophils			10 ⁹ /L	
					Other	
				15		
*	Booss	hile		•	10 ⁹ /L	
	Basop	iiiiS			Other	
				15		
	Granu	locytes		-	10 ⁹ /L	
	Jianalooy tos			88	Other	

[Day	Date Dr Month	awn Ye	ar
		I		1 1
	Test	Result	Unit	Specify if Othe Unit
RE	3C		106/mm³ 1012/L 88 Other	
Не	emoglobin		4 g/L 12 g/dL 6 mmol/L 88 Other	
Не	ematocrit		15 % 5 L/L 7 frac of 1 88 Other	
M	CV		88 fL 8 Other	
Platelets			10°/L 10°/L 10°/mm³ 88 Other	
W	вс		1 /uL 9 10°/L 10 10°/mm³ 88 Other	
	Neutrophils		15	
D I F	Lymphocytes	3	15	
F E R E	Monocytes		15	
N T I	Eosinophils		15	
A L *	Basophils		15	
	Granulocytes	3	15 % 9 10 9/L 88 Other	

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

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

Rlue - CRA: White Card - Investigator 24.03

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.		Subject ID N	lo.
	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 res	ults below th	nat were taken on the plann	ned Day 1			e Chemistry results below for delay on the chemo ac	
Day N	Date D	rawn Year		Day	Date D Month	rawn Year	
Day	ionun	Teal		Day	WOTHT	Teal	
	1		1 L		1 1		ı
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Spec if Oth Uni
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L	
Potassium		mEq/L ₈₈ Other of mmol/L		Potassium		mEq/L ₈₈ Other of mmol/L	
Chloride		mEq/L ₈₈ Other mmol/L		Chloride		mEq/L ₈₈ Other mmol/L	
Bicarbonate (HCO ₃))	mEq/L ₈₈ Other of the medical		Bicarbonate (l	HCO ₃)	mEq/L ₈₈ Other of the modern	
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL	
Albumin		4 g/L 88 Other 12 g/dL		Albumin		4 g/L 88 Other 12 g/dL	
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L	
Magnesium		$_{11}$ mEq/L $_{6}$ mmol/L $_{14}$ mg/L $_{88}$ Other $_{13}$ mg/dL	-	Magnesium		mEq/L 6 mmol/l mg/L 88 Other mg/dL	-
Phosphorus		mg/dL ₈₈ Other 6 mmol/L		Phosphorus		mg/dL ₈₈ Other 6 mmol/L	
BUN		mg/dL 88 Other 6 mmol/L		BUN	D	mg/dL ₈₈ Other of the other	
— — — OR — Urea		mg/dL 88 Other 6 mmol/L		— — — O Urea		mg/dL ₈₈ Other of the other	
Creatinine		mg/dL ₈₈ Other other umol/L		Creatinine		mg/dL ₈₈ Other other umol/L	
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		ng/dL 16 umol/L umol/L 0 mmol/L 88 Other	
Total Bilirubin		mg/dL 88 Other umol/L		Total Bilirubin		mg/dL 88 Other umol/L	
Alk. Phos.		U/L 88 Other 18 ukat/L		Alk. Phos.		U/L 88 Other 0 Other 18 Ukat/L	
AST (SGOT)		U/L 88 Other ukat/L		AST (SGOT)		U/L 88 Other ukat/L	
ALT (SGPT)		U/L 88 Other ukat/L		ALT (SGPT)		U/L 88 Other ukat/L	
LDH		U/L 88 Other ukat/L		LDH		U/L 88 Other 0 Other 18 Ukat/L	
LDH	Local Labo	pratory Range			LDH Local Labo	oratory Range	
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

deministration NECK	Site No.	Subject ID No.
AMG 954 20050203	- - -	-
		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

ol" is Specify DOSE CHANGE/ Son for Specify DOSE if "88 Other" e code		Package Lot Number	-
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_		
Reason for Jose Change Jose Withhel	_	ION if "88 Othe	
Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Year	_ _ _	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	20	Was If in Infusion rupted time time (not in No. 1, Yes	

INFUSION REACTION

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

UNo The Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code C20 Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reason Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year Cycle 20 04 Per protocol88 Other (specify below) Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO 010 If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line# 2 3 4 2 9

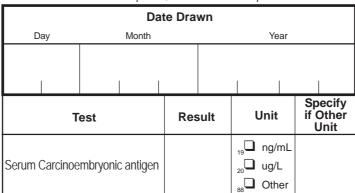
WEEK 40 ASSESSMENTS

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		W40

Week 40

CEA

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



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	D	Pate of Pr	ocedure Year	Method of Assess- ment	Subsite Describe specific location	Lesion Site Code	Measurable Lesions * (mm) (Longest Diameter) Must be unidimensionally measurable Dimensions (mm)	Was Interventional Therapy Performed On This Lesion Since the Last Assessment?
01	1	1 1					1 1	
02								
03								
04								i i
05								
06								
07								
08								
09								
10								1
					Sum of T Les	arget sions		
			IENT CODES: outed Tomograph	y (CT)	04 MRI (NMR) 23 Spiral Computed	d Tomogra	ohy (CT)	
00 L 01 7 02 0 03 F 08 F 09 E	ON SITE Lymph no Thyroid Oral cavin Pharynx Pelvis Breast Pleural e	ty	13 Lung paren 17 Pleura or pl 20 Liver 30 Bone 40 Chest wall 49 Pericardial 50 Spinal cord	effusion	51 Brain 69 Anus 61 Esophagus 70 Ascites 62 Stomach 73 Retroperiton 63 Pancreas 74 Peritoneum 64 Small intestine 79 Gall bladder 65 Colon 81 Kidney 66 Rectum 82 Heart	8		

^{*} 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 20	0050203

Site No.		Subjec	t ID N	0.			
	2 1		ı	ı	ı	ı	

W40

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	e r	D		of flont		oce	dur	'e		Meth of Asse mer	ss- nt	Desci	Subsite ibe specific loc	ation	Lesi Site Coc	e de	Lesi	ew ions 'Yes	Lo Dia	onges amete (mm)	st er*	Resp (Re if boo code "04"	mor ponse cord dy site is NOT Bone"	Interv The Perf On Le Sind	entional erapy ormed This sion ce the ast ssment?
11			1				ı	ı	1						1					ı	ı		ı		
12																									
13																									
14																		 							
15																									- - - -
16							[1		1								
17							1								1								1		
18															1		1				1				
19			-				1		1						1		i !				1				 - -
20									1											I			<u> </u>		_ _ _
03	X-Ra	ıy /entid	onal							ny (CT)			oiral Computed one Scan	Tomo	graphy	y (C	CT)	6(8)				aminati ify belo			
	Lymp Thyro Oral o Phary Pelvis Breas Pleur	h no bid cavity nx s st al eff	de y fusio	on		17 20 30 40 49 50	Ple Live Bor Che Per Spi	ura er ne est rica	or p	nchyma leural w effusion	vall	61 62 63 64 65	Brain Esophagus Stomach Pancreas Small intestin Colon Rectum	е	73 74 79	As Re Pe Ga Kie	scites etrope eritone all bla dney	eritone eum	eum	84 85 86 88	Sp SI O		gland pecify above)		
CR	TUMOR REPONSE CODES: CR Complete response																								

Line #	Specify if "88 Other" Method of Assessment					

^{*} 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'.

W40

Week 40 TUMOR RESPONSE

Date of Assessment Day Month Year			Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	No Yes	Overall Tumor Response Code
RESPOI CR Co PR Pa SD Sta PD Pr UE Ur NA No	LL TARGET LESION NSE CODES: omplete response artial response able disease ogressive disease able to evaluate ot applicable ot done	LESION RES CR Comple SD Stable PD Progre: UE Unable	ISTING NON-TARGET PONSE CODES: ete response disease ssive disease to evaluate blicable ne	OVERALL TUMOR CR Complete re PR Partial respo SD Stable disease PD Progressive UE Unable to ev ND Not done	esponse onse ase disease	ODES:

	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL		OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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
1			

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 nontarget 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-	Progressive Disease (PD)
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)	

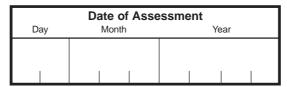
CYCLE 21



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? D No D Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

	Date of Exar	nination	Weight	Body Surface Area
Day	Month	Year	│	(m ²)
			1 - 19 2 - 11	` ′

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

ECOG PERFORMANCE STATUS

	Date	Performance Status ECOG KPS						
Day	Month	Year	■ ECOG ■ KPS					
① ECOG	① ECOG PERFORMANCE STATUS CODES:							
Fully active, able to carry on all pre-disease performance without restriction.								
	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

C21D1

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 phys	sical examination perfor	rmed? 。	No ₁☐ Yes				
				Date of Exan	nination	\neg		
			Day	Month	Year			
descril	oe find	bject have any abnorma ings below.	al clinical fii	ndings relating t	o the following re	quired sites?	₀ No ₁ □	Yes - If yes,
		Head, Ears, Eyes, Nose, Throat (HEENT) / Neck Cardiovascular Respiratory	04 05 06 07	Abdomen Musculoskeletal Skin Lymph nodes	08 09 10 11	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
			indicate if a	a required asses	ssment was not d	one. 		
Code (as listed above)					e findings ntry per line.			
ı								
i								

AMGEN	Panitumumab
AMG 954 20	0050203

////	Site No.		Su	ıbject	t ID N	lo.			
	1 1 1	2,1,	1	ı	ſ	ſ	1	ı	

C21D1

Cycle 21, Day 1

HEMATOLOGY

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

If chamother and was delayed record the Hamatology results below that were

Rec	ord Hematology re		t were taken on the pl	anned Day 1
	Day	Date Dra Month	awn Year	
	-	<u> </u>	1541	
	Test	Result	Unit	Specify if Other Unit
			₁☐ /uL	
RE	2C		₂ 10 ⁶ /mm ³	
IXL	SC .		₃ 10 ¹² /L	
			88 Other	
			₄☐ g/L	
He	emoglobin		₁₂ g/dL	
	arrogiosii i		₆ □ mmol/L	
			88 Other	
			₁₅ %	
He	ematocrit		₅ L/L	
			₇ frac of 1	
			88 Other	
MO	21/		₈ □ fL	
IVIC	√ ∨		₈₈ Other	
			₁☐ /uL	
			₉ 🗖 10 ⁹ /L	
Pla	atelets		$_{10}$ 10 3 /mm 3	
			₈₈ Other	
			₁☐ /uL	
			₉ 🗖 10 ⁹ /L	
WI	ВС		₁₀ 10 ³ /mm ³	
			88 Other	
			₁₅ %	
			₉ 10 ⁹ /L	
	Neutrophils		88 Other	
			₁₅ %	
D	Lymphocytes	3	9 10°/L	
1			88 Other	
F F			15 %	
Е			₉ 10 ⁹ /L	
R	Monocytes		88 Other	
E N			₁₅ %	
T	Eosinophils		9 10º/L	
ı	_00110011110		88 Other	
A L			₁₅ %	
*			.9 10°/L	
	Basophils		88 Other	
			% 15 %	
	Granulocytes		9 10º/L	
	Statiologies		88 Other	

[Day	Date Dr Month	awn	Year	
		1		1 1	1
	Test	Result		Unit	Specify if Othe Unit
RE	3C		3 1	0 ⁶ /mm ³	
Не	emoglobin		4 9	g/dL nmol/L	
Не	ematocrit		15 c	%	
М	CV		88 8 f	L	
Pla	atelets		''		
W	вс		₁		
	Neutrophils		15 9 1 9 1 1 88 0	0 ⁹ /L	
D I F	Lymphocytes		9 1 88	% 0º/L Other	
r F E R E	Monocytes		9 1 88 0	0º/L Other	
N T I A	Eosinophils		9 1 88 0	0º/L Other	
L *	Basophils		9 1 88 0	0º/L Other	
	Granulocytes		₁₅ 0 9		

AMGEN	Panitumumab
AMG 954 2	0050203

,,,,	Site N	Νο.				Subj	ect II	N C	0.
			ı	2	1,			ı	
			_						

C21D1

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 res	ults below tl	nat were taken on the plann	ned Day 1			ne Chemistry results below n for delay on the chemo ac	
Day N	Date D	rawn Year		Day	Date D Month	Prawn Year	
Day	Юпип	Teal		Day	WOTH	Teal	
	1				1 1		ſ
Test	Result	Unit	Specify if Other Unit	Test	Result	Unit	Speci if Oth Unit
Sodium		mEq/L 88 Other 6 mmol/L		Sodium		mEq/L 88 Other 6 mmol/L	
Potassium		mEq/L ₈₈ Other of mmol/L		Potassium		mEq/L ₈₈ Other of mmol/L	
Chloride		mEq/L ₈₈ Other of mmol/L		Chloride		mEq/L ₈₈ Other of mmol/L	
Bicarbonate (HCO ₃))	mEq/L ₈₈ Other of mmol/L		Bicarbonate ((HCO ₃)	mEq/L ₈₈ Other mmol/L	
Total Protein		₄ g/L ₈₈ Other ₁₂ g/dL		Total Protein		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL	
Albumin		₄ □ g/L ₈₈ □ Other ₁₂ □ g/dL		Albumin		$_{4}$ g/L $_{88}$ Other $_{12}$ g/dL	
Calcium		mg/dL 88 Other 6 mmol/L		Calcium		mg/dL 88 Other 6 mmol/L	
Magnesium		111 mEq/L 6 mmol/L 14 mg/L 88 Other 13 mg/dL	-	Magnesium		mEq/L 6 mmol/L mg/L 88 Other mg/dL	_
Phosphorus		mg/dL 88 Other 6 mmol/L		Phosphorus		ng/dL 88 ☐ Other 6 ☐ mmol/L	
BUN		mg/dL ₈₈ Other 6 mmol/L		BUN	\D	mg/dL ₈₈ Other 6 mmol/L	
— — — OR — Urea		ng/dL 88 Other 6 mmol/L		Urea	OR — — — —	ng/dL 88 Other 6 mmol/L	
Creatinine		mg/dL ₈₈ Other ₁₆ umol/L		Creatinine		mg/dL ₈₈ Other ₁₆ umol/L	
Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other		Uric Acid		$_{13}$ mg/dL $_{16}$ umol/L $_{6}$ mmol/L $_{88}$ Other	
Total Bilirubin		mg/dL 88 Other of the other othe		Total Bilirubin	1	mg/dL 88 Other of the other othe	
Alk. Phos.		U/L 88 Other labeled Other labeled Other		Alk. Phos.		$_{17}$ U/L $_{88}$ Other $_{18}$ ukat/L	
AST (SGOT)		U/L 88 Other labeled U/L 000 Other		AST (SGOT)		U/L 88 Other 18 ukat/L	
ALT (SGPT)		U/L 88 Other ukat/L		ALT (SGPT)		U/L 88 Other ukat/L	
LDH		U/L 88 Other ukat/L		LDH		U/L 88 Other ukat/L	
LDH	Local Labo	oratory Range			LDH Local Lab	oratory Range	
Lower		Upper		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

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Danitumimah	Site No.	Subject ID No.
	7	
AMG 954 20050203	- - -	
		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

son for Specify DOSE CHANGE/ Son for Specify DOSE (f''88 Other" ie code		Package Lot Number	-
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	· ·	
Reason for Jose Change Ose Withhel	_	ION if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Year		If infusion was interrupted provide the Reason for Infusion Interruption	_
Date Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Day	_		
Cycle	21	Was Infusion Interrupted? No Yes	

INFUSION REACTION

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

protocol" is specified for "Reason for Dose Change", indicate code C_{2} Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year 04 Per protocol88 Other (specify below) Start Date Cycle 21 Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

CYCLE 22

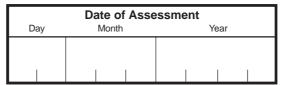


Cycle 22, Day 1

SKIN TOXICITY ASSESSMENT

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

Was the subject assessed for skin toxicity? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Day Month Year		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Examination Day Month Year		Weight	Body Surface Area
			1 - 19 2 - 11	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

