

NRG Oncology/RTOG-0521 Data Dictionary
NCTN/NCORP Data Archive
Data Dictionary for *NCT00288080-D1-Dataset.csv*

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).

In order to protect patient privacy, the two patients with grade 5 AEs have been grouped with patients who experienced a maximum grade of 4.

Causes of death for five patients who were excluded from the analysis did not undergo central review of cause of death.

The following inconsistencies with the manuscript exist:

- Number of patients lost to follow-up in the CONSORT diagram should be 10 in the AS+RT arm and 17 in the AS+RT+CT arm; the number of patients who withdrew consent should be 9 and 16, respectively.

#	Variable	Type	Len	Description	Format/Coding for categorical data
1	study	Char	9	Study number	Character length 9
2	patid	Char	11	De-identified patient ID	Character length 11
3	include_in_analysis	Char	3	Indicator for inclusion in analysis	Yes=Include in analysis No=Exclude from analysis
4	exclusion_reason	Char	60	Reason excluded from analysis	Character, maximum length 60. <i>Note: Blank for patients not excluded.</i>
5	arm	Char	12	Assigned treatment arm	1=AS + RT 2=AS + RT + CT
6	age	Num	8	Age at study entry (years)	Continuous
7	age_group	Num	8	Age at study entry, grouped	0= <65 1= ≥65
8	race	Char	41	Race	Character, maximum length 41.
9	ethnicity	Char	22	Ethnicity	Character, maximum length 22
10	race_minority	Num	8	Race/ethnicity grouping	0=Non-hispanic white 1=Hispanic or non-white
11	zubrod	Num	8	Zubrod performance status at study entry	0=Normal activity 1=Symptoms, but nearly fully ambulatory <i>Note: Blank for 2 patients for whom Zubrod was not reported</i>
12	gleason	Num	8	Gleason score at study entry	Gleason score at study entry
13	baseline_psa	Num	8	PSA at study entry (ng/dl)	Continuous

#	Variable	Type	Len	Description	Format/Coding for categorical data
14	tstage	Char	2	T-stage at study entry (AJCC Staging System, 6 th edition)	T1= Clinically inapparent tumor neither palpable or visible by imaging T2= Tumor confined within prostate T3=Tumor extends through prostate capsule T4=Tumor is fixed or invades adjacent structures other than seminal vesicles: bladder neck, external sphincter, rectum, levator muscles and/or pelvic wall
15	nstage_clinical	Char	3	N-Stage at study entry per clinical assessment (AJCC Staging System, 6 th edition)	N0=No regional lymph node metastasis N1=Metastasis in regional lymph node(s) NX=Regional lymph nodes cannot be assessed Unk=Clinical N-Stage not reported by site
16	nstage_path	Char	3	N-Stage at study entry per pathologic assessment (AJCC Staging System, 6 th edition)	pN0=No regional lymph node metastasis pNX=Regional lymph nodes not sampled Unk=Pathologic N-Stage not reported by site
17	mstage	Char	3	M-Stage at study entry (AJCC Staging System, 6 th edition)	M0=No distant metastasis Unk=M-Stage not reported by site
18	risk_group	Char	37	Prostate cancer risk group	Character, maximum length 37 <i>Note: Blank for 6 patients whose gleason, PSA, and T-stage combination was not among the risk groups.</i>
19	risk_group_model	Num	8	Prostate cancer risk group, categorical	1=Gleason >= 9, PSA <= 150, any T-stage 2=Gleason 8, PSA < 20, >= T2 3=Gleason 8, PSA >= 20-150, any T-stage 4=Gleason 7, PSA >= 20-150, any T-stage <i>Note: Blank for 6 patients whose gleason, PSA, and T-stage combination was not among the risk groups.</i>
20	received_rt	Char	3	Indicates whether patient received radiation therapy	Yes=Received radiation therapy No=Did not receive radiation therapy Unk=Unknown – site did not report any data relating to radiation therapy delivery
21	no_rt_reason	Char	20	Reason for no radiation therapy	Character, maximum length 20 <i>Note: Limited to patients where received_rt=No</i>
22	rt_reviewed	Char	3	Radiation therapy compliance review status	Yes=Radiation therapy reviewed No=Radiation therapy not reviewed
23	rt_delivery_review	Char	33	Radiation therapy protocol compliance	Character, maximum length 33
24	received_lhrh	Char	3	Indicates whether patient received LHRH agonist therapy	Yes=Received LHRH agonist therapy Unk=Unknown – site did not report any data relating to LHRH agonist therapy
25	received_ct	Char	3	Indicates whether patient received chemotherapy	Received chemotherapy <i>Note: Blank for patients on arm 1: AS+RT</i>
26	ct_reviewed	Char	3	Chemotherapy protocol compliance review status	Yes=Chemotherapy reviewed No=Chemotherapy not reviewed <i>Note: Blank for patients on arm 1: AS+RT</i>

