Core Variables - Variables common to all data sets						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
STUDYID	Study ID	Char / 20		CRF or Protocol	x	
SITEID	Site ID	Char / 10		CRF		Site ID values de-identified
SUBJID	Subject ID	Char / 11		CRF or Derived	x	Subject ID values de-identified
AGE	Age in Years at Screening	Num	3.	Derived		floor((randdt-birthdt)/365.25)
SEXCD	Sex Code	Char / 1	Follow SEX.	CRF		
SEX	Sex	Char / 10		Derived		Decode of SEXCD
RACCATCD	Race Category Code	Num	8., follow RACE.	Derived		Assign 88 (other) to any non-missing value other than 1 (caucasian).
RACCAT	Race Category	Char / 60		Derived		Decode of RACCATCD
TRTDOSE	Treatment Dose (mg/kg)	Num	8.2	Derived		As randomized or enrolled. Leave blank if subject was not randomized/enrolled. Hardcode to 6 if randomized to pmab, 0 otherwise
TRTFRQCD	Treatment Frequency Code	Char / 4	Follow $FREQ.	Derived		As randomized or enrolled. Leave blank if subject was not randomized/enrolled.
TRTFREQ	Treatment Frequency	Char / 20		Derived		Decode of TRTFRQCD
TRTCD	Assigned Treatment Code	Num	8., follow TRT.	CRF or raw data or rand.		As randomized or enrolled. TRTCD = 0 must be used for Placebo only. Leave blank if subject was not randomized/enrolled.
TRT	Assigned Treatment	Char / 60		Derived		Decode of TRTCD.
ATRTCD	Actual Treatment Code	Num	8., follow TRT	Derived		Notes: (1) If a subject is exposed to the assigned treatment then ATRTCD will be identical to TRTCD. (2) If a subject was not exposed to any study treatment, leave blank. if any Pmab dose then assign to Pmab arm otherwise to non-Pmab arm
ATRT	Actual Treatment	Char / 60		Derived		Decode of ATRTCD
REGMNCD	Assigned Chemo Regimen Code	Num	8.2, follow CHREG.	CRF/Derived		
REGMN	Assigned Chemo Regimen	Char / 60		Derived		Decode of REGMNCD
AREGMNCD	Actual Chemo Regimen Code	Num	8.2, follow CHREG.	CRF or Derived		REGIMEN.REGIMEN where EVENT_ID=week 0
AREGMN	Actual Chemo Regimen	Char / 60		Derived		Decode of AREGMNCD
CHEMOCD	Assigned Chemo Drug Code	Num	8., follow TRT.	CRF or Derived		Based on RAND.REGIMEN, assign 78 if oxaliplatin-containing regimen, 72 if irinotecan-containing regimen
CHEMO	Assigned Chemo Drug	Char / 60		Derived		Decode of CHEMOCD
CHEMOICD	IVRS Assigned Chemo Drug Code	Num	8., follow TRT.	Raw		(40249) if regrand='0' then assign 78, if regrand='1' then 72;
CHEMOI	IVRS Assigned Chemo Drug	Char / 60		Derived		
ACHEMOCD	Actual Chemo Drug Code	Num	8., follow TRT.	Derived		From REGIMEN at week 0, map to either oxaliplatin or irinotecan from Appendix E in Protocol
ACHEMO	Actual Chemo Drug	Char / 60		Derived		Decode of ACHEMOCD
ACHEMMCD	Actual Chemo Drug Code - Modified	Num	8., follow TRT.	Derived		From REGIMEN.REGIMEN at week 0, map to either oxaliplatin or irinotecan from Appendix E in Protocol. If no chemo drug received on week0, then use assigned chemo from the randomization page
ACHEMM	Actual Chemo Drug - Modified	Char / 60		Derived		Decode of ACHEMOCD
FCHEMOCD	First Chemo Drug Received Code	Num	8., follow TRT.	Derived		Assign 78 if first chemo drug is oxaliplatin (dose > 0), and 72 if first chemo drug is irinotecan (dose > 0)
FCHEMO	First Chemo Drug Received	Char / 60		Derived		Decode of FCHEMOCD
B_LESNM	Number of BL Lesion-Total	Num	8.	Derived		sum (B_LESNMT, B_LESNMN)
B_LESNMT	Number of BL Lesion-Target	Num	8.	Derived		Total number of target lesions from screen page.
B_LESNMN	Number of BL Lesion-Non-target	Num	8.	Derived		Total number of non-target lesions from screen page
B_METANM	Number of BL Metas Site	Num	8.	CRF or Derived		Baseline records only
B_METACT	Number of BL Metas Site (cat)	Char / 4		Derived		From B_METANM, group into 0, 1 and > 1

Core Variables - Variables common to all data sets						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
BMETACTI	IVRS Number of BL Metas Site (cat)	Char / 4		raw data		
FSTOXDS	First Oxaliplatin Adj-dose (mg/m^2)	Num	8.2	Derived		First adj-dose of Oxaliplatin (week 0)
FSTIRDS	First Irinotecan Adj-dose (mg/m^2)	Num	8.2	Derived		First adj-dose of Irinotecan (week 0)
DURSURG	Dur. Dis. Diag to Surg (month)	Num	8.2	Derived		(last surg/adjuvant chemo date-diagdt)/30.5, which ever the last for surg/adjuvant, where chemo date is the end date of the prior chemo.
PRADJYN	Prior Adjuvant Therapy?	Char / 1	Y, N	Derived		From Prior chemo page, adjuvant or neo-adjucant check box/treatment line.
PRADJICD	IVRS Prior Adjuvant Therapy Code	Num	3., (0, 1), follow YESNO.	raw data		
PRADJI	IVRS Prior Adjuvant Therapy ?	Char / 1	Y, N	Derived		
B_LDHYN	Baseline LDH >= 1.5 Times Upper Limit?	Char / 1	Y, N	Derived		Derived as 'Y' if baseline LDH value is greater than or equal to 1.5*upper range, and 'N' otherwise. Leave missing if no baseline LDH available
TRTDUR	Treatment Duration	Num		Derived		LDOSDT - FDOSDT + 1
B_ECOGCD	Baseline ECOG Performance Status Code	Num	3., follow ECOG.	Derived		Most recent measurement on or before study day 1 (per SAP). If study day 1 cannot be defined for a subject (eg, not enrolled or not dosed), take the last measurement for that subject. If the assessment date is missing, nominal visits of Screening are viable candidates. Use screening ecog score.
B_ECOG	Baseline ECOG Performance Status	Char / 42		Derived		Decode of B_ECOGCD
BECOGICD	IVRS ECOG Performance Status Code	Num	3., follow ECOG.	Derived or Raw		IVRS ECOG Status at randomization
B_ECOGI	IVRS ECOG Performance Status	Char / 42		Derived		Decode of BECOGICD
DIAGTYCD	Primary Tumor Diagnosis Code	Num	8., follow DIAGTYPE.	CRF		
DIAGTYPE	Primary Tumor Diagnosis	Char / 40		Derived		Decode of DIAGTYCD
DIAGICD	IVRS Primary Tumor Diagnosis Code	Num	8., follow DIAGTYPE.	raw data		
DIAGI	IVRS Primary Tumor Diagnosis	Char / 40		Derived		Decode of DIAGICD
RESPSTAT	Response on Study?	Char / 1	Y, N	Derived		At least one response (CR/PR) at week 12 assessment?
PDYN	Protocol Deviation?	Char / 1	Y, N	Derived		Set to Y if any of the above applicable PD* variables(except PDSTRAT for 141 per Sam Suzuki) is Y, N otherwise.
PDADEN	Not Having Adenocarcinoma	Char / 1	Y, N	Derived		From eligibility CRF page (102 for 60141)
PDICSIG	IC Not Obtained	Char / 1	Y, N	Derived		From eligibility CRF page, Y if ELIGNO=112
PDICMIS	IC Not Signed	Char / 1	Y, N	Derived		(40249, 50184) from eligibility CRF page, Y if ELIGNO=111/?
PDPROMED	Proscribed Medication?	Char / 1	Y, N	Derived		Derived from all criteria listed in SAP and specified in the Addenda
KRASCD	Kras Result Code	Num	2., follow KRAS.	Derived		Assign 1 if KRAS.MUTATION='No', 2 if KRAS.MUTATION='Yes' and 88 if KRAS.MUTATION='FAIL'. If both a valid result (mutation no or yes) and failed result exist, use the valid result. If there exist both No and Yes mutation values, then set to missing
KRAS	Kras Result	Char / 20		Derived		decode of KRASCD
EVALITT	Included in Subjects Enrolled Set?	Char / 1	Y, N	Derived		See study SAP for definition.
EVALPP	Included in Per Protocol Set?	Char / 1	Y, N	Derived		See study SAP for definition.
EVALKEA	Incl in K-ras Efficacy Analysis Set?	Char / 1	Y, N	Derived		EVALITT ='Y' & KRASCD in (1, 2) & FDOSDT ne .
EVALKSA	Incl in K-ras Safety Analysis Set?	Char / 1	Y, N	Derived		Same as EVALKEA
EVALKUE	Incl in K-ras Unevaluable Set?	Char / 1	Y, N	Derived		EVALITT='Y' and EVALKEA ne 'Y'