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 Exa	mination		\neg		
		Day	Month	Υ	⁄ear			
						1		
describ	Does the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites? One of the subject have any abnormal clinical findings relating to the following required sites?							
SITE C		04 A	bdomen		08	Neurological	50	Extremities
	Throat (HEENT) / Neck	05 N	1usculoskeletal		09	Genitourinary Breast / Chest	88	Other
02			kin ymph nodes		10 11	Breast / Chest Rectal		
		Indicate if a re		ssment wa				
Code			-					
(as listed above)				e findings entry per line				

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	_
	2,1, , , , , , ,	

C22D1

Cycle 22, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that were

Record Hematology results below that were taken on the planned Day 1						
	Day		Date Dra Month	awn	Year	
	,		-			
	Test		Result		Unit	Specify if Other Unit
				1	/uL	
RE	RC			$_{2}$	10 ⁶ /mm ³	
IXL				•	10 ¹² /L	
				88	Other	
					g/L	
Нє	emoglob	oin		12	g/dL	
				0	mmol/L	
					Other	
				15		
He	ematocr	it		5	L/L	
				,	frac of 1	
					Other	
NAC	CV			\square_8		
IVIV					Other	
					/uL	
				•	10 ⁹ /L	
Platelets					10 ³ /mm ³	
				88	Other	
					/uL	
				•	10 ⁹ /L	
W	ВС				10 ³ /mm ³	
					Other	
				15		
	Neutro	nhile		-	10 ⁹ /L	
	rvound	priiis		88	Other	
				15		
D	Lymph	nocytes			10 ⁹ /L	
I F					Other	
F				15		
E	Monod	ov to c		-	10 ⁹ /L	
R E	IVIOLIOC	Lytes			Other	
N				15		
T I A	Eosino	Eosinophils			10 ⁹ /L	
	-1				Other	
L				15		
*	Booss	hile		•	10 ⁹ /L	
	Basop	iiiiS			Other	
				15		
	Granu	locytes		-	10 ⁹ /L	
	J. a. raiooy 100			88	Other	

[Day	Date Dr Month	awn Ye	ar
		I		1 1
	Test	Result	Unit	Specify if Othe Unit
RE	3C		106/mm³ 1012/L 88 Other	
Не	emoglobin		4 g/L 12 g/dL 6 mmol/L 88 Other	
Hematocrit			15 % 5 L/L 7 frac of 1 88 Other	
M	CV		88 fL 8 Other	
Pla	atelets		10°/L 10°/L 10°/mm³ 88 Other	
W	вс		1 /uL 9 10°/L 10 10°/mm³ 88 Other	
	Neutrophils		15	
D I F	Lymphocytes	3	15	
F E R E	Monocytes		15	
N T I	Eosinophils		15	
A L *	Basophils		15	
	Granulocytes	3	15 % 9 10 9/L 88 Other	

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

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

* Blue - CRA: White Card - Investigator 27.03

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.		Subj	ect II	O No.	
///////////////////////2	1,				

C22D1

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 Mo			onth			Υ	⁄ear	
	Test		Result		U	Init		Specify if Other Unit
Sodiu	m			l	mEq/L mmol/l	00	Other	
Potas	sium			l	mEq/L mmol/l	00	Other	
Chlori	de			l	mEq/L mmol/l	00	Other	
Bicark	oonate	(HCO ₃)		6	mEq/L mmol/l	L		
Total I	Protein	l		120	g/L g/dL			
Album	nin			12	g/L g/dL			
Calciu	ım			6	mg/dL mmol/	'L		
Magn	Magnesium			14	mEq/L mg/L mg/dL	88	mmol/L Other	
Phosp	horus			l .	mg/dL mmol/		Other	
BUN				1.0	mg/dL mmol/	00	Other	
Urea		OR — -		13	mg/dL mmol/	88	Other	
Creati	inine			1	mg/dL umol/L		Other	
Uric A	cid			1,0	mg/dL mmol/	10	umol/L Other	
Total I	Bilirubi	n		1	mg/dL umol/L		Other	
Alk. P	hos.			1	U/L ukat/L	00	Other	
AST (SGOT)		17	U/L ukat/L	88	Other	
ALT (SGPT)			1	U/L ukat/L	00	Other	
LDH				l	U/L ukat/L	00	Other	
		LDH	Local Labo	rato	y Rang	ge		
Lower				Upper				

nken on the actua		Date D					
Day	IVIU	onth	—		Y	'ear	
1	I	ı				ı	
Test		Result		ι	Jnit		Specify if Other Unit
Sodium			6	mEq/L	L L		
Potassium			6	mEq/L	/L		
Chloride			6	mEq/L mmol/	/L		
Bicarbonate	(HCO ₃)		6	mEq/L mmol/	/L		
Total Protein	ı		12	g/L g/dL			
Albumin			12	g/L g/dL			
Calcium			6	mg/dL mmol/	/L		
Magnesium			14	☐ mEq/L ☐ mg/L ☐ mg/dL	88	Other	
Phosphorus			1 -	☐ mg/dL☐ mmol/		Other	
BUN (or —		6	mg/dL mmol/	/L		
Urea			6	☐ mg/dL☐ mmol/	/L		
Creatinine			16	☐ mg/dL ☐ umol/l	L		
Uric Acid			6	☐ mg/dL ☐ mmol/	/L ₈₈	Other	
Total Bilirubi	n		1 -	☐ mg/dL ☐ umol/l		Other	
Alk. Phos.			1.,	❑ U/L ❑ ukat/L	00	Other	
AST (SGOT)			☐ U/L ☐ ukat/L		Other	
ALT (SGPT)			1	☐ U/L ☐ ukat/L		Other	
LDH				❑ U/L ❑ ukat/L		Other	
	LDH I	Local Labo	orat	ory Ran	ge		
Lower			Upp	er			

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

	Site No.	Subject ID No.	
	7/		
AMG 954 20050203	- - -	7	-
2020202 TC 2011 TC 201			
		CZ2	322D1

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

col" is Specify DOSE CHANGE/ ason for Specify DOSE (f "88 Other" ate code		Package Lot Number	- - - -
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code		ויי	
Reason for Jose Change Jose Withhel	_	10N if "88 Other	
Total Volume Administered of Panitumumab plus Saline Solution (mL)		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Total Dose Administered (mg)		REASON FOR	
Stop Time (24 hour clock)		Specify	
Start Time (24 hour clock)		S	
Year	- -	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
Cycle	22	Was If in Infusion ruptic Interrupted? time time (not	

INFUSION REACTION

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

UND Yes If yes, record all details on the Adverse Events Summary CRF

protocol" is specified for "Reason for Dose Change", indicate code Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity for Dose Change Reasor Subject ID No. 3 "04 PER PROTOCOL" DOSE CHANGE CODES:
 100 Weight change
 386 Chemotherapy related hematologic dose limi
 387 Chemotherapy related non-hematologic dose Stop Time (24 hour clock) Specify REASON FOR DOSE CHANGE "88 Other" Year Other" CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Stop Date 88 Month Specify REASON Day Site No. .☐ Yes If yes, please enter reason code: Start Time (24 hour clock) . . CHEMOTHERAPY DELAY Year 04 Per protocol88 Other (specify below) Cycle 22 Start Date Month Interventional therapy for metastases Line # Protocol specified adverse event Day REASON FOR DOSE CHANGE CODES:
01 Adverse event
02 Noncompliance
03 Dose administration error Protocol specified lab value OTO If chemotherapy was administered, was it delayed? □ No Freq. $\overline{\mathbf{c}}$ $\overline{\mathbf{c}}$ Other (specify) Actual Total Dose Administered **®REASON CODES:** Specify REASON FOR DOSE CHANGE "88 Other" (mg) 229 230 316 88 **Drug Type** racemic (dl-) leucovorin racemic (dl-) leucovorin /-leucovorin /-leucovorin Did subject receive chemotherapy? 🖵 No record all that apply) ① Reason for Delay **AMGEN** Panitumumab 5-FU Continuous Infusion 5-FU Continuous **Drug Name** AMG 954 20050203 5-FU Bolus 5-FU Bolus Leucovorin Leucovorin Oxaliplatin CI Continuous infusion OTO One time only Infusion FREQUENCY CODES: Study Day 3 2 S $\overline{}$ Line # Line # 2 3 4 2 9

END OF TREATMENT

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

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 ®
04 Noncompliance [®]
05 Adverse event ⁽¹⁾ (FAX this form to Amgen)
06 Consent withdrawn [®]
13 Subject request [®]
07 Disease progression [®]
Criteria CRITERIA CODES:
01 Radiographically determined disease progression
04 Non-Radiographically determined disease progression
09 Administrative decision [®]
10 Lost to follow-up ®
11 Death [®]
(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 ®
Criteria CODES:
52 Intervention toxicities (not resolved within 6 weeks)
14 Pregnancy ® (complete Pregnancy Notification Worksheet)
88 Other ®
 Record date the decision was made to end the treatment phase as Date Subject Discontinued Panitumumab Record date of death as Date Subject Discontinued Panitumumab
Please provide any additional relevant information on the PRIMARY reason for ending
Please provide any additional relevant information on the PRIMARY reason for ending treatment phase:

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

END OF FOLFOX TREATMENT

		decided to discontinue all FOLFOX components:		
		Date Investigator Decided to Discontinue FOLFOX		
		Day Month Year		
nter PRIMARY reas	on for end	ding FOLFOX:		
	_	y determined ®		
		deviation [®]		
	Noncomp			
		event [®] (FAX this form to Amgen)		
		vithdrawn®		
	Subject re			
	Disease progression ®			
	Criteria			
	Code	CRITERIA CODES: 01 Radiographically determined disease progression		
		01 Radiographically determined disease progression04 Non-Radiographically determined disease progression		
09	Administrative decision ®			
10	Lost to follow-up ^①			
11	Death [®]			
	(Record ca	ause of death on the Death Summary CRF and FAX completed		
	Serious Ac	dverse Event form to Amgen within one working day.)		
12	12 Protocol-specified criteria ®			
	Criteria	CRITERIA CODES:		
	Code	52 Intervention toxicities (not resolved within 6 weeks)		
	,			
		y [®] (complete Pregnancy Notification Worksheet)		
88	Other ¹			
Record date the de-	ecision was n	made to end the treatment phase as Date Subject Discontinued FOLFOX		
		Subject Discontinued FOLFOX		
Please provide any	/ addition:	al relevant information on the PRIMARY reason for ending		
treatment phase:	, additioni	a		

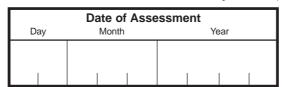
SAFETY FOLLOW-UP



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? D No D Yes



VITAL SIGNS

	Date		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
Day	Month	Year	(9/	,	, ,	1 0 2
			/			

WEIGHT

	Weight		
Day	Month	Year	₁ kg ₂ lb
			1 32
1	1 1		

ECOG PERFORMANCE STATUS

	Date)	Performance Status		
Day	Month	Year	☑ ECOG ☐ KPS		
'					

① ECOG PERFORMANCE STATUS CODES:

- ${\bf 0} \quad \text{Fully active, able to carry on all pre-disease performance without restriction.} \\$
- 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

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

Safety Follow-Up PHYSICAL EXAMINATION

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

Necord arry new linding or cha	rige (wors	eriling) or arr ex	Suring initiating of the A	Adverse Everils Summary Orti
Was a physical examination perform	med? ₀□	No ₁☐ Yes		_
		Date of Exan	nination	
	Day	Month	Year	

Does descr	the su	bject have any abnorm lings below.	al clinical fi	ndings relating to th	ne following re	equired sites?	₀□ No ₁□	Yes - If yes,
SITE	CODES 01 02 03		04 05 06 07 Indicate if	Abdomen Musculoskeletal Skin Lymph nodes a required assessm	08 09 10 11 ent was not d	Neurological Genitourinary Breast / Chest Rectal	50 88	Extremities Other
Code (as listed above)		Describe findings List one entry per line.						
<u> </u>								

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.		Subject ID No.	
	2,1,		
			FUP

Safety Follow-Up HEMATOLOGY

CHEMISTRY

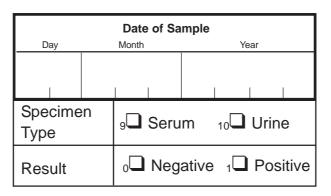
	If an abnori		y value resulted in clinical sequela Drawn
[Day	Month	Year
	Test	Resul	t Unit Specify if Other Unit
RE	BC		1 /uL 2 106/mm³ 3 1012/L 88 Other
Не	emoglobin		4 g/L 12 g/dL 6 mmol/L 88 Other
Не	ematocrit		15 % 5 L/L 7 frac of 1 88 Other
M	CV		8 ☐ fL 88 ☐ Other
Pla	Platelets		1 /uL 9 10°/L 10°/mm³ 88 Other
WBC			1 /uL 9 10°/L 10°/mm³ 88 ○ Other
	Neutrophils		15
D I F	Lymphocyte	es	15 % 9 □ 10 ⁹ /L 88 □ Other
F E R E	Monocytes		15 % 9 □ 10 ⁹ /L 88 □ Other
N T I	Eosinophils		15 % 9 □ 10 ⁹ /L 88 □ Other
A L *	Basophils		15 % 9 □ 10 ⁹ /L 88 □ Other
	Granulocyte	es	15 % 9 □ 10°/L 20 □ Other

ord clinical sequelae on to Day N	<i>he Adverse</i> Date D Month			ear	
Day	Юпит		10		
	1		I	ı	1
Test	Result		Unit		Specify if Other Unit
Sodium		_ m	nEq/L ₈₈ 🖵 (nmol/L		
Potassium		n	nEq/L ₈₈		
Chloride		1	nEq/L ₈₈ 🖵 (nmol/L	Other	
Bicarbonate (HCO ₃)	6 n	mEq/L ₈₈ 🖵 (nmol/L		
Total Protein		₄	/L 88 1 1/dL	Other	
Albumin		12 0			
Calcium		r	mg/dL ₈₈ 🗖 mmol/L		
Magnesium		₁₄ □ r	nEq/L ₆		
Phosphorus		13 n	ng/dL ₈₈ 🖵 (Other	
BUN		l -	ng/dL ₈₈ 🖵 (nmol/L	Other	
———— OR — Urea	T	₁₃ r	ng/dL ₈₈	Other	
Creatinine			ng/dL ₈₈ 🖵 (ımol/L	Other	
Uric Acid		1.0	ng/dL ₁₆		
Total Bilirubin		1 -	ng/dL ₈₈ 🖵 (ımol/L	Other	
Alk. Phos.		17 U	J/L ₈₈ □ ıkat/L	Other	
AST (SGOT)		1	J/L ₈₈ □ (ukat/L	Other	
ALT (SGPT)			J/L ₈₈ 🖵 (ukat/L	Other	
LDH		1	J/L ₈₈ □ (ukat/L	Other	
LDH	Local Labo	oratory	Range		
Lower		Upper			

Safety Follow-Up

PREGNANCY TEST

Is subject of child bearing potential? $_{_{0}}\square$ No $_{_{1}}\square$ Yes
Was pregnancy test performed? $_{_{0}}\square$ No $_{_{1}}\square$ Yes. If Yes, specify below



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)

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)

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

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

Date Drawn					
Day	Month			Year	
т	Res	sult	Unit	Specify if Other Unit	
Serum Carcinoe			ng/mL ug/L 8 Other		

AMGEN	Panitumumab
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Site No.	Subject ID No.	
	2,1, , , , , , ,	

Lesions

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

Lesion Note: Always maintain the same order of lesion numbers	C Day	Pate of Pro	ocedure Year	Method of Assess- ment	Subsite Describe specific location	Lesion Site Code	Measurable Lesions * (mm) (Longest Diameter) Must be unidimensionally measurable Dimensions (mm)	Was Interventional Therapy Performed On This Lesion Since the Last Assessment?
	Duy		100.				Zimenerene (min)	
01								
02								1
03								1
04								1
05								1
06								1 1 1
07								
80								
09								1
10								

_	OF ASSESSMEN entional Computed	T CODES: d Tomography (CT)	04	MRI (NMR)	23 Sp	iral Computed Tomo	graph	y (CT)
② LESION S	ITE CODES:							
00 Lymp 01 Thyro 02 Oral o 03 Phary	id 17 avity 20	Lung parenchyma Pleura or pleural wall Liver Bone	61 62	Brain Esophagus Stomach Pancreas		Anus Ascites Retroperitoneum Peritoneum	84 85 86 88	Adrenal gland Spleen Skin Other (specify in
08 Pelvis		Chest wall		Small intestine		Gall bladder	50	subsite above)

81

Kidney

Colon

Rectum

65

49 Pericardial effusion

50 Spinal cord

09 Breast

10 Pleural effusion

^{*} 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 2	0050203

Site No.	Subject I	ID No.
	2,1, , ,	1 1 1 1

FÜP

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	e r	D		of flont	oce	dur	'e		Meth of Asse mer	ss- nt	Desci	Subsite ibe specific loc	ation	Lesi Site Coc	e de	Lesi	ew ions 'Yes	Lo Dia	onges amete (mm)	st er*	Resp (Re if boo code "04"	mor ponse cord dy site is NOT Bone"	Interv The Perf On Le Sind	entional erapy ormed This sion ce the ast ssment?
11			1			ı	ı	1						1					ı	ı		ı		
12																								
13																								
14																	 							
15																								- - - -
16						[1		1								
17						1								1								1		
18														1		1				1				
19			-			1		1						1		i !				1				 - -
20								1													_ _ _			
03	X-Ra	ıy /entid	onal						ny (CT)			oiral Computed one Scan	Tomo	graphy	y (C	CT)	6(8)				aminati ify belo			
② LESI 00 L 01 7 02 G 03 F 08 F 09 E 10 F	Lymp Thyro Oral o Phary Pelvis Breas Pleur	h no bid cavity nx s st al eff	de y fusio	on	17 20 30 40 49 50	Ple Live Bor Che Per Spi	ura er ne est rica	or p	nchyma leural w effusion	vall	61 62 63 64 65	Brain Esophagus Stomach Pancreas Small intestin Colon Rectum	е	73 74 79	As Re Pe Ga Kie	scites etrope eritone all bla dney	eritone eum	eum	84 85 86 88	Sp SI O		gland pecify above)		
CR SD	Com	plete	e res	spo								disease valuate					Not a		able					

Line #	Specify if "88 Other" Method of Assessment

^{*} 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'.

