NRG Oncology/RTOG-9601 Data Dictionary
NCTN Data Archive
NCTNCT00002874-D1-Dataset.csv

- Only patients included in the analysis have data for variables 7-63 (*include_in_analysis=1)*
- In addition, only patients who received protocol treatment (*rt_treated=1* or *ht_treated=1*) have toxicity data (variables 40-63). [denominator for toxicity tables]
- In addition, if a protocol treated patient was not reported to have experienced a given toxicity then that patient will have a missing value for the applicable toxicity variable.
- Additional information appears in notes within the table and corresponding footnotes.

#	Variable	Description	Format/Coding for categorical data
1	study	Study number	RTOG-9601
2	CN_DeIdentified	Case number de-identified	Continuous
3	rx	Assigned treatment arm	1 = Bicalutimide + Radiotherapy 2 = Placebo + Radiotherapy
4	case_status	Case status	1 = Eligible 2 = No protocol treatment 3 = Ineligible 4 = Withdrew consent
5	include_in_analysis	Indicator for inclusion in analysis	0 = Excluded 1 = Included
6	reason_for_exclusion	Reason for Exclusion	Character maximum length 100 *Note: Missing for patients not excluded*
7	rt_treated	Indicator for protocol radiation therapy	0 = Did not start protocol radiation therapy 1 = Started protocol radiation therapy
8	RT_review	Central radiation therapy review (on sampled patients)	1 = Per protocol 2 = Acceptable variation 3 = Unacceptable deviation *Note: 227 randomly sampled patients were reviewed for radiation therapy. The rest are missing.*
9	ht_treated	Indicator for protocol hormone therapy (24 months)	0 = Did not start hormone therapy 1 = Started hormone therapy
10	ht_duration18mo	Indicator for receiving protocol hormone therapy at 18 months	0 = Terminated protocol hormone therapy by 18 months 1 = Receiving protocol hormone therapy at 18 months
11	ht_completed	Indicator for completion of protocol hormone therapy	0 = Did not complete hormone therapy 1 = Completed hormone therapy *Used for "Completed Therapy" in CONSORT diagram and for "24 month adherence" in Results-Adherence section.*
12	reason_for_incomplete_treatment	Reason protocol treatment was not completed	1 = Death 2 = Disease progression 3 = Toxicity 5 = Patient condition (not toxicity progression)

#	Variable	Description	Format/Coding for categorical data
			6 = Patient withdrawal on advice of physician 7 = Patient withdrawal 8 = Other 9 = Unknown *Note: Missing for additional 516 patients who completed protocol treatment*
13	salvage_ht	Indicator for salvage hormone therapy*	0 = Did not receive salvage hormone therapy 1 = Received salvage hormone therapy
14	age_grp	Age (years)	1 = low-49 2 = 50-59 3 = 60-69 4 = 70-79 5 = 80-high
15	race	Race	1 = White 2 = Hispanic 3 = African American 4 = Asian 6 = Native American 7 = Other
16	kps	Karnofsky performance status	Continuous
17	gleason_grp	Gleason score	1 = 2-6 2 = 7 3 = 8-10 *Note: Missing for 2 additional patients without this data*
18	tstage	Tumor stage	1 = T2 2 = T3
19	prior_ht	Neoadjuvant hormone use	1 = No neoadjuvant hormone use 2 = Neoadjuvant hormone use
20	positive_margins	Postive surgical margins	1 = Negative surgical margins 2 = Positive surgical margins
21	psa_nadir_grp	PSA nadir category after surgery	1 = '<0.5 ng/ml' 2 = '>= 0.5 ng/ml'
22	psa_entry_grp	PSA at study entry	1='<0.7 ng/ml' 2='0.7-1.5 ng/ml' 3=>1.5-4.0 ng/ml'
23	sx2rand_years	Time from surgery to randomization (years)	Continuous
24	sx2psa_years	Time from randomization to first detectable PSA (years)	Continuous *Note: Median interval from randomization to first detectable PSA value was misreported as 1.4 years. It should have been reported as 1.1 years. This error appears in the last sentence in the section "Characteristics of the Patients" under "Results"*
25	survival	Overall survival status	0 = Alive 1 = Dead