A_EENDPT.xpt - Efficacy Endpoint Analysis File, One record per subject per period, SAF						
Variable Name	**Variable Label**	**Type / Length**		**Origin**	**Key**	**Comments**
<Core Variables>						
LASTCRDY	Day of Last PD-Free Relative to 1st Dose	Num	8.	Derived		LASTCRDT - FDOSDT + 1
R12LR	Resp at 12 wks (Invest, RECIST)?	Num	3., (0, 1)	Derived		Set to 1 if R12LRCA=CR or PR, set to 0 otherwise
R12LRCA	Resp at 12 wks (Invest, RECIST) - Cat.	Char / 2	CR,PR,SD,PD,UE,ND	Derived		If PDLR=1 and PDDYLR <=98, then PD. If FDOSDT is missing then set R12LRCA to missing.
R12LRSD	Resp at 12 wks (Invest, RECIST)-SD?	Num	3., (0, 1)	Derived		Set to 1 if R12LRCA=CR or PR or SD, 0 otherwise
R12CR	Resp at 12 wks (Central, RECIST)?	Num	3., (0, 1)	Derived		Set to 1 if R12CRCA=CR or PR, otherwise set to 0.
R12CRCA	Resp at 12 wks (Central, RECIST) - Cat.	Char / 2	CR,PR,SD,PD,UE,ND	Derived		If PDCR=1 and PDDYCR <=98, then PD. If FDOSDT is missing then set R12LRCA to missing.
R12CRSD	Resp at 12 wks (Central, RECIST)-SD?	Num	3., (0, 1)	Derived		Set to 1 if R12LRCA=CR or PR or SD, 0 otherwise
ROSCR	Resp, on Study (Central, RECIST)?	Num	3., (0, 1)	Derived		Set to 1 if ROSCRCA=CR or PR, otherwise set to 0.
ROSLR	Resp, on Study (Invest, RECIST)?	Num	3., (0, 1)	Derived		Set to 1 if ROSLRCA=CR or PR, otherwise set to 0.
ROSLRCA	Resp, on Study (Invest, RECIST) - Cat.	Char / 2	CR,PR,SD,PD,UE,ND	Derived		See amg954_vardef_addenda.doc (section 7: How to Classify Response) for algorithm
RLR	Resp on FLT (Invest, RECIST)	Num	3., (0, 1)	Derived		Set to 1 if any investigator assessed RESPEVAL.RSRESPCD in (CR,PR) while on FLT, otherwise set to 0
RCR	Resp on FLT (Invest, RECIST)	Num	3., (0, 1)	Derived		Set to 1 if any central assessment RESPEVAL.RSRESPCD in (CR,PR) while on FLT, otherwise set to 0
RDURCR	Resp Dur (Central, RECIST)	Num	6.	Derived		Set to PDDYCR - RDYCR+1 if central RECIST PR/CR (ROSCR=1), otherwise leave missing.
RDURWKCR	Resp Dur (Central, RECIST)-Wks	Num	6.	Derived		RDURCR/7
RDURCRC	Resp Dur (Central, RECIST) Cens/Obs	Num	3., (0, 1, .)	Derived		Set to central RECIST progression indicator (PDCR) if central RECIST PR/CR (ROSCR=1), otherwise leave missing.
RDURLR	Resp Dur (Invest, RECIST)	Num	6.	Derived		Set to PDDYLR – RDYLR+1 if any investigator RECIST PR/CR (RLR=1), otherwise leave missing.
RDURWLR	Resp Dur (Invest, RECIST)-Wks	Num	6.	Derived		RDURLR/7
RDURLRC	Resp Dur (Invest, RECIST) Cens/Obs	Num	3., (0, 1, .)	Derived		Set to PDLR if any investigator RECIST PR/CR (RLR=1), otherwise set to missing.
RDYCR	Resp Day (Central, RECIST)	Num	6.	Derived		If central RECIST PR/CR (ROSCR=1), select the earliest post-baseline day (DOSREFDY-1 for other studies) where RESPEVAL.RSTYPE=CENTRAL and RESPEVAL.RSRESP=CR/PR and RESPEVAL.RSCONFYN=Y. If no central RECIST PR/CR (ROSCR=0), if the last evaluable (not UE ND) post baseline (central) radiology assessment=SD then calculate the study day relative to reference day (DOSREFDY-1 for other studies); otherwise, calculate the maximum value of RDYCR for all subjects where ROSCR=1 and add 1 to that value.
RDYLR	Resp Day (Invest, RECIST)	Num	6.	Derived		RESPEVAL.rsasmdt-DISPOSIT.RANDDT+1 where rsasmdt is the first RSRESPCD in (CR,PR) for an investigator assessment while on FLT. If no CR/PR on FLT, leave missing.
PFSDYCR	PFS Day (Central, RECIST) (62079) PFS Day (Central, WHO) (62080) PFS Day (Central, WHO)	Num	6.	Derived		If central modified RECIST progression or death (PFSCR=1), set to the minimum of PDDYCR and DTHDY if both PDCR and DTH are 1. Otherwise, set to PDDYCR if PDCR=1 and DTH=0. Otherwise, set to DTHDY if PDCR=0 and DTH=1. If no central RECIST progression and no death (PFSCR=0), let PFSDYCR=PDDYCR.
PFSMTCR	PFS Month (Central, RECIST)	Num	6.	Derived		12*PFSDYCR/365.25

A_EENDPT.xpt - Efficacy Endpoint Analysis File, One record per subject per period, SAF						
Variable Name	**Variable Label**	**Type / Length**		**Origin**	**Key**	**Comments**
PFSCR	PD on Study (Central, RECIST) or Death	Num	3., (0, 1)	Derived		Set to 1 if any central modified RECIST progression (RESPEVAL.RSTYPE=CENTRAL and RESPEVAL.RSRESP=PD) for any post-baseline record (PHASECD=> 10)or death (DTH=1), otherwise set to 0.
PFSDYLR	PFS Day (Invest, RECIST)	Num	6.	Derived		If investigator RECIST progression or death (PFSLR=1), set to the minimum of PDDYLR and DTHDY if both PDLR and DTH are 1. Otherwise, set to PDDYLR if PDLR=1 and DTH=0. Otherwise, set to DTHDY if PDLR=0 and DTH=1. If no investigator RECIST progression and no death (PFSLR=0), set to DISPOSIT.LASTOSDT-DISPOSIT.RANDDT+1.
PFSMTLR	PFS Month (Invest, RECIST)	Num	6.	Derived		12*PFSDYLR/365.25
PFSLR	PD on Study (Invest, RECIST) or Death	Num	3., (0, 1)	Derived		Set to 1 if investigator RECIST progression (PDLR=1) or death (DTH=1), otherwise set to 0.
PDDYCR	PD Day (Central, RECIST)	Num	6.	Derived		
PDMTCR	PD Month (Central, RECIST)	Num	6.	Derived		12*PDDYCR/365.25
PDCR	PD (Central, RECIST) on Study	Num	3., (0, 1)	Derived		Set to 1 if RESPEVAL.RSTYPE=CENTRAL and (RESPEVAL.RSRESP=PD or RSRESP=CR followed by RSRESP=PR) for any post-baseline record or if study is not 50181, 50203, 62079 or 62080 and DEATH.DTCAUS is disease progression. Otherwise, set to 0.
PDDYLR	PD Day (Invest, RECIST)	Num	6.	Derived		
PDMTLR	PD Month (Invest, RECIST)	Num	6.	Derived		
PDLR	PD (Invest, RECIST) on Study	Num	3., (0, 1)	Derived		Set to 1 if (LESION.LSDT (where VISIT='PROGRESS') is non missing or (RESPEVAL.RSTYPE=LOCAL and RESPEVAL.RSRESP=PD for any post-baseline record (phasecd >= 10)) or if DEATH.DTCAUS is disease progression
DTHDY	Death Day	Num	6.	Derived		
DTHMT	Death Month	Num	6.	Derived		12*DTHDY/365.25
DTH	Death	Num	3., (0, 1)	Derived		Set to 1 if DEATH.DTHDTV is present else set to 0.
TFAILDY	Treatment Failure Day	Num	6.	Derived		If DISPOSIT.DECISDT is present then:If (DISPOSIT.EOTACD=15 and subject appears in SURGHIST with PHASECD=30) then TFAILDY=min(SURGHIST.VISITDT where PHASECD=30)-DISPOSIT.RANDDT+1. Else If (DISPOSIT.EOTACD=15 and the last RESPEVAL.RSTYPE=LOCAL and PHASECD=30 has RESPEVAL.RSRESPCD=2) then TFAILDY=DISPOSIT.DECISDT-DISPOSIT.RANDDT+1.Otherwise if DISPOSIT.DECISDT is present then TFAIL=min(DISPOSIT.DECISDT, min(RESPEVAL.RASMDT where RESEVAL.RSRESP=PD),FUP.FUPDDT, DEATH.DTHDTI) TFAILDY=FAIL - DISPOSIT.RANDDT+1. (where fail=min(decisdt, dthdti, pddt, fupddt)) else If DISPOSIT.DECISDT is NOT present then: TFAILDY=DISPOSIT.LASTOSDT - DISPOSIT.RANDDT+1
TFAILMT	Treatment Failure Month	Num	6.	Derived		12*TFAILDY/365.25

A_EENDPT.xpt - Efficacy Endpoint Analysis File, One record per subject per period, SAF						
Variable Name	**Variable Label**	**Type / Length**		**Origin**	**Key**	**Comments**
TFAIL	Treatment Failure	Num	3., (0, 1)	Derived		If DISPOSIT.DECISDT is present then: If (DISPOSIT.EOTACD=15 and subject appears in SURGHIST with PHASECD=30) OR (DISPOSIT.EOTACD=15 and the last RESPEVAL.RSTYPE=LOCAL and PHASECD=30 has RESPEVAL.RSRESPCD=2) then set to 0. Otherwise if DISPOSIT.DECISDT is present then Set to 1. If DISPOSIT.DECISDT is NOT present, then set to 1 if DISPOSIT.EOSDTV is not missing, else set to 0.
SDDURCR	SD Dur (Central, RECIST)	Num	6.	Derived		Set to central RECIST day of disease progression (PDDYCR) if best central RECIST assessement is SD (ROSCRCA=SD), otherwise leave missing.
SDDURCRC	SD Dur (Central, RECIST) Cens/Obs	Num	3., (0, 1, .)	Derived		Set to central RECIST progression indicator (PDCR) if best central RECIST assessment is SD (ROSCRCA=SD), otherwise leave missing. (20408) See amg954_vardef_addenda.doc (section 17: 20020408 Primary and Sensitivity Efficacy Analyses)
SDDURLR	SD Dur (Invest, RECIST)	Num	6.	Derived		Set to investigator RECIST day of disease progression (PDDYLR) for the subset of subjects who were assessed a tumor response of SD at week 12 by the investigator while on FLT (R12LRCA=SD). Otherwise set to missing.
SDDURWLR	SD Dur (Invest, RECIST)-Wks	Num	6.	Derived		SDDURLR/7
SDDURWCR	SD Dur (Central, RECIST)-Wks	Num	6.	Derived		SDDURCR/7
SDDURLRC	SD Dur (Invest, RECIST) Cens/Obs	Num	3., (0, 1, .)	Derived		Set to investigator RECIST progression indicator (PDLR) if best investigator RECIST assessment is SD (ROSLRCA=SD), otherwise leave missing.
DTH30	Death w/in 30 day,	Num	3., (0, 1)	Derived		Set to 1 if (DEATH.DTHDTI - LASTTXDT +1 <= 30), otherwise set to 0.
DTHDY30	Death Day, w/in 30 Day Last dose	Num	6.	Derived		if death (DTH30=1) then DTHDY30 is: DEATH.DTHDTI - DISPOSIT.RANDDT+1; Else if DEATH=1 then censor at last date of contact prior to DTHDY; else censor at DISPOSIT.LASTOSDT-DISPOSIT.RANDDT+1.
DTHMT30	Death Month, w/in 30 Day Last Dose	Num	6.	Derived		12*DTHDY30/365.25
PDCR30	PD w/in 30 Day of Last Dose, Cent.	Num	3., (0, 1)	Derived		Set to 1 (if PDCR=1 and PDDYCR<=(LASTTXDY+30)); Otherwise, set to 0.
PDDYCR30	PD Day w/ 30 Day, Cent.	Num	6.	Derived		If PDCR30=1, PDDYCR30=PDDYCR; else if PDCR=1, then censor at the last central tumor assessment prior to PDDYCR; else censor at max(LASTCRDT, RANDDT) -DISPOSIT.RANDDT+1.
PDMTCR30	PD Month w/ 30 Day, Cent.	Num	6.	Derived		12*PDDYCR30/365.25
PDLR30	PD w/in 30 Day of Last Dose, Local	Num	3., (0, 1)	Derived		Set to 1 (if PDLR=1 and PDDYLR<=(LASTTXDY+30)); Otherwise, set to 0.
PDDYLR30	PD Day w/ 30 Day, Local	Num	6.	Derived		If PDLR30=1, PDDYLR30=PDDYLR; else if PDLR=1 then censor at last date of contact prior to PDDYLR; else censor at max(LASTOSDT, RANDDT) -DISPOSIT.RANDDT+1.
PDMTLR30	PD Month w/ 30 Day, Local	Num	6.	Derived		12*PDDYLR30/365.25
PFSCR30	PFS w/in 30 Day of Last Dose, Cent.	Num	3., (0, 1)	Derived		Set to 1 if PFSCR=1 and PFSDYCR<=(LASTTXDY+30); Otherwise, set to 0.

