CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	All methods reported in previously published papers for IX and XI
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	

concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Supplementary figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Supplementary figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	Previously published
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Supplementary table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7 and 9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9-13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15-16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14-16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-16
Other information			

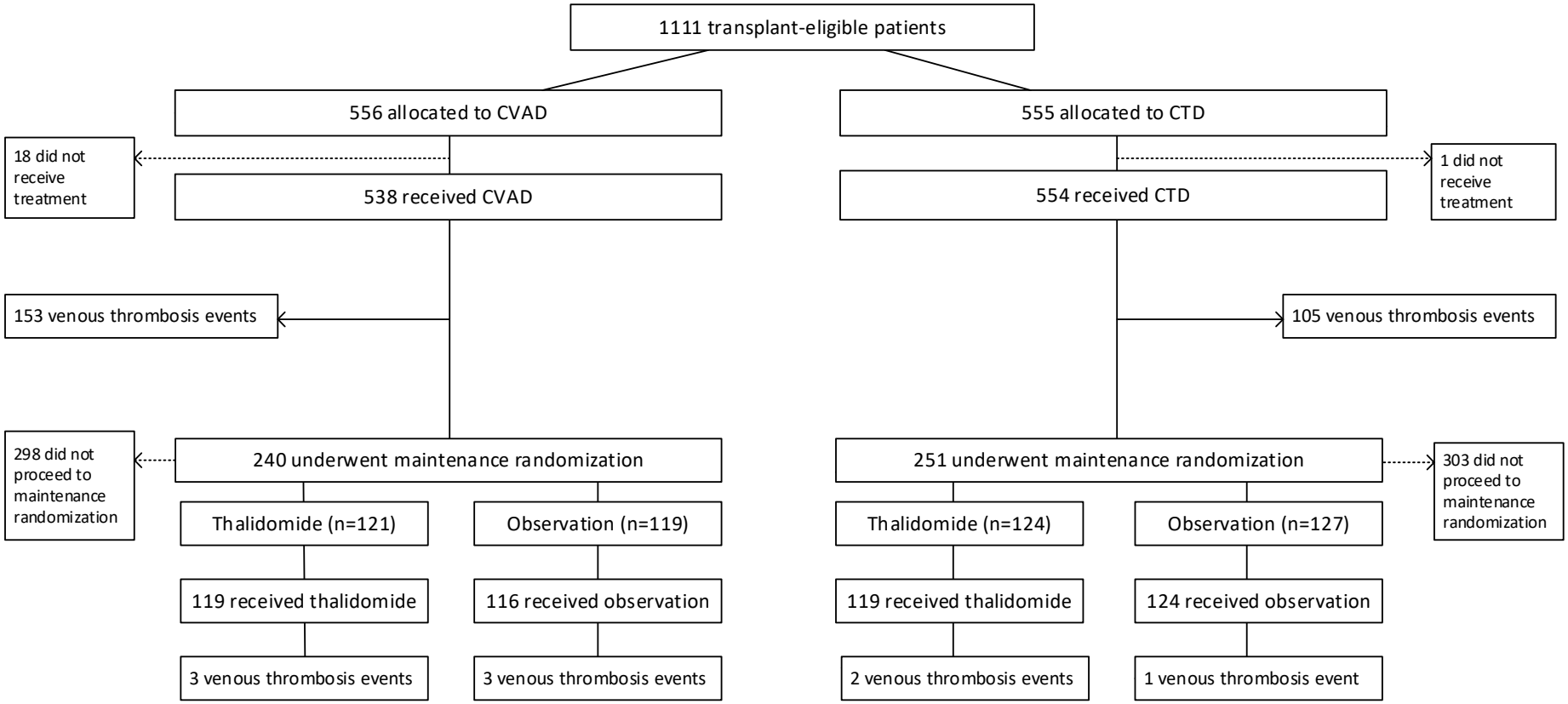
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

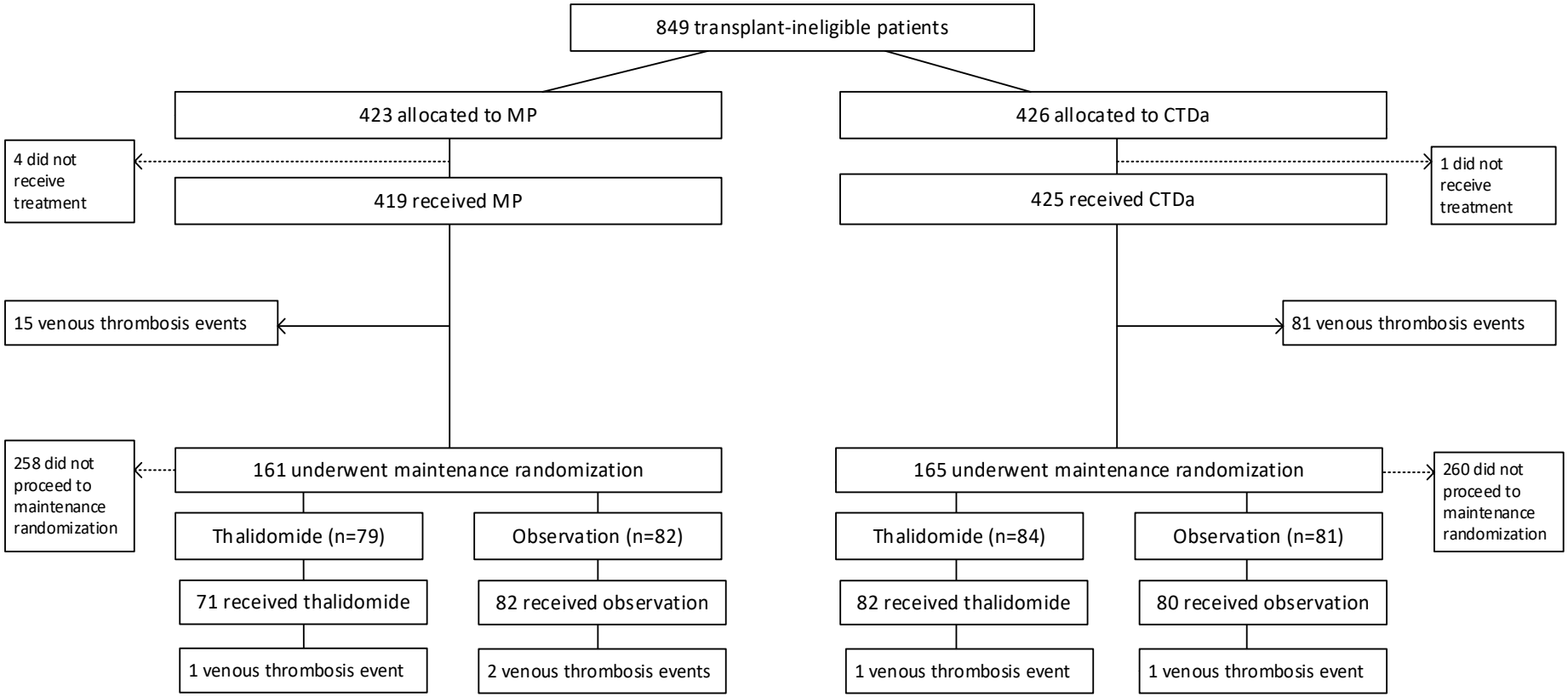
Supplementary material

Figure 1. CONSORT flow diagram for Myeloma IX transplant-eligible (A) and transplant-ineligible (B) pathways and Myeloma XI transplant-eligible (C) and transplant-ineligible (D) pathways

