

NRG Oncology/RTOG 0126 Data Dictionary
Dictionary for NCT00033631-D1-Dataset.csv

Note #1: Acute (≤ 90 days of treatment start) and late RT toxicities (> 90 days) were graded using the NCI common toxicity criteria v2.0 and the RTOG/EORTC Late Radiation Morbidity Scoring Scheme

Note #2: Data required for replicating the number of institutions in the primary publication for this trial is not contained within this data submission due to de-identification procedures.

Note #3: The prostate cancer mortality hazard ratio in the Outcomes portion of the Results section of the primary publication should be 0.66 not 0.6. It is correct in Figure 2B of the primary publication.

Note #4: There is an error in the p-value at the end of the Adverse Events portion of the Results section of the primary publication for this trial. It should be 0.003 not 0.03 (late grade ≥ 2 GU toxic effects).

#	Variable	Description	Coding for categorical/Min-max for continuous
1	study_no	Study number	Character length 9 [RTOG-0126]
2	cn_deidentified	De-identified patient ID	Length 8
3	rx	Assigned treatment	1 = 70.2 Gy [Standard Dose] 2 = 79.2 Gy [High Dose]
4	case_status	Case Status	1 = Eligible 2 = No protocol treatment 3 = Ineligible
5	analysis_flag_1	Eligible and evaluable for efficacy endpoints	1=No (n=33) 2=Yes (n=1499)
6	reason_for_exclusion	Reason for Exclusion	Character length 100 Reason is not blank (n=33) [analysis_flag_1=1]
7	analysis_flag_2	Eligible and received protocol treatment	1=No (n=14) 2=Yes (n=1485) . = Not applicable (n=33; analysis_flag_1=1)
8	reason_no_treatment	Reason patient did not receive protocol treatment	Character length 100 Reason is not blank (n=14) [analysis_flag_2=1]
9	acute_tox_flag	Eligible and evaluable for acute toxicities <i>Note: Evaluable = received protocol treatment and has case report forms that cover the acute time period</i>	1=No (n=71) 2=Yes (n=1461)
10	late_tox_flag	Eligible and evaluable for late toxicities <i>Note: Evaluable = received protocol treatment and has case report forms that cover the late time period</i>	1=No (n=55) 2=Yes (n=1477)
11	third_interim_flag	Evaluated in the third interim analysis	1 = Not included in the third interim analysis 2 = Included in the third interim analysis
12	third_interim_event	Overall survival status at the third interim analysis	0 = Not an overall survival event [third_interim_flag=2] 1 = Yes an overall survival event [third_interim_flag=2] . = Not applicable (n=30; third_interim_flag=1)
13	age	Age (years)	Continuous Min-max = 33-87

#	Variable	Description	Coding for categorical/Min-max for continuous
			. = Not applicable (n=33; analysis_flag_1=1)
14	psa	Prostate Specific Antigen (PSA), ng/mL	Continuous Min-max = 0.1-19.9 . = Not applicable (n=33; analysis_flag_1=1)
15	race	Race	1 = American Indian or Alaskan Native 2 = Asian 3 = Black or African American 4 = Native Hawaiian or other Pacific Islander 5 = White 6 => 1 Race 9 = Unknown . = Not applicable (n=33; analysis_flag_1=1)
16	ethnicity	Ethnicity	1 = Hispanic or Latino 2 = Not Hispanic or Latino 9 = Unknown . = Not applicable (n=33; analysis_flag_1=1)
17	zubrod	Zubrod performance status	Values = 0, 1 . = Not applicable (n=33; analysis_flag_1=1)
18	psa_cat	PSA level at study entry, ng/mL (categorized)	0 = <10 1 = 10 to <15 2 = 15 to 20 . = Not applicable (n=33; analysis_flag_1=1)
19	gleason_grp	Combined Gleason Score (GS)	1 = 2-6 2 = 7 . = Not applicable (n=33; analysis_flag_1=1)
20	gs7_grp	Eligible and included in the combined GS =7 analysis? <i>Note: To be included in this analysis, patients had to be eligible with known GS primary and secondary patterns.</i>	1=No (n=276) 2=Yes (n=1256)
21	gs7_analysis	What is the distribution of GS primary pattern and GS secondary pattern when the Combined GS score = 7?	1 = 3 + 4 2 = 4 + 3 . = Not applicable (n=276; gs7_grp = 1)
22	psags	PSA and GS at study entry	1 = GS 2-6 and 10 ng/mL ≤ PSA < 20 ng/mL 2 = GS 7 and PSA < 15 ng/mL . = Not applicable (n=33; analysis_flag_1=1)
23	tstage	T stage	1 = T1 2 = T2 . = Not applicable (n=33; analysis_flag_1=1)
24	nstage	N stage	0 = N0 9 = NX . = Not applicable (n=33; analysis_flag_1=1)
25	mstage	M stage	0 = M0 9 = MX . = Not applicable (n=33; analysis_flag_1=1)
26	incontinence	Urinary incontinence at study entry (severity)	0 = Grade 0 1 = Grade 1 2 = Grade 2 3 = Grade 3 9 = Unknown

