NRG Oncology/RTOG-0534 Data Dictionary for NCT00567580-D1-Dataset.csv

PMID: 35569466

Note #1:
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).

Note #2:
Variables 6-94 are blank when include_in_analysis = 0 (variable #4). Additional reasons for blank values are noted in the table below.

Note #4:
Data required for replicating "Figure S1" (cumulative number patients randomized by month) in the supplemental materials are not contained within this data submission due to de-identification procedures.

Note #5:
For endpoints with competing risks, the competing risk was used in the estimation of cumulative incidence, but was censored for log-rank tests and cause-specific hazard rates.

Note #6:
Older data used for the interim analysis results reported in the manuscript are not provided.

Note #7:
Two subjects received radiation therapy off-protocol. They were considered as treated (*treated*=1) and their radiation therapy was recorded and centrally reviewed. They are designated by *received_rt*=1 and *rt_reason*=6.

Note #8
After publication, a correction was made to the variable *completed_treatment* (changed from 1 to 0) and *termination_reason* (changed from blank to 99) for three subjects. This impacts the following parts of Figure 1 in the publication: Arm 2 and Arm 3 counts for "deviations from per-protocol treatment" and the counts of "other or unknown reasons" in the corresponding footnotes.

Abbreviations:

AA	Anti-androgen (used here to refer to the AA component of ADT)
ADT	Androgen deprivation therapy
AE	Adverse event
LHRH	Luteinizing hormone-releasing hormone (used here to refer to the LHRH targeted component of ADT)
PBRT	Prostate bed radiotherapy
PLNRT	Pelvic lymph node radiotherapy
PSA	Prostate-specific antigen
RT	Radiation therapy
STADT	Short-term androgen deprivation therapy
SV	Seminal vesicle

See also the companion datasets and data dictionaries:
NCT00567580-D2-Dataset.csv and NCT00567580-D2-Data-Dictionary.pdf
NCT00567580-D3-Dataset.csv and NCT00567580-D3-Data-Dictionary.pdf
NCT00567580-D4-Dataset.csv and NCT00567580-D4-Data-Dictionary.pdf

#	Variable	Description	Coding
1	study	Study number	Character
2	deident_subjectid	De-identified patient ID	Character
3	rx	Assigned treatment arm	1=PBRT Alone 2=PBRT+STADT 3=PLNRT+PBRT+STADT
4	include_in_analysis	Indicator for inclusion in final analysis	0=No 1=Yes
5	reason_for_exclusion	CONSORT: Reason for exclusion *(When include_in_analysis=0)*	Character
6	completed_treatment	CONSORT: Completed protocol treatment	0=No 1=Yes
7	termination_reason	CONSORT: Overall reason for incomplete protocol treatment *(When completed_treatment=0)*	3=Toxicity 4=Death 5=Patient withdrawal or refusal after starting protocol therapy 6=Patient refusal prior to starting protocol therapy 7=Alternative treatment given 8=Other complicating disease 98=Other 99=Missing
8	age	Age at randomization (years)	Continuous
9	race	Race	1=American Indian/Alaska Native 2=Asian 3=Black or African American 4=Native Hawaiian or Other Pacific Islander 5=White 6=More than one race 9=Unk or not reported
10	ethnicity	Ethnicity	1=Hispanic or Latino 2=Not Hispanic or Latino 9=Unknown
11	gender	Gender	1=Male
12	zubrod	Zubrod performance status	0=Fully active able to carry on all predisease activities without restriction 1=Restricted in physically strenuous activity but ambulatory and able to carry work of a light or sedentary nature.
13	sv_involvement	SV involvement	1=No 2=Yes
14	tstage_nctn	Pathological tumor stage	1=pT2 5=pT3 Extraprostatic extension NOS 6=pT3a Extraprostatic extension 7=pT3b Seminal vesicle invasion

