NRG Oncology/RTOG 0522 Data Dictionary for NCT00265941-D1-Dataset.csv

Note #1:
Variables 6-65 are missing when include_in_analysis = 1 (variable #4).

See also the companion dataset and data dictionary:
NCT00265941-D2-Dataset.csv and NCT00265941-D2-Data-Dictionary.pdf

#	Variable	Description	Coding
1	study_no	Study number	Character
2	pt_id	De-identified patient ID	Character
3	rx	Assigned treatment	1=RT + cisplatin 2=RT + cisplatin + cetuximab
4	include_in_analysis	Include in primary endpoint analysis	1=No 2=Yes
5	reason_for_exclusion	Reason for exclusion (when include_in_analysis = 1)	Character
6	consort_lost	CONSORT: lost to follow-up	1=No 2=Yes
7	consort_tx	CONSORT: treatment received	1=Received RT + cisplatin + cetuximab 2=Received RT + cisplatin 3=Received RT + cetuximab 4=Received RT only 6=Received cetuximab only 7=No protocol treatment
8	consort_tx_rt_665gy	CONSORT: received < 66.5Gy (95% of prescribed RT)	1=No 2=Yes
9	rt_reason_disc	Radiation reason discontinued	1=Treatment completed per protocol criteria 2=Disease progression, relapse during active treatment 3=Adverse event/side effects/complications 4=Death on study 5=Patient withdrawal/refusal after beginning protocol therapy 6=Patient withdrawal/refusal prior to beginning protocol therapy 8=Patient off (protocol) treatment for other complicating disease 98=Other 99=Unknown
10	consort_tx_cis_2cyc	CONSORT: received < 2 cycles of cisplatin	1=No 2=Yes
11	cisplatin_reason_disc	Cisplatin reason discontinued	1=Treatment completed per protocol criteria 2=Disease progression, relapse during active treatment 3=Adverse event/side effects/complications 4=Death on study

#	Variable	Description	Coding
			5=Patient withdrawal/refusal after beginning protocol therapy 6=Patient withdrawal/refusal prior to beginning protocol therapy 7=Alternative therapy 8=Patient off (protocol) treatment for other complicating disease 98=Other 99=Unknown
12	consort_tx_cetux_6wks	CONSORT: received < 6 weekly doses of cetuximab (when rx=2)	1=No 2=Yes
13	cetuximab_reason_disc	Cetuximab reason discontinued (when rx=2)	1=Treatment completed per protocol criteria 2=Disease progression, relapse during active treatment 3=Adverse event/side effects/complications 4=Death on study 5=Patient withdrawal/refusal after beginning protocol therapy 6=Patient withdrawal/refusal prior to beginning protocol therapy 8=Patient off (protocol) treatment for other complicating disease 98=Other 99=Unknown
14	age	Age (years)	Continuous
15	gender	Gender	1=Male 2=Female
16	race	Race	1=American Indian or Alaskan native 2=Asian 3=Black or African-American 4=Native Hawaiian or other pacific islander 5=White 9=Unknown
17	zubrod	Zubrod performance status	Continuous
18	hemoglobin	Hemoglobin (g/dl)	Continuous
19	anemia	Anemia	1=No 2=Yes
20	weight_loss	Weight loss in last 6 months	1=< 5% of body weight 2=5 to < 10% of body weight 3=10 to < 20% of body weight 4=≥ 20% of body weight 9=Unknown
21	feeding_tube	Feeding tube	0=No feeding tube 1=Feeding tube, < 50% nutritional support

#	Variable	Description	Coding
			2=Feeding tube, ≥ 50% nutritional support 3=Feeding tube, unknown nutritional support 9=Unknown
22	pack_years	Cigarette pack-years (patient-reported)	Continuous (blank=data not available)
23	primary_site	Primary site	30=Oropharynx, NOS (oropharynx) 32=Tonsillar fossa, tonsil (oropharynx) 33=Base of tongue (oropharynx) 34=Pharyngeal oropharynx (oropharynx) 35=Soft palate (oropharynx) 40=Hypopharynx, NOS (hypopharynx) 41=Pyriform fossa (hypopharynx) 42=Postcricoid area (hypopharynx) 43=Posterior wall (hypopharynx) 50=Supraglottic larynx, NOS (larynx) 51=Ventricular band (larynx) 52=Arytenoid (larynx) 53=Suprahyoid epiglottis (larynx) 54=Infrahyoid epiglottis (larynx) 55=Aryepiglottic fold (larynx) 60=Glottic larynx, NOS (larynx) 61=Vocal cords (larynx) 70=Subglottic larynx, NOS (larynx) 71=Subglottis (larynx)
24	p16_status	p16 status (when primary site = 30-35)	0=Negative 1=Positive 9=Not evaluable and/or no tumor 99=Not tested
25	egfr_level	EGFR level	0=Negative 1=< 80% 2=≥ 80% 9=Not evaluable and/or no tumor 99=Not tested
26	egfr_score	EGFR score	0=Negative 1=1 2=2 3=3 9=Not evaluable and/or no tumor 99=Not tested
27	t_stage	T stage	2=T2 3=T3 4=T4
28	n_stage	N stage	0=N0 1=N1