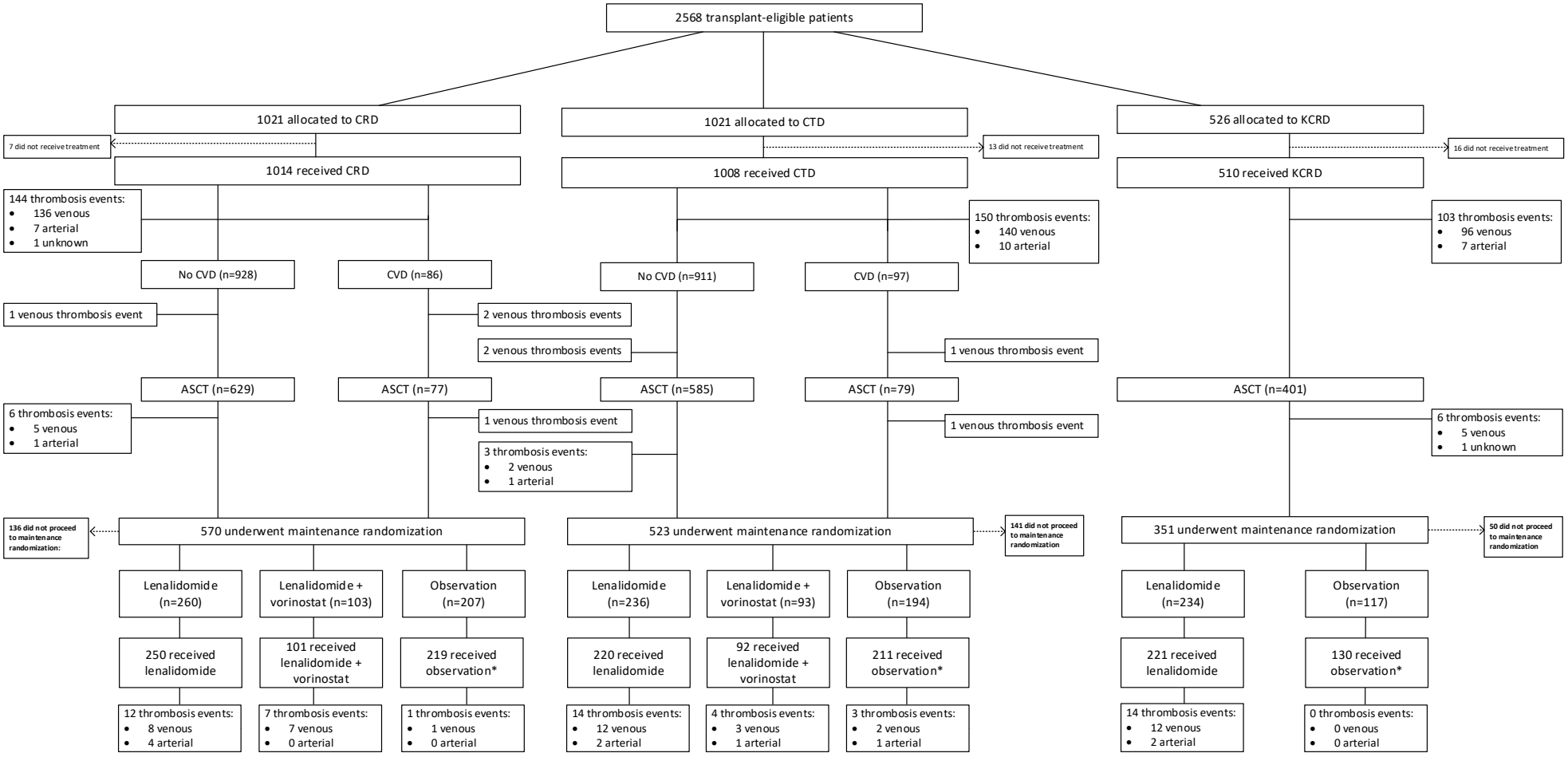
A



B


849 transplant-ineligible patients
423 allocated to MP
426 allocated to CTDa
4 did not receive treatment
419 received MP
425 received CTDa
1 did not receive treatment
15 venous thrombosis events
81 venous thrombosis events
258 did not proceed to maintenance randomization
161 underwent maintenance randomization
165 underwent maintenance randomization
260 did not proceed to maintenance randomization
Thalidomide (n=79)
Observation (n=82)
Thalidomide (n=84)
Observation (n=81)
71 received thalidomide
82 received observation
82 received thalidomide
80 received observation
1 venous thrombosis event
2 venous thrombosis events
1 venous thrombosis event
1 venous thrombosis event

C


2568 transplant-eligible patients
1021 allocated to CRD
7 did not receive treatment
1014 received CRD
144 thrombosis events:
• 136 venous
• 7 arterial
• 1 unknown
No CVD (n=928)
CVD (n=86)
1 venous thrombosis event
2 venous thrombosis events
2 venous thrombosis events
ASCT (n=629)
ASCT (n=77)
6 thrombosis events:
• 5 venous
• 1 arterial
1 venous thrombosis event
3 thrombosis events:
• 2 venous
• 1 arterial
136 did not proceed to maintenance randomization:
570 underwent maintenance randomization
Lenalidomide (n=260)
Lenalidomide + vorinostat (n=103)
Observation (n=207)
250 received lenalidomide
101 received lenalidomide + vorinostat
219 received observation*
12 thrombosis events:
• 8 venous
• 4 arterial
7 thrombosis events:
• 7 venous
• 0 arterial
1 thrombosis events:
• 1 venous
• 0 arterial
* Includes 12 who were randomised to lenalidomide ± vorinostat but did not received this treatment
1021 allocated to CTD
13 did not receive treatment
1008 received CTD
150 thrombosis events:
• 140 venous
• 10 arterial
No CVD (n=911)
CVD (n=97)
1 venous thrombosis event
ASCT (n=585)
ASCT (n=79)
1 venous thrombosis event
141 did not proceed to maintenance randomization
523 underwent maintenance randomization
Lenalidomide (n=236)
Lenalidomide + vorinostat (n=93)
Observation (n=194)
220 received lenalidomide
92 received lenalidomide + vorinostat
211 received observation*
14 thrombosis events:
• 12 venous
• 2 arterial
4 thrombosis events:
• 3 venous
• 1 arterial
3 thrombosis events:
• 2 venous
• 1 arterial
* Includes 17 who were randomised to lenalidomide ± vorinostat but did not received this treatment
526 allocated to KCRD
16 did not receive treatment
510 received KCRD
103 thrombosis events:
• 96 venous
• 7 arterial
ASCT (n=401)
6 thrombosis events:
• 5 venous
• 1 unknown
50 did not proceed to maintenance randomization
351 underwent maintenance randomization
Lenalidomide (n=234)
Observation (n=117)
221 received lenalidomide
130 received observation*
14 thrombosis events:
• 12 venous
• 2 arterial
0 thrombosis events:
• 0 venous
• 0 arterial
* Includes 13 who were randomised to lenalidomide but did not received this treatment