#	Variable	Description	Coding for categorical/Min-max for continuous
			. = Not applicable (n=33; analysis_flag_1=1)
27	urinary_freq	Urinary frequency/urgency at study entry (severity)	0 = Grade 0 1 = Grade 1 2 = Grade 2 3 = Grade 3 9 = Unknown . = Not applicable (n=33; analysis_flag_1=1)
28	rt_method	Radiation therapy modality	1 = 3-Dimensional conformal radiation therapy 2 = Intensity-modulated radiation therapy . = Not applicable (n=33; analysis_flag_1=1)
29	vvscore_tv	Central review of tumor volume contouring	1 = Per protocol 2 = Acceptable variation 3 = Unacceptable variation 9 = Not evaluable . = Not applicable (n=33; analysis_flag_1=1)
30	vvscore_oar	Central review of organs at risk contouring	1 = Per protocol 2 = Acceptable variation 3 = Unacceptable variation 9 = Not evaluable . = Not applicable (n=33; analysis_flag_1=1)
31	vvscore_tv_dva	Central review of tumor dose-volume coverage	1 = Per protocol 2 = Acceptable variation 3 = Unacceptable variation 9 = Not evaluable . = Not applicable (n=33; analysis_flag_1=1)
32	survival	Overall survival status	0 = censored 1 = event . = Not applicable (n=33; analysis_flag_1=1)
33	survival_years	Overall survival time (years)	. = Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of death or last follow-up.</i>
34	cod_reviewed	Cause of death (centrally reviewed)	1 = Study cancer 2 = Second primary 3 = Protocol treatment 4 = Other cause 9 = Unknown . = Not applicable <i>Note: Only has a value when survival=1 (dead)</i>
35	phoenix_bf	Biochemical failure status using the Phoenix definition	0 = censored 1 = event 2 = competing event . = Not applicable (n=33; analysis_flag_1=1)
36	phoenix_bf_years	Biochemical failure time (years) using the Phoenix definition	. = Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of failure or last follow-up.</i>
37	astro_bf	Biochemical failure status using the American Society for Radiation Oncology definition	0 = censored 1 = event 2 = competing event . = Not applicable (n=33; analysis_flag_1=1)
38	astro_bf_years	Biochemical failure time	. = Not applicable (n=33; analysis_flag_1=1)