Safety Follow-Up TUMOR RESPONSE

Day	Date of Assessme	e nt Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	No Ves	Overall Tumor Response Code
RESPO CR C PR PS SD SI PD PI UE U NA N	LL TARGET LESION NSE CODES: omplete response artial response table disease rogressive disease nable to evaluate ot applicable ot done	LESION RES CR Comple SD Stable PD Progres		OVERALL TUMOR CR Complete re PR Partial responsive SD Stable disea PD Progressive UE Unable to ex ND Not done	esponse onse ise disease	ODES:

	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL		OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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
1			

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 nontarget 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-	Progressive Disease (PD)
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)	

SAFETY FOLLOW-UP VISIT

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , ,
AIVIG 934 20030203		
		FUP
SAF	FETY FOLLOW-UP	VISIT
, , , , ,		vents considered related to the please follow until resolved or
the safety follow-up was completed a	nd do not record a reason code. If No in which case record the date of dea	No 1 Yes - If Yes, record the date o, record the date of the subject's last ath) and enter the primary reason code
Da	ate Subject Completed Last Safety Fo Up Assessment OR Date of Last Stu- Assessment Day Month Year	
If subject did not do any safety	follow-up assessments, enter	PRIMARY reason code:
Enter Code: CODES:		
02 Ineligibility	determined ®	
05 Adverse ev	vent ⁽¹⁾ (FAX this form to Amgen)	
06 Consent wi	ithdrawn [®]	
09 Administrati	tive decision [®]	
10 Lost to follo	ow-up ^①	
11 Death [®]		
	use of death on the Death Summ	·
	verse Event form to Amgen within	n one working day.)
12 Protocol Sp	pecified Criteria ®	
Criteria Code	CRITERIA CODES: 40 Deterioration of condition (If possible p	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)

If subject did not complete any safety follow-up assessments, provide any additional relevant

88 Other ^①

① Record date of last assessment

2 Record date of death

information:

CLINICAL EVENTS

										_	iss	Site No.					Subject ID No.	ID No.			
AMG	AIMCHA Panitumumab AMG 954 20050203	ab								<u> </u>	- 	_	_	~	_	_	_	_	_	_	
	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.	ies, recor	rd as	secona	entry.	CONCOMITANT MEDICATIONS If concomitant medication is for an adverse event, please e	MIT	ANT ation is fo	MEI rr an ad	JC.	ATIC vent, p	NS Vease	enter ev	rent or	ı Adve,	rse Ev	ent Su	mmary		CM1	7
≥ [Were any concomitant medications used?	ations us	ed?	°N □°		Tes - If yes, specify below.	cify b	elow.											L	г	
Line				Category	>	Indication		Dose	Unit	Route	ш		Date	ا ق		•	Date	O .	ication continuing Pety Follow Up	do wono i ko	
#	Record one per line	d)	✓ Prophylaxi	Θ					⊗	⊚	4	Day	FIRST Taken	Taken _Y	Year	D	LAST Taken Month	aken Year		מי דווח חו סקו	
7												_	_		_	_		_	_		
7													_		_	_		_			
က													_		_			_			
4	1												_		_			_			
2														_							
9	10												_			_		_			
												_	_	_		_		_			
00	00											_	_	_	_	_	_	_			
Θ	© 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	© UNIT CODES: AMP Ampule CAP Capsule GM Gram GR Grain GTT Drop IU Internati MCG Microgra	CODES: Ampule Capsule Gram Grain Drop Internation: Microgram Milliequival	CODES: Ampule Capsule Gram Grain Drop International unit Microgram	MG ML TAB TBS TSP it U	Milligram Milliliter (cc) Tablet Tablespoon Teaspoon Unit Other (specify	© ET CT	ROUTE CODES: ET Endotracheal tube GT Gastrostomy IA Intra-arterial ID Intradermal IH Inhaled IM Intramuscular IP Intraperitoneal IT Intrathecal IV Intravenous	al tube	OP Ophr PR Rect PV Vagin SC Subc SL Subli TD Tran TP Topic OT Othe	Ophthalmic Oral Rectal Vaginal Subcutaneous Sublingual Transdermal Topical	us - <i>fy belo</i> w		FREQUENT TWING TO TWING	 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 	DES: sek nuly nuly seks seks	a alw and and and awk Tiw		Once a day 4 times a week Once a month Every other day Every week 3 times a week Other (specify	T .	
<u>ב</u>][Line # Specify UNIT "OT	Other"			Line #	Spec	ify RO	Specify ROUTE "OT (Other"		Line#	#	ॲ 	oecify F	Specify FREQUENCY "OT	ENCY		Other"		1 —	

	MGEN Panitumumab	nab									Site No.	No.		7		Subject	Subject ID No.		
16 954	1G 954 20050203								///		-	-	1		-	_	_	_	
				S	CONCOMITANT MEDICATIONS	Σ	IAN	Σ	EDIC	SAT	<u>Ö</u>	S						O	CM2
	For dosage changes, record as second entry. If concomitant medication is for an adverse event, please enter event on Adverse Event Summary CRF.	anges, record	l as secor	nd entry. If	concomitar	t medi	ication is	for an	advers	e even	ıt, plei	ase er	ıter evei	nt on Adı	verse E	event St	ummary C	:RF:	
											pənu <u>i</u> tuos uoi		3					dU wollo² gniuniinos noi	
# #	Medication Record one per line		Prophylaxis	<u>ک</u>	Indication		Dose	© ⊗	Route ⊚	Freq.	Check if medical	T	FIRST Taken	ken	Dav	LAST Taken	Taken	Check if medicati at End of Safety i	
1															-			•	
7												-	_	— — —	_				
က																			
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2														— — —		_	_		
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8												_	_	_ _ _	_	_			
① CATEG	① CATEGORY CODES:	© UNIT CODES:	S:		(8)		ROUTE CODES:					Ť	4 FREQU	♠ FREQUENCY CODES:	DES:				
O1 Sterc	Steroids or narcotics given for treatment	AMP Ampule CAP Capsule	elle Jle	MG Mil	Milligram Milliliter (cc)		Endotracheal tube Gastrostomy	al tube	OP Opht PO Oral PR Rect	Ophthalmic Oral	O		B ⊡ E	Twice a week Continuous infusion	/eek Js infusi			ay week	
	Infusion reaction			' '	Tablespoon	E	Intradermal	_		Vaginal	ŭ		0 TO	One time only	only	Q Q Q		er day	
for th	Antiblotic/Antifungal for the treatment of	IC Interna	Drop International unit	U Unit	leaspoon Jnit Geogrify		Intramuscular Intraperitoneal	lar eal		Sublingual Transdermal	<u>a</u>		Q2WK	Q2WK Every 2 weeks	reeks	¥ ≥ ₹		ek week	
04 Anti- 66 Not	Anti-emetic Not applicable		Milliequivalent		below)	<u> </u>	Intrathecal Intravenous		1P 이 한 한	Topical Other (specify below)	cify be	(wo,	Q4WK	Q4WK Every 4 weeks	eeks	5	below)	ecily	
Line #	Specify UNIT "OT Other"	OT Other"		Line #	Spe	cify RC	Specify ROUTE "OT Other"	T Other	£		Line #		Spec	Specify FREQUENCY "OT Other"	NENC	Y "OT C)ther"		. —

3		400							S	Site No.				Subject ID No.	ID No.		
1 0 0	1G 954 20050203	man						<u> </u>	~///7/	_		7	_	_	_	_	
												- - - -	-	-			CM3
				CONCOMITANT MEDICATIONS	TIMO	NA.	M	DIC	ATIC	SNO							
	For dosage ch≀	anges, record	as second	For dosage changes, record as second entry. If concomitant medication is for an adverse event, please enter event on Adverse Event Summary CRF.	ınt medic	ation is	for an a	dverse	event, p	lease (enter eve	nt on Adv	erse E	vent Su	ımmary C	RF.	
	:									тлој рәМ па	2			2		д∪ wollo∃ 9niuniinos noi	
# #	Medication Record one per line		rophylaxis © © ©	Indication		Dose	© ©	Koute ⊚ ©	- Freq ⊕ Isoibam ii xoar	eck if medicar O suoivərd m	Date FIRST Taken	ıken		LAST Taken	aken	eck if medicaty End of Safety	
		u ,	4 >						40	ν Įνο V Įνο	Month	Year	Day	Month	Year	st i	
1										_	_	_	_	_	_		
7												_	_	_			
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00													_	_	_		
© CA	① CATEGORY CODES:	© UNIT CODES:	S:		® ROUTE	ROUTE CODES:					4 FREQ	♠ FREQUENCY CODES:	JES:				
۶	Steroids or narcotics given for treatment	AMP Ampule CAP Capsule		MG Milligram	ET En Ga	Endotracheal tube Gastrostomy		OP Ophtl PO Oral	Ophthalmic Oral		<u>8</u> 5	Twice a week	eek s infusic	O O	Once a day	ay week	
	related skin/nail toxicity					Intra-arterial		PR Rectal			¥.	At bedtime				onth	
3 8	Infusion reaction Antibiotic/Antifungal	GR Grain GTT Drop		TSP Teaspoon		nhaled			Subcutaneous		PRN	One time only As needed	only -	a a w X	Every other day Every week	er day	
	for the treatment of skin/nail infection	IU Internation	al unit			Intramuscular Intraperitoneal		0, 1	Sublingual Transdermal		QZWI	Q2WK Every 2 weeks	eks	≱ t		week	
94	Skiirriali illiectiori Anti-emetic Not applicable		ent	below)	<u>₽</u> <u>₽</u>	Intrathecal Intravenous		TP Topical OT Other (Topical Other (specify below)	below)	Q4W	Q4WK Every 4 weeks	eks	5	below)		

Specify FREQUENCY "OT Other"

Line #

Specify ROUTE "OT Other"

Line #

Specify **UNIT** "OT Other"

Line #

skin/nail infection Anti-emetic Not applicable

99

Adverse Events Summary Instructions

- 1. Record all adverse events as specified in protocol.
- 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. ر ا
- 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. က
- Do not record unconfirmed diagnoses using "rule out, presumed or possible", instead record signs or symptoms. 4.
- Do not record treatments or procedures as adverse events (ie, "pleural effusion" could be recorded as an adverse event but not "thoracentesis" which is the treatment for the event). Avoid "due to" or "related to" or "secondary to. 5
- The adverse event description should be complete and unambiguous, using medical terminology when possible. When reporting chest pain, indicate the nature of the pain, ie, cardiac or musculoskeletal. Avoid use of abbreviations. Avoid concurrent reporting of like or similar events, for example, hypoxia and respiratory insufficiency, or anxiety and nervousness. 6
- "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".
- "Intermittent" column should be checked if an event does not occur continuously, but involves several episodes (eg, cluster headaches, bouts of nausea) unless otherwise specified in the protocol. ω.
- Under "Action Taken For This Event", "Investigational product dose altered" means any investigational product alteration including dose increased, decreased, interrupted or delayed. "Investigational product discontinued" means investigational product was stopped and not restarted. <u>ග</u>
- 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.

1	AMCEN Desituation									Site	Site No.			Subje	Subject ID No.		
AM	AMG 954 20050203							_(////		_	_	<u></u>		_	_	_	_
-			ADVERSE	RSE E	K	NTS:	EVENTS SUMMARY	Z	A	R	_	_	-	_	_		AE1
Tas L	Has the subject had any Adverse Events ?	 No J _o	of No fres - If yes, specify below.	/es, specin)	oelo	· 			9	-						ŀ	
	Adverse Event Diagnosis or Syndrome	Did event start before first dose				Date Ended, Changed in	ded,	gniunisn guiunisn guiunisn		Severity (use CTCAE (Grading Scale)	*If CTCAE Grade 04, did the event place	Relationship Is there a reasonable possibility		- 6886	Action Taken for This Svent (record all that apply, 1 No action taken 2 Pantlumumab dose altered 3 Medication taken 4 Hosenjalized 4 Hosenjalized	or This erapply)	
Line #	Sign(of Panitu- mumab or FOLFOX		Date Started	Re	Severity or Resulted in Death	y or n Death	os if event co nd of Safety i	ermittent	4)		inat the event may have been caused by Panitumumab?		, 000Ka	Profonged hospitalization S Removed from study G Panitumunab discontinued IT Transtusion performed To Panitumunab Indiscoin interrupted C Panitumunab Indiscoin interrupted C Channel Ansach Ansach Ansach and Channel Ansach	ion nued interrupted	Serious ?
	List one per line	No Yes	Day Month	Year	Day	Month	Year	Sh5 StE			No 11 Yes	No Yes	No TYes	81 Chemoth 82 Chemoth 88 Other (sp	herapy dose a herapy dose a herapy dose d pecify below)	tered elayed	No Yes
1			_	_ _ _	_	_				_				_	_	_	
7			_	_						_		 -					
က										-							
4												 		_			
2			_			_				_				_			
9			_			_				_				_	_		
_			_											_			
∞			_							_				_		_	
6			_													_	
10																	
ď	* * Criteria for Serious Adverse Event:	Frse Ever	<u> </u>	Fine #					ဗြိ	Specify if	88	Other" Action Taken	n Taken				
3	• fatal • life threatening (places subject at immediate ris	k of death)	2 2 3 3 4														
	 requires inpatient hospitalization or prolongation of existing hospitalization results in persistent or significant disability / incapacity a congenital anomaly / birth defect 	apacity	nospitalizatioi		\perp												
If e for	 other significant medical hazard If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day. 	dverse Eve	int Report		$\perp \!\!\! \perp \!\!\! \perp$												