D

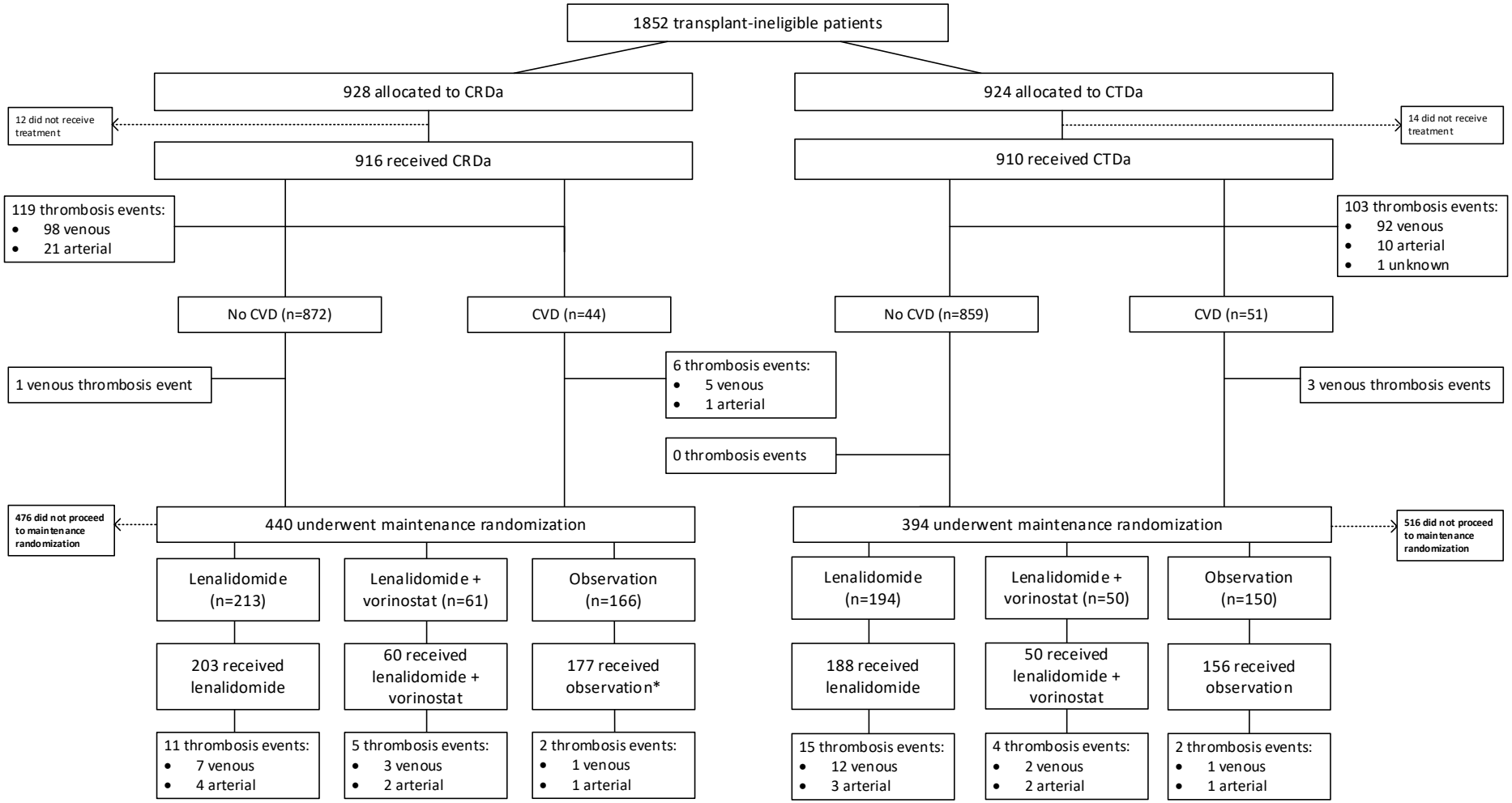

1852 transplant-ineligible patients
928 allocated to CRDa
924 allocated to CTDa
12 did not receive treatment
14 did not receive treatment
916 received CRDa
910 received CTDa
119 thrombosis events:
98 venous
21 arterial
103 thrombosis events:
92 venous
10 arterial
1 unknown
No CVD (n=872)
CVD (n=44)
No CVD (n=859)
CVD (n=51)
1 venous thrombosis event
6 thrombosis events:
5 venous
1 arterial
3 venous thrombosis events
0 thrombosis events
476 did not proceed to maintenance randomization
440 underwent maintenance randomization
394 underwent maintenance randomization
516 did not proceed to maintenance randomization
Lenalidomide (n=213)
Lenalidomide + vorinostat (n=61)
Observation (n=166)
Lenalidomide (n=194)
Lenalidomide + vorinostat (n=50)
Observation (n=150)
203 received lenalidomide
60 received lenalidomide + vorinostat
177 received observation*
188 received lenalidomide
50 received lenalidomide + vorinostat
156 received observation
11 thrombosis events:
7 venous
4 arterial
5 thrombosis events:
3 venous
2 arterial
2 thrombosis events:
1 venous
1 arterial
15 thrombosis events:
12 venous
3 arterial
4 thrombosis events:
2 venous
2 arterial
2 thrombosis events:
1 venous
1 arterial

Table 1. Myeloma IX and Myeloma XI baseline characteristics

	Myeloma IX					Myeloma IX					
	Transplant-eligible pathway		Transplant-ineligible pathway			Transplant-eligible pathway			Transplant-ineligible pathway		
Characteristic	CVAD (n=538)	CTD (n=554)	MP (n=419)	CTDa (n=425)	Total (n=1936)	CTD (n=1008)	CRD (n=1014)	KCRD (n=510)	CTDa (n=910)	CRDa (n=916)	Total (n=4358)
Age											
Median (range)	58 (31, 74)	59 (33, 79)	73 (57, 89)	73 (58, 87)	65 (31, 89)	61 (29, 80)	61 (28, 75)	60 (33, 80)	74 (54, 89)	74 (60, 92)	67 (28, 92)
Sex											
Male	339 (63.0%)	339 (61.2%)	231 (55.1%)	241 (56.7%)	1150 (59.4%)	605 (60.0%)	605 (59.7%)	309 (60.6%)	529 (58.1%)	503 (54.9%)	2551 (58.5%)
Female	199 (37.0%)	215 (38.8%)	188 (44.9%)	184 (43.3%)	786 (40.6%)	403 (40.0%)	409 (40.3%)	201 (39.4%)	381 (41.9%)	413 (45.1%)	1807 (41.5%)
Ethnicity											
White	528 (98.1%)	526 (94.9%)	411 (98.1%)	413 (97.2%)	1878 (97.0%)	932 (92.5%)	938 (92.5%)	479 (93.9%)	868 (95.4%)	857 (93.6%)	4074 (93.5%)
Black (black Caribbean, black African, other)	4 (0.7%)	12 (2.2%)	6 (1.4%)	5 (1.2%)	27 (1.4%)	13 (1.3%)	21 (2.1%)	9 (1.8%)	20 (2.2%)	12 (1.3%)	75 (1.7%)
Asian (Indian, Pakistani, Bangladeshi, other)	4 (0.7%)	8 (1.4%)	1 (0.2%)	2 (0.5%)	15 (0.8%)	26 (2.6%)	28 (2.8%)	9 (1.8%)	10 (1.1%)	19 (2.1%)	92 (2.1%)
Other	2 (0.4%)	8 (1.4%)	1 (0.2%)	5 (1.2%)	16 (0.8%)	14 (1.4%)	10 (1.0%)	8 (1.6%)	3 (0.3%)	4 (0.4%)	39 (0.9%)
Unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	23 (2.3%)	17 (1.7%)	5 (1.0%)	9 (1.0%)	24 (2.6%)	78 (1.8%)
WHO performance status											
0	158 (29.4%)	151 (27.3%)	70 (16.7%)	86 (20.2%)	465 (24.0%)	435 (43.2%)	420 (41.4%)	216 (42.4%)	227 (24.9%)	248 (27.1%)	1546 (35.5%)

