

This dictionary file is for Dataset NCT01169337-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).				
This dataset corresponds to information in J Clin Oncol. 2020 Apr 10;38(11):1126-1137				
<a href="#">PMC7145586</a>				
Note: Unless otherwise specified, blank values indicate missing data or not applicable.				
Dataset description: Clinical information				
Observations: 226				
Variables: 43				
List of Variables and Attributes				
#	Variable	Type	Description	Code
1	case	Num	A blinded ID generated by ECOG-ACRIN	
2	arm_s1	Num	Step 1 (S1) arm assignment	1=A: Lenalidomide, 2=B: Observation
3	elig	Num	Eligibility status	0=Eligible, 1=Not Eligible
4	inelig_reas_class	Num	Reason excluded	1=Abnormal FLC ratio criteria not met, 2=UPEP not done, 3=Baseline BM outside registration window, 4=Baseline SPEP or UPEP outside registration window, 5=Baseline BM levels criteria not met, 6=No measurable disease in serum or urine, 7=Baseline labs not done or unconfirmed, 8=MRI unconfirmed, 9=Present prior malignancy, 10=Baseline HgB level criteria not met, 98=Ineligible prior to randomization
5	ontx_stat	Num	On treatment status	0=Off treatment, 1=On treatment

6	offtx_reas	Num	Reason off-treatment	0=Unknown, 2=Disease progression, 3=Adverse event, 4=Death, 5=Withdrawal, 6=Alternative therapy, 7=Other complicating disease, 98=Changed hospital, 99=Other, 100=MD decision, 101=Clinical disease progression, 102=Noncompliance
7	phase	Num	Phase	2=Phase II, 3=Phase III
8	age	Num	Age at randomization	In years
9	sex	Num	Sex	1=Male, 2=Female
10	race	Char	Race	White, Black or African American, Asian, Not Reported
11	ethnicity	Num	Ethnicity	1=Hispanic or Latino, 2=Non-Hispanic, 12=Not Reported, -1=Missing/Unknown
12	ecogps	Num	ECOG performance status	0=0, 1=1, 2=2
13	t_smm	Num	Time from SMM diagnosis to randomization	In months
14	t_hrsmm	Num	Time from high-risk SMM diagnosis to randomization	In months
15	plasma	Num	Bone marrow plasma cell	In percentage
16	flc	Num	Free light chain (FLC) ratio	
17	flc_inv	Num	Involved FLC	mg/dL
18	serum	Char	Serum M protein	g/dL <1 1 to 2 2 to 3 >/= 3
19	iga	Num	Immunoglobulin A (IgA)	mg/dL
20	mri	Num	MRI abnormality	1=No Abnormality, 2=BM Signal Abnormal, 3=Bone Lesions, 4=Other
21	fish	Num	Fluorescence in situ hybridization risk stratification	0=High, 1=Intermediate, 2=Low

22	mayo2008	Num	Mayo 2008 risk stratification	0=Low, 1=Intermediate, 2=High
23	mayo2018	Num	Mayo 2018 risk stratification	0=Low, 1=Intermediate, 2=High
24	t2pfs	Num	Progression-Free Survival (PFS) from registration date	In months
25	c4pfs	Num	Censor for PFS	0=Censor: No (Event), 1=Censor: Yes
26	t2surv	Num	Overall Survival (OS) from registration date	In months
27	c4surv	Num	Censor for OS	0=Censor: No (Event), 1=Censor: Yes
28	t2prog	Num	Time to progression (TTP) from registration date	In months
29	c4prog	Num	Censor for TTP	0=Censor: No (Event), 1=Censor: Yes
30	strat_new	Num	Amendment stratification factor: time from SMM diagnosis to randomization	1=SMM diagnosis < 1y, 2=SMM diagnosis > 1y, 3=Enrolled before amendment
31	bestresp	Num	Best confirmed overall response	2=CR, 3=VGPR, 4=PR, 5=SD, 7=Unevaluable, -1=Insufficient
32	t2pr	Num	Time to first at least partial response from registration date	In months
33	t2alt	Num	Time to alternative therapy from registration date	In months
34	lastcyc	Num	Treatment duration	In cycles
35	txdur	Num	Treatment duration	In months
36	pfs_trtend	Num	Time to PFS follow-up from treatment end	In months
37	spmsite	Char	Second primary cancer (SPC) site	
38	spmtype	Num	SPC type	1=SPC: Heme, 2=SPC: Solid, 3=SPC: Non-Melanoma Skin
39	spminv	Num	SPC invasive status	1=SPC: Invasive, 2=SPC: Non-Invasive
40	t2spm	Num	Time to SPC	In months
41	tx_nev_strt_reas	Char	Reason for not starting assigned treatment	1=No treatment assigned, 2=Patient ineligible,

				3=Disease progression, 4=Adverse event/Side effect, 5=Death, 6=Patient withdrawal or refusal, 7=Medical decision, 99=Other
42	obs_nev_strt_reas	Char	Reason for not starting assigned observation	2=Patient ineligible, 3=Disease progression, 4=Adverse event/Side effect, 5=Death, 6=Patient withdrawal or refusal, 7=Medical decision, 99=Other
43	surv_stat	Char	Survival status	1=Alive, 2=Dead, 7=Withdrew consent for continued follow-up, 8=Official lost to follow-up