15	gleason_category	Gleason Score, combined (sevens categorized)	4=4 5=5 6=6 7.1=Gleason 7 (3+4) 7.2=Gleason 7 (4+3) 7.3=Gleason 7 (primary/secondary not indicated) 8=8 9=9
16	gleason_gt7	Gleason score > 7	0=No 1=Yes
17	margins	Prostatectomy margins	1=Positive 2=Negative 9=Unknown
18	pelvic_lymphadenectomy	Pelvic lymphadenectomy	0=No 1=Yes
19	pelvic_nodes_total_dissected	Total number of lymph nodes dissected *(When pelvic_lymphadenectomy=1; of which, 90 are blank due to missing data.)*	Continuous
20	psa	Baseline PSA(ng/mL)	Continuous
21	psa_gt1	Baseline PSA(ng/mL) > 1	0=No 1=Yes
22	psa_gt_median	Baseline PSA(ng/mL) > median [0.3475]	0=No 1=Yes
23	sx2rand_years	Time from surgery to randomization (years)	Continuous
24	dt_months	PSA doubling time post-surgery (months) *(The requirement to record PSA doubling time before enrollemnt was removed in the March 31, 2009 protocol ammendment, such that only 471 patients have this value.)*	Continuous
25	treated	Started any protocol treatment	0=No 1=Yes
26	received_rt	Started protocol radiation therapy	0=No 1=Yes
27	received_aa	Started protocol AA	0=No 1=Yes
28	received_lhrh	Started protocol LHRH	0=No 1=Yes
29	rt_review_total_dose	Central review of radiation therapy: Total dose	0=N/A 1=Per protocol 2=Variation- acceptable 3=Deviation- unacceptable 9=Not evaluable

30	rt_review_fractionation	Central review of radiation therapy: Fractionation	0=N/A 1=Per protocol 2=Variation- acceptable 3=Deviation- unacceptable 9=Not evaluable
31	rt_review_elapsed_days	Central review of radiation therapy: Elapsed days	0=N/A 1=Per protocol 2=Variation- acceptable 3=Deviation- unacceptable 9=Not evaluable
32	rt_review_tvoar	Central review of radiation therapy: Target volume / organs at risk	0=N/A 1=Per protocol 2=Variation- acceptable 3=Deviation- unacceptable 9=Not evaluable
33	rt_review_overall	Central review of radiation therapy: Overall	1=Per protocol 2=Variation- acceptable 3=Deviation- unacceptable 7=Incomplete RT- refused 8=No RT given 9=Not evaluable
34	rt_type	Type of RT administered *(When received_rt=1)*	1=3D conformal 2=IMRT
35	rt_dose	RT total dose to 95% PTV *(When received_rt=1)*	Continuous
36	rt_fx	RT total fraction count *(When received_rt=1)*	Continuous
37	rt_reason	Reason for not starting (received_rt=0) or early termination of radiation therapy (received_rt=1) *(Blank for 17 subjects missing data.)*	1=N/A 3=Toxicity 4=Death 5=Patient withdrawal or refusal after starting protocol therapy 6=Patient refusal prior to starting protocol therapy 7=Alternative treatment given 8=Other complicating disease 98=Other
38	ht_review_dose_aa	Central review of AA: Dose *(513 randomly sampled subjects from Arm 2 and Arm 3 were centrally reviewed for ADT. The rest are blank.)*	1=80-120% 2= <80% due to protocol-specified reasons 3= <80% due to non-protocol-specified reasons 4= >120% 5=Wrong drug/agent given 99=No treatment