													Site No.			Subje	Subject ID No.			
	IMG 954 20050203										<u> </u>	1/////	_	<u></u>	2	· _	_	_	_	
				AD	ADVERSI	ш	ΞΛΕ	L	EVENTS SUMMARY	N D	Σ	AR							AE2	
Line #	Adverse Event Diagnosis or Syndrome (if known) OR Sign(s) / Symptom(s)	ck if event continued mroi 3A suoivery	Did event start before first dose of Panitu- mumab or FOLFOX	te e c	Date Started	te ted	Re	Date E Chanດ Sever	Date Ended, Changed in Severity or Resulted in Death		ck if event continuing nd of Safety Follow Up	Se Sign	Tif CTCAE Grade 04, did the event place event place the subject at immediate risk of death?		Relationship Relationship Is there a reasonable possibility that the event may have been caused by Panitumumab? Chemotherapy?	Event (record all that ago II No action taken 10 No action taken 22 Panitumumab dose altered 03 Medicalion taken 10 Hospitalized Prolonged hospitalization 10 Removed from study 06 Panitumumab discontinued 17 I Panitumumab discontinued 17 I Panitumumab discontinued 17 Panitumumab discontinued 17 Panitumumab discontinued 17 Pentumumab discontinued 17 Pentumumab discontinued 17 Pentumumab discontinued 17 Pentumumab discontinued 18 Pentumumab discontinu	Action Taken for This Event (record all that apply) I Noaction taken 2 Panitumumab dose altered 3 Medication taken 4 Hospitalized Prolonged hospitalization 5 Removed from Study 6 Panitumumab discontinued 6 Panitumumab discontinued 7 Transfusion performed 9 Panitumumab infusion interrupted 10 Panitumumab infusion interrupted		** Serious	
	List one per line	Ohe Fron	No Yes	Day.	Month	Year	Day	Month	Year				No 17 Yes	No 17 Yes	No Yes	$-\infty$	oy dose altered by dose delayed y below)	2 ,>	No 1 Yes	
1				_	_	_	_	_	_	_		_				_	_	_		
2				_	_		_			-		_								
3				_	_		_	_	_	_		_								
4				_	_		_	_	_	_		_								
5				_				_	_			_								
9				_	_	_	_		_			_				_				
7				_	_ 				_			_								
00							_			_		_				_	_	_		
9									_			_				_	_	_		
10		-		\dashv			_			\dashv										
	** Criteria for Serious Adverse Event:	Adve	rse Eve	nt:		Fine #	#					Specify	Specify if "88 (Other" Action Taken	งท Taken					
7 · · · · · · · · · · · · · · · · · · ·	• fatal • fatalization or prolongation of existing hospitalization • results in persistent or significant disability / incapacity • a congenital anomaly / birth defect • other significant medical hazard • other significant medical hazard • dafined as capture complete Serious Adverse Event Report	that (is attention by / inca	of death) of existing pacity	g hospi	talization															
for	form and FAX to Amgen within one working day.	day.					-													

AE3 Serions § \ Event (record all that apply)
01 Noaction taken
02 Paniturnanab dose altered
03 Medication taken
04 Hospitalized/
04 Hospitalized/
05 Removed from study
06 Paniturnumab discontinued
07 Translosion penformat
07 Translosion penformat
08 Chemotherapy dose discontinued
18 Chemotherapy dose altered
18 Chemotherapy dose altered
18 Chemotherapy dose altered
18 Chemotherapy dose altered
19 Observative and the study of the stu Action Taken for This Subject ID No. No Tes Relationship Relationship Panitumumáb?|Chemotherapy?| Is there a reasonable possibility that the event may have been caused by Other" Action Taken reasonable possibility that the event may have been No Yes caused by Is there a Yes the subject at immediate CTCAE Grade 04, event place did the risk of death? Specify if "88 Site No. ٤, **ADVERSE EVENTS SUMMARY** Severity (use CTCAE Grading Scale) one code Record 22823 Intermittent Check if event continuing at End of Safety Follow Up Resulted in Death Year Changed in Date Ended, Severity or Month Day Line # Year Date Started requires inpatient hospitalization or prolongation of existing hospitalization Month If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day. B Criteria for Serious Adverse Event: start before first dose of Panitu-mumab or FOLFOX Did event life threatening (places subject at immediate risk of death) results in persistent or significant disability / incapacity Serious adverse event includes any event that (is): mnot 3A suoivenq mont Check if event continued **AMGEN** Panitumumab a congenital anomaly / birth defect Sign(s) / Symptom(s) other significant medical hazard List one per line Adverse Event Diagnosis or Syndrome (if known) AMG 954 20050203 Line # 10 3 ∞ 6 2 4 5 9 **N**

	+; •	9							Site No.		Subject ID No.	No.	
G 954 20050203	50203							_/////	- - - -	7	_	_	_
													HOSP
If hospin	tal utilizatior	n was d	ue to an	Adve	erse Event,		SPIT ord event	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.	JNS Ind complete a Serious A	4dverse Even	rt Report (SAEI	R) form.	
las the subject	t had any hc	ospitaliz	zations f	rom ti	me of sign	ing ir	formed	las the subject had any hospitalizations from time of signing informed consent through to end of safety follow up visit?			√ Yes - If yes, specify below.	cify below.	
Date of Admission	dmission		Date of Discharge	f Disc	harge	not discharged Safety Follow U _l		Primary Reason for Admission Enter primary reason code	r Admission son code	Unit in Hospital	Did the subject visit the emergency department hefore heind	Reason for dis-	
Day Month	Year	Day	/ Month	£	Year	Check if ≥ Check if	Reason Code	Specify if	Specify if "88 Other"	9	admitted?	crial ye ©	
		_	_		_ _ _		_			_		_	
_		_	_	_	_		_						
							_						
							_						
				_			_						
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			_	_			_						
© REASON CODES: 02 Adverse event 04 Respite care 05 Normal clinica	SON CODES: Adverse event Respite care Normal clinical practice		4400	40 RB 41 Pla 88 Oth	RBC transfusion Platelet transfusion Chemotherapy Other	rois		© UNIT IN HOSPITAL CODES: 01 ICU (Intensive care unit (includes any cardiac care unit) 03 General Ward 07 Monitored Bed		REASON FOR DISCHARGE CODES: O1 Improvement in condition O2 End of respite care O3 Normal clinical practice O4 Admission to palliative care D5 Death R8 Other	RGE CODES: dition tice Ive care		

86 Skin88 Other(specify above) PROC Subject ID No. Adrenal gland Peritoneum Gall bladder Kidney Specify BODY SITE if "88 Other" Spleen Heart 74 79 81 84 85 85 Description/Findings Retroperitoneum Small intestine Colon Rectum Ascites Anns Site No. 64 65 69 70 73 Pericardial effusion
 Spinal cord
 Brain
 Esophagus
 Stomach Has the subject had any additional procedures during the study? DNO TONS - If Yes, provide details below. Pancreas **PROCEDURES** 50 51 62 63 63 Line # Lung parenchyma Pleura or pleural wall Pleural effusion Body Site Code Chest wall (0) Bone Liver 527284 31", were there any malignant cells? code = "30 orIf Procedure No · Yes © BODY SITE CODES:
00 Lymph node
01 Thyroid
02 Oral cavity
03 Pharynx
08 Pelvis
09 Breast Specify PROCEDURE if "88 Other" Procedure Code Θ Sigmoidoscopy Other (specify below) Year **AMGEN** Panitumumab Colonoscopy Date of Procedure AMG 954 20050203 33 34 88 PROCEDURE CODES:
 30 Paracentesis 3.
 31 Thoracentesis 3.
 32 Surgical 88 Paracentesis Thoracentesis Surgical Day Line # Line 8 # 4 5 6

ANCEN Desitionings	Site No.	Subject ID No.
	7/	
AMG 954 20050203	- - -	-
		INTHER

INTERVENTIONAL THERAPY FOR METASTASES

POST INTERVENTION TUMOR EVALUATION

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

Post Intervention TUMOR EVALUATION - TARGET LESIONS

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

Measurable

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 Pro		Method of Assess- ment ①	Subsite Describe specific location	Lesion Site Code	Measurable Lesions (mm) (Longest Diameter) Must be unidimensionally measurable	Was interventional therapy performed on this lesion?
	Day	Month	Year	1			Dimensions (mm)	~ / · /
01								i
02	I							1
03	I							
04								
05	i							
06								
07								
08	i							1
09	i							
10	ı							1
					Sum of Le	Target esions		
	-		MENT CODES: outed Tomograp	ohy (CT)	04 MRI (NMR) 23 Spiral Con	nputed Tom	ography (CT)	
00 L 01 7 02 0 03 F 08 F 09 E	Lymph no Thyroid Oral cavin Pharynx Pelvis Breast Pleural e	ty	13 Lung parer 17 Pleura or p 20 Liver 30 Bone 40 Chest wall 49 Pericardial 50 Spinal cord	leural wall effusion	51 Brain 69 Anus 61 Esophagus 70 Ascites 62 Stomach 73 Retrope 63 Pancreas 74 Peritone 64 Small intestine 79 Gall bla 65 Colon 81 Kidney 66 Rectum 82 Heart		 84 Adrenal gland 85 Spleen 86 Skin 88 Other (specify subsite above) 	

Locion

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

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

Lesion Note: Always maintain the same order of lesion numbers	Day	Date o		ocedu	re Ye	ar	Meth of Asse me	f ess- nt	Subsite Describe specific I	ocation	Lesion Site Code	m 5 reco	(m. (Record) leasure imm, ot ord 5mi on-mea	Diameter m) I actual ment if ≥ herwise m.For truly ssurable cord 'NA')	Interve The Perfor This L	las entiona erapy med o Lesion ₁Yes
11	l		1	1												
12	l		1													
13			1			l										
14			1			1										
15			1													
16	l		ı		ı	I							ı	I		
17			1			-										
18			1		1											
19	· 		i		ı	İ										
20			i		ı	ı										
		nal Comp				hy (CT)		Spiral Computed Tomog Bone Scan	raphy (CT				examinati pecify belo		_
01 Th 02 Or 03 Ph 08 Pe 09 Br	mph nod nyroid ral cavity narynx elvis	е	17 20 30 40 49	Lung p Pleura Liver Bone Chest Perica Spinal	or p wall rdia	oleural I effusi	wall	62 63 64 65	Esophagus 7 Stomach 7 Pancreas 7 Small intestine 7 Colon 8	Anus Ascites Retrop Peritor Gall bla Kidney Heart	eritoneum neum adder	84 85 86 88	Sple Skin Othe			
Line #							Specify	/ ME	THOD OF ASSESSM	ENT if "8	8 Other"					

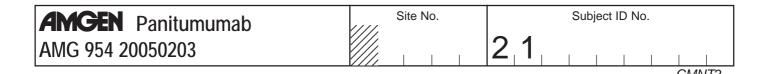
GENERAL COMMENTS



GENERAL COMMENTS

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

	Data Informatio	- Dalataa Ta	1 1 7 7 7 7 7	
Day	Date Informatio Month	n Relates To Year	Refers to CRF page no.(s)	
Details	:			
Day	Date Informatio Month	n Relates To Year	Refers to CRF page no.(s)	
Details	:			
Day	Date Informatio	n Relates To Year	Refers to CRF page no.(s)	
ı				
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Details	:			



GENERAL COMMENTS

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

	Date Informatio		Refers to CRF page no.(s)	
Day	Month	Year	notes to one page notes	
Details:	:			
	Data late at	- B. I. (=		
Day	Date Informatio	n Relates To Year	Refers to CRF page no.(s)	
Day	Moriai	1001	 	
			<u> </u>	
Details:	·			
	Date Informatio	n Relates To	Refers to CRF page no.(s)	
Day	Month	Year	Treiers to GRF page 110.(5)	
Details:				



GENERAL COMMENTS

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

Day	Date Information	n Relates To Year	Refers to CRF page no.(s)	
Day	Worter	rear		
Details:	:			
		·		
	Date Information		Refers to CRF page no.(s)	
Day	Month	Year	1 3 ()	
Details:	:			
	Date Information		Refers to CRF page no.(s)	
Day	Month	Year	receis to ord page no.(3)	
Details:	:			

DEATH SUMMARY

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

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? Did subject die during the study? Did Subject die during the study? Did Subject die during the study?

Primary Cause of Death	PRIMAI	RY CAUSE OF DEATH CODES: Disease progression	Specify PRIMARY CAUSE OF DEATH if "88 Other"
	88	Other (specify)	

INVESTIGATOR VERIFICATION

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

INVESTIGATOR VERIFICATION

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

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

ADDITIONAL ASSESSMENTS FOR SUBJECTS DISCONTINUING PRIOR TO DISEASE PROGRESSION

AMG 954 20050203	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?' □ No □ Yes - If yes, specify below.	Primary Reason for Admission Enter primary reason code Unit in emergency equation to the subject visit the emergency equation to the subject visit the emergency equation to the subject visit the emergency experiment to the subject visit t	Reason Specify if "88 Other"				ASON CODES: 40 RBC transfusion Respite care A1 Platelet transfusion Normal clinical practice B2 Chemotherapy C3 Chemotherapy C4 RBC transfusion C5 Chemotherapy C6 Chemotherapy C7 Monitored Bed C7 Monitored Bed C8 Chemotherapy C8 Chemotherapy C9 Chemo
AMG 954 20050203		If hospital utilizati the subject had any	Date of Admission		——————————————————————————————————————	 	 	 © REASON CODES: 02 Adverse event 04 Respite care 05 Normal clinical practic

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

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

Lesion Note: Always maintain the same order of lesion numbers	Date of Procedure						Method of Subsite Assessment ① Method of Subsite Describe specific location						C	sion lite ode	(Lon	easur Lesio (mm gest Did Must b dimensi measura	Was Interventiona Therapy Performed On This Lesion Since the Last Assessment?							
	Day		Mon	th		١	Year													Dim	ensio	ns (mm)		ı₁Yes ı√
01																								
02				1																				
03				1															1					
04			l	I		1	1	ı											I					
05																			1					
06			ı	1			ı	ı																
07			ı	1															1		1			
08			1	1		<u> </u>													1					
09			1	1															1		1			
10																								
															5	Sum		Tarç sio						
	HOD OF Convent	_	_			_		_	hy (CT)	04	MF	RI (NMR)	23	Spi	iral Co	mpute	d Tor	nogra	phy (C	T)			
00 01 02 03 08 09	Lymph n Thyroid Oral cav Pharynx Pelvis Breast Pleural e	ode ity		S:	17 20 30 40 49	Ple Liv Bo Ch Pe	eura ver one nest erica	or p	l effusi	wall	51 61 62 63 64 65 66	S P S C	rain sophagus tomach ancreas mall intes colon ectum	7 7 7 7 8	70 73 74 79 81	Retro Perito Gall b	peritor neum ladde y		8	35 Sp 36 Sk 38 Ot	renal (leen in her (sµ bsite a	ecify in		

^{*} 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	Site No.	Subject ID No.
AMG 954 20050203		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	D	ate of Pro	ocedure Year	Method of Assess- ment	Subsite Describe specific location	Lesion Site Code	New Lesions	Longest Diameter* (mm)	Tumor Response (Record if body site code is NOT "04 Bone"	Was Interventional Therapy Performed On This Lesion Since the Last Assessment?
11		1 1						, ,		
- • • •										
12										
13										
14										
15										
16										
17							1			
18										
19							 			
20										
01 X 03 C	K-Ray	onal Comp	ENT CODE		23 Spiral Computed Tomo25 Bone Scan	ography (0	CT) 66 88	O Physical Exa Other (special)		
© LESION SITE CODES: 00 Lymph node 13 Lung parenchyma 51 Brain 69 Anus 84 Adrenal gland 1 Thyroid 17 Pleura or pleural wall 61 Esophagus 70 Ascites 85 Spleen 62 Stomach 73 Retroperitoneum 86 Skin 91 Pleura 92 Liver 62 Stomach 73 Retroperitoneum 93 Pharynx 30 Bone 63 Pancreas 74 Peritoneum 94 Other (specify in 94 Stein 95 Spleen 96 Stomach 96 Stein 96 Stein 97 Gall bladder 97 Gall bladder 98 Subsite above) 98 Peast 49 Pericardial effusion 65 Colon 81 Kidney 10 Pleural effusion 50 Spinal cord 66 Rectum 82 Heart										
CR (Complete Stable dis			UE Unal	ressive disease ble to evaluate		NA Not a	one		

Line #	Specify if "88 Other" Method of Assessment

^{*} 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'.