A_EENDPT.xpt - Efficacy Endpoint Analysis File, One record per subject per period, SAF						
Variable Name	**Variable Label**	**Type / Length**		**Origin**	**Key**	**Comments**
PFSDCR30	PFS Day w/ 30 Day, Cent.	Num	6.	Derived		If PFSCR30=1, PFSDCR30=PFSDYCR; else if PFSCR=1 then censor at last central tumor assessment prior to PFSDYCR; else censor at max(LASTCRDT, RANDDT) -DISPOSIT.RANDDT+1.
PFSMCR30	PFS Month w/ 30 Day, Cent.	Num	6.	Derived		12*PFSDCR30/365.25
PFSLR30	PFS w/in 30 Day of Last Dose, Local	Num	3., (0, 1)	Derived		Set to 1 if PFSLR=1 and PFSDYLR<=(LASTTXDY+30); Otherwise, set to 0.
PFSDLR30	PFS Day w/ 30 Day, Local	Num	6.	Derived		If PFSLR30=1, PFSDLR30=PFSDYLR; else if PFSLR=1 then censor at last date of contact prior to PFSDYLR; else censor at max(LASTOSDT, RANDDT) -DISPOSIT.RANDDT+1.
PFSMLR30	PFS Month w/ 30 Day, Local	Num	6.	Derived		12*PFSDLR30/365.25
PDCRND	PD (Not From Death), Cent.	Num	3., (0, 1)	Derived		Set to 1 if RESPEVAL.RSTYPE=CENTRAL and RESPEVAL.RSRESP=PD for any post-baseline (and PHASECD=> 10) record, Otherwise, set to 0.
PDDYCRND	PD (Not From Death) Day, Cent.	Num	6.	Derived		If PDCRND=1, PDDYCRND=PDDYCR; else censor at max(LASTCRDT, RANDDT) -DISPOSIT.RANDDT+1.
PDMTCRND	PD (Not From Death) Month, Cent.	Num	6.	Derived		12*PDDYCRND/365.25

A_SENDPT.xpt - Safety Endpoint Analysis File, One record per subject per record type, SAF						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						Retain only subjects who are in the safety evaluable analysis set. In the definitions below, "on-study" refers to events with phase code >=20 and <60 and occurring prior to cutoff, if applicable. Note: Skin toxicity and (skin) rash are interchangeable terms.
INFREAC	Any Infusion Reaction	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AEINFYN is Y, otherwise set to N.
AE34	Any Grade 3 or higher AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AESEVCD is 3 or higher, otherwise set to N.
AE4	Any Grade 4 AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AESEVCD is 4, otherwise set to N.
AESER	Any Serious AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AESER is Y, otherwise set to N.
AEREL	Any Tx-related AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AEREL is Y, otherwise set to N.
AEREL34	Any Tx-related Grade 3 or higher AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AEREL is Y and AE.AESEVCD is 3 or higher, otherwise set to N.
AEREL4	Any Tx-related Grade 4 AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AEREL is Y and AE.AESEVCD is 4, otherwise set to N.
AERELSER	Any Tx-related Serious AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AEREL is Y and AE.AESER is Y, otherwise set to N.
AETXDIS	Dose Discontinued Due to Any AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AEACT06 is Y, otherwise set to N.
AEBEVDIS	Bmab Discontinued Due to Any AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AEACT09 is Y, otherwise set to N.
AETRTDIS	Ended 1st Line treat Due to Any AE	Char / 1	Y, N	Derived		Set to Y if any on-study occurrence of AE.AEACT85 is Y, otherwise set to N.
DEATH	Died on Study	Char / 1	Y, N	Derived		Set to Y if DEATH.DTHDTI is not missing, otherwise set to N.
DEATH60	Died <= 60 Days After 1st Dose	Char / 1	Y, N	Derived		Set to Y if DEATH.DTHDTI-COREVAR.FDOSDT+1 <= 60, otherwise set to N.
DEATH30	Died <= 30 Days After Last Dose Stop	Char / 1	Y, N	Derived		First calculate the last drug date by taking the MAX (stop dates of all chemo components, start dates of pmab), then Set to Y if DEATH.DTHDTI-this last drug date+1 <= 30, otherwise set to N.
DTHREL	Death Related to Study Drug	Char/ 1	Y,N	Derived		libcrt.ae where aesevcd = 5 and aerel = 'Y' or libcrt.death where dtcauscd = 16
NUMINF	Number of Infusions	Num	6.	Derived		Number of infusions in EXPOSURE where pmab dose > 0, count as one infusion for interrupted doses.
NUMBINF	Number of Bmab Infusions	Num	6.	Derived		Number of infusions in EXPOSURE where Bmab dose > 0
NUMOXINF	Number of OX Infusions	Num	6.	Derived		Number of infusions in EXPOSURE where OX dose > 0
NUMIRINF	Number of IR Infusions	Num	6.	Derived		Number of infusions in EXPOSURE where IR dose > 0
NUMALINF	Number of Cycle of 1st-line Treat.	Num	6.	Derived		Number of cycles where any component dose > 0.
NUMFBINF	Number of B 5-FU Infusions	Num	6.	Derived		Number of infusions in EXPOSURE where Bolus 5-FU dose > 0
NUMFIINF	Number of I 5-FU Infusions	Num	6.	Derived		Number of infusions in EXPOSURE where Infusion 5-FU dose > 0
AINFTM	Avg Minutes of Infusion Delivered	Num	8.1	Derived		Only for pmab, (sum of EXDURMN)/NUMINF
AINFHR	Avg Hours of Infusion Delivered	Num	8.1	Derived		AINFTM/60, only for pmab records
CDOSE	Cumulative Dose (mg)	Num	8.2	Derived		Sum of EXPOSURE.DOSE for panitumumab. If the sum is 0 or missing, set to missing.)
ADOSE	Avg Dose Delivered (mg/inf)	Num	8.2	Derived		Only for pmab, CDOSE/NUMINF
CWDOSE	Cumulative Wt-adj Dose (mg/kg)	Num	8.2	Derived		For panitumumab, sum of EXPOSURE.WDOSE. If the sum is 0 or missing, then set to missing.
AWDOSE	Avg Wt-adj Dose Delivered (mg/kg/inf)	Num	8.2	Derived		Only for pmab, CWDOSE/NUMINF
BCDOSE	Cumulative Bmab Dose (mg)	Num	8.2	Derived		see definition for CDOSE
BADOSE	Avg Bmab Dose Delivered (mg/inf)	Num	8.2	Derived		see definition for ADOSE
BCWDOSE	Cumulative Wt-adj Bmab Dose (mg/kg)	Num	8.2	Derived		see definition for CWDOSE

A_SENDPT.xpt - Safety Endpoint Analysis File, One record per subject per record type, SAF						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
BAWDOSE	Avg Wt-adj Bmab Delivered (mg/kg/inf)	Num	8.2	Derived		see definition for AWDOSE
OXCDOSE	Cumulative OX Dose (mg)	Num	8.2	Derived		see definition for CDOSE
OXADOSE	Avg OX Dose Delivered (mg/inf)	Num	8.2	Derived		see definition for ADOSE
OXCWDOSE	Cumulative BSA-adj OX Dose (mg/m^2)	Num	8.2	Derived		see definition for IRCWDOSE
OXAWDOSE	Avg BSA-adj OX Delivered (mg/m^2/inf)	Num	8.2	Derived		see definition for IRAWDOSE
IRCDOSE	Cumulative IR Dose (mg)	Num	8.2	Derived		see definition for CDOSE
IRADOSE	Avg IR Dose Delivered (mg/inf)	Num	8.2	Derived		see definition for ADOSE
IRCWDOSE	Cumulative BSA-adj IR Dose (mg/m^2)	Num	8.2	Derived		Only for Pmab: sum of EXPOSURE.BSADOSE. If the sum is 0 or missing, then set to missing.
IRAWDOSE	Avg BSA-adj IR Delivered (mg/m^2/inf)	Num	8.2	Derived		Divide IRCWDOSE by the number of records with values greater than 0 in EXPOSURE.BSADOSE. If IRCWDOSE is missing, then set IRAWDOSE to missing.
FBCDOSE	Cumulative B 5-FU Dose (mg)	Num	8.2	Derived		see definition for CDOSE
FBADOSE	Avg B 5-FU Dose Delivered (mg/inf)	Num	8.2	Derived		see definition for ADOSE
FBCWDOSE	Cumu. BSA-adj B 5-FU Dose (mg/m^2)	Num	8.2	Derived		see definition for IRCWDOSE
FBAWDOSE	Avg BSA-adj B 5-FU Deliv. (mg/m^2/inf)	Num	8.2	Derived		see definition for IRAWDOSE
FICDOSE	Cumulative I 5-FU Dose (mg)	Num	8.2	Derived		see definition for CDOSE
FIADOSE	Avg I 5-FU Dose Delivered (mg/inf)	Num	8.2	Derived		see definition for ADOSE
FICWDOSE	Cumu. BSA-adj I 5-FU Dose (mg/m^2)	Num	8.2	Derived		see definition for IRCWDOSE
FIAWDOSE	Avg BSA-adj I 5-FU Deliv. (mg/m^2/inf)	Num	8.2	Derived		see definition for IRAWDOSE
DUREXP	Duration of Exposure	Num	6.	Derived		COREVAR.LDOSDT-COREVAR.FDOSEDT+14;
EXPWK	Duration of Exposure (weeks)	Num	8.1	Derived		DUREXP/7; duration of first line treatment
BDURWK	Bmab Duration of Exposure (weeks)	Num	6.	Derived		(last non-zero Bmab start date- first non-zero Bmab start date +14)/7
BDSINT	Bmab Avg. Q2W Dose Intensity	Num	8.1	Derived		(BCWDOSE/BDURWK)*2
BDSINTR	Bmab Avg. Relative Dose Intensity (%)	Num	8.1	Derived		(BDSINT/5)*100, where 5 is the planned dose for Bmab, either be week 0 dose if present or 5.
IPDURWK	Pmab Duration of Exposure (weeks)	Num	6.	Derived		see definition for BDURWK
IPDSINT	Pmab Avg. Q2W Dose Intensity	Num	8.1	Derived		see definition for BDSINT
IPDSINTR	Pmab Avg. Relative Dose Intensity (%)	Num	8.1	Derived		see definition for BDSINTR, use 6 for planned dose
OXDURWK	OX Duration of Exposure (weeks)	Num	6.	Derived		see definition for BDURWK
OXDSINT	OX Avg. Q2W Dose Intensity	Num	8.1	Derived		see definition for BDSINT
OXDSINTR	OX Avg. Relative Dose Intensity (%)	Num	8.1	Derived		see definition for BDSINTR, or planned dose, modified FOLFOX 6, bFOL; use 100 for FOLFOX5 FOLFOX 6; use 130 for FOLFOX 7 from SAP, where regimen should be determined by week 0 regimen code if possible, use the first dose for regimen 'Other' types
IRDURWK	IR Duration of Exposure (weeks)	Num	6.	Derived		see definition for BDURWK
IRDSINT	IR Avg. Q2W Dose Intensity	Num	8.1	Derived		see definition for BDSINT
IRDSINTR	IR Avg. Relative Dose Intensity (%)	Num	8.1	Derived		see definition for BDSINTR, or planned dose, use 180 for FOLFIRI, DOUILLARD, where regimen should be determined by week 0 regimen code if possible, use the first dose for regimen 'Other' types
FBDURWK	B 5-FU Duration of Exposure (weeks)	Num	6.	Derived		see definition for BDURWK
FBDSINT	B 5-FU Avg. Q2W Dose Intensity	Num	8.1	Derived		see definition for BDSINT