#	Variable	Description	Format/Coding for categorical data
26	survival_years	Time from randomization to death or last follow-up (years)	Continuous
27	cod_reviewed	Cause of death (centrally reviewed)	1=Treated cancer 2=Second primary 5=Other cause 9=Unknown *Note: Missing for additional 521 patients who are alive*
28	cod_other_specified_by_site	Cause of death specified by site for patients with centrally reviewed cause of death = "Other"	Character *Note: Missing for patients without COD="Other".* *Note: Any causes specified by only one patient on an arm (regardless of the number on the other arm) are grouped into "Other, NOS" to avoid identification of individual patients.* *Note: Supplementary Appendix Table S2 has an error. Respiratory Failure should have n=2 for RT+Placebo. (The values in the table only sum to 46, not 47 as they should).*
29	death_from_prostate_cancer	Death from prostate cancer status	0= Censored 1= Failure (death from prostate cancer) 2= Competing event (other death)
30	death_from_prostate_cancer_years	Time from randomization to failure, competing event, or last follow-up (years)	Continuous
31	death_from_other_cause	Death from other cause status	0= Censored 1= Failure (death from other cause) 2= Competing event (other death)
32	death_from_other_cause_years	Time from randomization to failure, competing event, or last follow-up (years)	Continuous
33	metastatic_prostate_cancer	Metastatic prostate cancer status	0= Censored 1= Failure (metastatic prostate cancer) 2= Competing event (death without failure)
34	metastatic_prostate_cancer_years	Time from randomization to failure, competing event, or last follow-up (years)	Continuous
35	psa_recurrence_2nd	Second biochemical recurrence status	0= Censored 1= Failure (second biochemical recurrence) 2= Competing event (death without failure)
36	psa_recurrence_2nd _years	Time from	Continuous

#	Variable	Description	Format/Coding for categorical data
		randomization to failure, competing event, or last follow-up (years)	
37	psa_recurrence_3rd	Third biochemical recurrence status	0= Censored 1= Failure (third biochemical recurrence) 2= Competing event (death without failure) *Note: Third biochemical recurrence only calculated for 279 patients who started salvage hormone therapy**
38	psa_recurrence_3rd_years	Time from randomization to failure, competing event, or last follow-up (years)	Continuous *Note: Third biochemical recurrence only calculated for 279 patients who started salvage hormone therapy**
39	local_failure	Local failure status	0= Censored 1= Failure (local failure) 2= Competing event (death without failure)
40	local_failure_years	Time from randomization to failure, competing event, or last follow-up (years)	Continuous
41	Acute_Skin	Worst grade acute radiotherapy skin toxicity	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5 *Note: Blank for additional 4 patients who did not start any protocol treatment*
42	Acute_Bladder	Worst grade acute radiotherapy toxicity: bladder	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5 Note: Blank for additional 4 patients who did not start any protocol treatment
43	Acute_Bowel	Worst grade acute radiotherapy toxicity: bladder	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
44	Acute_Other	Worst grade acute radiotherapy toxicity: other	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
45	Acute_Hematologic	Worst grade acute hematolgic	1 = grade 1 2 = grade 2

#	Variable	Description	Format/Coding for categorical data
		radiotherapy toxicity	3 = grade 3 4 = grade 4 5 = grade 5
46	Late_Neurologic	Worst grade hormone therapy or late radiotherapy toxicity: Neurologic	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
47	Late_Hot_flashes	Worst grade hormone therapy or late radiotherapy toxicity: Hot flashes	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
48	Late_Bowel_GI	Worst grade hormone therapy or late radiotherapy toxicity: Bowel/GI	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
49	Late_Skin_within_XRT_field	Worst grade hormone therapy or late radiotherapy toxicity: Skin within XRT field	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
50	Late_Bladder_GU	Worst grade hormone therapy or late radiotherapy toxicity: Bladder/GU	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
51	Late_Gynecomastia	Worst grade hormone therapy or late radiotherapy toxicity: Gynecomastia	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
52	Late_Headache	Worst grade hormone therapy or late radiotherapy toxicity: Headache	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
53	Late_Other	Worst grade hormone therapy or late radiotherapy toxicity: Other	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
54	Late_Hematologic	Worst grade hormone therapy or late radiotherapy toxicity: Hematologic	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
55	Late_Impotence	Worst grade	1 = grade 1

#	Variable	Description	Format/Coding for categorical data
		hormone therapy or5late radiotherapy toxicity: Impotence	2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
56	Late_Skin_general	Worst grade hormone therapy or late radiotherapy toxicity: Skin general	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
57	Late_Nausea_vomiting	Worst grade hormone therapy or late radiotherapy toxicity: Nausea/vomiting	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
58	Late_Cardiac	Worst grade hormone therapy or late radiotherapy toxicity: Cardiac	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
59	Late_Dyspnea	Worst grade hormone therapy or late radiotherapy toxicity: Dyspnea	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
60	Late_Pain	Worst grade hormone therapy or late radiotherapy toxicity: Pain	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
61	Late_Fluid_Retention	Worst grade hormone therapy or late radiotherapy toxicity: Fluid retention	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
62	Late_Liver	Worst grade hormone therapy or late radiotherapy toxicity: Liver	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5
63	Late_Unknown	Worst grade hormone therapy or late radiotherapy toxicity: Unknown	1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5

*   The first footnote in Supplementary Appendix Table S4 is incorrect. The number of patients who
     started salvage hormone therapy (and therefore are at risk for third biochemical recurrence) was

misreported as 128 [167] for the Bicalutimide arm and 90 [112] for the Bicalutimide arm. Correct values are in brackets.