Weeks After Previous On-Study Tumor Evaluation TUMOR RESPONSE

Day	Date of Assessn Month	ent Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	No Yes	Overall Tumor Response Code
RESPO CR (CPR FSD SD SPD FUE UE UE NA NA NA	ALL TARGET LESION ONSE CODES: Complete response Partial response Stable disease Progressive disease Unable to evaluate Not applicable Not done	LESION RES CR Comple SD Stable PD Progre UE Unable	(ISTING NON-TARGET PONSE CODES: ete response disease ssive disease e to evaluate plicable ne	© OVERALL TUMOR CR Complete re PR Partial responsor SD Stable diseat PD Progressive UE Unable to even ND Not done	esponse onse ase disease	ODES:

	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL		OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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-	Progressive Disease (PD)
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)	

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

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? One No Description Yes - If No, record the date the last radiographic assessment was completed, on the last radiographic assessment was completed, or the last radiographic assessment was completed.
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:
CODES: 05 Adverse event ® 06 Consent withdrawn ® 13 Subject request ® 07 Disease progression ®
Criteria Code Code CRITERIA CODES: 04 Non-radiographically determined disease progression
09 Administrative decision [®]
10 Lost to follow-up [®] 11 Death [®]
(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 ®
Criteria Code Code Code Code Code Code Code Code
14 Pregnancy [®] (Complete Pregnancy Notification Worksheet)
88 Other ®
Record date of last additional radiographic assessment or date of decision not to perform additional radiographic assessments Record date of death
If subject did not complete additional radiographic assessments until disease progression was confirmed, provide any additional relevant information:

SURVIVAL STATUS





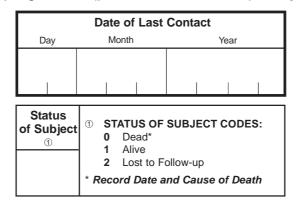
Subject ID No.

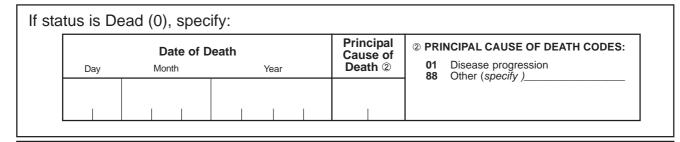
ITFI

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.





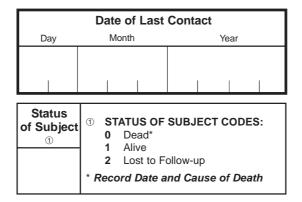
For all subject statuses (0,1 or 2), specify: Since the last assessment has the subject received any treatment for colorectal cancer?

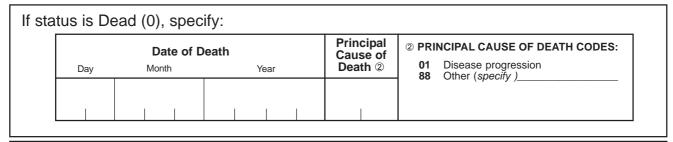
And Turner Treatment Char	③ ANTI TUMOR TREATMENT GIVE CANCER CODES:	EN FOR COLORECTAL
Anti Tumor Treatment Given	00 None	10 Other Anti VEGF unspecified
for Colorectal Cancer	11 Panitumumab	16 Oxaliplatin
(3)	12 Cetuximab	17 Irinotecan
	13 Other EGFr moAb	18 Fluoropyrimidine
	14 Other EGFr small molecule	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.





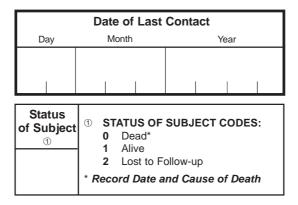
For all subject statuses (0,1 or 2), specify: Since the last assessment has the subject received any treatment for colorectal cancer?

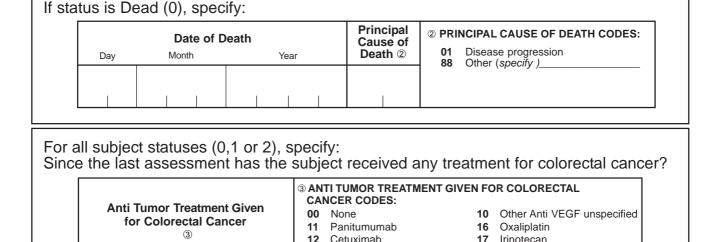
Anti Tumo	r Troots	aant Civ			TI TUMOR TREATMENT GIVE NCER CODES:	N FC	DR COLORECTAL
			en	00	None	10	Other Anti VEGF unspecified
for Col	orectal	Cancer		11	Panitumumab	16	Oxaliplatin
	(3)			12	Cetuximab	17	Irinotecan
				13	Other EGFr moAb	18	Fluoropyrimidine
				14	Other EGFr small molecule	99	Not 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.





Other EGFr moAb

15 Bevacizumab

Other EGFr small molecule

18

99

88

Fluoropyrimidine

Other (specify)

Not known

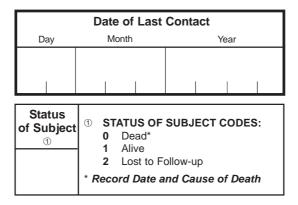
13

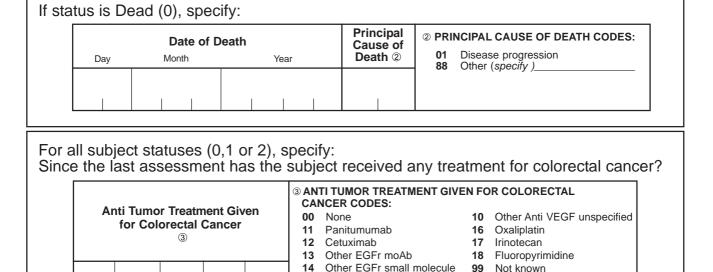
14

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.





15 Bevacizumab

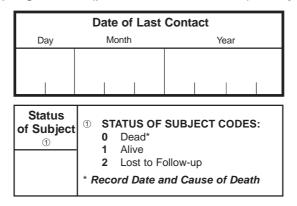
88

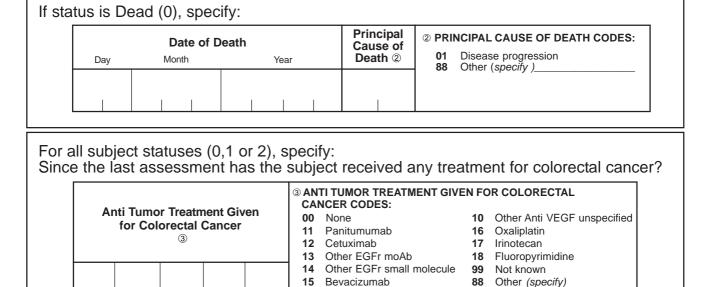
Other (specify)

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.

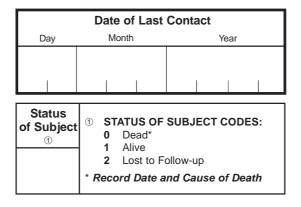


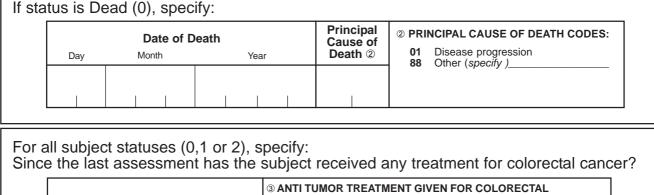


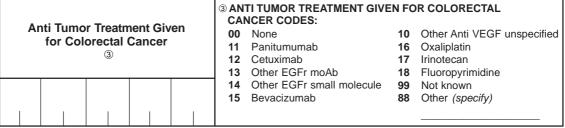
Month 18 SURVIVAL STATUS

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.







EXTRA FORMS



SCR

MEDICAL & SURGICAL HISTORY

	02 03	Special senses (vision, hearing, olfaction and taste) Cardiovascular Respiratory Gastrointestinal	05 Hepatic / Biliary06 Genitourinary / Reproductive07 Renal08 Endocrine / Metabolic09 Musculoskeletal	10 H 12 D 13 Ir 50 N 51 P 88 C	Derma mmu Jeurc Psych	atolo nolog ologic niatric	gic gic	_ymp	hatio	;	
lis	ode 'as sted ove)		or Procedure entry per line.		Da	App ate or or Pu if a	f Dia	gno dure	sis ,	<	✓ Resolved
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SCR Subject ID No. Site No. AMGEN Panitumumab AMG 954 20050203

PRIOR THERAPY FOR NON-METASTATIC COLORECTAL CANCER Screening

Item #	Drug	Type of ment Therapy Setting	Treat- ment Setting		Date of First Dose of Therapy	e of Ther	ару	Date of	Date of Last Dose of Therapy	e of The	rapy	Date of	Disease Prog Recurrence	Date of Disease Progression/ Recurrence	/u
				Day	Month	Year		Day	Month	Year	-L	Day	Month	Year	
1	1		_			_ _			_	_			_	_	_
7	6														
(3)	ဇ	_													
4	#	_													
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ter	Item # Specify if TYPE OF THERAPY is "88 Other"	. "88 Other"			Item #			Specify	Specify if TREATMENT SETTING is "88 Other"	MENT SE	ETTING	is "88 Ot	her"		

① TYP	① TYPE OF THERAPY CODES:	© TRE	© TREATMENT SETTING CODES:
01 05 13 14 15	Chemotherapy Immunotherapy Hormonal Targeted biologics Targeted small molecules	00 07 88	Adjuvant Neo-adjuvant Other (Spe <i>cify above)</i>
17 88	Chemoembolization Other (Specify above)		

Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

PROCEDURES

Line #		Date of Procedure	cedure	-	If Procedure code = "30 or sold all malignant code any malignant colls?	If Procedure code = "30 or 31", were there any malignant calls?	or ere Body Site ant Code	ite .		Description/Findings	sbu	
:	Day	Month	Year	ar		No Yes	es s					
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©		_ _		_	_							
⊖ 30 31 32	① PROCEDURE CODES:30 Paracentesis31 Thoracentesis32 Surgical	33 34 88	Colonoscopy Sigmoidoscopy Other (specify below)		© BODY SITE CODES. 00 Lymph node 01 Thyroid 02 Oral cavity 03 Pharynx 08 Pelvis 09 Breast	E CODES:	10 Pleural e 13 Lung par 17 Pleura or 20 Liver 30 Bone 40 Chest wa	Pleural effusion Lung parenchyma Pleura or pleural wall Liver Bone Chest wall	49 Pericardial effusion50 Spinal cord51 Brain61 Esophagus62 Stomach63 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)
Line #	#		Specify	PROCEL	Specify PROCEDURE if "88 Other"	Other"		Fine #		Specify BODY SITE if "88 Other"	E if "88 Other"	

	Site No.	Subject ID No.
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AMG 954 20050203	- - -	
		INTHER

INTERVENTIONAL THERAPY FOR METASTASES

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Lesion Numbers Affected Record lesion number from tumor evaluation				_		_		88
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L ord							β,, ,±	© UNIT CODES:
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rocedu is '08 - iotheral	(G)						"	
If Procedure is '08 - Radiotherapy Specify Inter	3							74 79 82 84 85 88 88
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dure rapy								<u> </u>
If Procedure is '08 - Radiotherapy' Specify Unit	⊕							fusic
Pro is idio	2							al ef rd us us setin
# Re	1)							Pericardial effusion Spinal cord Brain Brain Esophagus Stomach Pancreas Small intestine Colon Rectum Anus Rectum
If Procedure is'08 - Radiotherapy'								Pericarc Spinal of Brain Esopha, Small in Colon Rectum Anus Ascites
rocedu is'08 - iothera	ج ت						#	665 663 73 73 73 74 75 75 75 75 75 75 75 75 75 75 75 75 75
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	_	_	_	_				© BODY SITE CODES: 00 Lymph node 01 Thyroid 02 Oral cavity 03 Pharynx 08 Peivis 09 Breast 10 Pleural effusion 11 Lung parenchyma 17 Pleura or pleural wall 20 Liver 30 Bone 40 Chest wall
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End								ITE of no poid cavification of the poid cavification of the point of t
Date Ended	Month	_			_	_		DY SITE CC Lymph nod- Thyroid Oral cavity Pharynx Pelvis Breast Pleural effu Lung paren Pleura or pl Liver Bone Chest wall
ă								⊕ BODY 01 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
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ted	Year				_		Other"	L ČĚ
Date Started								o on retio
ate (Month	_					,	URE ion ductii /redt
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Body Site Code	 						Specify BODY SITE if "88	© RESULTS OF PROCEDURE CODES: 00 No removal/reduction 09 Partial removal/reduction 10 Complete removal/reduction
S T							B ∠	TS (oreland)
Results of Proce-	8 ⊗	_		_	_	_)eci	Ja č č č
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ure								
ecify Procedu if "88 Other"								atior e)
Program								S: abla
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Specify Procedure if "88 Other"								PROCEDURE CODES: 03 Radiofrequency ablation 04 Cryotherapy 07 Surgery 08 Radiotherapy 88 Other (specify above)
								SEDURE CC Radiofreque Cryotherapy Surgery Radiotherap Other (speci
Proce- dure Code	Θ	-	_	_	_	_		CEDURE Radiofree Cryother: Surgery Radiothe Other (sp
							Line #	03 03 04 08 88 88
Line #		1	7	S	4	5	- 년	
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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	C	oate of	Prod	ced	ure		Method of Assess- ment		Subsite e specific loca	ation	S	sion ite ode 2	(Long unic	easura Lesior (mm) gest Dia Must be dimensioneasural	meter) enally	Interve The Perfo On Les Sinc La Assess	las entiona erapy ormed This sion ee the ast sment?
	Day	Month	1		Year	r							Dime	ension	s (mm)	∘No ✓	ı ₁Yes ı ✓
01																	
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1	HOD OF Conventi						ny (CT)	04 MRI (NMR)	23 Sp	piral Computed	d Ton	nogra	ohy (C	Т)			
00 01 02 03 08	ON SITE Lymph no Thyroid Oral cavit Pharynx Pelvis Breast	ode	1 1 2 3 4	17 F 20 L 30 E 10 C	Pleura iver Bone Chest	a or p	nchyma bleural wall effusion	51 Brain61 Esophagus62 Stomach63 Pancreas64 Small intes65 Colon	73 74	Anus Ascites Retroperitone Peritoneum Gall bladder Kidney	eum	8 8 8	5 Spl6 Ski8 Oth		ecify in		

^{*} 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 20	0050203

Site No.		Subjec	t ID N	0.			
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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	e r	D		of flont		oce	dur	'e		Meth of Asse mer	ss- nt	Desci	Subsite ibe specific loc	ation	Lesi Site Coc	e de	Lesi	ew ions 'Yes	Lo Dia	onges amete (mm)	st er*	Resp (Re if boo code "04"	mor ponse cord dy site is NOT Bone"	Interv The Perf On Le Sind	entional erapy ormed This sion ce the ast ssment?
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	Lymp Thyro Oral o Phary Pelvis Breas Pleur	h no bid cavity nx s st al eff	de y fusio	on		17 20 30 40 49 50	Ple Live Bor Che Per Spi	ura er ne est rica	or p	nchyma leural w effusion	vall	61 62 63 64 65	Brain Esophagus Stomach Pancreas Small intestin Colon Rectum	е	73 74 79	As Re Pe Ga Kie	scites etrope eritone all bla dney	eritone eum	eum	84 85 86 88	Sp SI O		gland pecify above)		
CR	MOR REPONSE CODES: Complete response PD Progressive disease NA Not applicable Stable disease UE Unable to evaluate ND Not Done																								

Line #	Specify if "88 Other" Method of Assessment

^{*} 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'.