A_SENDPT.xpt - Safety Endpoint Analysis File, One record per subject per record type, SAF						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
FBDSINTR	B 5-FU Avg. Relative Dose Intensity (%)	Num	8.1	Derived		see definition for BDSINTR, or planned dose, use 800 for FOLFOX4 (50203), 5, use 400 for FOLFOX6, Modified FOLFOX 6, FOLFOX7, FOLFIRI, DOUILARD,use 500 for bFOL; where regimen should be determined by week 0 regimen code --SEE SAP FOR EXACT and DETAILS
FIDURWK	I 5-FU Duration of Exposure (weeks)	Num	6.	Derived		see definition for BDURWK
FIDSINT	I 5-FU Avg. Q2W Dose Intensity	Num	8.1	Derived		see definition for BDSINT
FIDSINTR	I 5-FU Avg. Relative Dose Intensity (%)	Num	8.1	Derived		see definition for BDSINTR, or planned dose, use 2400 or 1st dose if 1st dose > 2400 for FOLFOX6, Modified FOLFOX 6, FOLFOX7, FOLFIRI, DOUILARD, use 500 for bFOL; where regimen should be determined by week 0 regimen code --SEE SAP FOR EXACT and DETAILS
IPDLYPC	Prop. of IP Dose Delayed	Num	8.2	Derived		IPDLYNM/NUMINF
BDLYNM	Number of Bmab Dose Delayed	Num	3.	Derived		See definition for IPDLYNM
BDLYPC	Prop. of Bmab Dose Delayed	Num	8.2	Derived		BDLYNM/NUMBINF
OXDLYNM	Number of OX Dose Delayed	Num	3.	Derived		see definition for IPDLYNM
OXDLYPC	Prop. of OX Dose Delayed	Num	8.2	Derived		OXDLYNM/NUMOXINF
IRDLYNM	Number of IR Dose Delayed	Num	3.	Derived		See definition for IPDLYNM
IRDLYPC	Prop. of IR Dose Delayed	Num	8.2	Derived		IRDLYNM/NUMIRINF
FBDLYNM	Number of B 5-FU Dose Delayed	Num	3.	Derived		See definition for IPDLYNM
FBDLYPC	Prop. of B 5-FU Dose Delayed	Num	8.2	Derived		FBDLYNM/NUMFBINF
DSDLYNM	Number of 1st-line Cycles Delayed	Num	3.	Derived		count of number of cycles with 1st line therapy delayed. Delayed if the current cycle start date (EXCYCLDT) is out of 21 days (28 days for Q3W) of the previous cycle start date.
DSDLYPC	Prop. of 1st-line Cycles Delayed	Num	8.2	Derived		DSDLYNM/NUMALINF
IPDECPCW	Prop. of IP Wt-adj Dose Reduced	Num	8.2	Derived		
BDECPCW	Prop. of Bmab Wt-adj Dose Reduced	Num	8.2	Derived		BDECNMW / NUMBINF
OXDECPCW	Prop. of OX BSA-adj Dose Reduced	Num	8.2	Derived		OXDECNMW / NUMOXINF
IRDECPCW	Prop. of IR BSA-adj Dose Reduced	Num	8.2	Derived		IRDECNMW / NUMIRINF
FBDECPCW	Prop. of B 5-FU BSA-adj Dose Reduced	Num	8.2	Derived		FBDECNMW / NUMFBINF
DECPCW	Prop. of adj 1st-line Cycle Reduced	Num	8.2	Derived		DECNMW / NUMALINF
CHDUREXP	Chemo exposure duration (months)	Num	8.2	Derived		

AE.xpt - Adverse Events, One record per subject per adverse event, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
AEANY	Any Adverse Events?	Char / 1	Y, N	CRF		If raw var INDICNY (AEOCCUR for 60141 and 60277) indicates No or is missing, set AEANY to Y if any information was entered from the CRF. In all other cases, set to the value of INDICNY.
AEPAGENO	Page Number	Num	6.2	CRF	x	
AELINENO	Line Number	Num	3.	CRF	x	
AESTDY	Study Day of Start of Event	Num	6.	Derived		AESTDT – COREVAR.FDOSDT. If AESTDT is on or after FDOSDT, then add 1 to the resulting AESTDY.
AESTDYI	Imputed Study Day of Start of Event	Num	6.			
AEENDY	Study Day of End of Event	Num	6.	Derived		AEENDT – COREVAR.FDOSDT. If AEENDT is on or after FDOSDT, then add 1 to the resulting AEENDY.
AEENDYI	Imputed Study Day of End of Event	Num	6.	Derived		AEENDTI - COREVAR.FDOSDT. If AEENDTI is on or after FDOSDT, then add 1 to the resulting AEENDYI.
AETERM	Reported Term	Char / 200		CRF	x	
AELLT	Low Level Term (MedDRA)	Char / 150		Raw data or derived		If AETERM is not missing but AELLT is missing then set to NOT CODED FOR AELLT.
AEPT	Preferred Term (MedDRA)	Char / 150		Raw data or derived	x	If AETERM is not missing but AEPT is missing then set to NOT CODED FOR AEPT.
AEHLT	High Level Term (MedDRA)	Char / 150		Raw data or derived		If AETERM is not missing but AEHLT is missing then set to NOT CODED FOR AEHLT.
AEHLGT	High Level Group Term (MedDRA)	Char / 150		Raw data or derived		If AETERM is not missing but AEHLGT is missing then set to NOT CODED FOR AEHLGT.
AESOC	System Organ Class (MedDRA)	Char / 150		Raw data or derived		If AETERM is not missing but AESOC is missing then set to NOT CODED FOR AESOC.
MEDDRA_V	MedDRA Version	Num	8.1	Derived		MedDRA Dictionary version used to code AE terms = version 8.0
PRECUT	On or Before Data Cutoff Date	Char / 1	Y, N	Derived		If AESTDTI <= cutoff, PRECUT=Y, Else N if cutoff is used
AEDUR	Duration of Event (in Days)	Num	6.	Derived		(AEENDT – AESTDT) + 1
AEDURI	Imputed Duration of Event (in Days)	Num	6.	Derived		(AEENDTI – AESTDTI) + 1
AECONT	Event Continuing?	Char / 1	Y, N	CRF		Note: If a partial or complete end date is given (other than UNK), set AECONT to N.
AEPRCNT	Event Continuing From Previous Form?	Char / 1	Y, N	CRF		
AENUMINF	Number of Infusions Prior to Start of AE	Num	6.	Derived		Counts only panitumumab infusions.
AESEVCD	Grade/Severity Code	Num	8., follow SEV.	CRF	x	
AESEV	Grade/Severity	Char / 20		Derived		Decode of AESEVCD
AEREL	Related to Investigational Product?	Char / 1	Y, N	CRF or derived	x	
AEINFYN	Infusion Related?	Char / 1	Y, N	CRF		
AEENDPG	Last AE page?	Char / 1	Y, N	CRF		
AEACTCDS	Action Taken Codes	Char / 30	Follow AEACT.	Derived	x	Left-justified comma-delimited list of all specified action codes in ascending order. Each comma should be followed by a space. Remove leading zeroes from each action code if present in the raw data.
AEACT01	No Action Taken?	Char / 1	Y, N	CRF		

AE.xpt - Adverse Events, One record per subject per adverse event, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
AEACT02	Investigational Product Dose Altered?	Char / 1	Y, N	CRF		
AEACT03	Medication Taken?	Char / 1	Y, N	CRF		
AEACT04	Hospitalized/Prolonged Hospitalization?	Char / 1	Y, N	CRF		
AEACT05	Removed From Study?	Char / 1	Y, N	CRF		
AEACT06	Investigational Product Discontinued?	Char / 1	Y, N	CRF		
AEACT07	Transfusion Performed?	Char / 1	Y, N	CRF		
AEACT08	Other Protocol Drug Altered?	Char / 1	Y, N	CRF		Bevacizumab dose altered?
AEACT09	Other Protocol Drug Discontinued?	Char / 1	Y, N	CRF		Bevacizumab discontinued?
AEACT81	Chemotherapy Dose Altered?	Char / 1	Y, N	CRF		
AEACT83	Chemotherapy Discontinued?	Char / 1	Y, N	CRF		
AEACT85	Ended All Study Treatment?	Char / 1	Y, N	CRF		
AEACT88	Other?	Char / 1	Y, N	CRF		
AESER	Serious?	Char / 1	Y, N	CRF or derived		
SAELIFE	Is Life-Threatening?	Char / 1	Y, N	CRF		

