Data Dictionary for SWOG S1400I Clinical Dataset
(NCT02785952-D1-Dataset.csv)

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blanks indicate missing value

Variable Name	Variable description	Type	Code	Code definition
ALTPATID	Pseudo patient ID	Char		
DERIVED_RACE	Race	Char	B	Black
			M	Multi-Racial
			N	Native American
			P	Pacific Islander
			S	Asian
			U	Unknown
			W	White
SEX	Sex	Char	F	Female
			M	Male
HISPANIC	Hispanic Ethnicity	Char	N	No
			U	Unknown
			Y	Yes
NUMPT	Number of prior therapies for stage IV or recurrent disease (0 or more)	Num		
STRAT_TRMT	Number of prior therapies (stratification factor)	Char	One	
			Two or more	
CIGHIST1	Smoking status	Char	CURRENT	Current smoker
			FORMER	Former smoker
			NEVER	Never smoked
P6WTLOSS	Weight loss in past 6 months	Char	<5	<5% of body weight
			<10	5% to <10% of body weight
			<20	10% to <20% of body weight
			>=20	≥20% of body weight

ZUBRODPS	ECOG performance status	Num	0	Fully active, able to carryout on all pre-disease performance withoutrestriction.
			1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g.light housework, office work.
CURBRNMET	Brain Metastases at baseline	Char	N	No
			Y	Yes
LVRMETS	Liver metastases at baseline	Char	N	No
			Y	Yes
LOCPALRT	Prior radiation therapy (localized)	Char	N	No
			Y	Yes
CURATRT	Prior radiation therapy (with curative intent)	Char	N	No
			Y	Yes
tte_osrv2	Overall survival (calculated), months	Num		
ind_osrv	Indicator of death (1) or censored for death (0)	Num	0	Censored for death
			1	Death
tte_pfsrv2	Investigator- Assessed Progression free survival (calculated), months	Num		
ind_pfsrv	Indicator of progression (1) or censored for progression (0)	Num	0	Censored for progression
			1	Progression
RESP4	Best objective response	Char	CR	Complete response
			PR	Partial response
			UPR	Unconfirmed complete response
			STA	Stable disease
			INC	Increasing disease
			SYMP	Symptomatic deterioration
			NASS	Inadequate assessment
resptim	Date of substudy registration to first documentation of response, among responders, months	Num		

Variable	Description	Type	Code	Label
tte_resprv2	Duration of response [among responders] (calculated), months	Num		
ARMNAME	Treatment Arm (Nivolumab/Ipilimumab or nivolumab)	Char	Nivolumab	
			Nivolumab + Ipilimumab	
timetooff	Duration of protocol treatment from registration to off treatment date, months	Num		
OFFTX	Indicator of off-treatment status	Num	0	No
			1	Yes
OFFREASON	Reason off treatment	Char	DEAD	Death
			OTH	Other – not protocol specified
			PROG	Progression/relapse
			REF	Refusal unrelated to adverse event
			TSC	Adverse events or side effects
			" "	Missing value
age_cat	Age at randomization, years	Char		
CLINTOX	Evaluable for toxicities	Char	N	No
			Y	Yes
tmb_num	Tumor Mutational Burden (mt/Mb)	Num		
PDL1_num	Programmed Death-Ligand 1 expression (%)	Num		
num_cycles	Number of treatment cycles	Num		
pro_diarrhea_max	PRO diarrhea frequency	Num	0	None
			1	Rarely
			2	Occasionally
			3	Frequently
			4	Almost constantly

pro_diarrhea_max_adjust	PRO diarrhea frequency, baseline adjustment	Num	0	None
			1	Rarely
			2	Occasionally
			3	Frequently
			4	Almost constantly
pro_fatigueS_max	PRO fatigue severity	Num	0	None
			1	Mild
			2	Moderate
			3	Severe
			4	Very severe
pro_fatigueS_max_adjust	PRO fatigue severity, baseline adjustment	Num	0	None
			1	Mild
			2	Moderate
			3	Severe
			4	Very severe
pro_fatigueI_max	PRO fatigue interference	Num	0	Not at all
			1	A little bit
			2	Somewhat
			3	Quite a bit
			4	Very much

			0	Not at all
pro_fatigueI_max_adjust	PRO fatigue interference, baseline adjustment	Num	1	A little bit
			2	Somewhat
			3	Quite a bit
			4	Very much
pro_itch_max	PRO itching severity	Num	0	None
			1	Mild
			2	Moderate
			3	Severe
			4	Very severe
pro_itch_max_adjust	PRO itching severity, baseline adjustment	Num	0	None
			1	Mild
			2	Moderate
			3	Severe
			4	Very severe