Unscheduled

TUMOR RESPONSE

D ay	Date of Assessment Day Month Year						Target esponse Non-Target Lesion Response Code 2			esions Yes	Overall Tumor Response Code
① OVERALL TAI	GET LESION	(2	OVER	ALLEX	STING NON-TA	RGET	® OVE	 RALL TUMOR	R RESP	ONSE C	ODES:
RESPONSE O CR Complet PR Partial re SD Stable di PD Progress	response sponse ease ve disease evaluate		_	Comple Stable Progres	PONSE CODES ete response disease ssive disease to evaluate blicable		CR PR SD PD UE ND	Complete re Partial respo Stable disea Progressive Unable to ev Not done	esponse onse ise disease		55 <u>2</u> 5.

	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL		OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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	Progressive Disease (PD)
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)	

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

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		Sum of Non-Target Lesions Identified
	Day	Month	Year	to Have Progressed

EXTRA PADS

Marian Bapitumumah	Site No.	Subject ID No.
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MG 954 20050203	_ _ _	2

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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.

Did the subject visit the emergency Reason department for dis-								_	GE CODES: Ition Se care
Unit in Hospital		_	_	_		_	_	_	SON FOR DISCHARGE (Improvement in condition End of respite care Normal clinical practice Admission to palliative ca Death Other
Ľ.									REASON FOR DISCHARGE CODES: Of Improvement in condition O2 End of respite care O3 Normal clinical practice O4 Admission to palliative care O5 Death 88 Other
Primary Reason for Admission Enter primary reason code	Specify if "88 Other"								UNIT IN HOSPITAL CODES: O1 ICU (Intensive care unit (includes any cardiac care unit) 03 General Ward 07 Monitored Bed
	Reason Code		_	_		_		_	
not discharged f Safety Follow Up	Check ii at End o								<u>د</u>
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e G	Year	_	_	_	_	_	_	_	ansfu t tran ithera
Date of Discharge		_	_	_	_	_	_	_	RBC transfusion Platelet transfusion Chemotherapy Other
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Date of Admission	‡	_	_	_	_	_	_	_	Adverse event Respite care Normal clinical practice
ate o	Month	_	_	_	_	_	_	_	SON (Adver: Respit Jorms
Ď	Day				_	_		_	© REASON CODES: 02 Adverse event 04 Respite care 05 Normal clinical
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AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , ,
		AFUP

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

Was Interventional Therapy Lesion Measurable Performed Note: Lesions * Method On This Always **Subsite** Lesion (mm) of maintain Lesion **Date of Procedure** (Longest Diameter) Site Assess-Describe specific location the same Since the Must be Code ment Last unidimensionally of lesion 1 2 Assessment? measurable numbers _₀No ₁,Yes Day Dimensions (mm) Month Year 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 Adrenal gland Anus 84 17 Pleura or pleural wall **01** Thyroid 61 Esophagus 70 Ascites 85 Spleen 02 Oral cavity 20 Liver 62 Stomach Retroperitoneum 86 Skin Other (specify in 03 Pharynx 30 Bone 63 **Pancreas** Peritoneum 88 08 Pelvis 40 Chest wall 64 Small intestine 79 Gall bladder subsite above)

81

Kidney

Colon

Rectum

65

66

49 Pericardial effusion

50 Spinal cord

09 Breast

10 Pleural effusion

^{*} 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	Site No.	Subject ID No.	
AMG 954 20050203		2,1, , , , , ,	
Mooks After Draviou	o On Study	Tumor Evaluation	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	Da		ate	of		осе		r e		Method of Assess- ment	Desci	Subsite ibe specific location	Les Sit Co	te de	New Lesions		onges amete (mm)		Resp (Re if boo code i "04 L	mor Jonse Cord If site Is NOT Bone"	Interve The Perfo On Les Sino La Asses	las entional erapy ormed This sion ee the ast sment?
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2 LESIO 00 L 01 T 02 C 03 F 08 F 09 E 10 F	Jympl Thyro Dral o Phary Pelvis Breas Pleura	h noo id avity nx it al eff	de /	on		17 20 30 40 49 50	Ple Live Bor Che Per Spi	ura er ne est rica	or p	nchyma leural wall effusion	61 62 63 64 65		70 73 74 79 81	Re Pe Ga	scites etroperiton eritoneum all bladder dney		84 85 86 88	Sp Sk Ot	her (s	gland pecify i	in	
CR SD	Com Stabl	plete e dis	res seas	poi e	nse					PD Prog UE Unab	le to e	valuate			NA Not a	one						

Line #	Specify if "88 Other" Method of Assessment

^{*} 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'.

Weeks After Previous On-Study Tumor Evaluation TUMOR RESPONSE

D ay	te of Assessr Month	nent Year		Overall Target Lesion Response Code ①	Non-Tar	I Existing get Lesion se Code ②	No	esions Yes	Overall Tumor Response Code
		1, 1						 	
PR Partial re SD Stable di	DDES: response sponse ease ve disease evaluate	LESION CR (SD S PD F UE U	RES omple table rogres nable	CISTING NON-TARGET PONSE CODES: ete response disease ssive disease to evaluate plicable ne	CR PR SD PD UE	CALL TUMOI Complete re Partial respo Stable disea Progressive Unable to ev Not done	esponse onse ase disease		ODES:

	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL		OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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-	Progressive Disease (PD)
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)	



Site No.

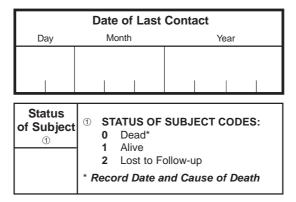
Subject ID No.

LTFU

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 I	Death	Principal Cause of	② PRINCIPAL CAUSE OF DEATH CODES					
Day	Month	Year	Death 2	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	3 ANTI TUMOR TREATMENT GIVE CANCER CODES:	EN FOR COLORECTAL
	00 None	10 Other Anti VEGF unspecified
for Colorectal Cancer	11 Panitumumab	16 Oxaliplatin
(3)	12 Cetuximab	17 Irinotecan
	13 Other EGFr moAb	18 Fluoropyrimidine
	14 Other EGFr small molecule	99 Not known
	15 Bevacizumab	88 Other (specify)

									S	Site No.				Subject ID No.	ID No.		
	MOEN Panitumumab 1G 954 20050203	mab						<u> </u>	- []]]]]	_	_	7	_	_	_	_	
														_		CM	1~
	For dosage ch	anges, record	as second (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.	OMI Int medic	AN I	ME for an a	dverse	AIIC event, p	CN	enter eve	ent on Adv	erse E	vent Su	mmary CRI	li:	
	M Science							1		шлој рәүү ио	Date	a		Date	a	gniunitoon oit g∪ wollo∃	
# P	Record one per line		eixelydqord ≯	Indication		Dose	- 6		⊕ ⊕ szibem ii ¥zed2	Check if medics from previous C	FIRST Taken	aken Year	Day	LAST Taken	aken Year	Check if medical safety	
1											_	_	_	_			
8											_		_	_			
8											_		_	_ _	 		
4											_	_	_	_	_ _ _		
2											_		_	_	_		
9											_	_	_	_			
7										_	_		_	<u> </u>			
00											_	_	_	_ _			
© CA	① CATEGORY CODES:	© UNIT CODES:	.;		® ROUTE	ROUTE CODES:					⊕ FREQ	♠ FREQUENCY CODES:	ES:				
6	Steroids or narcotics given for treatment	AMP Ampule CAP Capsule		MG Milligram ML Milliliter (cc)	ЕТ 6Т ©	Endotracheal tube Gastrostomy		OP Ophtl PO Oral	Ophthalmic Oral		C B	Twice a week	sek s infusio	O O	Once a day 4 times a week		
_ ;			ł			Intra-arterial		PR Rectal			£				Once a month	<u> </u>	
3 8	Intusion reaction Antibiotic/Antifungal	GK Grain GTT Drop		TSP Teaspoon		nhaled			Subcutaneous		PRN	One time only As needed	ylly _	Q W W		Tay	
	for the treatment of skin/nail infection	IU Internationa MCG Microgram	al unit			Intramuscular Intraperitoneal			Sublingual Transdermal		Q2W Q3W	Q2WK Every 2 weeks Q3WK Every 3 weeks	eeks eeks	M TO		- k	
4 8			ent	below)	<u>±</u> ±	Intrathecal Intravenous	- 0	TP Topical OT Other (Topical Other (s <i>pecify below)</i>	below)	Q4W	Q4WK Every 4 weeks	eks		below)		

Specify FREQUENCY "OT Other"

Line #

Specify ROUTE "OT Other"

Line #

Specify **UNIT** "OT Other"

Line #

Not applicable Anti-emetic

99

Serions § \ Event (record all that apply)
01 Noaction taken
02 Paniturnanab dose altered
03 Medication taken
04 Hospitalized/
04 Hospitalized/
05 Removed from study
06 Paniturnumab discontinued
07 Translosion penformat
07 Translosion penformat
08 Chemotherapy dose discontinued
18 Chemotherapy dose altered
18 Chemotherapy dose altered
18 Chemotherapy dose altered
18 Chemotherapy dose altered
19 Observative and the study of the stu Action Taken for This Subject ID No. Relationship Relationship Panitumumáb?|Chemotherapy?| Is there a reasonable possibility that the event may have been caused by Other" Action Taken reasonable possibility that the event may have been No Yes caused by Is there a Yes the subject at immediate CTCAE Grade 04, event place did the risk of death? Specify if "88 Site No. ٤, **ADVERSE EVENTS SUMMARY** Severity (use CTCAE Grading Scale) one code Record 22823 Intermittent Check if event continuing at End of Safety Follow Up Resulted in Death Year Changed in Date Ended, Severity or Month Day Line # Year Date Started requires inpatient hospitalization or prolongation of existing hospitalization Month If event is defined as serious, complete Serious Adverse Event Report form and FAX to Amgen within one working day. B Criteria for Serious Adverse Event: start before first dose of Panitu-mumab or FOLFOX Did event life threatening (places subject at immediate risk of death) results in persistent or significant disability / incapacity Serious adverse event includes any event that (is): mnot 3A suoivenq mont Check if event continued **AMGEN** Panitumumab a congenital anomaly / birth defect Sign(s) / Symptom(s) other significant medical hazard List one per line Adverse Event Diagnosis or Syndrome (if known) AMG 954 20050203 Line # 10 3 ∞ 6 2 4 5 9 **N**



GENERAL COMMENTS

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

	Date Information	n Polatos To	I	
Day	Month	Year	Refers to CRF page no.(s)	
- Duy	11101101	1001		
Details				
	Date Information	n Relates To	Refers to CRF page no.(s)	
Day	Month	Year	Neiers to Civi page 110.(s)	
1				
Details	·			
	Date Information	n Relates To	Refers to CRF page no.(s)	
Day	Month	Year	Refers to ONT page 110:(3)	
1				
Datalla				
Details	·			

AMGEN Panitumumab	Site No.		Subject ID No		
AMG 954 20050203		2,1,	<u> </u>		

Cycle ____, Day 1 HEMATOLOGY

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

	Day		Date Dr.		Year	lae on the Adv
			I			ı
	Test		Result		Unit	Specify if Other Unit
RE	3C				/uL 10 ⁶ /mm ³ 10 ¹² /L Other	
Не	emoglobin	l			g/L g/dL mmol/L Other	
Нє	ematocrit			15 5 7	%	
M	CV					
Platelets			90			
W	вс			10	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
	Neutrop	hils		88	10 ⁹ /L Other	
D I F	Lympho	cytes		88	10 ⁹ /L Other	
F E R E	Monocy	tes			10 ⁹ /L Other	
N T A	Eosinop	hils		88	10 ⁹ /L Other	
L *	Basophi	ls			10 ⁹ /L Other	
	Granulo				% 10 ⁹ /L Other ermine ANC at	

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

C__D1



е	,	Da	v 1	
			1	

Site No.

Subject ID No.

C__D1

Day I	Da Month	te Di	ra۱	wn Yea	ar	
Test	Res	sult		Unit		Specify if Other Unit
Sodium			6	mEq/L ₈₈ C		
Potassium			6	mEq/L ₈₈ O		
Chloride			6	mEq/L ₈₈ O		
Bicarbonate (HCO	3)		6	mEq/L ₈₈ O		
Total Protein			12	g/L ₈₈ □ C		
Albumin			12	☐ g/L 88 ☐ O		
Calcium			6	mg/dL ₈₈ C		
Magnesium			14	□ mEq/L ₆ □ m □ mg/L ₈₈ □ C □ mg/dL		
Phosphorus				☐ mg/dL ₈₈ ☐ C ☐ mmol/L	ther	
BUN — — — OR —			_	mg/dL ₈₈ C	ther	
Urea				☐ mg/dL ₈₈ ☐ C ☐ mmol/L	ther	
Creatinine				☐ mg/dL ₈₈ ☐ C ☐ umol/L	ther	
Uric Acid				☐ mg/dL ₁₆ ☐ u ☐ mmol/L ₈₈ ☐ C		
Total Bilirubin				☐ mg/dL ₈₈ ☐ O ☐ umol/L	ther	
Alk. Phos.			17	U/L ₈₈ U C ukat/L	Other	
AST (SGOT)				U/L ₈₈ U O ukat/L	ther	
ALT (SGPT)			17	U/L ₈₈ U C ukat/L	ther	
LDH				U/L ₈₈ U O ukat/L	ther	
LDI	H Local	Labo	rat	ory Range		
Lower		U	Upp	er		

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.	Subject ID No.
	2.1

C__D1

Cycle ___, Day 1 HEMATOLOGY

	Day		Date Dr.		Clinical sequela Year	
	ı	ı	ı			
	Test		Result		Unit	Specify if Other Unit
RE	3C			2 Q	/uL 10 ⁶ /mm ³ 10 ¹² /L Other	
Не	emoglob	oin		12 6	g/L g/dL mmol/L Other	
Нє	ematocr	it		15 5		
M	CV				fL Other	
Platelets			9 0	/uL 10 ⁹ /L 10 ³ /mm ³ Other		
W	вс			90	/uL 10 ⁹ /L 10 ³ /mm ³ Other	
	Neutro	ophils		88	10º/L Other	
D I F	Lymph	nocytes		88	10 ⁹ /L Other	
F E R E	Monod	cytes			10 ⁹ /L Other	
N T I	Eosino	ophils		88	10 ⁹ /L Other	
L *	Basop	hils		88	10 ⁹ /L Other	
		locytes		88	% 10°/L Other termine ANC at y	

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

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.		Subject	t ID N	0.		
	2,1,	1 1	ı	ı	ı	ı

C__D1

Cycle ___, Day 1 CHEMISTRY

Date Drawn Day Month Day Month Day Month					
Test	Result		Unit	Specify if Other Unit	
Sodium		6	☐ mEq/L ₈₈ ☐ Other☐ mmol/L		
Potassium		6	☐ mEq/L ₈₈ ☐ Other ☐ mmol/L		
Chloride		6	mEq/L ₈₈ Other mmol/L		
Bicarbonate (HC	CO ₃)	6	☐ mEq/L ₈₈ ☐ Other☐ mmol/L		
Total Protein		12	□ g/L 88 □ Other □ g/dL		
Albumin		12	☐ g/L 88☐ Other☐ g/dL		
Calcium		6	mg/dL 88 Other mmol/L		
Magnesium		14	☐ mEq/L ₆ ☐ mmol/L ☐ mg/L ₈₈ ☐ Other ☐ mg/dL		
Phosphorus		1	☐ mg/dL ₈₈ ☐ Other☐ mmol/L		
BUN ———— OR		1.0	☐ mg/dL ₈₈ ☐ Other☐ mmol/L		
Urea		1	☐ mg/dL ₈₈ ☐ Other☐ mmol/L		
Creatinine		1	☐ mg/dL ₈₈ ☐ Other☐ umol/L		
Uric Acid		1	mg/dL 16 umol/L mmol/L ₈₈ Other		
Total Bilirubin		1 .	☐ mg/dL ₈₈ ☐ Other☐ umol/L		
Alk. Phos.		1	U/L 88 Other ukat/L		
AST (SGOT)			U/L 88 Other ukat/L		
ALT (SGPT)		1	U/L 88 Other ukat/L		
LDH		1	U/L 88 Other ukat/L		
	LDH Local Lab	orat	ory Range		
Lower		Upp	per		