	Myeloma IX					Myeloma IX					
	Transplant-eligible pathway		Transplant-ineligible pathway			Transplant-eligible pathway			Transplant-ineligible pathway		
Characteristic	**CVAD (n=538)**	**CTD (n=554)**	**MP (n=419)**	**CTDa (n=425)**	**Total (n=1936)**	**CTD (n=1008)**	**CRD (n=1014)**	**KCRD (n=510)**	**CTDa (n=910)**	**CRDa (n=916)**	**Total (n=4358)**
1	222 (41.3%)	240 (43.3%)	208 (49.6%)	201 (47.3%)	871 (45.0%)	364 (36.1%)	361 (35.6%)	192 (37.6%)	398 (43.7%)	404 (44.1%)	1719 (39.4%)
2	102 (19.0%)	91 (16.4%)	83 (19.8%)	88 (20.7%)	364 (18.8%)	135 (13.4%)	120 (11.8%)	56 (11.0%)	187 (20.5%)	147 (16.0%)	645 (14.8%)
3	47 (8.7%)	58 (10.5%)	51 (12.2%)	42 (9.9%)	198 (10.2%)	32 (3.2%)	46 (4.5%)	19 (3.7%)	48 (5.3%)	61 (6.7%)	206 (4.7%)
4	4 (0.7%)	7 (1.3%)	5 (1.2%)	6 (1.4%)	22 (1.1%)	2 (0.2%)	8 (0.8%)	1 (0.2%)	5 (0.5%)	6 (0.7%)	22 (0.5%)
Missing	5 (0.9%)	7 (1.3%)	2 (0.5%)	2 (0.5%)	16 (0.8%)	40 (4.0%)	59 (5.8%)	26 (5.1%)	45 (4.9%)	50 (5.5%)	220 (5.0%)
Haemoglobin g/dl											
Mean (s.d.)	10.7 (2.0)	10.8 (2.0)	10.7 (4.2)	10.8 (4.5)	10.8 (3.2)	10.9 (1.98)	10.9 (2.0)	11.1 (2.0)	10.5 (1.7)	10.5 (1.7)	10.8 (1.9)
Missing	1	0	0	0	1	1	0	0	1	0	2
Platelets (*10/l)											
Mean (s.d.)	251.3 (93.3)	256.0 (97.7)	249.9 (102.5)	233.8 (94.8)	248.5 (97.2)	255.0 (105.0)	249.3 (97.7)	249.1 (90.7)	235.5 (89.9)	239.0 (94.5)	245.6 (96.6)
Missing	1	0	0	0	1	0	0	0	0	0	0
Creatinine (µmol/l)											
Mean (s.d.)	118.3 (65.4)	116.1 (67.1)	116.6 (52.6)	121.3 (62.7)	118.0 (62.7)	98.0 (56.2)	97.8 (52.1)	92.9 (43.6)	105.7 (52.1)	106.5 (59.3)	100.7 (54.0)
Missing	17	23	10	17	67	1	0	0	0	0	1
β2 microglobulin (mg/l)											
Mean (s.d.)	5.8 (5.6)	5.8 (7.5)	6.2 (4.4)	6.4 (5.0)	6.0 (5.9)	4.7 (3.9)	4.8 (4.1)	4.6 (3.5)	5.8 (4.2)	5.9 (5.1)	5.2 (4.3)
Missing	43	40	33	46	162	354	360	176	342	339	1571

Characteristic	Myeloma IX					Myeloma IX					
	Transplant-eligible pathway		Transplant-ineligible pathway		Total (n=1936)	Transplant-eligible pathway			Transplant-ineligible pathway		Total (n=4358)
	CVAD (n=538)	CTD (n=554)	MP (n=419)	CTDa (n=425)		CTD (n=1008)	CRD (n=1014)	KCRD (n=510)	CTDa (n=910)	CRDa (n=916)	
Calcium (µmol/l)											
Mean (s.d.)	2.4 (0.5)	2.4 (1.1)	2.4 (0.2)	2.4 (0.2)	2.4 (0.7)	2.4 (0.2)	2.4 (0.3)	2.4 (0.2)	2.4 (0.2)	2.4 (0.2)	2.4 (0.2)
Missing	17	25	16	18	76	1	1	0	0	1	3
Paraprotein type											
IgG	319 (59.3%)	331 (59.7%)	256 (61.1%)	249 (58.6%)	1155 (59.7%)	596 (59.1%)	632 (62.3%)	292 (57.3%)	576 (63.3%)	572 (62.4%)	2668 (61.2%)
IgA	120 (22.3%)	119 (21.5%)	100 (23.9%)	98 (23.1%)	437 (22.6%)	266 (26.4%)	221 (21.8%)	126 (24.7%)	229 (25.2%)	234 (25.5%)	1076 (24.7%)
IgM	3 (0.6%)	2 (0.4%)	1 (0.2%)	2 (0.5%)	8 (0.4%)	3 (0.3%)	4 (0.4%)	4 (0.8%)	2 (0.2%)	3 (0.3%)	16 (0.4%)
IgD	9 (1.7%)	14 (2.5%)	3 (0.7%)	10 (2.4%)	36 (1.9%)	9 (0.9%)	11 (1.1%)	4 (0.8%)	3 (0.3%)	8 (0.9%)	35 (0.8%)
Non-secretor	11 (2.0%)	9 (1.6%)	5 (1.2%)	7 (1.6%)	32 (1.7%)	7 (0.7%)	5 (0.5%)	4 (0.8%)	5 (0.5%)	5 (0.5%)	26 (0.6%)
Light chain only	71 (13.2%)	72 (13.0%)	49 (11.7%)	54 (12.7%)	246 (12.7%)	127 (12.6%)	140 (13.8%)	79 (15.5%)	95 (10.4%)	91 (9.9%)	532 (12.2%)
Missing	5 (0.9%)	7 (1.3%)	5 (1.2%)	5 (1.2%)	22 (1.1%)	0 (0.0%)	1 (0.1%)	1 (0.2%)	0 (0.0%)	3 (0.3%)	5 (0.1%)
Light Chain Type											
Lambda	171 (31.8%)	168 (30.3%)	148 (35.3%)	133 (31.3%)	620 (32.0%)	337 (33.4%)	344 (33.9%)	180 (35.3%)	296 (32.5%)	291 (31.8%)	1448 (33.2%)
Kappa	312 (58.0%)	342 (61.7%)	241 (57.5%)	258 (60.7%)	1153 (59.6%)	661 (65.6%)	660 (65.1%)	325 (63.7%)	609 (66.9%)	611 (66.7%)	2866 (65.8%)
Missing	55 (10.2%)	44 (7.9%)	30 (7.2%)	34 (8.0%)	163 (8.4%)	10 (1.0%)	10 (1.0%)	5 (1.0%)	5 (0.5%)	14 (1.5%)	44 (1.0%)