CHEMOTX.xpt - Chemotherapy, One record per subject per start date per regimen/line per agent, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
CHANY5YR	Any Chemotherapy in the Past 5 Yrs?	Char / 1	Y, N	CRF		
PHASECD	Phase Code	Num	8., follow PHASE.	Derived		
PHASE	Phase	Char / 40		Derived		Decode of PHASECD
CHSTDY	Study Day of Start of Regimen	Num	6.	Derived		CHSTDT – COREVAR.FDOSDT. If CHSTDT is on or after FDOSDT, then add 1 to the resulting CHSTDY.
CHENDY	Study Day of End of Regimen	Num	6.	Derived		CHENDT – COREVAR.FDOSDT. If CHENDT is on or after FDOSDT, then add 1 to the resulting CHENDY.
CHREG	Reported Name of Regimen	Char / 200		CRF	x	
CHREGPT	Preferred Name of Regimen	Char / 200		CRF		
CHREGCLS	Class Name of Regimen	Char / 200		CRF		

DEATH.xpt - Death, One record per subject, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
DTHDY	Day of Death	Num	8.	Derived		DTHDT-COREVAR.FDOSDT+1
DTHDYI	Imputed Day of Death	Num	8.	Derived		DTHDTI-COREVAR.FDOSDT+1
PHASECD	Phase Code	Num	8., follow PHASE.	Derived		Study phase in which the death occurred, based on DTHDTI.
PHASE	Phase	Char / 40		Derived		Decode of PHASECD
DTCAUSCD	Primary Cause of Death Code	Num	8., follow EOIP.	CRF		
DTCAUS	Primary Cause of Death	Char / 20		Derived		Decode of DTCAUSCD
DTAEPT	Fatal AEs	Char / 200		Derived		Preferred term of the fatal AE, in uppercase. If multiple fatal AEs exist in the AE data set, concatenate alphabetically separated by a comma and a space.

DEMO.xpt - Demographics and BL Characteristics, One record per subject, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
B_WEIGHT	Weight in Kilograms at Baseline	Num	5.1	CRF		Most recent measurement on or before study day 1 (per SAP). If in pounds (lbs), convert to kilograms by dividing by 2.2 and round to 2 decimals. If multiple weights recorded on the selected day, take the average. If study day 1 cannot be defined for a subject (eg, not enrolled or not dosed), take the last measurement on study. If the assessment date is missing, nominal visits of Screening are viable candidates. If study day 1 is defined as day of first dose, and 1 or more weight values are present on that same day with a time, choose the weight on or closest before the infusion start time. (70820) Take last assessment on or before first dose date in Part1. If multiple assessments are done on the closest day on or before first dose date in part1 then take average of those assessments.
B_HEIGHT	Height in Centimeters at Baseline	Num	3.	CRF		Use screen page
B_BSA	Body Surface Area (m^2) at Baseline	Num	4.1	Derived		If not provioded in raw data, use take square root of (b_height*b_weight/3600)
DIAGMONS	Months Since Primary Diagnosis	Num	8.	Derived		(DT of Randomization - DIAGDT) / 30.5, do not round.
METMONS	Months Since Metastatic Disease Dx	Num	8.	Derived		(DT of Randomization - METDXDT) / 30.5, do not round
BIOPDY	Biopsy Day Relative to First Dose	Num	8.	Derived		If biopsy date available, set to BIOPDT - FDOSDT + (BIOPDT>=FDOSDT)
BIOPTISB	Biopsy Tissue by Tissue Block?	Char / 1	Y, N	CRF		
BIOPTISS	Biopsy Tissue by Unstained Slide?	Char / 1	Y, N	CRF		
BIOPSITP	Biopsy From Primary Tumor Site?	Char / 1	Y, N	CRF		
BIOPSITM	Biopsy From Metastatic Tumor Site?	Char / 1	Y, N	CRF		
BIOPTPCT	Pct of Tumor Area Present	Num	5.2	Raw data		
BIOPRSCD	Overall EGFr Result Code	Num	2., follow BMRSLT.	Raw data		
BIOPRS	Overall EGFr Result	Char / 20		Raw data		decode of BIOPRSCD
BIOPEFCD	Analytical EGFr Failure Code	Num	2., follow BMFAILE.	Raw data		
BIOPEF	Analytical EGFr Failure	Char / 60		Derived		decode of BIOPEFCD
BIOPNEG	EGFr Staining Negative (Pct of Cells)	Num	5.1	CRF or raw		If missing in raw, leave missing in CRT.
BIOPWEAK	EGFr Staining Weak (Pct of Cells)	Num	5.1	CRF or raw		If missing in raw, leave missing in CRT.
BIOPMOD	EGFr Staining Moderate (Pct of Cells)	Num	5.1	CRF or raw		If missing in raw, leave missing in CRT.
BIOPSTRG	EGFr Staining Strong (Pct of Cells)	Num	5.1	CRF or raw		If missing in raw, leave missing in CRT.
BIOP3	EGFr Staining Strong	Char / 1	Y, N	Derived		If BIOPSTRG > 0 then Y else N.

DEMO.xpt - Demographics and BL Characteristics, One record per subject, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
BIOPS123	Sum of Pct of Cells With 1+, 2+, 3+	Num	5.1	Derived or raw		Sum of BIOPWEAK (1+), BIOPMOD (2+), and BIOPSTRG (3+). If any of these 3 values are missing: - if the non-missing values in BIOPNEG, BIOPWEAK, BIOPMOD, and BIOPSTRG sum to 100, then assume 0 for missing values - otherwise set BIOPS123=.
BIOPCYTO	EGFr Cytoplasmic Staining (Pct of Cells)	Num	5.1	Raw data		
H11NEG	EGFr H11 Staining Neg. (Pct of Cells)	Num	5.1	Raw data		
H11WEAK	EGFr H11 Staining Weak (Pct of Cells)	Num	5.1	Raw data		
H11MOD	EGFr H11 Staining Mod. (Pct of Cells)	Num	5.1	Raw data		
H11STRG	EGFr H11 Staining Strong (Pct of Cells)	Num	5.1	Raw data		
BIOPMAXC	Maximum Cyto Staining Intensity	Char / 3	0, 1+, 2+, 3+	Derived		The highest staining intensity (0, 1+, 2+, or 3+) recorded for the subject at baseline using H11NEG(0), H11WEAK(1+), H11MOD(2+) and H11STRG(3+)
BIOPCYCD	Sum of Pct of Cells w/Cyto Stn,Cat Code	Num	8., follow STAINCAT.	Derived		Categorization of BIOPCYTO per staincat. format. Set to missing if BIOPCYTO is missing.
BIOPCY	Sum of Pct of Cells w/Cyto Stn,Cat	Char / 15		Derived		Decode of BIOPCYCD
CHILDPOT	Is Subject of Childbearing Potential?	Char / 1	Y, N	CRF		
PREGDY	Pregnancy Sample Day Relative to First Dose	Num	8.	Derived		If pregnancy sample date is available, set to PREGDT - FDOSDT + (PREGDT>=FDOSDT)
PREGTYCD	Pregnancy Sample Type Code	Num	8., follow TESTTYPE.	CRF or derived		Can be 9 (pregnancy - serum) or 10 (pregnancy - urine). If not an explicit variable in the raw data, but the lab test name indicates serum or urine, then derive based on the lab test name. Otherwise, leave blank.
PREGTYPE	Pregnancy Sample Type	Char / 20		Derived		Decode of PREGTYCD
PREGRSCD	Pregnancy Sample Result Code	Num	8., follow neg_pos.	CRF or raw		
PREGRES	Pregnancy Sample Result	Char / 15		Derived		Decode of PREGRSCD

DISPOSIT.xpt - Disposition, One record per subject, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
ICSIGN	Signed Informed Consent?	Char / 1	Y/ N	CRF or derived		Set to Y if complete or partial IC date is present, set to N otherwise.
LDOSDSDY	Study Day of Last Dose Relat to 1st Dose	Num	6.	Derived		COREVAR.LDOSDT – COREVAR.FDOSDT. If LDOSDT is on or after FDOSDT, then add 1 to the resulting LDOSDSDY.
EOIPCD	Reason for Ending Inv Prod Code	Num	8., follow EOIP.	CRF		Reason for study drug discontinuation. For Pmab subjects, use the reason permanently discontinue pmab if EOIPDT <= cutoff (where applicable), otherwise leave blank.
EOIP	Reason for Ending Inv Prod	Char / 70		Derived		Decode of EOIPCD
EOTACD	Reason for Ending 1st Line Trt Code	Num	8., follow EOIP.	CRF		From End of 1st-line treatment page
EOTA	Reason for Ending 1st Line Trt	Char / 70		Derived		
EOBCD	Reason for Ending Bevacizumab Code	Num	8., follow EOIP.	CRF		
EOB	Reason for Ending Bevacizumab	Char / 70		Derived		
EOOXIRCD	Reason for Ending OX/IR Code	Num	8., follow EOIP.	CRF		Use reason code for either OX or IR (whichever applicable) and column for 'dose not delivered' to determine
EOOXIR	Reason for Ending OX/IR	Char / 70		Derived		
EOLEUCCD	Reason for Ending Leucovorin Code	Num	8., follow EOIP.	CRF		
EOLEUC	Reason for Ending Leucovorin	Char / 70		Derived		
EO5FUBCD	Reason for Ending 5-FU bolus Code	Num	8., follow EOIP.	CRF		
EO5FUB	Reason for Ending 5-FU bolus	Char / 70		Derived		
EO5FUICD	Reason for Ending 5-FU infusion Code	Num	8., follow EOIP.	CRF		
DSDOSDY	Study Day of Safety FUP Rel to 1st Dose	Num	6.	Derived		DSDT – FDOSDT. If DSDT is on or after FDOSDT, then add 1 to the resulting DSDOSDY.
DSEOSYN	Ended Study?	Char / 1	Y / N	Derived		Set to Y if end of study date (on the EOS page) not missing, N otherwise
DSEOSCD	Reason for Not Completing Study Code	Num	8., follow EOIP.	CRF		NOTE: intended to be populated only when the subject has been withdrawn from study (i.e., Not Completed). Subjects having completed safety FUP should have DSEOSCD missing. If cutoff is defined and eosdt is after cutoff, set to missing .
DSEOS	Reason for Not Completing Study	Char / 70		Derived		Decode of DSEOSCD
EOIPDY	Day of Inv Prod Discont Relative to First Dose	Num	8.	Derived		EOIPDT - FDOSDT + 1
EOBDY	Day of Bevacizumab Discont Relative to First Dose	Num	8.	Derived		If subject received Bevacizumab, then EOBDT - FDOSDT + 1
EOXIRDY	Day of OX/IR Discont Relative to First Dose	Num	8.	Derived		If subject received OX/IR, then EOXIRDT - FDOSDT + 1
EOLEUDY	Day of Leucovorin Discont Relative to First Dose	Num	8.	Derived		If subject received Leucovorin, then EOLEUDT - FDOSDT + 1