#	Variable	Description	Coding for categorical/Min-max for continuous
		(years) using the American Society for Radiation Oncology definition	<i>Note: Time from the date of randomization to the date of failure or last follow-up.</i>
39	prostatecancer_mortality	Prostate Cancer Mortality status	0 = censored 1 = event 2 = competing event . = Not applicable (n=33; analysis_flag_1=1)
40	prostatecancer_mortality_years	Prostate Cancer Mortality Time (years)	. = Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of failure or last follow-up.</i>
41	distant_metastasis	Distant metastasis status	0 = censored 1 = event 2 = competing event . = Not applicable (n=33; analysis_flag_1=1)
42	distant_metastasis_years	Distant metastasis time (years)	. = Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of failure or last follow-up/death.</i>
43	local_progression	Local progression status	0 = censored 1 = event 2 = competing event . = Not applicable (n=33; analysis_flag_1=1)
44	local_progression_years	Local failure time (years)	. = Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of failure or last follow-up/death.</i>
45	dmfs	Distant metastasis-free survival status	0 = censored 1 = event . = Not applicable (n=33; analysis_flag_1=1)
46	dmfs_years	Distant metastasis-free survival time (years)	. = Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of death/failure or last follow-up.</i>
47	salvage_any	Any Salvage Therapy?	0 = No salvage treatment 1 = Yes salvage treatment . = Not applicable (n=33; analysis_flag_1=1)
48	salvage_failure	Salvage Therapy status	0 = censored 1 = event 2 = competing event . = Not applicable (n=33; analysis_flag_1=1)
49	salvage_failure_years	Salvage Therapy time (years)	. = Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of salvage treatment or last follow-up/death.</i>
50	salvage_type	Type of Salvage Therapy	Character length 100 Reason is blank (n=33) [analysis_flag_1=1] <i>Note: salvage_type = "None" for salvage_any = 0</i>
51	acute_gu	Overall highest grade for acute genitourinary (GU) toxicities	0 = grade 0 1 = grade 1 2 = grade 2

#	Variable	Description	Coding for categorical/Min-max for continuous
			3 = grade 3 .= Not applicable (n=71; acute_tox_flag=1)
52	acute_gi	Overall highest grade for acute gastrointestinal (GI) toxicities	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 .= Not applicable (n=71; acute_tox_flag=1)
53	late_gu	Overall highest grade for late GU toxicities	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 .= Not applicable (n=55; late_tox_flag=1)
54	late_gi	Overall highest grade for late GI toxicities	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5 .= Not applicable (n=55; late_tox_flag=1)
55	late_ge2_gu	Late grade ≥ 2 GU toxicities status	0 = censored 1 = event (grade ≥ 2 GU toxicity) 2 = competing event .= Not applicable (n=33; analysis_flag_1=1) <i>Note: If a patient did not have late toxicities or died prior to the late time period, they were censored at last follow-up</i>
56	late_ge2_gu_years	Time to late grade ≥ 2 GU toxicities	.= Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of grade ≥ 2 GU toxicity or last follow-up/death.</i>
57	late_ge3_gu	Late grade ≥ 3 GU toxicities status	0 = censored 1 = event (grade ≥ 3 GU toxicity) 2 = competing event .= Not applicable (n=33; analysis_flag_1=1) <i>Note: If a patient did not have late toxicities or died prior to the late time period, they were censored at last follow-up</i>
58	late_ge3_gu_years	Time to late grade ≥ 3 GU toxicities	.= Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of grade ≥ 3 GU toxicity or last follow-up/death.</i>
59	late_ge2_gi	Late grade ≥ 2 GI toxicities status	0 = censored 1 = event (grade ≥ 2 GI toxicity) 2 = competing event .= Not applicable (n=33; analysis_flag_1=1) <i>Note: If a patient did not have late toxicities or died prior to the late time period, they were censored at last follow-up</i>
60	late_ge2_gi_years	Time to late grade ≥ 2 GI toxicities	.= Not applicable (n=33; analysis_flag_1=1)

#	Variable	Description	Coding for categorical/Min-max for continuous
			<i>Note: Time from the date of randomization to the date of grade ≥ 2 GI toxicity or last follow-up/death.</i>
61	late_ge3_gi	Late grade ≥ 3 GI toxicities status	0 = censored 1 = event (grade ≥ 3 GI toxicity) 2 = competing event . = Not applicable (n=33; analysis_flag_1=1) <i>Note: If a patient did not have late toxicities or died prior to the late time period, they were censored at last follow-up</i>
62	late_ge3_gi_years	Time to late grade ≥ 3 GI toxicities	. = Not applicable (n=33; analysis_flag_1=1) <i>Note: Time from the date of randomization to the date of grade ≥ 3 GI toxicity or last follow-up/death.</i>