Table 2. Myeloma IX baseline characteristics by thrombosis occurrence, split by pathway

Characteristic	Transplant-eligible pathway				Transplant-ineligible pathway			
	Thrombosis (n=210)	No thrombosis (n=882)	Total (n=1092)	P	Thrombosis (n=85)	No thrombosis (n=759)	Total (n=844)	P
Sex								
Male	120 (57.1%)	558 (63.3%)	678 (62.1%)	0.1003	34 (40.0%)	438 (57.7%)	472 (55.9%)	0.0018
Female	90 (42.9%)	324 (36.7%)	414 (37.9%)		51 (60.0%)	321 (42.3%)	372 (44.1%)	
Age								
Mean (SD)	57.1 (7.44)	57.8 (7.44)	57.7 (7.44)	0.1941	73.2 (5.47)	73.4 (5.48)	73.3 (5.48)	0.8444
Median (Range)	58.0 (31.0, 74.0)	59.0 (31.0, 79.0)	59.0 (31.0, 79.0)		73.0 (63.0, 87.0)	73.0 (57.0, 89.0)	73.0 (57.0, 89.0)	
Ethnicity								
White	207 (98.6%)	847 (96.0%)	1054 (96.5%)	0.7172	85 (100.0%)	739 (97.4%)	824 (97.6%)	1.0000
Black (black Caribbean, black African, other)	1 (0.5%)	15 (1.7%)	16 (1.5%)		0 (0.0%)	11 (1.5%)	11 (1.3%)	
Asian (Indian, Pakistani, Bangladeshi, other)	1 (0.5%)	11 (1.2%)	12 (1.1%)		0 (0.0%)	3 (0.4%)	3 (0.4%)	
Other	1 (0.5%)	9 (1.0%)	10 (0.9%)		0 (0.0%)	6 (0.8%)	6 (0.7%)	
WHO performance status								
0	61 (29.0%)	248 (28.1%)	309 (28.3%)	0.8722	18 (21.2%)	138 (18.2%)	156 (18.5%)	0.7529
1	90 (42.9%)	372 (42.2%)	462 (42.3%)		44 (51.8%)	365 (48.1%)	409 (48.5%)	
2	38 (18.1%)	155 (17.6%)	193 (17.7%)		13 (15.3%)	158 (20.8%)	171 (20.3%)	
3	19 (9.0%)	86 (9.8%)	105 (9.6%)		10 (11.8%)	83 (10.9%)	93 (11.0%)	
4	1 (0.5%)	10 (1.1%)	11 (1.0%)		0 (0.0%)	11 (1.4%)	11 (1.3%)	
Missing	1 (0.5%)	11 (1.2%)	12 (1.1%)		0 (0.0%)	4 (0.5%)	4 (0.5%)	
β2 microglobulin (mg/l)								
Mean (SD)	5.7 (5.62)	5.9 (6.87)	5.8 (6.65)	0.5614	5.5 (3.48)	6.4 (4.82)	6.3 (4.71)	0.2383

Characteristic	Transplant-eligible pathway				Transplant-ineligible pathway			
	Thrombosis (n=210)	No thrombosis (n=882)	Total (n=1092)	P	Thrombosis (n=85)	No thrombosis (n=759)	Total (n=844)	P
Median (Range)	4.1 (0.2, 58.0)	4.0 (0.1, 114.1)	4.0 (0.1, 114.1)		4.5 (0.4, 21.2)	5.0 (0.3, 64.0)	4.9 (0.3, 64.0)	
Missing	17	66	83		10	69	79	
Creatinine (µmol/l)								
Mean (SD)	115.8 (61.17)	117.6 (67.38)	117.2 (66.22)	0.6675	122.2 (83.06)	118.6 (54.42)	118.9 (57.88)	0.0547
Median (Range)	98.0 (49.0, 439.0)	98.0 (2.4, 462.0)	98.0 (2.4, 462.0)		95.0 (50.0, 495.0)	102.0 (42.0, 468.0)	102.0 (42.0, 495.0)	
Missing	9	31	40		3	24	27	
Calcium (µmol/l)								
Mean (SD)	2.4 (0.24)	2.4 (0.93)	2.4 (0.84)	0.3175	2.4 (0.29)	2.4 (0.22)	2.4 (0.23)	0.7035
Median (Range)	2.4 (1.6, 3.4)	2.4 (1.3, 26.4)	2.4 (1.3, 26.4)		2.4 (1.6, 3.5)	2.4 (1.4, 3.5)	2.4 (1.4, 3.5)	
Missing	8	34	42		3	31	34	
Platelets (*10/l)								
Mean (SD)	260.3 (93.57)	252.1 (95.97)	253.7 (95.53)	0.2652	238.4 (96.54)	242.2 (99.26)	241.8 (98.94)	0.7386
Median (Range)	251.0 (43.0, 540.0)	241.0 (17.0, 647.0)	242.0 (17.0, 647.0)		230.0 (82.0, 642.0)	228.0 (15.0, 825.0)	228.0 (15.0, 825.0)	
Missing	0	1	1		0	0	0	
Haemoglobin g/dl								
Mean (SD)	10.8 (1.89)	10.8 (2.04)	10.8 (2.01)	0.7923	10.4 (1.77)	10.8 (4.54)	10.7 (4.34)	0.1614
Median (Range)	10.8 (6.5, 17.8)	10.6 (4.0, 17.8)	10.7 (4.0, 17.8)		10.4 (6.5, 14.9)	10.5 (5.3, 95.0)	10.4 (5.3, 95.0)	
Missing	0	1	1		0	0	0	
Paraprotein type								
IgG	139 (66.2%)	511 (57.9%)	650 (59.5%)	0.0096	54 (63.5%)	451 (59.4%)	505 (59.8%)	0.9399
IgA	38 (18.1%)	201 (22.8%)	239 (21.9%)		21 (24.7%)	177 (23.3%)	198 (23.5%)	