#	Variable	Type	Len	Description	Format/Coding for categorical data
27	ct_per_prot	Char	19	Chemotherapy protocol compliance	Per protocol=Chemotherapy delivered per protocol requirements Not per protocol=Chemotherapy not delivered per protocol requirements Cannot be evaluated=Chemotherapy could not be evaluated due to missing data <i>Note: Limited to patients where ct_reviewed=Yes</i>
28	ct_delivery_delays	Char	23	Chemotherapy delays for per protocol patients	No modifications/delays: Modifications/delays of chemotherapy were not needed. Modifications/delays: Modifications/delays of chemotherapy were needed. Not specified: Insufficient data to determine. <i>Note: Limited to patients where ct_per_prot=Yes</i>
29	oral_antiandrogen	Char	3	Indicates whether patient received oral antiandrogen therapy	Yes=Received oral antiandrogen therapy No=Did not receive oral antiandrogen therapy Unk=Unknown – site did not report any data relating to oral antiandrogen therapy
30	full_rx_sensitivity	Char	3	Full protocol treatment sensitivity analysis inclusion status	Yes=Include in sensitivity analysis No=Exclude from sensitivity analysis
31	max_ae_grade	Char	3	Maximum treatment-related adverse event grade, graded per CTCAE v3.0 criteria.	0=Grade 0, 1=Grade 1, 2=Grade 2, 3=Grade 3, 4 or 5=Grade 4 or 5 <i>Note: Blank for 1 patient who did not receive LHRH agonist, 1 patient whose LHRH status was unknown, and 4 patients for whom AE information was not reported.</i>
32	max_ae_hem_grade	Num	8	Maximum treatment-related hematologic adverse event grade, graded per CTCAE v3.0 criteria.	0=Grade 0, 1=Grade 1, 2=Grade 2, 3=Grade 3, 4=Grade 4 <i>Note: Blank for 1 patient who did not receive LHRH agonist, 1 patient whose LHRH status was unknown, and 4 patients for whom AE information was not reported.</i>
33	survival	Num	8	Overall survival status	0=Alive(censored) 1=Dead(event) <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>

#	Variable	Type	Len	Description	Format/Coding for categorical data
34	survival_years	Num	8	Time since randomization to death/last follow-up (years)	Continuous <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>
35	central_dss	Num	8	Centrally-reviewed disease-specific survival status	0=Alive (censored) 1=Death due to cancer under study (event) 2=Dead due to other cause (competing risk) <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>
36	cause_of_death	Char	18	Centrally-reviewed cause of death	Character, maximum length 18 <i>Note: Limited to patients who were reported as dead</i>
37	biochemical_failure	Num	8	Biochemical/PSA failure status	0=Alive without failure (censored), 1=PSA failure/initiation of non-protocol hormone therapy (event) 2=Death without failure (competing risk) <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>
38	biochemical_failure_years	Num	8	Biochemical/PSA failure time since randomization (years)	Continuous <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>
39	disease_free_survival	Num	8	Disease-free survival status	0=Alive without failure (censored), 1=First of biochemical, local, or distant failure or death (event) <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>
40	disease_free_survival_years	Num	8	Disease-free survival time since randomization (years)	Continuous <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>
41	any_distant_mets	Num	8	Distant metastasis failure status	0=Alive without distant metastasis (censored) 1=Distant metastasis (event) 2=Death without distant metastasis (competing risk) <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>
42	any_distant_mets_years	Num	8	Distant metastasis time since randomization (years)	Continuous <i>Note: Blank for 6 patients for whom no follow-up data was submitted.</i>
43	lost_to_followup	Char	3	Lost to follow-up status	Yes=Patient is lost to follow-up No=Patient is not lost to follow-up
44	lost_to_followup_reason	Char	51	Lost to follow-up reason	Reason lost to follow-up <i>Note: Blank for patients not lost to follow-up</i>