N0147 Data Definition Table

CHARACTERISIC	
Adherence: 1=Yes 2=No	ADHERENC
Age category: < 40, 40-69, >=70	AGECAT
Experimental arm: A, B, C, D, E, F*	ARM
Grade 4/5 event: 1 = patient experienced a grade 4 or 5 adverse event, regardless of attribution 2 = otherwise	BAD_TOX
BMI	BMI2
Bowel obstruction : 1=Yes 2=No	BWL_OBS
Bowel perforation: 1=Yes 2=No	BWL_PERF
Grade 5 event: 1 = patient experienced a grade 5 adverse event, regardless of attribution 2 = otherwise	DRG_DTH
Days from randomization until last protocol therapy was given	ENDAT_TIME
Reason Treatment Ended: 1 = Treatment completed per protocol criteria 3 = Adverse Event/Side Effects/Complications 4 = Disease Progression, relapse during active treatment 5 = Alternative therapy 6 = Other Medical Problems 7 = Death on Study 8 = Other 10 = Disease progression before active treatment 11 = Cytogenetic Resistance 12 = Refused further treatment before beginning protocol therapy	ENDATRSN
Indicator if patient has been determined to be: 9=Ineligible 8=Major Violation 7=Cancel Missing = not excluded	EXCLUDED
Histology: 1=High (poorly differentiated or undifferentiated) 2=Low (well or moderately differentiated)	HISTO_G
Patient was lost to follow up: y = Yes Missing = No	LOST2FUP
Unique identifier for each patient	MASK_ID
Positive lymph node involvement: 1 = 1-3 2 = >=4	NODES
Total Number of Cycles Given	NUMCYCLE

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Response status at the most recent assessment (on treatment): 0=NED 6=Recurrence 8=Not evaluated	OBJ_STAT
ECOG Performance Status: 0 = 0 1 = 1 2 = 2+	PS
Race: b=black w=white oth=other	RACECAT
Sex: m=Male f=Female	SEX
Clinical T Stage: 1=T1 or T2 2=T3 3=T4	STAGE_G
Biomarker KRAS: 0 = Mutant 1 = Wild-type Missing = indeterminate	WILD
OBJECTIVES	
Disease free survival status (5yr censor): 0 = Event-Free 1 = Event	DFSSTAT5
Time in days of disease free survival	DFSTIME5
Overall survival status (8 year censor): 0 = Alive 1 = Dead	FUSTAT8
Time in days of overall survival	FUTIME8
Unique identifier for each patient	MASK_ID
Time to recurrence status: 0 = Recurrence-Free 1 = Recurrence	PGSTAT5
Time in days of time to recurrence	PGTIME5
TOX (highest grade per patient per adverse event)	
Experimental arm: A, B, C, D, E, F*	ARM
Severity of the adverse event according to CTC guidelines (>= 3)	GRADE
Adverse event	TOX
Unique identifier for each patient	MASK_ID

* A: (FOLFOX) Oxaliplatin + 5-fluorouracil/Leucovorin Regimen (KRAS wildtype)

B: 5-fluorouracil/Leucovorin + Irinotecan (KRAS wildtype)

C: 5-fluorouracil/Leucovorin + Irinotecan (KRAS mutant)

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D: FOLFOX + Cetuximab (KRAS wildtype)
E: 5-fluorouracil/Leucovorin + Cetuximab + Irinotecan (KRAS wildtype)
F: 5-fluorouracil/Leucovorin + Cetuximab + Irinotecan (KRAS wildtype)
Arms B, C, E, and F were discontinued as of June 1, 2005.
See protocol for more details.