#	Variable	Description	Coding
			2=N2a 3=N2b 4=N2c 5=N3
29	ajcc_stage	AJCC stage (6th ed.)	3=III 4=IV
30	pet_ct	Pretreatment PET/CT	1=No 2=Yes
31	rt_type_planned	Type of RT planned	1=3DCRT 2=IMRT
32	rt_type_admin	Type of RT administered	1=3DCRT 2=IMRT 3=None
33	rt_dose	Radiation dose (Gy)	Continuous
34	rt_fx	Radiation total fractions	Continuous
35	rt_elapsed_days	Radiation elapsed days	Continuous
36	rt_interruptions	Radiation interruptions (when rt_dose > 0)	1=No 2=Yes, due to toxicity 3=Yes, due to other reason
37	rt_score_tv	Radiation review score, target volume	1=Per protocol 2=Acceptable variation 3=Unacceptable variation 9=Not evaluable
38	rt_score_oar	Radiation review score, organs at risk (when rt_type_planned = 2)	1=Per protocol 2=Acceptable variation 3=Unacceptable variation 9=Not evaluable
39	rt_score_tv_dva	Radiation review score, target volume, dose volume analysis (when rt_type_planned = 2)	1=Per protocol 2=Acceptable variation 3=Unacceptable variation 9=Not evaluable
40	cisplatin_cycles	Cisplatin cycles given	Continuous
41	cisplatin_dose_per_m2	Cisplatin total dose (mg/m2)	Continuous
42	cetuximab_loading_given	Cetuximab loading dose given	1=No 2=Yes
43	cetuximab_weeks_given	Cetuximab weeks given	Continuous
44	survival	Survival status	0=Censored 1=Event
45	survival_years	Survival time (years)	Continuous
46	pfs	Progression-free survival status	0=Censored 1=Event
47	pfs_years	Progression-free survival time (years)	Continuous
48	loc_reg_failure	Local-regional failure status	0=Censored

#	Variable	Description	Coding
			1=Event 2=Competing event
49	loc_reg_failure_years	Local-regional failure time (years)	Continuous
50	distant_mets	Distant metastases status	0=Censored 1=Event 2=Competing event
51	distant_mets_years	Distant metastases time (years)	Continuous
52	include_opc_p16	Include in analysis: oropharynx cancer with known p16 status	1=No 2=Yes
53	include_egfr	Include in analysis: known EGFR expression	1=No 2=Yes
54	include_mv_model	Include in analysis: multivariable model, all primary tumor sites	1=No 2=Yes
55	include_mv_model_opc	Include in analysis: multivariable model, oropharynx cancer	1=No 2=Yes
56	death_within_30	Death within 30 days of treatment completion	1=No 2=Yes
57	grade_5_ae_tx_rel	Treatment-related grade 5 adverse event (CTCAE version 3.0 with relationship definitely, probably, or possibly related to protocol treatment)	1=No 2=Yes
58	include_ft_12mo	Include in analysis: feeding tube at 12 months	1=No 2=Yes
59	feeding_tube_12months	Feeding tube at 12 months	1=No 2=Yes (blank=no assessment at 12 months)
60	include_ft_24mo	Include in analysis: feeding tube at 24 months	1=No 2=Yes
61	feeding_tube_24months	Feeding tube at 24 months	1=No 2=Yes (blank=no assessment at 24 months)
62	include_ft_36mo	Include in analysis: feeding tube at 36 months	1=No 2=Yes
63	feeding_tube_36months	Feeding tube at 36 months	1=No 2=Yes (blank=no assessment at 36 months)
64	include_ae_acute	Include in analysis: acute adverse events	2=Yes
65	include_ae_late	Include in analysis: late adverse events	1=No 2=Yes