Data Dictionary for SWOG S1216 Clinical Dataset (NCT01809691-D1-Dataset.csv)

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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).

Variable Name	Variable Description	Туре	Code	Code Definition
ALTPATID	Pseudo patient ID	Char		Pseudo patient ID
RACE	Race	Char	В	Black
			М	Multi-Racial
			N	Native American
			Р	Pacific Islander
			S	Asian
			U	Unknown
			W	White
AGE	Age at registration (years)	Num	Integer	Discrete age
				Age > 86 years
FOLLOW	Follow-up status	Char	Y	Yes, in follow-up
			N	No, not in follow-up
			L	Lost to follow-up
CLINTOX	Adverse event evaluability	Char	Y	Evaluable
			N	Not evaluable
ARMNAME	Treatment arm to which	Char	LHRHa +	
	patient was randomized		Bicalutamide	
			LHRHa + TAK-	
			700	
SURIND	Overall survival indicator	Num	0	Alive
			1	Dead
SURTIM	Overall survival time; days	Num		
	from randomization to last			
	contact or death			
PFSIND	Progression free survival	Num	0	Alive, no progression
	indicator		1	Progression or death
PFSTIM	Progression free survival	Num		
	time; days from			
	randomization to			
	progression, last contact, or death			
ТАК700	Treatment arm indicator	Num	0	LHRHa + Bicalutamide
1711700		Num	1	LHRHa + TAK-700
EXTENSIVE	Severity of disease	Num	0	Minimal
	stratification factor	Nulli	1	Extensive
		<u> </u>	1	LALCHSIVE

PS01	Zubrod performance status	Num	0	PS 2-3
	stratification factor indicator		1	PS 0-1
CADLATE	Induction treatment	Num	0	Early induction
	stratification factor		1	Late induction
EXTENTTX	Severity of disease indicator	Num	0	Minimal
	for treatment interaction		1	Extensive
PSTX	Zubrod performance status	Num	0	PS 2-3
	indicator for treatment interaction		1	PS 0-1
LATETX	Induction treatment	Num	0	Early induction
	indicator for treatment interaction		1	Late induction
ZUBRODPS	Zubrod performance status	Num	0	PS 0
	as reported by site on		1	PS 1
	Onstudy form		2	PS 2
			3	PS 3
				Unknown
LVRMETS	Liver metastases indicator	Num	0	Liver metastases not
				present
			1	Liver metastases present
VISCMETS	Visceral metastatic disease indicator	Num	0	Visceral metastatic disease
				not present
			1	Visceral metastatic disease present
BMETS	Bone metastases indicator	Num	0	Bone metastases not
			4	present
	Lymph node metastases indicator	Num	1	Bone metastases present
LNDZMETS			0	Lymph node metastases not present
			1	Lymph node metastases present
BONEPN	Bone pain indicator	Char	Y	Bone pain present
			Ν	Bone pain not present
			U	Unknown
PRIDENBIS	Denosumab or	Char	Y	Yes
	bisphosphonate usage prior to registration		N	No
PSA_RESP	PSA response	Char	NR	No response
			PR	Partial response
			CR	Complete response
			11	Missing/Not evaluable for response
BLACKTX	Black race indicator for	Num	0	Not black
	treatment interaction		1	Black

LIFE_SAVE_TX	Life-saving treatment indicator	Num	0 1 .	Received only non-life- prolonging post-protocol treatment, or died on treatment or within 1 month of going off treatment Received life-prolonging post-protocol treatment Post-protocol treatment data unavailable (not reported by site), or patient is still on protocol treatment
NONLIFE_SAVE _TX	Non-life-saving treatment indicator	Num	0 1 .	Received life-prolonging post-protocol treatment, or died on treatment or within 1 month of going off treatment Received only non-life- prolonging post-protocol treatment Post-protocol treatment data unavailable (not reported by site), or patient is still on protocol treatment
D_1MONTH	Death within first month off of protocol treatment indicator	Num	0	Did not die within 1 month of going off protocol treatment and received post-protocol therapy Died on protocol treatment or within 1 month of going off protocol treatment Post-protocol treatment data unavailable (not reported by site), or patient is still on protocol treatment

AA_INHIB	Androgen axis inhibitor therapy indicator	Num	0	Received post-protocol treatment, but not androgen axis inhibitor therapy
			1	Received subsequent androgen axis inhibitor therapy
				Did not receive post- protocol treatment, died on treatment or within 1 month of going off treatment, post-protocol treatment data unavailable (not reported by site), or patient is still on protocol treatment
PP_TX	Post-protocol treatment indicator	Num	0	Post-protocol treatment data unavailable (not reported by site)
			1	Received post-protocol treatment, or died on treatment or within 1 month of going off treatment
			99	Missing data Patient is still on protocol treatment
ELIGIBLE	Eligibility	Char	Y N	Eligible Ineligible
WITHDREW	Pre-treatment withdrawal indicator	Char	Y N	Withdrew Did not withdraw
ITT	ITT analysis indicator	Num	0	Excluded from ITT analysis Included in ITT analysis
OTHER	Race other than White or Black indicator for treatment interaction	Num	0	Race is either White or Black Race other than White or
		Char		Black
RADPROS	Prior radical prostatectomy	Char	Y N	Yes No
BI_ORCH	Prior bilateral orchiectomy	Char	Y N	Yes No

RXSTAT2	Treatment status/reason off	Char	ON	On treatment
	treatment		OTH	Other reasons, not
				specified
			REF	Patient refusal, unrelated
				to toxicity
			TSC	Toxicity/adverse event
			DEAD	Death
			PROG	Disease progression or
				relapse
			No T	Did not receive protocol
				treatment
GLEAS_CAT	Gleason score	Char	GI < 7	Gleason score less than 7
			GI = 7	Gleason score 7
			GI = 8	Gleason score 8
			GI = 9, 10	Gleason score 9 or 10
				Unknown/not reported