

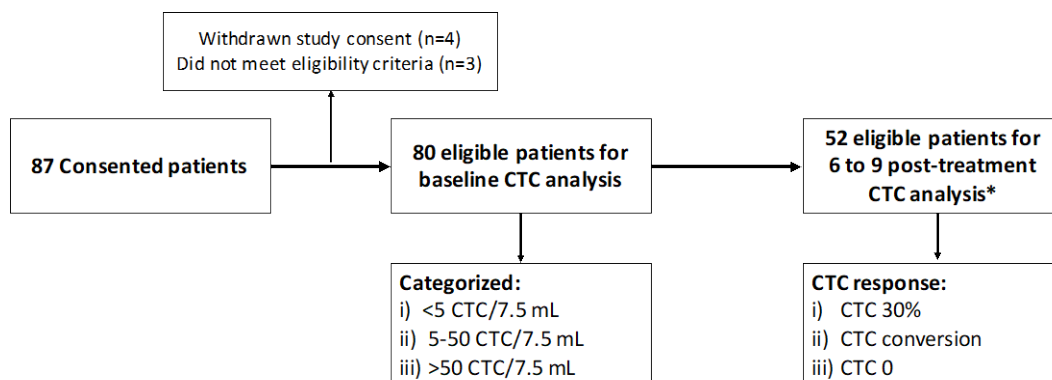
Supplementary

Value of Early Circulating Tumor Cells Dynamics to Estimate Docetaxel Benefit in Metastatic Castration-Resistant Prostate Cancer (mCRPC) Patients

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Supplementary Statistical Methods

OS was defined as the time from blood collection to the date of death or the last follow-up. Progression-free survival (PFS) was defined as the time from blood collection to disease progression based on a composite end-point including: i) radiographic progression according to PCWG2 and/or RECIST 1.1 criteria, ii) clinical progression defined by investigator criteria or iii) death. Time to PSA progression (TTPP) was defined as the time from blood collection to PSA progression, according to PCWG2 criteria.



*Only those patients with baseline ≥ 5 CTC/7.5 mL

Figure S1. Study flowchart.

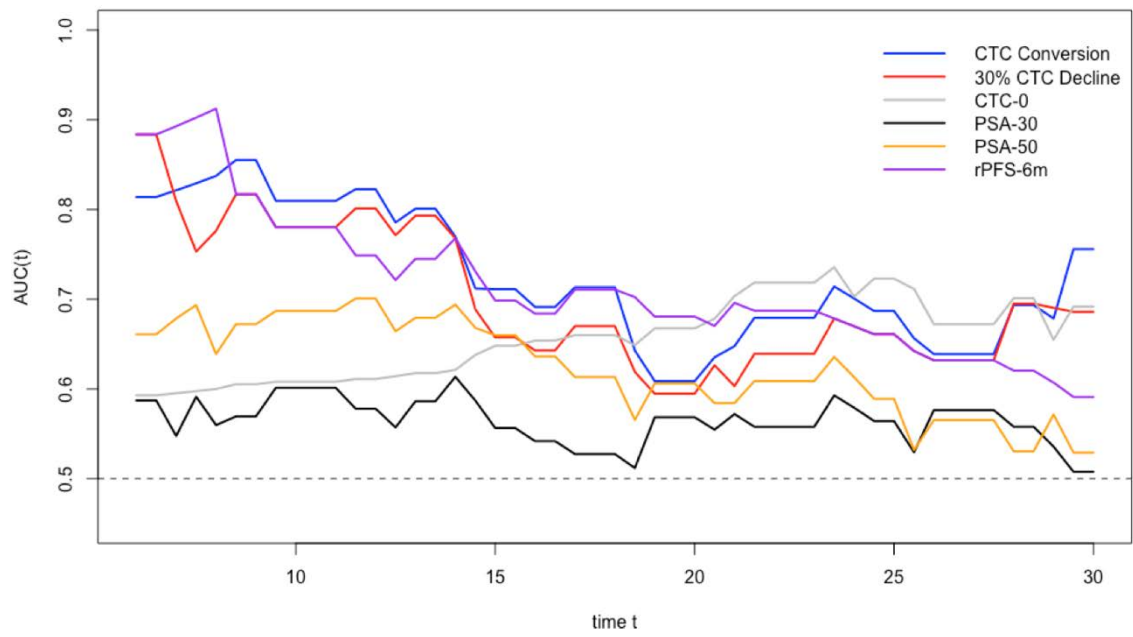


Figure S2. Time-dependent ROC areas under the curve (AUCs) of the CTC response endpoints, PSA response endpoints and 6-month radiographic progression-free survival.