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.				
	2,1, , , , , , ,				

UNSCHED

Week ___ HEMATOLOGY

Date Drawn Day Month Year								
	Test		Re	sult		Unit		Specify if Other Unit
RBC				2 3	/uL 10 ⁶ /mm ² 10 ¹² /L Other	3		
Hemoglobin				12	g/L g/dL mmol/L Other			
Hematocrit				15 5	% L/L frac of f	1		
M	CV				8	fL Other		
Platelets				9	/uL 10º/L 10³/mm²	3		
WBC				10	/uL 10º/L 10³/mm² Other	3		
	Neutro	ophils			9 88	☐ % ☐ 10%L ☐ Other		
D I F	Lymph	nocytes			9 2 88	☐ % ☐ 10º/L ☐ Other		
F E R E	Monod	cytes] _e	3 % 10 ⁹ /L Other		
N T I A L *	Eosinophils] _e	☐ % ☐ 10 ⁹ /L ☐ Other		
	Basop	hils			9 88	3 % 10 ⁹ /L Other		
	Granu	locytes			ا و	☐ % ☐ 10 ⁹ /L ☐ Other		

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

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID	No.
	2,1, , ,	
/ -		

UNSCHED

Week ____ CHEMISTRY

Date Drawn Day Month Year						11107101
Test		Result		Ur	nit	Specify if Other Unit
Sodium			6	mmol/L	Other	
Potassium			6	mmol/L	Other	
Chloride			6	mmol/L	Other	
Bicarbonate	e (HCO ₃)		6	mmol/L	Other	
Total Proteir	า		12	⊒ g/dL	88 Other	
Albumin			12	☐ g/dL	38 Other	
Calcium			9	mmol/L		
Magnesium			14		₆ □ mmol/L ₃₈ □ Other	-
Phosphorus	3		1 '	☐ mg/dL ॄ ☐ mmol/L	₈₈ Other	
BUN	OD		1.0	☐ mg/dL ॄ ☐ mmol/L	38 ☐ Other	
Urea	OR —		1.0	mg/dL _{	Other	
Creatinine				☐ mg/dL _{ ☐ umol/L	Other	
Uric Acid			13	mg/dL ,	umol/L 88 Other	
Total Bilirub	in		1	☐ mg/dL ॄ ☐ umol/L	Other	
Alk. Phos.				Ū U/L Ū ukat/L	Other	
AST (SGOT)			U/L _{	Other	
ALT (SGPT)		18	ukat/L	Other	
LDH				U/L _{	Other	
	LDH I	Local Labo			9	
Lower			Upp	er		

CYCLE 23 TO PROGRESSIVE DISEASE NON-RADIOGRAPHIC ASSESSMENTS

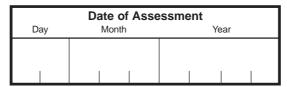
CYCLE __

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? Dan No



VITAL SIGNS

Day	Date Day Month Year		Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

	Date of Exan	nination	П	Weight	Body Surface Area
Day	Month	Year	П	, □ kg , □ lb	(m ²)
			Ш	1 32	, ,
			Ш		
					•

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600) $^{1/2}$

ECOG PERFORMANCE STATUS

	Date)	Performance Status
Day	Month	Year	☑ 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

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		C D1

Cycle ____, Day 1

PHYSICAL EXAMINATION

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

Necord arry new infamily or cha	inge (wors	seriirig) or arr ex	isting infamig on the 7	Adverse Everils Surfillary (
Was a physical examination perform	med? ₀□	l No ₁☐ Yes		_				
		Date of Examination						
	Day	Month	Year					

descri	Does the subject have any abnormal clinical findings relating to the following required sites? ₀ No ₁ Yes - If yes, lescribe findings below.							
	CODES: D1 Head, I Throat D2 Cardiov Respira	Ears, Eyes, Nose, (HEENT) / Neck ascular itory	06 07	Abdomen Musculoskeletal Skin Lymph nodes a required assessme	08 09 10 11 ent was not de	Neurological Genitourinary Breast / Chest Rectal one.	50 88	Extremities Other
Code (as listed above)				Describe fin <i>List one entry</i>				

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C__D1

Cycle___, Day 1

HEMATOLOGY

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

If chemotherapy was delayed record the Hematology results below that were

Rec		ults below tha	t were taken on the pla	
)ay	Date Dr Month	awn Year	
			100.	
		1		
	Test	Result	Unit	Specify if Other Unit
			₁☐ /uL	
RE	0.0		₂ 10 ⁶ /mm ³	
KE	SC .		₃ □ 10¹²/L	
			₈₈ Other	
			₄ □ g/L	
На	emoglobin		₁₂ g/dL	
110	moglobin		₆ □ mmol/L	
			₈₈ Other	
			₁₅ %	
He	ematocrit		₅ □ L/L	
			₇ frac of 1	
			88 Other	
	2)./		₈ □ fL	
IVIC	CV		88 Other	
			₁☐ /uL	
			₉ 1 0º/L	
Pla	atelets		10 ³ /mm ³	
			88 Other	
			₁☐ /uL	
			₉ 1 0 ⁹ /L	
W	ВС		10 ³ /mm ³	
			88 Other	
			15 %	
			₉ 1 0 ⁹ /L	
	Neutrophils		88 Other	
			15 %	
D	Lymphocytes		₉ 1 0 ⁹ /L	
1			88 Other	
F F			15 %	
E			₉ 1 0º/L	
R	Monocytes		88 Other	
E N T			15 %	
	Eosinophils		₉ 1 0%/L	
I			88 Other	
A L *			₁₅ %	
			₉ 10 ⁹ /L	
	Basophils		88 Other	
			15 %	
	Granulocytes		₉ 1 0°/L	
			88 Other	

[Day	Date Dr Month	awn	Year	
		1		1 1	1
	Test	Result		Unit	Specify if Othe Unit
RE	3C		3 1	0 ⁶ /mm ³	
Не	emoglobin		4 9	g/dL nmol/L	
Не	ematocrit		15 c	%	
M	CV		88 8 f	L	
Pla	atelets		''		
W	вс		₁		
	Neutrophils		15 9 1 9 1 1 88 0	0 ⁹ /L	
D I F	Lymphocytes		9 1 88	% 0º/L Other	
r F E R E	Monocytes		9 1 88 0	0º/L Other	
N T I A	Eosinophils		9 1 88 0	0º/L Other	
L *	Basophils		9 1 88 0	0º/L Other	
	Granulocytes		₁₅ 0 9		

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

C__D1

Cycle ___, Day 1 CHEMISTRY

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

Record	the Che	mistry resu					n on the	e plann	ed Day 1
Day	y	Mo	Date onth) Di	raw	n	Ye	ar	
	Test		Resu	ılt		ι	Jnit		Specify if Other Unit
Sodiu	m					mEq/L mmol/	_ ₈₈ 🖵 (L	Other	
Potas	sium				··	mEq/l	_ ₈₈ C	Other	
Chlori	de				110		_88_	Other	
Bicark	oonate	(HCO ₃)			11		-88	Other	
Total I	Protein	1			4		88	Other	
Album	nin				4		88	Other	
Calciu	ım				13		- ₈₈ 🖵 (Other	
Magnesium				11 14	mEq/L	r			
Phosphorus				13			Other		
BUN					13			Other	
Urea		OR — -				mg/dL		Other	
Creati	inine			- 1	13		C	Other	
Uric A	cid				13	mg/dL	16 U		
Total E	Bilirubi	n		- 1	13				
Alk. P	hos.				17		88	Other	
AST (SGOT	·)			17		88	Other	
ALT (S	SGPT)	١			17		₈₈	Other	
LDH					17		88	Other	
		LDH I	_ocal L						
Lower				ı	Upper				

aken on the actua		Date D					
Day	Mo	onth	\neg		Y	ear	
1	1	1		1		t	1
Test		Result		U	Jnit		Specify if Other Unit
Sodium			6	mEq/L mmol/l	L		
Potassium			6	mEq/L mmol/	L L		
Chloride			6	mEq/L mmol/	L_		
Bicarbonate	HCO ₃		6	mEq/L mmol/	L		
Total Protein	1		12	□ g/L □ g/dL			
Albumin			12	g/L g/dL			I
Calcium			6	mg/dL mmol/	/L		
Magnesium			14	☐ mEq/L ☐ mg/L ☐ mg/dL			
Phosphorus	i		6	☐ mg/dL ☐ mmol/	L_		
BUN	or — -		6	mg/dL mmol/	′L		
Urea			6	☐ mg/dL☐ mmol/	L		
Creatinine			16	☐ mg/dL ☐ umol/L	L		
Uric Acid			6	☐ mg/dL ☐ mmol/	/L ₈₈	Other	
Total Bilirubi	n		16	☐ mg/dL ☐ umol/l	L		
Alk. Phos.			18	☑ U/L ☑ ukat/L	•		
AST (SGOT)		18	☐ U/L ☐ ukat/L	-		
ALT (SGPT)			18	U/L ukat/L	-		
LDH			18	Ū U/L Ū ukat/L	-	Other	
	LDH I	Local Labo			ge		
Lower		1	Upp	er			

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

Subject ID No. Site No. **AMGEN** Panitumumab AMG 954 20050203

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

sol" is Specify DOSE CHANGE/ Bose WITHHELD DOSE if "88 Other"			Package Lot Number	
If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	(2)	_	,,	
Reason for lose Change ose Withheld		_	ION if "88 Othe	
Total Volume Administered of Danitumumab plus Saline Solution	(,,,,,)		Specify REASON FOR INFUSION INTERRUPTION if "88 Other"	
Adn	(mg)		REASON FOR	
Stop Time (24 hour clock)		•	Specify	
Start Time (24 hour clock)			0	
	Year	- -	If infusion was interrupted provide the Reason for Infusion Interruption	_
Date	Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
	Day	_		
Cycle			Was Infusion Interrupted? ,No Yes	

INFUSION REACTION

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

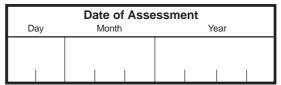
T	D	AMGEN Panitumumab	qt							0) //	Site No.			Subjec	Subject ID No.		
A	1G 9E	AMG 954 20050203										_	7	_	_	_	
						-	Cycle	<u>ه</u>	I							O	
s pic	ubject ı	CHEMOTHERAPY ADMINISTRATION - FOLFOX Regimen Did subject receive chemotherapy? D No D Yes If yes, please enter details below:		RAF s If yes	Y AD,	MINI nter detai	STR Is belov	ATIC	NO.	-0LF	XC	Regir	nen				
Line #	Study Day	Drug Name	Drug Type	Ad	Actual Total Dose Administered	Freq.	Dav	Start Date	e Year	Start Time (24 hour clock)	Dav	Stop Date	ate Year	Stop Time (24 hour clock)	Reason for Dose Change	lf "04 Per protocol" is specified for "Reason for Dose Change", indicate code	
1	_	Oxaliplatin					_	 - -	- - -		_	_	- - -		_	_ 	
2	_	Leucovorin	/leucovorin 1 racemic (dl-) 2 leucovorin 2				_				_	_			_		
က	_	5-FU Bolus				ОТО	_	_			_				_		
4	_	5-FU Continuous Infusion				5	_	_			_				_		
5	2	Leucovorin	/leucovorin 1 racemic (dl-) [leucovorin 2		r / / / / / /		_				_	_			_		
9	2	5-FU Bolus				ОТО	_	_	_ _ _		_	_	_ _ _		_	<u>-</u>	
7	7	5-FU Continuous Infusion				5	_				_	_			_		
⊕ ₹ 2 P	FREQUEN CI Cont OTO One	© FREQUENCY CODES: CI Continuous infusion OTO One time only	© REASC 01 Ad 02 No 03 Do	ASON FOR DOS Adverse event Noncompliance Dose administra	 © REASON FOR DOSE CHANGE 01 Adverse event 02 Noncompliance 03 Dose administration error 	COD 04 88	: S: Per proto Other (<i>sp</i>	ES: Per protocol Other (specify below)	()	© "04 100 386 387	1 111	"04 PER PROTOCOL 100 Weight change 386 Chemotherapy re 387 Chemotherapy re	" DOSE CHAI	PER PROTOCOL" DOSE CHANGE CODES: Weight change Chemotherapy related hematologic dose limiting toxicity Chemotherapy related non-hematologic dose limiting toxicity	ling toxicity limiting tox	icity	
Line	#	Specify REASON	Specify REASON FOR DOSE CHANGE "88 Other"	NGE "8	8 Other"		Line #		Sk	pecify REAS	SON FOR	DOSEC	Specify REASON FOR DOSE CHANGE "88 Other"	Other"			
	_								į								
		CHEMO If chemotherapy was administered, was it delayed? □	was administered	d. was	CHEMO	_ z	7 5 8 8 8		HEKAPY DELAY O D Yes If ves, please enter re	EKAPY DELAY O Yes If yes, please enter reason code;	:ode:						
		Reason for Delay	lelay ①	REASO	①REASON CODES:					Spe	Specify REASON	88, NOS	Other"				
		(record all that apply) ①		229 Prc 230 Prc	Protocol specified adverse event Protocol specified lab value	ied adverse ied lab valu	event e										
		- - - -			Interventional therapy for metastases Other (specify)	herapy for r	netastas	Se									

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? $_{0}\Box$ No $_{1}\Box$ Yes



VITAL SIGNS

Day	Date Month	Year	Blood Pressure (mmHg)	Heart Rate (beats/minute)	Respiration (breaths/minute)	Temperature
			1			

BODY SURFACE AREA

Day	Date of Exan Month	nination Year	Weight ₁☐ kg ₂☐ lb	Body Surface Area (m²)
			1 02	

BSA Formula

BSA (m²) = ([Height (cm) x Weight (kg)] / 3600)^{1/2}

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , ,
		C D1

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 perform	med? ₀□	No ₁☐ Yes	
		Date of Exan	nination
	Day	Month	Year

descri	be findings be	ave any abnorn low.	nal clinical fii	ndings relating to the	e following re	quired sites?	₀ No ₁ □	Yes - If yes,
	CODES: D1 Head, I Throat D2 Cardiov Respira	Ears, Eyes, Nose, (HEENT) / Neck ascular itory	06 07	Abdomen Musculoskeletal Skin Lymph nodes a required assessme	08 09 10 11 ent was not de	Neurological Genitourinary Breast / Chest Rectal one.	50 88	Extremities Other
Code (as listed above)				Describe fin <i>List one entry</i>				

AMGEN	Panitumumab
AMG 954 2	0050203

Site No.	Subject ID No.	
	2,1, , , , , , ,	

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Cycle___, Day 1

HEMATOLOGY

If an abnormal laboratory value resulted in clinical sequelae, record clinical sequel

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

Hematology results below that were taken on the planned Day 1

If chemotherapy was delayed record the Hematology results below that were taken or

Red	Record Hematology results below that were taken on the planned Day 1 Date Drawn						
	Day		Date Dr. Month	awn	Year		
	Test		Result		Unit	Specify if Other	
RE	зс				/uL 10 ⁶ /mm³ 10 ¹² /L Other	Unit	
Нє	emoglobi	in		12 6 88	g/L g/dL mmol/L Other		
Hematocrit				7 88	L/L frac of 1 Other		
MCV					fL Other		
Platelets				901	/uL 10 ⁹ /L 10 ³ /mm ³ Other		
WBC				901	/uL 10°/L 10°/mm³ Other		
	Neutrophils D Lymphocytes				% 10 ⁹ /L Other		
				9 88	% 10 ⁹ /L Other		
F E R E	Monocytes				% 10 ⁹ /L Other		
N T I A L *	Eosinophils				% 10 ⁹ /L Other		
	Basoph	nils			% 10º/L Other		
<u></u>	Granul	ocytes			% 10 ⁹ /L Other		