Characteristic	Transplant-eligible pathway				Transplant-ineligible pathway			
	Thrombosis (n=210)	No thrombosis (n=882)	Total (n=1092)	P	Thrombosis (n=85)	No thrombosis (n=759)	Total (n=844)	P
IgM	0 (0.0%)	5 (0.6%)	5 (0.5%)		0 (0.0%)	3 (0.4%)	3 (0.4%)	
IgD	8 (3.8%)	15 (1.7%)	23 (2.1%)		1 (1.2%)	12 (1.6%)	13 (1.5%)	
Non-secretor	6 (2.9%)	14 (1.6%)	20 (1.8%)		0 (0.0%)	12 (1.6%)	12 (1.4%)	
Light chain only	17 (8.1%)	126 (14.3%)	143 (13.1%)		9 (10.6%)	94 (12.4%)	103 (12.2%)	
Missing	2 (1.0%)	10 (1.1%)	12 (1.1%)		0 (0.0%)	10 (1.3%)	10 (1.2%)	
Light Chain Type								
Lambda	69 (32.9%)	270 (30.6%)	339 (31.0%)	0.5987	32 (37.6%)	249 (32.8%)	281 (33.3%)	0.4344
Kappa	124 (59.0%)	530 (60.1%)	654 (59.9%)		48 (56.5%)	451 (59.4%)	499 (59.1%)	
Missing	17 (8.1%)	82 (9.3%)	99 (9.1%)		5 (5.9%)	59 (7.8%)	64 (7.6%)	

Table 3. Myeloma XI baseline characteristics by thrombosis occurrence, split by pathway

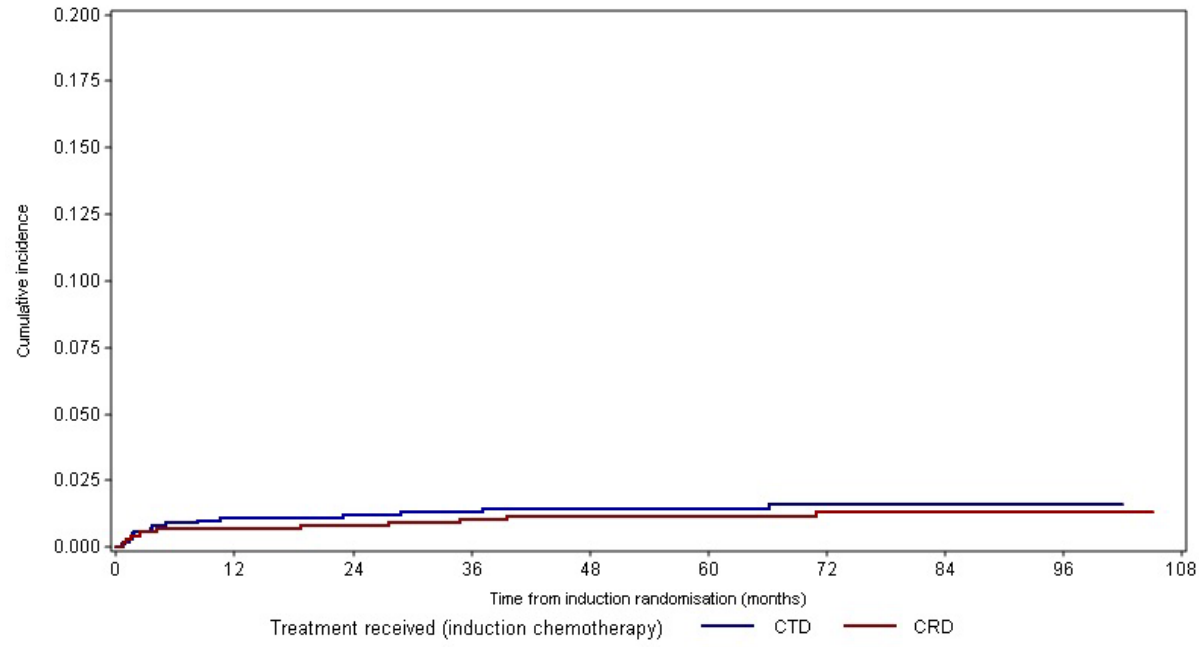
	Transplant-eligible pathway				Transplant-ineligible pathway			
Characteristic	**Thrombosis (n=371)**	**No thrombosis (n=2161)**	**Total (n=2532)**	**P**	**Thrombosis (n=228)**	**No thrombosis (n=1598)**	**Total (n=1826)**	**P**
Patients sex								
Male	244 (65.8%)	1275 (59.0%)	1519 (60.0%)	0.0140	129 (56.6%)	903 (56.5%)	1032 (56.5%)	0.9839
Female	127 (34.2%)	886 (41.0%)	1013 (40.0%)		99 (43.4%)	695 (43.5%)	794 (43.5%)	
Age								
Mean (SD)	60.3 (7.80)	59.2 (8.08)	59.4 (8.04)	0.0156	74.0 (5.49)	74.5 (5.39)	74.4 (5.40)	0.1796
Median (Range)	62.0 (37.0, 80.0)	61.0 (28.0, 80.0)	61.0 (28.0, 80.0)		73.5 (61.0, 89.0)	75.0 (54.0, 92.0)	74.0 (54.0, 92.0)	
Ethnicity								
White	357 (96.2%)	1992 (92.2%)	2349 (92.8%)	0.1657	219 (96.1%)	1506 (94.2%)	1725 (94.5%)	0.9967
Black (black Caribbean, black African, other)	2 (0.5%)	41 (1.9%)	43 (1.7%)		4 (1.8%)	28 (1.8%)	32 (1.8%)	
Asian (Indian, Pakistani, Bangladeshi, other)	3 (0.8%)	60 (2.8%)	63 (2.5%)		2 (0.9%)	27 (1.7%)	29 (1.6%)	
Other	4 (1.1%)	28 (1.3%)	32 (1.3%)		0 (0.0%)	7 (0.4%)	7 (0.4%)	
Unknown	5 (1.3%)	40 (1.9%)	45 (1.8%)		3 (1.3%)	30 (1.9%)	33 (1.8%)	
WHO performance status								
0	127 (34.2%)	944 (43.7%)	1071 (42.3%)	0.0061	60 (26.3%)	415 (26.0%)	475 (26.0%)	0.9588
1	145 (39.1%)	772 (35.7%)	917 (36.2%)		103 (45.2%)	699 (43.7%)	802 (43.9%)	
2	61 (16.4%)	250 (11.6%)	311 (12.3%)		41 (18.0%)	293 (18.3%)	334 (18.3%)	
3	16 (4.3%)	81 (3.7%)	97 (3.8%)		12 (5.3%)	97 (6.1%)	109 (6.0%)	
4	1 (0.3%)	10 (0.5%)	11 (0.4%)		2 (0.9%)	9 (0.6%)	11 (0.6%)	
Missing	21 (5.7%)	104 (4.8%)	125 (4.9%)		10 (4.4%)	85 (5.3%)	95 (5.2%)	
β2 microglobulin (mg/l)								