39	ht_review_delay_aa	Central review of AA: Treatment delay *(513 randomly sampled subjects from Arm 2 and Arm 3 were centrally reviewed for ADT. The rest are blank.)*	1=No delays 2= <2 weeks 4= >2 weeks due to non-protocol-specified reasons 99=No treatment
40	ht_review_score_aa	Central review of AA: Overall score *(513 randomly sampled subjects from Arm 2 and Arm 3 were centrally reviewed for ADT. The rest are blank.)*	1=Per protocol 2=Unacceptable deviation 99=No treatment
41	aa_reason	AA: Reason for not starting (received_aa=0) or early termination (received_aa=1). *(Blank: all Arm 1 subjects; 45 subjects from Arm 2 and Arm 3 missing data.)*	1=N/A 3=Toxicity 4=Death 5=Patient withdrawal or refusal after starting protocol therapy 6=Patient refusal prior to starting protocol therapy 7=Alternative treatment given 8=Other complicating disease 98=Other
42	aa_duration_months	AA: duration (months) *(Blank: all Arm 1 subjects; 54 subjects from Arm 2 and Arm 3 missing data.)*	Continuous
43	ht_review_dose_lhrh	Central review of LHRH: Dose *(513 randomly sampled subjects from Arm 2 and Arm 3 were centrally reviewed for ADT. The rest are blank.)*	1=80-120% 2= <80% due to protocol-specified reasons 3= <80% due to non-protocol-specified reasons 4= >120% 5=Wrong drug/agent given 99=No treatment
44	ht_review_delay_lhrh	Central review of LHRH: Treatment delay *(513 randomly sampled subjects from Arm 2 and Arm 3 were centrally reviewed for ADT. The rest are blank.)*	1=No delays 2= <2 weeks 4= >2 weeks due to non-protocol-specified reasons 99=No treatment
45	ht_review_score_lhrh	Central review of LHRH: Overall score *(513 randomly sampled subjects from Arm 2 and Arm 3 were centrally reviewed for ADT. The rest are blank.)*	1=Per protocol 2=Unacceptable deviation 99=No treatment
46	lhrh_reason	LHRH: Reason for not starting (received_lhrh=0) or early termination (received_lhrh=1). *(Blank: all Arm 1 subjects; 51 subjects from Arm 2 and Arm 3 missing data.)*	1=N/A 3=Toxicity 4=Death 5=Pt w/d or refusal after starting protocol therapy 6=Pt refusal prior to starting protocol therapy 7=Alternative treatment given 8=Other complicating disease 98=Other

47	lhrh_duration_months	LHRH: duration (months) *(Blank: all Arm 1 subjects; 48 subjects from Arm 2 and Arm 3 missing data.)*	Continuous
48	has_ae_data	Evaluated for adverse events	0=No 1=Yes
49	has_late_ae_data	Started radiation therapy and were evaluated for adverse events > 90 days after the end of radiation therapy	0=No 1=Yes
50	ae_grade2plus_acute	Acute AE ≥ Grade 2 *(When has_ae_data=1 and treated=1)*	0=No 1=Yes
51	ae_grade3plus_acute	Acute AE ≥ Grade 3 *(When has_ae_data=1 and treated=1)*	0=No 1=Yes
52	ae_grade2plus_acute_gi	Acute gastrointestinal AE ≥ Grade 2 *(When has_ae_data=1 and treated=1)*	0=No 1=Yes
53	ae_grade3plus_acute_gi	Acute gastrointestinal AE ≥ Grade 3 *(When has_ae_data=1 and treated=1)*	0=No 1=Yes
54	ae_grade2plus_acute_renalgu	Acute renal/genitourinary AE ≥ Grade 2 *(When has_ae_data=1 and treated=1)*	0=No 1=Yes
55	ae_grade3plus_acute_renalgu	Acute renal/genitourinary AE ≥ Grade 3 *(When has_ae_data=1 and treated=1)*	0=No 1=Yes
56	ae_grade2plus_late	Late AE ≥ Grade 2 *(When has_late_ae_data=1)*	0=No 1=Yes
57	ae_grade3plus_late	Late AE ≥ Grade 3 *(When has_late_ae_data=1)*	0=No 1=Yes
58	ae_grade2plus_late_renalgu	Late renal/genitourinary AE ≥ Grade 2 *(When has_late_ae_data=1)*	0=No 1=Yes
59	ae_grade3plus_late_renalgu	Late renal/genitourinary AE ≥ Grade 3 *(When has_late_ae_data=1)*	0=No 1=Yes
60	ae_grade2plus_late_gi	Late gastrointestinal AE ≥ Grade 2 *(When has_late_ae_data=1)*	0=No 1=Yes
61	ae_grade3plus_late_gi	Late gastrointestinal AE ≥ Grade 3 *(When has_late_ae_data=1)*	0=No 1=Yes
62	ae_grade2plus_acute_blood	Acute blood/bone marrow AE ≥ Grade 2 *(When has_ae_data=1)*	0=No 1=Yes
63	ae_grade3plus_acute_blood	Acute blood/bone marrow AE ≥ Grade 3 *(When has_ae_data=1 and treated=1)*	0=No 1=Yes