If cher	notherapy was the actual Da	delayed rec ay 1 (record	e Adverse E ord the Hemato reason for dela Date Dr		ults below the chemo adm.	nat were in page).	taken on
ı	Day	N	Month			/ear	
			1		1		
	Test		Result		Unit		Specify if Other Unit
RI	3C			2	/uL 10 ⁶ /mm ³ 10 ¹² /L Other		
He	emoglobir	n		60	g/L g/dL mmol/L Other		
He	ematocrit			15 5 T	% L/L frac of 1 Other		
M	CV			D ₈	fL Other		
PI	atelets			10	/uL 10 ⁹ /L 10 ³ /mm ³ Other		
W	вс				10 ⁹ /L 10 ³ /mm ³ Other		
	Neutrop	hils			% 10 ⁹ /L Other		
D I F	Lympho	ocytes			10 ⁹ /L Other		
F E R E	Monocy	rtes			10º/L Other		
N T I A	Eosinop	ohils			10º/L Other		
L *	Basoph	ils			10º/L Other		
	Granulo	ocytes			% 10 ⁹ /L Other		

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

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

AMGEN	Panitumumab
AMG 954 20	0050203

Site No.	Subject ID No.	
	2,1, , , , , ,	ı

C__D1

Cycle ___, Day 1 CHEMISTRY

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

Record	the Che	mistry resu	lts bei	low th	at w	ere take	en on th	e plann	ed Day 1
Da	v	Mo	Da onth	te D	raw	/n	Υє	ear	
	Test		Res	sult		ι	Jnit		Specify if Other Unit
Sodiu	m				l · ·	mEq/L mmol/		Other	
Potas	sium				l · ·	mEq/l		Other	
Chlori	de				6	mEq/l mmol/	L L		
Bicart	oonate	(HCO ₃)			6	mEq/l	L L		
Total I	Proteir	1			12] g/L] g/dL			
Album	nin				12] g/L] g/dL			
Calciu	ım				6	mg/dl mmol	/L		
Magn	esium				14	¶ mEq/L ¶ mg/L ¶ mg/dl	88		
Phosp	ohorus				l -	mg/dL mmol/		Other	
BUN		0.5			13	mg/dL mmol/	88	Other	
Urea		OR — -			13	mg/dL mmol/	88	Other	
Creat	inine				1	mg/dL umol/l		Other	
Uric A	cid				13	mg/dL mmol/	16 U		
Total I	Bilirubi	n			13	mg/dL umol/l			
Alk. P	hos.				17	U/L ukat/L	88	Other	
AST (SGOT	-)			17	U/L ukat/L	88	Other	
ALT (SGPT))			17	U/L ukat/L	88	Other	
LDH					17	U/L ukat/L	88	Other	
		LDH I	ocal	Labo	rato	ry Ran	ge		
Lower					Uppe	er			

If chemotherapy aken on the actua		ord reason	for	r delay on			
Day	Мс	Date D	ra.	<i></i> ∕n	Ye	'ear	
	1						
Test		Result		l	Jnit		Specify if Other Unit
Sodium			6	mEq/L	L L		-
Potassium			6	mEq/L mmol/	/L		
Chloride			6	mEq/L mmol/	/L		
Bicarbonate	HCO ₃		6	mEq/L mmol/	/L		
Total Proteir	1		12	g/L g/dL			
Albumin			12	g/L g/dL			
Calcium			6	mg/dL mmol/	/L		<u></u>
Magnesium			14 13	☐ mEq/L ☐ mg/L ☐ mg/dL	88	Other	
Phosphorus	;		1	☐ mg/dL ☐ mmol/		Other	
BUN	OR —		.s [mg/dL mmol/	/L		
Urea			6	mg/dL mmol/	/L		
Creatinine			16	☐ mg/dL ☐ umol/L	L		
Uric Acid			6	☐ mg/dL☐ mmol/	/L ₈₈	Other	
Total Bilirubi	in		16	☐ mg/dL ☐ umol/l	L		
Alk. Phos.			1	❑ U/L ❑ ukat/L	00	Other	
AST (SGOT	<u> </u>		18	U/L ukat/L	=		
ALT (SGPT))		18	U/L ukat/L	-		
LDH				☐ U/L ☐ ukat/L		Other	
	LDH I	Local Labo			ge		
Lower			Upp	ber			

PANITUMUMAB ADMINISTRATION

PANITUMUMAB DOSE CHANGE and DOSE WITHHELD CODES

DOSE CHANGE CODES

① DOSE CHANGE CODES:

01 Adverse Events **03** Dose administration error

02 Noncompliance **04** Per protocol

41 Dose reinstated42 Dose increase88 Other (*specify*)

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

88 Other (specify)

	:		
Danitumumah	Site No.	Subject ID No.	
	7		
AMC, 05/1 20050203		2	
AIVIO 734 20030203			
		S	

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

	sason for Specify DOSE CHANGE/ / Dose WITHHELD DOSE if "88 Other"		Package Lot Number	-
-	If "04 per protocol" is indicated for "Reason for Dose Change / Dose Withheld", indicate code	_	الم.،	
-	Reason for Jose Change A Jose Withheld	_	10N if "88 Othe	
	Total Volume Administered of Panitumumab plus Saline Solution (mL)		ASON FOR INFUSION INTERRUPTION if "88 Other"	
	Total Dose Administered (mg)		REASON FOR	
	Stop Time (24 hour clock)		Specify RE	
	Start Time (24 hour clock)			
	Year	_ _	If infusion was interrupted provide the Reason for Infusion Interruption	
	Date Day Month		If infusion was inter- rupted provide the total time of administration (not including interrup- tions)	
	Cycle		Was Infusion Interrupted?	

INFUSION REACTION

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

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

											ŀ					
₹ ₹	AMG 954 2	AMG 954 20050203	ab						is -	Site No.		7	Subject	Subject ID No.	-	
	2	21 20000200									1	-				
						Cycle	<u>e</u>	ļ							ပ	
s pic	ubject r	CHEMOTHERAPY ADMINISTRADIA subject receive chemotherapy? DNO DYes If yes, please enter details below:		RAPY If yes, plex	ADMIN ase enter det	ISTR ails below	ATIC	N-N	NISTRATION - FOLFOX Regimen	X Re	∍gim	en				
Line #	Study Day	Drug Name	Drug Type	Actual Total Dose Administered (mg)	se Freq.	Š	Start Date	9	Start Time (24 hour clock)	č	Stop Date	8	Stop Time (24 hour	Reason for Dose Change	If "04 Per protocol" is specified for "Reason for Dose Change", indicate code	
1	_	Oxaliplatin		////		<u> </u>) _	_ 	
2	_	Leucovorin	Heucovorin 1 racemic (dl-) 2 leucovorin 2			_	_			_	_			_		
က	_	5-FU Bolus		/////	ОТО	_	_	_		_				_		
4	_	5-FU Continuous Infusion			2		_			_				_		
5	2	Leucovorin	/-leucovorin 1 racemic (dl-) 2 leucovorin 2			_	_			_	_			_		
9	2	5-FU Bolus			010	_	_	_ _ _		_	_	_ _		_	_	
7	7	5-FU Continuous Infusion		/////	2	_				_				_		
© © ⊝	REQUEN Con TO One	① FREQUENCY CODES: CI Continuous infusion OTO One time only	© REASO 01 Adv 02 Nor 03 Dos	REASON FOR DOSE CHANG 01 Adverse event 02 Noncompliance 03 Dose administration error	 © REASON FOR DOSE CHANGE CODES: 01 Adverse event 02 Noncompliance 03 Dose administration error 	DES: Per protoc Other (spo	ES: Per protocol Other (specify below)		© "04 100 386 387	14	TOCOL" hange erapy rela	DOSE CHAN ted hematok ted non-hem	"04 PER PROTOCOL" DOSE CHANGE CODES: 100 Weight change 386 Chemotherapy related hematologic dose limiting toxicity 387 Chemotherapy related non-hematologic dose limiting toxicity	ing toxicity limiting toxi	icity	
Line #	#	Specify REASON	Specify REASON FOR DOSE CHANGE "88 Other"	IGE "88 Oth	her"	Line #		S	Specify REASON FOR DOSE CHANGE "88 Other"	ON FOR D	OSE CH	ANGE "88	Other"			
				ᆼ	CHEMOTI	HER/	γPΥ	THERAPY DELAY	≽							
		If chemotherapy \	If chemotherapy was administered, was it delayed?	, was it del	ayed? ₀□ No	_	If yes, p	lease ente	□ Yes If yes, please enter reason code:	ode:						
		Reason for Delay (record all that apply) ①		©REASON CODES:	ifie	se event			Spec	Specify REASON	88,	Other"				
		-	-		Protocol specified lab value Interventional therapy for metastases Other (specify)	lue metastase	SS									
	_				(6,,,,,,											

CYCLE 23 TO PROGRESSIVE DISEASE RADIOGRAPHIC ASSESSMENTS

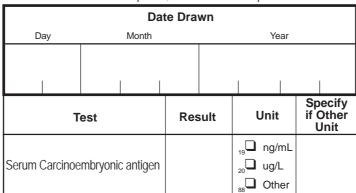
WEEK __

AMGEN Panitumumab	Site No).			Sub	oject	ID No			
AMG 954 20050203			2	1	[1	1			
				,	_	,	,	,	1/	/

Week ____

CEA

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



AMGEN Panitumumab	(///	Site I	No.				Sub	ject	ID No).			
AMG 954 20050203		1		ı	2	1		1			1		
												1//	

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	D	Oate of Pr	ocedure Year	Method of Assess- ment	Subsite Describe specific location	Lesion Site Code	Measurable Lesions * (mm) (Longest Diameter) Must be unidimensionally measurable Dimensions (mm)	Was Interventional Therapy Performed On This Lesion Since the Last Assessment?
01		1 1						
02								
03								
04								1
05								
06								
07								
08								
09								
10								1
					Sum of T Les	arget sions		
1			IENT CODES: uted Tomograph	y (CT)	04 MRI (NMR) 23 Spiral Computed	d Tomogra	phy (CT)	
00 01 02 03 08 09	ON SITE Lymph no Thyroid Oral cavi Pharynx Pelvis Breast Pleural e	ty	13 Lung paren 17 Pleura or pi 20 Liver 30 Bone 40 Chest wall 49 Pericardial 50 Spinal cord	leural wall effusion	51 Brain 69 Anus 61 Esophagus 70 Ascites 62 Stomach 73 Retroperiton 63 Pancreas 74 Peritoneum 64 Small intestine 79 Gall bladder 65 Colon 81 Kidney 66 Rectum 82 Heart	eum 8 8	4 Adrenal gland 5 Spleen 6 Skin 8 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'.

AMGEN Panitumumab	Site No.			Sı	ıbject I	D No).		
AMG 954 20050203		2	1	ı		ı	ı	ı	
V	/eek		·	·	·		·		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	Day	Date of Pro	oce	dure Year		Method of Assess- ment ①	Descr	Subsite ibe specific location	Lesi Sit Coo	e de		ions Yes	Dia	onges amete (mm)	if bod code i	onse cord ly site is NOT Bone"	Perfo On Les Sinc La Assess	ntional rapy ormed This sion e the
11		1 1			1													
12											 							
13											 							
14																		
15																		
16																		
17																		
18											 							
19																		
20																		
01 X 03 C	<-Ray	ASSESSM ional Comp IR)				ny (CT)		oiral Computed Tomo one Scan	ograph	y (C	CT)	60 88		nysical her <i>(sp</i>				
© 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 89 Pelvis 40 Chest wall 64 Small intestine 79 Gall bladder subsite above) 09 Breast 49 Pericardial effusion 65 Colon 81 Kidney 10 Pleural effusion 50 Spinal cord 66 Rectum 82 Heart © TUMOR REPONSE CODES: CR Complete response PD Progressive disease NA Not applicable																		
	Complete Stable di	e response sease				PD Prog UE Unab						Not a		able				

Specify if "88 Other" Method of Assessment

^{*} 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'.

AMGEN Panitumumab	Site No.	Subject ID No.
AMG 954 20050203		2,1, , , , , , , ,
		147

Week ____

TUMOR RESPONSE

Day	Date of Asses Month	sment Year	Overall Target Lesion Response Code ①	Overall Existing Non-Target Lesion Response Code ②	No Yes	Overall Tumor Response Code		
RESPOI CR Co PR Pa SD Sta PD Pr UE Ur NA No	LL TARGET LESION NSE CODES: omplete response artial response able disease ogressive disease able to evaluate ot applicable ot done	LESION RES CR Comple SD Stable PD Progre: UE Unable	ISTING NON-TARGET PONSE CODES: ete response disease ssive disease to evaluate blicable ne	OVERALL TUMOR CR Complete re PR Partial respo SD Stable disease PD Progressive UE Unable to ev ND Not done	esponse onse ase disease	ODES:		

	TUMOR RESPONSE IN	STRUCTIONS	
OVERALL	OVERALL	O I NOO I I ONO	OVERALL
TARGET LESIONS	NON-TARGET LESIONS	NEW LESIONS	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	Progressive Disease (PD)
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)	

SCR

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	ne er								Ass	chod of ess- ent	S Describe s	ubsit specifi		Lesi Sit Coo	e de	Longest I (m. (Record measuremen otherwise re For trui measurab record	m) actual nt if ≥ 5mm, ccord 5mm. y non- le lesions	
11		ı		l	I		ı	ı	1		I				ļ ,			1
12		i		ı	1		ı	i	1		1							ı
13		<u>'</u>		1	1		1	<u>'</u>	1		1							
14		1		1	1		<u> </u>		1		1							1
15				1	<u> </u>		1		<u> </u>		1							
16				1	<u> </u>		1		1		1							
17				<u> </u>	<u> </u>		<u> </u>				1							
18		1					<u> </u>											
19		1			<u> </u>		1											
20					<u> </u>		<u> </u>											
① MET	HOD	OF AS	POE	 	ENT	COL	LEC.					ļ.						
03	Conv	ventior (NMR)							(CT)		23 25	Spiral Computed Tor Bone Scan	nograp	bhy (CT)			al examination specify below	
② LES	IONS	ITEC	ODF	S:														
00 01 02 03 08 09	Lymp Thyro Oral Phar Pelvi Brea	oh noc oid cavity ynx s	de ,		17 20 30 40 49	Pleu Live Bon Che	ura o er ie est v icaro	or pl vall dial	chyma eural effusio	wall	61 62 63 64 65	Brain Esophagus Stomach Pancreas Small intestine Colon Rectum	70 73 74 79 81	Anus Ascites Retroperitoneum Peritoneum Gall bladder Kidney Heart	85 86 88	Sple Skir		subsite
Line	#									Spe	cify i	f "88 Other" Metl	nod o	f Assessment				

AMGEN Panitumumab	
AMG 954 20050203	

	Site No.	
	1 1	1

Subject ID No.

2,1

W__

TUMOR EVALUATION - NON-TARGET LESIONS

Week

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	D	Pate of Pro	ocedure Year	Method of Assess- ment ①	Subsite Describe specific location	Lesion Site Code	New Lesions	Longest Diameter* (mm)	Tumor Response (Record if body site code is NOT "04 Bone"	Was Interventional Therapy Performed On This Lesion Since the Last Assessment?
11		1 1						1 1		
12										
13										
14							-			
15							1			
16										
17										
18										
19										
20										
01 X 03 C	<-Ray	onal Comp	ENT CODES: uted Tomograp	hy (CT)	23 Spiral Computed Tomo25 Bone Scan	ography (0	CT) 66	Physical Exa Other (special		
LESION SITE CODES:00 Lymph node13 Lung parenchyma51 Brain69 Anus84 Adrenal gland01 Thyroid17 Pleura or pleural wall61 Esophagus70 Ascites85 Spleen02 Oral cavity20 Liver62 Stomach73 Retroperitoneum86 Skin03 Pharynx30 Bone63 Pancreas74 Peritoneum88 Other (specify in08 Pelvis40 Chest wall64 Small intestine79 Gall bladdersubsite above)09 Breast49 Pericardial effusion65 Colon81 Kidney10 Pleural effusion50 Spinal cord66 Rectum82 Heart									in	
CR C	3 TUMOR REPONSE CODES: CR Complete response PD Progressive disease NA Not applicable SD Stable disease UE Unable to evaluate ND Not Done									

Line #	Specify if "88 Other" Method of Assessment

^{*} 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'.