	Transplant-eligible pathway				Transplant-ineligible pathway			
Characteristic	**Thrombosis (n=371)**	**No thrombosis (n=2161)**	**Total (n=2532)**	**P**	**Thrombosis (n=228)**	**No thrombosis (n=1598)**	**Total (n=1826)**	**P**
Mean (SD)	4.2 (2.86)	4.8 (4.02)	4.7 (3.88)	0.0472	5.6 (4.17)	5.9 (4.75)	5.9 (4.68)	0.3798
Median (Range)	3.3 (1.4, 19.3)	3.6 (0.9, 57.9)	3.5 (0.9, 57.9)		4.3 (0.9, 33.9)	4.6 (0.0, 88.0)	4.6 (0.0, 88.0)	
Missing	136	754	890		85	596	681	
Creatinine (µmol/l)								
Mean (SD)	92.7 (40.17)	97.6 (54.00)	96.9 (52.22)	0.9541	108.3 (54.13)	105.8 (56.09)	106.1 (55.84)	0.3361
Median (Range)	84.0 (32.0, 340.0)	83.0 (32.0, 609.0)	83.0 (32.0, 609.0)		90.5 (34.0, 390.0)	91.0 (34.0, 551.0)	91.0 (34.0, 551.0)	
Missing	0	1	1		0	0	0	
Calcium (mmol/l)								
Mean (SD)	2.4 (0.21)	2.4 (0.26)	2.4 (0.25)	0.0175	2.4 (0.22)	2.4 (0.24)	2.4 (0.24)	0.6913
Median (Range)	2.4 (1.6, 3.6)	2.4 (1.6, 4.9)	2.4 (1.6, 4.9)		2.4 (2.0, 3.5)	2.4 (1.3, 4.4)	2.4 (1.3, 4.4)	
Missing	0	2	2		0	1	1	
Platelets (*10/l)								
Mean (SD)	252.8 (103.48)	251.3 (98.60)	251.5 (99.31)	0.8123	229.7 (78.12)	238.3 (94.00)	237.2 (92.19)	0.1288
Median (Range)	239.0 (57.0, 1112.0)	242.0 (2.0, 1093.0)	241.0 (2.0, 1112.0)		223.5 (3.0, 534.0)	227.0 (19.0, 726.0)	226.0 (3.0, 726.0)	
Haemoglobin g/dl								
Mean (SD)	11.4 (2.0)	10.9 (2.0)	11.0 (2.0)	0.0001	10.7 (1.7)	10.6 (1.7)	10.6 (1.7)	0.3344
Median (Range)	11.3 (5.2, 16.8)	10.9 (3.3, 17.4)	110.0 (3.3, 17.4)		10.5 (7.2, 14.8)	10.4 (3.4, 16.6)	10.4 (3.4, 16.6)	
Missing	0	1	1		1	0	1	
Paraprotein type								
IgG	230 (62.0%)	1290 (59.7%)	1520 (60.0%)	0.3891	142 (62.3%)	1006 (63.0%)	1148 (62.9%)	0.3323

	Transplant-eligible pathway				Transplant-ineligible pathway			
Characteristic	**Thrombosis (n=371)**	**No thrombosis (n=2161)**	**Total (n=2532)**	**P**	**Thrombosis (n=228)**	**No thrombosis (n=1598)**	**Total (n=1826)**	**P**
IgA	85 (22.9%)	528 (24.4%)	613 (24.2%)		53 (23.2%)	410 (25.7%)	463 (25.4%)	
IgM	1 (0.3%)	10 (0.5%)	11 (0.4%)		0 (0.0%)	5 (0.3%)	5 (0.3%)	
IgD	0 (0.0%)	24 (1.1%)	24 (0.9%)		1 (0.4%)	10 (0.6%)	11 (0.6%)	
Non-secretor	3 (0.8%)	13 (0.6%)	16 (0.6%)		3 (1.3%)	7 (0.4%)	10 (0.5%)	
Light chain only	52 (14.0%)	294 (13.6%)	346 (13.7%)		29 (12.7%)	157 (9.8%)	186 (10.2%)	
Missing	0 (0.0%)	2 (0.1%)	2 (0.1%)		0 (0.0%)	3 (0.2%)	3 (0.2%)	
Light chain type								
Lambda	108 (29.1%)	753 (34.8%)	861 (34.0%)	0.0385	71 (31.1%)	516 (32.3%)	587 (32.1%)	0.7504
Kappa	257 (69.3%)	1389 (64.3%)	1646 (65.0%)		154 (67.5%)	1066 (66.7%)	1220 (66.8%)	
Missing	6 (1.6%)	19 (0.9%)	25 (1.0%)		3 (1.3%)	16 (1.0%)	19 (1.0%)	

Figure 2. Arterial CIF curves for Myeloma XI transplant-eligible (A) and transplant-ineligible (B) pathways