DISPOSIT.xpt - Disposition, One record per subject, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
EO5FBDY	Day of 5-FU bolus Discont Relative to First Dose	Num	8.	Derived		If subject received bolus 5-FU, then EO5FBDT - FDOSDT + 1
EO5FIDY	Day of 5-FU infusion Discont Relative to First Dose	Num	8.	Derived		If subject received 5-FU infusion, then EO5FIDT - FDOSDT + 1
EOSDY	Day of End of Study Relative to First Dose	Num	8.	Derived		EOSDT - FDOSDT + 1
LASTOSDY	Last Day on Study Relative to First Dose	Num	8.	Derived		LASTOSDT - FDOSDT + 1

ELIGCRIT.xpt - Eligibility Criteria, One record per subject per eligibility criteria number, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
PERIODCD	Part of Study Code	Num	6., follow PERIOD.	Derived	x	
PERIOD	Part of Study	Char / 40		Derived		Decode of PERIODCD
ELIGIBLE	Is Subject Eligible?	Char / 1	Y, N	CRF		ELIGHDR.ELIGNY. Must be populated for every record.
ELIGNMCD	Eligibility Criteria Not Met Code	Num	8.3, follow ELIGNM. or ELIG[study]N.	CRF	x	ELIGDTL.ELIGNO. Responses to negatively stated criteria on the CRF may need to be reversed in order to determine whether all criteria were met. See inc/exc worksheets in this VDT for mapping of study-specific codes to the standard code list. Will be missing if the subject met all eligibility criteria.
ELIGNM	Eligibility Criteria Not Met	Char / 200		Derived		Decode of ELIGNMCD.
ELEXCP	Exception Granted?	Char / 1	Y, N	CRF		Missing if the subject met all eligibility criteria.
ELIGIBPK	Is Subject Eligiblefor PK ?	Char / 1	Y,N	CRF		

EXPOSURE.xpt - Study Drug Administration, One record per subject per dosing interval, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
DOSREFDY	Study Day Relative to First Dose	Num	6.	Derived		VISITDT – COREVAR.FDOSDT. If VISITDT is on or after FDOSDT, then add 1 to the resulting DOSREFDY.
DOSREFWK	Study Week Relative to First Dose	Num	6.	Derived		Ceiling of DOSREFDY / 7. If DOSREFDY < 1, use floor instead of ceil.
VISITCD	Visit Name Code	Char / 20	Follow $VISIT.	CRF or Derived		Only used in Amgen in-house trials.
VISIT	Visit Name	Char / 40		Derived	x	Decode of VISITCD.
PHASECD	Phase Code	Num	8., follow PHASE.	Derived		Study phase in which the administration occurred, based on VISITDT.
PHASE	Phase	Char / 40		Derived		Decode of PHASECD
EXENDY	Study Day Dose Stopped	Num	6.	Derived		EXENDT – COREVAR.FDOSDT. If EXENDT is on or after FDOSDT, then add 1 to the resulting EXENDY.
EXDURHR	Duration (Hours)	Num	8.	CRF or Derived		Duration of infusion based on start and end date and time. If no end date recorded on CRF, derive end date as next day if stop time < start time for the purposes of this calculation. Only calculate for pmab records.
EXDURMN	Duration (Minutes)	Num	8.	Derived		Duration of infusion based on start and end date and time. If no end date recorded on CRF, derive end date as next day if stop time < start time for the purposes of this calculation. Only calculate for pmab records.
ACTTRTCD	Name of Study Drug Administered Code	Num	8., follow TRT.	CRF / hardcode	x	Hardcode per protocol if not identified in the raw data.
ACTTRT	Name of Study Drug Administered	Char / 70		Derived		Decode of ACTTRTCD
QTY	Total Volume (mL)	Num	8.2	CRF		
CONC	Concentration (mg/mL)	Num	8.2	CRF		
DOSE	Dose	Num	8.2	CRF or derived		If not provided on CRF, multiply QTY by CONC.
DOSEUNCD	Dose Unit Code	Char / 5	Follow $DOSEU.	CRF or hardcode		If provided as an explicit raw data variable, then use the value of the raw data variable. If no such variable exists, then: - use the CRF to determine (see notes in the source columns) - if dose is missing, leave unit missing also.
DOSEUNIT	Dose Unit	Char / 40		Derived		Decode of DOSEUNCD
WDOSE	Weight Adjusted Dose (mg/kg)	Num	8.2	CRF or derived		If not provided on CRF, divide DOSE by the most recently recorded weight in kg on or before the dose date. If in pounds (lbs), convert to kilograms by dividing by 2.2 and rounding to 2 decimals. For safety purposes, this will provide the most accurate representation of actual weight-based dose. If multiple weights are recorded on the closest date, then take the average of those weights before calculating WDOSE.
WDOSUNCD	Weight Adjusted Dose Unit Code	Char / 8	Follow $WDOSEU.	Derived		If WDOSE is missing, set to missing.
WDOSUNIT	Weight Adjusted Dose Unit	Char / 40		Derived		Decode of WDOSUNCD
BSADOSE	BSA Adjusted Dose (mg/m^2)	Num	8.2	Derived		For chemotherapy infusions only. Leave blank for non-chemotherapy infusions. Divide DOSE by the BSA using the most recently recorded height (cm) and weight (kg) on or before the dose date. If height is in inches, convert to centimeters by multiplying by 2.54 and rounding to 2 decimals. If weight is in pounds (lbs), convert to kilograms by dividing by 2.2 and rounding to 2 decimals. If multiple heights or weights are recorded on the closest date, take the average before calculating BSA. BSA is square root [height (cm) x weight (kg) / 3600] (Mosteller's formula). Use screening height for all records, follow above instruction otherwise

EXPOSURE.xpt - Study Drug Administration, One record per subject per dosing interval, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
ROUTECD	Route Code	Char / 5	follow $CMROUTE.	Hardcode		
ROUTE	Route	Char / 40		Derived		Decode or ROUTECD
DOSCHGYN	Dose Change From Previous Visit?	Char / 1	Y, N	CRF		
DOSND	Dose Not Delivered?	Char / 1	Y, N	CRF		If ND box checked and also the dose is 0, then assign Y, otherwise leave blank
DOSNA	Dose Not Applicable?	Char / 1	Y, N	CRF		If NA box checked then assign Y, otherwise leave blank
EXREASCD	Reason for Dose Change Code	Num	8., follow EXREAS.	CRF		
EXREAS	Reason for Dose Change	Char / 80		Derived		Decode of EXREASCD
EXINTCD	Reason for Dose Interruption Code	Num	8., follow EXREAS.	CRF		
EXINT	Reason for Dose Interruption	Char / 40		Derived		Decode of EXINTCD
EXCYCLDY	Cycle Start Day	Num	6.	Derived		EXCYCLDT-FDOSDT+1
EXCYCLNM	Cycle Number	Num	8.2	Derived / CRF		Unique interger assigned to each of the cycle as distingushed by different cycle start dates, starting with 1
EXAEANY	Any Infusion-related AEs or SAEs?	Char / 1	Y, N	CRF		If infusion reaction checked for the visit and the reaction date and time occured within 1 hour on/after Pmab infusion, then assign Y, else N

LAB.xpt - Laboratory Results, One record per subject per lab test per visit/collection per lab unit per lab type, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
DOSREFDY	Study Day Relative to First Dose	Num	6.	Derived		VISITDT – COREVAR.FDOSDT. If VISITDT is on or after FDOSDT, then add 1 to the resulting DOSREFDY.
DOSREFWK	Study Week Relative to First Dose	Num	6.	Derived		Ceiling of DOSREFDY / 7. If DOSREFDY<1, use floor instead of ceil.
VISITCD	Visit Name Code	Char / 20	Follow $VISIT.	CRF or raw		
VISIT	Visit Name	Char / 40		Derived	x	Decode of VISITCD
PHASECD	Phase Code	Num	8., follow PHASE.	Derived		Study phase in which the assessment occurred, based on VISITDT.
PHASE	Phase	Char / 40		Derived		Decode of PHASECD
LBREPEAT	Lab Repeat Number	Num	3.	Derived	x	Used to identify value used in analysis when values of all keys are identical. TLGs are subset for LBREPEAT=1.
LBTYPECD	Lab Type (Central or Local) Code	Num	8., follow LABTYP.	Raw data or derived	x	Hardcode to 1 for central
LBTYPE	Lab Type (Central or Local)	Char / 8		Derived		Decode of LABTYPCD
LBPANEL	Lab Test Panel	Char / 16	Follow $LBPANEL	CRF or derived or raw	x	Follow the logic in format LBPANEL to go from the individual lab test to the panel.
LBACCNO	Central Lab Accession Number	Char / 20		Raw data		
LBTSTNUM	Lab Test Name Code (Numeric)	Num	8., follow LBTEST.	CRF or raw		
LBTESTCD	Lab Test Code	Char / 8	Follow $LBTEST.	CRF or raw	x	
LBTEST	Lab Test	Char / 40		Derived		Decode of LBTESTCD
LBSTRESN	Numeric Result in Analysis Std Units	Num	8.2	Raw or derived		
LBSTRESC	Character Result in Analysis Std Units	Char / 30		Derived		Standard unit value to be used for report display (rounded, includes <, > qualifier), left-justified.
LBSTUNIT	Analysis Standard Units	Char / 10		Raw or derived		If the reported result is missing, and the reported unit was not entered on the CRF (ie, does not apply to pre-printed units), then leave missing.
LBSTNRLO	Lower Limit of Ref Range in Std Units	Num	8.2	Raw or derived		
LBSTNRHI	Upper Limit of Ref Range in Std Units	Num	8.2	Raw or derived		
LBNRINCD	Reference Range Indicator Code	Char / 1	Follow $LBNRIND.	Derived		
LBNRIND	Reference Range Indicator	Char / 40		Derived		Decode of LBNRINCD
LBORRESN	Numeric Result in Original Units	Num	8.2	Derived		If LBORRES contains a signifier, leave LBORRESN missing.
LBORUNIT	Original Units	Char / 10		CRF or raw	x	If the reported result is missing, and the reported unit was not entered on the CRF (ie, does not apply to pre-printed units), then leave missing. For local labs, if no unit provided in the raw data, and no supporting data is available from CDM, then hardcode based on CRF and lab test.
LBORNRLO	Lower Limit of Ref Range in Orig Units	Num	8.2	CRF or raw		If the CRF data is prefaced by "<", strip this character and retain the numeric value after dropping the "<".

