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).

1 Study no Study number Character length 9 [RTOG-0126] 2 en deidentified De-identified patient ID Length 8 3 rx Assigned treatment 1 = 70.2 Gy [Standard Dose] 4 case_status Case Status 1 = 70.2 Gy [High Dose] 5 analysis_flag_1 Eligible and evaluable for efficacy endpoints 2 = No protocol treatment 6 reason_for_exclusion Reason for Exclusion of Exclusion of treatment 2 = Yes (n=145) 7 analysis_flag_2 Eligible and received 1=No (n=23) 9 acute_tox_flag Eligible and evaluable for acute toxicities 1=No (n=14) 9 acute_tox_flag Eligible and evaluable for acute toxicities 1=No (n=14) 9 acute_tox_flag Eligible and evaluable for acute toxicities 1=No (n=14) 10 late_tox_flag Eligible and evaluable for late toxicities 1=No (n=14) 10 late_tox_flag Eligible and evaluable for late toxicities 1=No (n=55) 11 third_interim_flag Evaluable = received protocol received protocol received protocol received protocol received protocol received protocol received protocol received protocol received protococol received protococl received protococol	#	Variable	Description	Coding for categorical/Min-max for continuous
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#	Variable	Description	Coding for categorical/Min-max for continuous
			. = Not applicable (n=33; analysis_flag_1=1)
27	urinary_freq	Urinary frequency/urgency	0 = Grade 0
		at study entry (severity)	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	1 = Per protocol
		volume contouring	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	1 = Per protocol
		risk contouring	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	1 = Per protocol
		dose-volume coverage	2 = Acceptable variation
			3 = Unacceptable variation
			9 = Not evaluable
20	• 1		. = Not applicable (n=33; analysis_flag_1=1)
32	survival	Overall survival status	0 = censored
			1 = event
22			$ = \text{Not applicable (n=33; analysis_flag_1=1)} $
33	survival_years	Overall survival time	. = Not applicable (n=33; analysis_flag_1=1)
		(years)	Note: Time from the date of randomization to the date of
			<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	1 = Study cancer
54	cou_reviewed	reviewed)	2 = Second primary
		icviewed)	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	0 = censored
	· _	using the Phoenix	1 = event
		definition	2 = competing event
			. = Not applicable (n=33; analysis_flag_1=1)
36	phoenix_bf_years	Biochemical failure time	. = Not applicable (n=33; analysis_flag_1=1)
		(years) using the Phoenix	
		definition	Note: Time from the date of randomization to the date of
			failure or last follow-up.
37	astro_bf	Biochemical failure status	0 = censored
		using the American	1 = event
		Society	2 = competing event
		for Radiation Oncology	. = Not applicable (n=33; analysis_flag_1=1)
		definition	
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	Note: Time from the date of randomization to the date of
		for Radiation Oncology	failure or last follow-up.
		definition	
39	prostatecancer_mortality	Prostate Cancer Mortality	0 = censored
		status	1 = event
			2 = competing event
			. = Not applicable (n=33; analysis_flag_1=1)
40	prostatecancer_mortality_years	Prostate Cancer Mortality	. = Not applicable (n=33; analysis_flag_1=1)
		Time (years)	
			<i>Note: Time from the date of randomization to the date of</i>
4.1	1. to at an effective	Distant and the instant	failure or last follow-up.
41	distant_metastasis	Distant metastasis status	0 = censored
			1 = event
			2 = competing event
40	1:	Distant materia is time	. = Not applicable (n=33; analysis_flag_1=1)
42	distant_metastasis_years	Distant metastasis time	. = Not applicable (n=33; analysis_flag_1=1)
		(years)	Note: Time from the date of randomization to the date of
			<i>Note: Time from the date of randomization to the date of</i>
43	local progression	Local progression status	<i>failure or last follow-up/death.</i> 0 = censored
43	local_progression	Local progression status	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)
	local_progression_years	Local failure time (years)	Not applicable (II-55, analysis_IIag_1-1)
			Note: Time from the date of randomization to the date of
			failure or last follow-up/death.
45	dmfs	Distant metastasis-free	0 = censored
	Gillip	survival status	1 = event
			. = Not applicable (n=33; analysis_flag_1=1)
46	dmfs years	Distant metastasis-free	. = Not applicable (n=33; analysis flag 1=1)
		survival time (years)	
			<i>Note: Time from the date of randomization to the date of</i>
			death/failure or last follow-up.
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
<u> </u>			. = Not applicable (n=33; analysis_flag_1=1)
49	salvage_failure_years	Salvage Therapy time	. = Not applicable (n=33; analysis_flag_1=1)
		(years)	
			Note: Time from the date of randomization to the date of
			salvage treatment or last follow-up/death.
50	salvage_type	Type of Salvage Therapy	Character length 100
			Reason is blank (n=33) [analysis_flag_1=1]
			Note: salvage_type = "None" for salvage_any = 0
51	acute_gu	Overall highest grade for	0 = grade 0
		acute genitourinary (GU)	1 = grade 1
	1	toxicities	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	0 = grade 0
		acute gastrointestinal (GI)	1 = grade 1
		toxicities	2 = grade 2
			3 = grade 3
			. = Not applicable (n=71; acute_tox_flag =1)
53	late_gu	Overall highest grade for	0 = grade 0
		late GU toxicities	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	0 = grade 0
54	late_gi	late GI toxicities	
		late Of toxicities	1 = grade 1
			2 = grade 2
1			3 = grade 3
1			4 = grade 4
			5 = grade 5
			. = Not applicable (n=55; late_tox_flag =1)
55	late_ge2_gu	Late grade $\geq 2 \text{ GU}$	0 = censored
		toxicities status	$1 = \text{event} (\text{grade} \ge 2 \text{ GU toxicity})$
			2 = competing event
			. = Not applicable (n=33; analysis_flag_1=1)
			Note: If a patient did not have late toxicities or died
			prior to the late time period, they were censored at last
			follow-up
56	late_ge2_gu_years	Time to late grade $\geq 2 \text{ GU}$. = Not applicable (n=33; analysis_flag_1=1)
		toxicities	
			<i>Note: Time from the date of randomization to the date of</i>
			grade $\geq 2 GU$ toxicity or last follow-up/death.
57	late_ge3_gu	Late grade \geq 3 GU	0 = censored
		toxicities status	$1 = \text{event} (\text{grade} \ge 3 \text{ GU toxicity})$
			2 = competing event
			. = Not applicable (n=33; analysis_flag_1=1)
1			Notes If a matimum did south and the states and the
			Note: If a patient did not have late toxicities or died
			prior to the late time period, they were censored at last
			follow-up
58	late_ge3_gu_years	Time to late grade \geq 3 GU	. = Not applicable (n=33; analysis_flag_1=1)
1		toxicities	
1			Note: Time from the date of randomization to the date of
			grade ≥ 3 GU toxicity or last follow-up/death.
59	late_ge2_gi	Late grade ≥ 2 GI toxicities	0 = censored
1		status	$1 = \text{event} (\text{grade} \ge 2 \text{ GI toxicity})$
			2 = competing event
			. = Not applicable (n=33; analysis_flag_1=1)
			Note: If a patient did not have late toxicities or died
			prior to the late time period, they were censored at last
()			follow-up
60	late_ge2_gi_years	Time to late grade ≥ 2 GI	. = Not applicable (n=33; analysis_flag_1=1)
		toxicities	

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