Table S1. Concordance between CTC and PSA response endpoints.

PSA 30 Response	CTC 30% Response	N (%)	Median OS (months)	HR (95% CI)	p-value
No	No	8 (15.4)	7.1 (4.5-NA)	5.12 (2.14-12.24)	<0.001
No	Yes	12 (23.1)	18.5 (13.9-NA)	1.18 (0.55-2.55)	0.667
Yes	No	10 (19.2)	9.8 (5.49-NA)	2.53 (1.15-5.53)	0.020
Yes	Yes	22 (42.3)	19.5 (15.9-28.5)	-	-
PSA 30 Response	CTC Conversion	N (%)	Median OS (months)	HR (95% CI)	p-value
No	No	10 (19.2)	7.8 (4.5-NA)	6.40 (2.67-15.34)	<0.001
No	Yes	10 (19.2)	18.8 (14.1-NA)	1.12 (0.47-2.67)	0.801
Yes	No	15 (28.8)	14.0 (7.8-21.5)	2.45 (1.17-5.14)	0.018
Yes	Yes	17 (32.7)	23.6 (18.2-34.4)	-	-
PSA 30 Response	CTC 0 Response	N (%)	Median OS (months)	HR (95% CI)	p-value
No	No	19 (36.5)	13.0 (8.4-20.8)	4.37 (1.45-13.15)	0.009
No	Yes	1 (1.9)	25.9 (NA-NA)	1.82 (0.20-16.48)	0.592
Yes	No	25 (48.1)	14.8 (14-20.6)	4.08 (1.40-11.91)	0.009
Yes	Yes	7 (13.5)	28.5 (23.6-NA)	-	-
PSA 50 Response	CTC 30% Response	N (%)	Median OS (months)	HR (95% CI)	p-value
No	No	13 (25)	8.3 (4.5-NA)	4.53 (2.07-9.9)	<0.001
No	Yes	17 (32.7)	18.4 (14.1-28.5)	1.07 (0.52-2.2)	0.848
Yes	No	5 (9.6)	16.7 (7.8-NA)	1.84 (0.66-5.08)	0.241
Yes	Yes	17 (32.7)	20.6 (18.2-29.1)	-	-
PSA 50 Response	CTC Conversion	N (%)	Median OS (months)	HR (95% CI)	p-value
No	No	16 (30.8)	7.8 (5.5-13)	5.76 (2.54-13.08)	<0.001
No	Yes	14 (26.9)	18.8 (14.7-NA)	0.94 (0.41-2.14)	0.879
Yes	No	9 (17.3)	16.7 (14-NA)	1.70 (0.71-4.10)	0.236
Yes	Yes	13 (25)	23.6 (18.2-NA)	-	-
PSA 50 Response	CTC 0 Response	N (%)	Median OS (months)	HR (95% CI)	p-value
No	No	27 (51.9)	11.1 (8.4-18.4)	4.20 (1.34-13.14)	0.013
No	Yes	3 (5.8)	28.5 (25.9-NA)	0.71 (1.13-3.93)	0.699
Yes	No	17 (32.7)	18.3 (14.8-25.3)	2.65 (0.83-8.50)	0.102
Yes	Yes	5 (9.6)	25.1 (23.6-NA)	-	-

Abbreviations: PSA, prostate-specific antigen; CTC, circulating tumor cell; OS, overall survival; HR, hazard ratio; PSA30, PSA response determined as 30% decline from baseline; PSA50, PSA response determined as 50% decline from baseline. NA, not available.