LAB.xpt - Laboratory Results, One record per subject per lab test per visit/collection per lab unit per lab type, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
LBORNRHI	Upper Limit of Ref Range in Orig Units	Num	8.2	CRF or raw		
LBBASE	Baseline?	Char / 1	Y, N	Derived		Identifies the most recent non-missing standard result (LBSTRESC) per analyte taken on or before first dose of study drug (or on-study chemo in 5404 and 5409) where LBREPEAT=1.
LBBLRES	Baseline Result in Analysis Std Units	Num	8.2	Derived		Value of LBSTRESN where LBBASE=Y for this analyte. Filled on all quantitative analyte records for a given subject, including pre-treatment and the record containing the BL value itself, unless no BL value could be identified for that subject. This variable remains missing for qualitative analytes and for CPK, CK, and troponin. If differentials are reported in the raw data in both % and count, then use the baseline result where the original unit was in absolute counts. LBBLRES is null if the baseline value starts with "<" or ">". Take the closest (considering both lab date and time) to first dose day
LBCHGBL	Chg from Baseline in Analysis Std Units	Num	8.2	Derived		Note: change values for pre-baseline measurements and for the baseline measurement should be set to missing.
LBGRDINC	NCI CTC Grade Increase	Num	3.	Derived		Notes: * the NCI CTC document provides grading for Bicarbonate in units of mEq/dL. This should be mEq/L instead of mEq/dL. * the CPK grading can be used to grade creatinine kinase but not any of the 3 isoenzymes (MM, MB, BB).
LBGRDDEC	NCI CTC Grade Decrease	Num	3.	Derived		
LBMIN	Lowest Value After Baseline?	Char / 1	Y, N	Derived		Consider all phases after baseline
LBMAX	Highest Value After Baseline?	Char / 1	Y, N	Derived		Consider all phases after baseline
LBLAST	Last Value After Baseline?	Char / 1	Y, N	Derived		Only consider assessments with phase codes 20 through 50. Set to Y if the value was the last non-missing character standard value (LBSTRESC) measured post BL for this subject and analyte where LBREPEAT=1, and to N in all other cases. If a subject is not in the safety analysis set (EVALSAFE=N), set to N for all records. If >1 records occur for the same test, date, and time that qualify for last on study, and the results differ, central values should preferentially be used. If this doesn't break the tie, then set LBLAST=N for those records and create a new record with LBLAST=Y and VISIT= "Average". Set variables LBID, LBACCNO, LBOR*, LBCOLL, LBCOLLSP, and LBCMNT to missing for this new record. Set LBSTRESN and LBSTRESC to the average value. Values starting with "<" or ">" are eligible for LBLAST.

LESION.xpt - Lesion Assessment, One record per subject per assessment type per exam date per lesion ID, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						For RadPharm data, exclude the screening record indicating chest X-ray from raw file RP_RECST. For LESION records (from the 3 Radpharm data) that are not linked to the RP_EXAM data (no EXAM_NO), only records with valid measurements will be kept, those with UE will be dropped (120day integrated-level) Keep only records with complete LSDT and LSDT < FDOSDT
DOSREFDY	Study Day Relative to First Dose	Num	6.	Derived		LSDT – COREVAR.FDOSDT. If LSDT is on or after FDOSDT, then add 1 to the resulting DOSREFDY.
DOSREFWK	Study Week Relative to First Dose	Num	6.	Derived		Ceiling of DOSREFDY / 7. If DOSREFDY<1, use floor instead of ceil.
VISITCD	Visit Name Code	Char / 20	Follow $VISIT.	CRF, rawdata		SCR' for all tumor assessment at screening, 'PROGRESS' for all records from the disease progression pages. For Central data, link the RadPharm data with our CRF data using the first central data assessment dates (min(RP_EXAM.EXAM_DT) on each Radpharm time point, with the first scan date on each visit [min(RADIO.RADIO_DT)] on our CRF data) and use the visit code (RADIO.EVENT_ID) as the visit code, applying +/- 7 day window around RAD_DT to get EVENT_ID if no exact date match. If multiple event_id occures on a single date from RADIO data, use the one giveing WEEK# Vs. unscheduled visits. For any visits that are on Central data but not on the CRF, assign visitcd='UNSCHEDULED'
VISIT	Visit Name	Char / 40		Derived	x	Decode of VISITCD
PHASECD	Phase Code	Num	8., follow PHASE.	Derived		Study phase in which the assessment occurred, based on LSDT. See amg954_vardef_addenda.doc for detailed specification.
PHASE	Phase	Char / 40		Derived		Decode of PHASECD
LSTYPECD	Evaluation Type (Central or Local) Code	Num	8., follow LABTYP.	Derived	x	If from central review, code to central. If from CRF, code to local.
LSTYPE	Evaluation Type (Central or Local)	Char / 8		Derived		Decode of LSTYPECD
LSCATCD	Lesion Category (Target/Non-target) Code	Num	8., follow LSTYPE.	CRF or derived/hardcode	x	Set Target or Non-Target or New Lesion according to source data
LSCAT	Lesion Category (Target/Non-target)	Char / 20		Derived		Decode of LSCATCD
LSNO	Lesion ID Number	Num	3.	CRF or raw	x	
LSSITECD	Lesion Site Code	Num	8., follow BODSYS.	CRF or raw		For central review records, derive as input(raw.sitecd, radsite.), where raw represents source data set target, nontar, or newles. This provides a less granular mapping of the detailed RadPharm sites. For local records, map from lesion raw file.
LSSITE	Lesion Site	Char / 60		Derived		Decode of LSSITECD

LESION.xpt - Lesion Assessment, One record per subject per assessment type per exam date per lesion ID, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
LSPROCCD	Means of Assessment Code	Num	8., follow DXPROC.	CRF or raw	x	
LSPROC	Means of Assessment	Char / 70		Derived		Decode of LSPROCCD
LSRAWCD	Lesion Site (Central, Detailed) Code	Num	8., follow BODSYS.	Raw data		For central review records only, provides the highly detailed location of the lesion as provided by RadPharm. First, recode to numeric via informat RP_SITE.
LSRAW	Lesion Site (Central, Detailed)	Char / 60		Derived		Decode of LSRAWCD
LSNEW	New Lesion?	Char / 1	Y, N	CRF		Derived from PROGLOC.PROGTYPE, set to 1 if type is '03' for new lesion, otherwise set to 0; for central data, set to Y if source data set is NEWLESION, otherwise N;
LSNEWANY	Any New Lesions?	Char / 1	Y, N	Raw data		Y if RP_RECST.NEW_LES=yes, N otherwise
LSNUM	Number of Lesions Within Site	Num	8.	CRF		
LSLD	Longest Diameter (mm)	Num	5.1	CRF or raw		If provided in cm in the raw data, multiply by 10 to obtain mm. If the raw data provides 2 measurements, assign the highest of the 2 measurements. If 1 of the 2 measurements is missing, set to the non-missing measurement.
LSSLD	Sum of Long. Diam Within Lesion Type(mm)	Num	8.1	CRF or raw		RP_RECST.SLD. If provided in cm in the raw data, multiply by 10 to obtain mm. Note: programming should check this derivation in the CRT code and immediately raise discrepancies to CDM.
LSSLDPCH	Percent Change From Baseline for SLD	Num	4.	Raw data or derived		RP_RECST.PCB_SLD
LSSLDPCN	Percent Change From Nadir for SLD	Num	4.	Raw data or derived		RP_RECST.PCN_SLD
LSRESPCD	Lesion Response Code	Num	8., follow DISRESP.	CRF		RP_NTARG.NT_RESP.
LSRESP	Lesion Response	Char / 40		Derived		
LSEXAMNO	Exam Number	Num	3.	Raw data	x	RP_TARG.EXAM_NO, RP_NTARG.EXAM_NO, and RP_NWLES.EXAM_NO. Only filled for central review records.
LSIMAGNO	Image Number	Char / 10		Raw data		RP_TARG.IMAGE_NO, RP_NTARG.IMAGE_NO, and RP_NWLES.IMAGE_NO Only filled for central review records.
LSRI	Reconstruction Interval (mm)	Num	5.2	Raw data		RP_EXAM.RI. Only filled for central review records. Merge to raw data files TARGET, NONTARGET, and NEWLESION by site, subject ID, timepoint, and exam sequence number.

MEDHIST.xpt - Medical History, One record per subject per condition/procedure, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
MHANY	Medical or Surgical History?	Char / 1	Y, N	CRF or derived		
MHTERM	Reported Term for Condition or Procedure	Char / 200		CRF or derived	x	Uppercase if not uppercased in raw data
DOSREFDY	Study Day Relative to First Dose	Num	6.	Derived		MHSTDT – COREVAR.FDOSDT. If VISITDT is on or after FDOSDT, then add 1 to the resulting DOSREFDY.
MHSTATCD	Medical History or Condition Status Code	Num	8., follow MHSTAT.	CRF		If NOYES=0 (no such medical history), then assigne 0 (for normal)
MHSTAT	Medical History or Condition Status	Char / 40		Derived		Decode of MHSTATCD

RADIOTX.xpt - Radiotherapy, One record per subject per treatment, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
RAANY5YR	Any Radiotherapy in the Past 5 Yrs?	Char / 1	Y, N	CRF		
VISITCD	Visit Name Code	Char / 20	Follow $VISIT.	CRF		
VISIT	Visit Name	Char / 40		Derived	x	Decode of VISITCD
PHASECD	Phase Code	Num	8., follow PHASE.	Derived		See amg954_vardef_addenda.doc for detailed specification.
PHASE	Phase	Char / 40		Derived		Decode of PHASECD
RASTDY	Study Day of Start of Radiotherapy	Num	6.	Derived		RASTDT – COREVAR.FDOSDT. If RASTDT is on or after FDOSDT, then add 1 to the resulting RASTDY.
RAENDY	Study Day of End of Radiotherapy	Num	6.	Derived		RAENDT – COREVAR.FDOSDT. If RAENDT is on or after FDOSDT, then add 1 to the resulting RAENDY.
RADOSE	Radiotherapy Dose (Gy)	Num	8.2	CRF		If provided in units of cGy, divide by 100 to obtain Gy