64	ae_grade2plus_late_blood	Late blood/bone marrow AE ≥ Grade 2 *(When has_late_ae_data=1)*	0=No 1=Yes
65	ae_grade3plus_late_blood	Late blood/bone marrow AE ≥ Grade 3 *(When has_late_ae_data=1)*	0=No 1=Yes
66	aelate2	First ≥ grade 2 late AE: status *(When has_late_ae_data=1)*	0=Alive without event or death 1=Event 2=Competing risk (death)
67	aelate2_years	First ≥ grade 2 late AE: time (years) *(When has_late_ae_data=1)*	Continuous
68	aelate3	First ≥ grade 3 late AE: status *(When has_late_ae_data=1)*	0=Alive without event or death 1=Event 2=Competing risk (death)
69	aelate3_years	First ≥ grade 3 late AE: time (years) *(When has_late_ae_data=1)*	Continuous
70	prog_free_survival_sc	Freedom from Progression [salvage censored] status	0=Alive without event or started second salvage therapy 1=Event
71	prog_free_survival_sc_years	Freedom from progression [salvage censored] time (years)	Continuous
72	prog_free_survival	Freedom from progression [sensitivity analysis] status	0=Alive without event 1=Event
73	prog_free_survival_years	Freedom from Progression [sensitivity analysis] time (years)	Continuous
74	distant_failure	Distant metastasis status	0=Alive without event or death 1=Event 2=Competing risk (death)
75	distant_failure_years	Distant metastasis time (years)	Continuous
76	prostate_cancer_death	Cause-specific mortality status (prostate cancer)	0=Alive without event or death 1=Event 2=Competing risk (death)
77	prostate_cancer_death_years	Cause-specific mortality time (years)	Continuous
78	prostate_cancer_death_cod	Cause of death per definition used in prostate cancer death endpoint *(When overall_survival=1 [death])*	1.1=Prostate cancer: centrally certified 1.2=Prostate cancer: following clinical or biochemical progression 3=Other cause 9=Unknown
79	overall_survival	Overall survival status	0=Alive without event 1=Event (death)
80	overall_survival_years	Overall survival time (years)	Continuous

81	bcf_phoenix	Biochemical failure [Phoenix] status	0=Alive without event or death 1=Event 2=Competing risk (death)
82	bcf_phoenix_years	Biochemical failure [Phoenix] time (years)	Continuous
83	bcf_alternative	Alternative biochemical failure status	0=Alive without event or death 1=Event 2=Competing risk (death)
84	bcf_alternative_years	Alternative biochemical failure time (years)	Continuous
85	salvage_hormone_therapy	Start of second salvage hormone therapy: status	0=Alive without event or death 1=Event 2=Competing risk (death)
86	salvage_hormone_therapy_years	Start of second salvage hormone therapy: time (years)	Continuous
87	hormone_refractory_ds	Hormone-refractory disease [castrate-resistant disease] status	0=Alive without event or death 1=Event 2=Competing risk (death)
88	hormone_refractory_ds_years	Hormone-refractory disease [castrate-resistant disease] time (years)	Continuous
89	local_failure	Local failure status	0=Alive without event or death 1=Event 2=Competing risk (death)
90	local_failure_years	Local failure time (years)	Continuous
91	regional_failure	Regional failure status	0=Alive without event or death 1=Event 2=Competing risk (death)
92	regional_failure_years	Regional failure time (years)	Continuous
93	metastasis_free_survival	Metastases-free survival status	0=Alive without event 1=Event
94	metastasis_free_survival_years	Metastases-free survival time (years)	Continuous