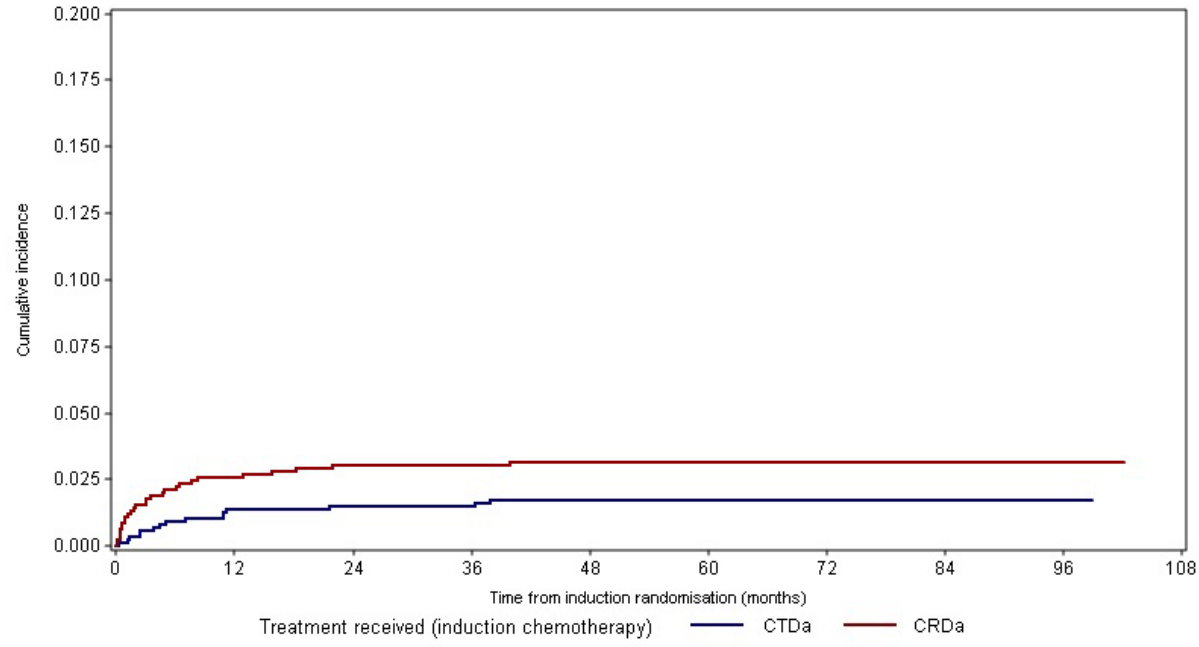
A



Number at risk

CTD	1008	910	821	699	559	411	224	95	8	0
CRD	1014	920	852	761	596	448	253	97	16	0

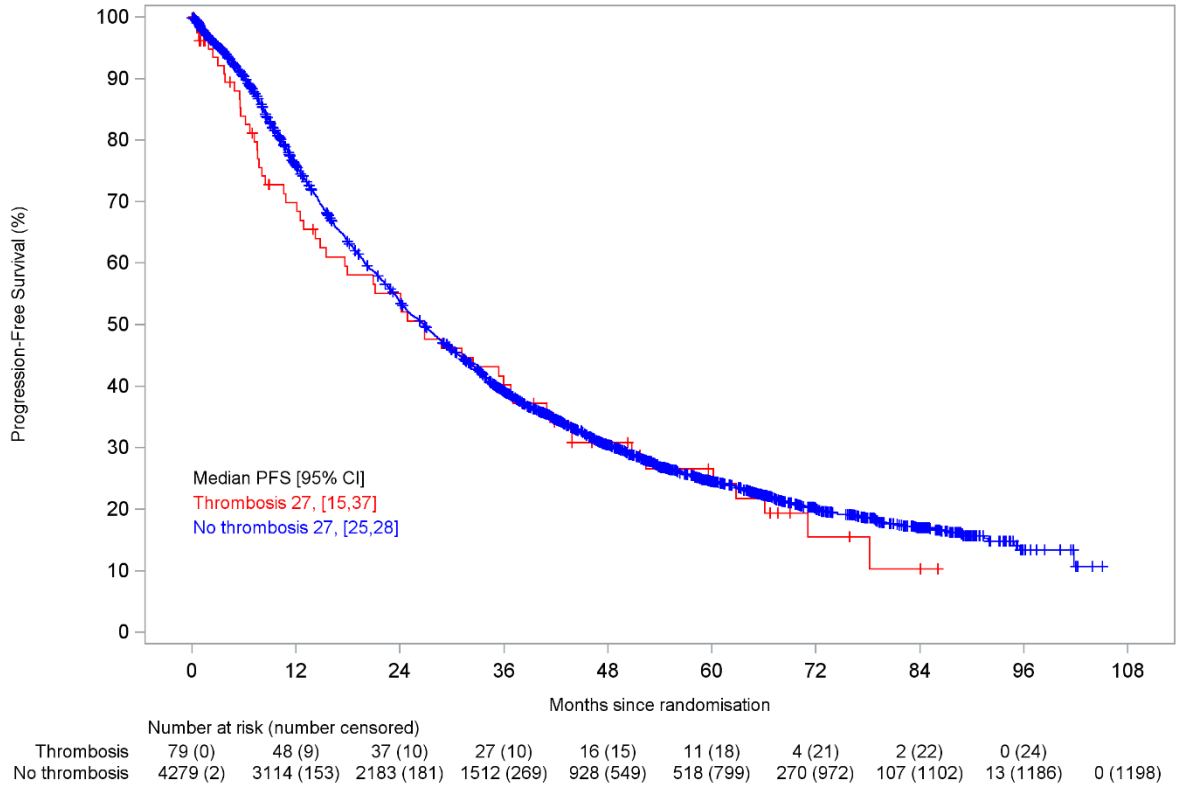
B



Number at risk

CTDa	910	699	588	483	340	199	100	28	4	0
RCDa	916	731	635	515	355	202	93	32	6	0

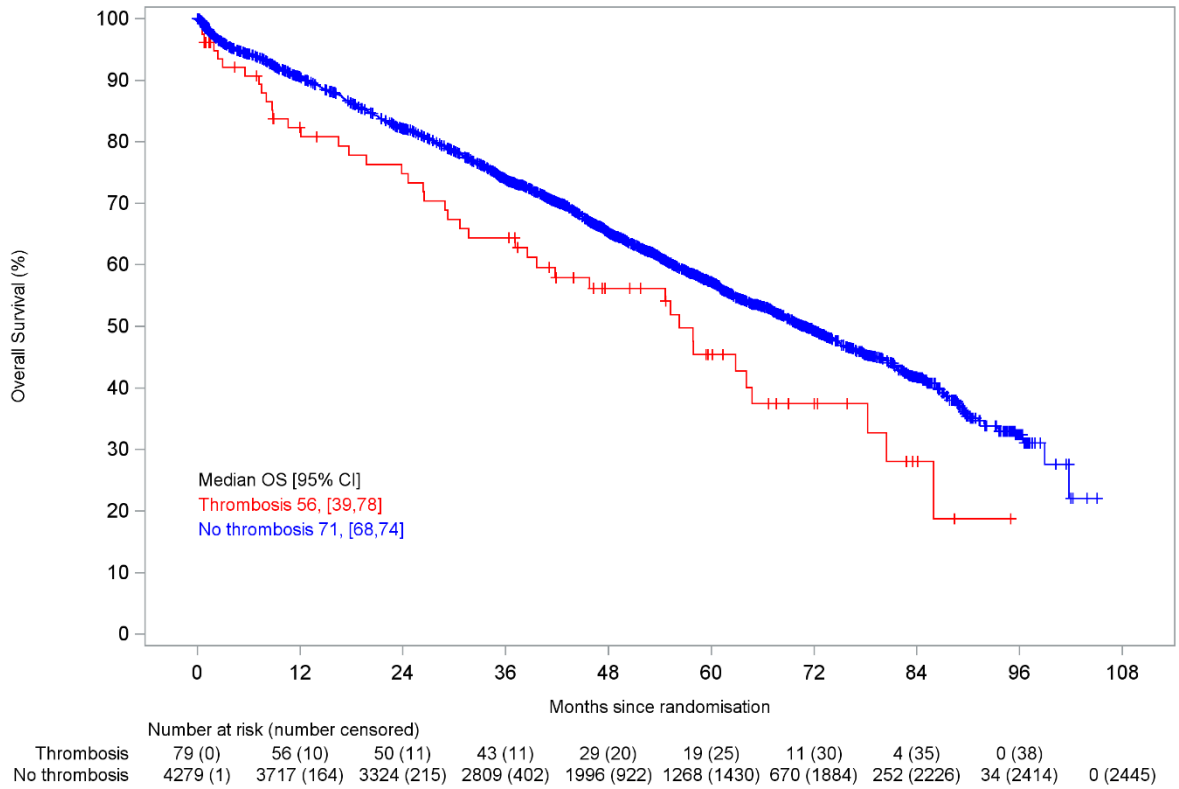
Figure 3. Myeloma XI PFS, by arterial thrombosis occurrence



Number at risk (number censored)

Thrombosis	79 (0)	48 (9)	37 (10)	27 (10)	16 (15)	11 (18)	4 (21)	2 (22)	0 (24)
No thrombosis	4279 (2)	3114 (153)	2183 (181)	1512 (269)	928 (549)	518 (799)	270 (972)	107 (1102)	13 (1186)	0 (1198)

Figure 4. Myeloma XI OS, by arterial thrombosis occurrence



Number at risk (number censored)

Thrombosis	79 (0)	56 (10)	50 (11)	43 (11)	29 (20)	19 (25)	11 (30)	4 (35)	0 (38)
No thrombosis	4279 (1)	3717 (164)	3324 (215)	2809 (402)	1996 (922)	1268 (1430)	670 (1884)	252 (2226)	34 (2414)	0 (2445)