

BIOSTAT PROJECT

SHEET 1

AEPR = Adverse Events Preferred Term

AESOC = Adverse Events System Organ Class

AESTDYI = Adverse Events Imputed Study Day of Start of Event

AEENDYI = Adverse Events Imputed Study Day of End of Event

AESEVCD = Adverse Events Grade/Severity Code

AECONT = Adverse Events Event Continuing?

SHEET 2

LBTEST = Laboratory Results Lab Test

LBBASE = Laboratory Results Baseline?

LBSTRESN = Laboratory Results Numeric Result in Analysis Std Units

LBSTUNIT = Laboratory Results Analysis Standard Units

VISITDY =

VISIT = Visit Name

SHEET 3

VISITDY =

VISIT = Visit Name

LSCAT = Lesion Category (Target/Non-target)

LSNEW = New Lesion?

LSSLD = Sum of Long. Diam Within Lesion Type(mm)

LSLD = Longest Diameter (mm)

LSSITE = Lesion Site

LSNEWANY = Any New Lesions?

LSREADER =

LSTYPE =

SHEET 4

VISIT = Visit Name

VISITDY =

WEIGHT = Weight in Kilograms at Baseline

SHEET 5

RSRESP = Overall Response Day Rel. to 1st Dose

VISITDY =

VISIT = Visit Name

RSCONFYN =

RSTRESP =

RSNTRESP =

RSNEW =

RSREADER =

SHEET 6

TRT = Treatment Dose (mg/kg)

ATRT = Actual Treatment

PRSURG =

DTHDY = Day of Death

DTH =

PFSDYCR = PFS Day (Central, RECIST) (62079) PFS Day (Central, WHO)
(62080) PFS Day (Central, WHO)

PFSCR = PD on Study (Central, RECIST) or Death

LIVERMET =

DIAGMONS = Months Since Primary Diagnosis

AGE =

SEX =

B_WEIGHT = Weight in Kilograms at Baseline

B_HEIGHT = Height in Centimeters at Baseline

RACE =

B_ECOG = Baseline ECOG Performance Status

HISSUBTY =

B_METANM = Number of BL Metas Site

DIAGTYPE = Primary Tumor Diagnosis

SHEET 7

BMMTNM1 =

BMMTR1 =

BMMTNM2 =

BMMTR2 =

BMMTNM3 =

BMMTR3 =

BMMTNM4 =

BMMTR4 =

BMMTNM5 =

BMMTR5 =

BMMTNM6 =

BMMTR6 =

BMMTNM7 =

BMMTR7 =

BMMTNM15 =

BMMTR15 =

BMMTNM16 =

BMMTR16 =