RESPEVAL.xpt - Response Evaluation, One record per subject per evaluation, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
DOSREFDY	Study Day Relative to First Dose	Num	6.	Derived		VISITDT – COREVAR.FDOSDT. If VISITDT is on or after FDOSDT, then add 1 to the resulting DOSREFDY.
DOSREFWK	Study Week Relative to First Dose	Num	6.	Derived		Ceiling of DOSREFDY / 7. If DOSREFDY<1, use floor instead of ceil.
VISITCD	Visit Name Code	Char / 20	Follow $VISIT.	CRF or derived		For CRF data, use the EVENT_ID. For Central data, link the RadPharm data with our CRF data using the first central data assessment dates (min(RP_EXAM.EXAM_DT) on each Radpharm time point, with the first scan date on each visit [min(RADIO.RADIO_DT)] on our CRF data) and use the visit code (RADIO.EVENT_ID) as the visit code, applying +/- 7 day window around RAD_DT to get EVENT_ID if no exact date match. If multiple event_id occures on a single date from RADIO data, use the one giving WEEK# Vs. unscheduled visits. For any visits that are on Central data but not on the CRF, assign visitcd='UNSCHEDULED'
VISIT	Visit Name	Char / 40		Derived	x	Decode of VISITCD.
RSASMDT	Assessment Date	Num	DATE9.	Derived		For LOCAL data, minimum assessment date for any radiological assessment for the matching EVENT_ID in DXPROC or the assessment date from TUMORRESP; min(DXPROC.VISITDTs, TUMORRESP.VISITDT) for this clinical assessment (where TUMORRESP.VISITCD=DXPROC.VISITCD). For Central data, use visitdt for this visitcd.
RSCOMPLT	Complete Assessment	Num	6.,	Derived		For this clinical assessment, set to 1 if all methods in LESION are present that were present in the baseline LESION assessment. Verify that any unique LESION.LSPROCCD on the screening assessment is present in the current assessment. Conventional CT/MRI/Spiral CT are considered to be interchangeable.
RSTYPECD	Evaluation Type (Central or Local) Code	Num	8., follow LABTYP.	Derived	x	When reading from raw file DISR, code to local. When reading from RadPharm DCM, code to central.
RSTYPE	Evaluation Type (Central or Local)	Char / 8		Derived		Decode of RSTYPECD

RESPEVAL.xpt - Response Evaluation, One record per subject per evaluation, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
RSCRITCD	Evaluation Criteria Code	Num	8., follow RSCRIT.	Derived	x	Set to 3 (modified RECIST)
RSCRIT	Evaluation Criteria	Char / 30		Derived		Decode of RSCRITCD
RSMETHCD	Method of Assessment Code	Num	8., follow RESPMETH.	Raw data		
RSRESPDY	Overall Response Day Rel. to 1st Dose	Num	8.	Derived		RSRESPDT - FDOSDT, if after first dose then add 1.
RSRESPCD	Overall Response Status Code	Num	8., follow DISRESP.	CRF		Note: for central evaluations, this is the integrated response.
RSRESP	Overall Response Status	Char / 40		Derived		Decode of RSRESPCD
RSBRCD	Best Response Code	Num	8., follow DISRESP.	Raw data		Central data only. Missing for local data.
RSBR	Best Response	Char / 40		Derived		Decode of RSBRCD
RSBRDY	Day of Best Response Relative to 1st Dose	Num	8.	Derived		RSBRDT - FDOSDT + 1
RSBORCD	Best Overall Response Code	Num	8., follow DISRESP.	Raw data		Central data only. Missing for local data.
RSBOR	Best Overall Response	Char / 40		Derived		Decode of RSBORCD
RSBORDY	Day of Best Overall Response Relative to 1st Dose	Num	8.	Derived		RSBORDT - FDOSDT + 1
RSTRSPCD	Radiol. Target Lesion Resp. Code	Num	8., follow DISRESP.	Raw data		
RSNTRESP	Radiol. Non-target Lesion Response	Char / 200		Derived		Decode of RSNTRSCD

SURGHIST.xpt - Surgical History, One record per subject per procedure, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
SXANY5YR	Any Surgery in the Past 5 Yrs?	Char / 1	Y, N	CRF		
DOSREFDY	Study Day Relative to First Dose	Num	6.	Derived		VISITDT – COREVAR.FDOSDT. If VISITDT is on or after FDOSDT, then add 1 to the resulting DOSREFDY.
DOSREFWK	Study Week Relative to First Dose	Num	6.	Derived		Ceiling of DOSREFDY / 7. If DOSREFDY<1, use floor instead of ceil.
PHASECD	Phase Code	Num	8., follow PHASE.	Derived		
PHASE	Phase	Char / 40		Derived		Decode of PHASECD
SXTYPECD	Type of Surgery Code	Num	8., follow SXTYPE.	CRF	x	
SXTYPE	Type of Surgery	Char / 30		Derived		Decode of SXTYPECD
SXINTTCD	Intent of Surgery Code	Num	8., follow SXINTENT.	CRF		
SXINTENT	Intent of Surgery	Char / 60		Derived		Decode of SXINTTCD
SXSITECD	Site of Surgery Code 1	Num	8., follow BODSYS.	CRF	x	
SXSITE	Site of Surgery 1	Char / 60		Derived		Decode of SXSITECD
SXHEALYN	Healing in Exp. Timeframe?	Char / 1	Y, N	CRF		

VITALS_V.xpt - Vital Signs (Vertical), One record per subject per visit per timepoint per vital sign, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
<Core Variables>						
DOSREFDY	Study Day Relative to First Dose	Num	6.	Derived		VISITDT – COREVAR.FDOSDT. If VISITDT is on or after FDOSDT, then add 1 to the resulting DOSREFDY.
DOSREFWK	Study Week Relative to First Dose	Num	6.	Derived		Ceiling of DOSREFDY / 7. If DOSREFDY<1, use floor instead of ceil.
VISITCD	Visit Name Code	Char / 20	Follow $VISIT.	CRF		Only used in Amgen in-house trials.
VISIT	Visit Name	Char / 40		Derived	x	Decode of VISITCD
PHASECD	Phase Code	Num	8., follow PHASE.	Derived		
PHASE	Phase	Char / 40		Derived		Decode of PHASECD
VSDONECD	Vital Signs Done? Code	Char / 1	Follow $YESNO.	CRF		
VSDONE	Vital Signs Done?	Char / 20		Derived		Decode of VSDONECD
VSPTMCD	Planned Timepoint Name Code	Num	8., follow TIMEPT.	CRF	x	For vitals collected on the vital signs log, assign 40 for 'Within 30 minutes Prior Infusion'
VSPTM	Planned Timepoint Name	Char / 40		Derived		Decode of VSPTMCD
VSTESTCD	Vital Signs Test Name Code	Char / 8	Follow $VSTEST.	Derived	x	
VSTEST	Vital Signs Test Name	Char / 40		Derived		Decode of VSTESTCD
VSTRTCD	Name of Study Drug Administered Code	Num	8., follow TRT.	CRF	x	Only filled for measurements from the infusion vitals CRF; leave blank for physical exam vitals or ECOG CRF.
VSTRT	Name of Study Drug Administered	Char / 70		Derived		Decode of VSTRTCD
VSSTRES	Result in Standard Units	Num	8.2	CRF or Derived		If temperature is in Fahrenheit, convert to Celsius as follows: Celsius = (Fahrenheit - 32) * 5/9. Round result to 2 decimals. If reported result present but unit unknown, do not calculate VSSTRES.
VSSTUNIT	Standard Units	Char / 20		CRF or Derived		Leave missing if VSSTRES is missing. Use MMHG for systolic/diastolic BP, BEATS/MINUTE for pulse, BREATHS/MINUTE for respiration, CELSIUS for temperature, and PERCENT for KPS. Leave blank for ECOG.
VSORRES	Result in Original Units	Num	8.2	CRF		
VSORUNIT	Original Units	Char / 20		CRF		If the reported result is missing, and the reported unit was not entered on the CRF (ie, does not apply to pre-printed units), then leave missing. For units pre-printed on the CRF that correspond to the units allowed in VSSTUNIT, use the same naming as VSSTUNIT. For all other units, display as in raw data.
VSBASE	Baseline?	Char / 1	Y, N	Derived		
VSBLRES	Baseline Result in Standard Units	Num	8.2	CRF or Derived		Filled on all records for a given subject, including pre-treatment and the record containing the BL value itself, unless no BL value could be identified for that subject.
VSCHGBL	Change from Baseline in Standard Units	Num	8.2	Derived		Filled for all post BL records. If no baseline was was assigned, leave missing.
VSSCRRES	Screening Result in Standard Units	Num	8.2	CRF or Derived		Values for VISIT of 'SCREENING'

VITALS_V.xpt - Vital Signs (Vertical), One record per subject per visit per timepoint per vital sign, CRT						
Variable Name	**Variable Label**	**Type / Length**	**Decodes / Format**	**Origin**	**Key**	**Comments**
VSCHGSCR	Change from Screening in Standard Units	Num	8.2	Derived		Filled for all post Screening Records for all time points whenever there is a value. Missing if no Screen value found.
VSMIN	Lowest Value After Baseline?	Char / 1	Y, N	Derived		Only select from post-baseline pre-infusion vitals, leave missing for vital signs not collected for pre-infusion for the control arm.
VSMAX	Highest Value After Baseline?	Char / 1	Y, N	Derived		Only select from post-baseline pre-infusion vitals, leave missing for vital signs not collected for pre-infusion for the control arm
VSLAST	Last Value After Baseline?	Char / 1	Y, N	Derived		Only consider assessments with phase codes 20 through 50. Set to Y if the value was the last non-missing value measured post BL to date for this subject and vital sign, and to N in all other cases. If a subject is not in the safety analysis set (EVALSAFE=N), set to N for all records.
VSMINCH	Lowest Pre to Post-infusion Chg at Visit	Num	8.2	Derived		Only derived for vital signs recorded on the infusion-related vitals CRF. Calculate the change from the pre-infusion measurement to the lowest non-missing peri or post-infusion measurement as recorded at this particular infusion. Do not involve data from other infusions.
VSMAXCH	Highest Pre to Post-infusin Chg at Visit	Num	8.2	Derived		Only derived for vital signs recorded on the infusion-related vitals CRF. Calculate the change from the pre-infusion measurement to the highest non-missing peri or post-infusion measurement as recorded at this particular infusion. Do not involve data from other infusions.
VSPCTCH	Post-infusion % Change From Pre-infusion	Num	8.	Derived		Only derived for vital signs recorded after the start of infusion on the infusion-related vitals CRF. Calculate as 100 * (current value - pre-infusion value at same infusion) / pre-infusion value. Negative percents are possible and indicate a decrease. Do not round.