

NRG Oncology/RTOG 1016 Data Dictionary for NCT01302834-D1-Dataset.csv

Note #1:

Variables 8-43, 46, and 48-185 are blank when include_in_analysis = 1 (variable #6). Additional reasons for blanks are noted in the table below.

Note #2:

Data required for replicating the reasons for exclusion in the CONSORT diagram are not contained within this data submission due to de-identification procedures.

Note #3:

Data required for replicating the descriptions of early deaths (*i.e.*, days after treatment and relationship to treatment) are not contained within this data submission due to de-identification procedures.

Note #4:

There was some known data discrepancies in variables 167, 169, 171, 173, 175, 177, 179, 181, 183, and 185 (*i.e.*, patients with 0 teeth pre-treatment and >0 post-treatment)

See also the companion dataset and data dictionary:

NCT01302834-D2-Dataset.csv and NCT01302834-D2-Data-Dictionary.pdf

#	Variable	Description	Coding
1	study_no	Study number	Character
2	pt_id	De-identified patient ID	Character
3	consort_rand	CONSORT: randomized	1=No 2=Yes
4	consort_not_rand_rsn	CONSORT: reason not randomized (blank when consort_rand=2)	1=Progression of disease 2=Patient is not p16-positive 3=Patient refusal 4=Physician preference 5=Failure to submit tissue assay 6=Other
5	arm_rand	Assigned treatment (randomization) (blank when consort_rand=1)	1=IMRT + Cisplatin 2=IMRT + Cetuximab
6	include_in_analysis	Include in primary endpoint analysis	1=No 2=Yes
7	reason_for_exclusion	Reason for exclusion (blank when include_in_analysis=2)	Character
8	consort_tx	CONSORT: treatment received	1=IMRT + cisplatin 2=IMRT + cetuximab 3=Received IMRT only 4=Received cisplatin only 5=Received cetuximab only 6=No protocol treatment
9	consort_lost	CONSORT: lost to follow-up	1=No 2=Yes
10	consort_lost_rsn	CONSORT: reason lost to follow-up (blank when consort_lost=1)	Character
11	consort_disc_rt	CONSORT: discontinued IMRT	1=No

#	Variable	Description	Coding
		(blank when consort_tx=4,5,6)	2=Yes
12	consort_disc_rt_rsn	CONSORT: reason discontinued IMRT (blank when consort_disc_rt=1)	Character
13	consort_disc_cisplatin	CONSORT: discontinued cisplatin (blank when consort_tx=2,3,5,6)	1=No 2=Yes
14	consort_disc_cisplatin_rsn	CONSORT: reason discontinued cisplatin (blank when consort_disc_cisplatin=1)	Character
15	consort_disc_cetuximab	CONSORT: discontinued cetuximab (blank when consort_tx=1,3,4,6)	1=No 2=Yes
16	consort_disc_cetuximab_rsn	CONSORT: reason discontinued cetuximab (blank when consort_disc_cetuximab=1)	Character
17	age	Age (years)	Continuous
18	gender	Gender	1=Male 2=Female
19	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=Unknown or not reported
20	ethnicity	Ethnicity	1=Hispanic or Latino 2=Not Hispanic or Latino 9=Unknown
21	zubrod	Zubrod performance status	Continuous
22	pack_years	Smoking history: pack-years	Continuous
23	primary_site_text	Primary site (with specify)	Character
24	t_stage_clinical	T stage, clinical, AJCC 7th edition	1=T1 2=T2 3=T3 4=T4
25	n_stage_clinical	N stage, clinical, AJCC 7th edition	0=N0 1=N1 2=N2a 3=N2b 4=N2c 5=N3
26	ajcc_stage_clinical	Overall stage, clinical, AJCC 7th edition	3=III 4=IV
27	n_stage_ajcc8	N stage, clinical, AJCC 8th edition	Character
28	stage_ajcc8	Overall stage, clinical, AJCC 8th edition	Character

#	Variable	Description	Coding
29	risk_group	Risk group per RTOG 0129	1=Low risk
			2=Intermediate risk
30	qol_consent	Consented to QOL	1=No
		(blank for patients enrolled after QOL substudy closed)	2=Yes
31	rt_dose	RT dose (Gy)	Continuous
32	rt_fx	RT fractions	Continuous
33	rt_elapsed_days	RT elapsed days (blank when rt_dose=0)	Continuous
34	include_rt_score	Include in RT review	1=No
			2=Yes
35	rt_score_overall	Radiation review score, overall	1=Per protocol
		(blank when include_rt_score=1)	2=Acceptable variation
			3=Unacceptable deviation
			5=Incomplete RT, death
			6=Incomplete RT, progression
			7=Incomplete RT, refusal
			8=No RT given
			9=Not evaluable
36	ct_score_overall	Chemotherapy review score, overall	1=Per protocol
			2=Acceptable variation
			3=Unacceptable deviation
			4=Not evaluable
37	cisplatin_doses	Cisplatin number of doses given (blank when arm_rand=2)	Continuous
38	cisplatin_dose_per_m2	Cisplatin total dose (mg/m2) (blank when arm_rand=2)	Continuous
39	cetuximab_doses	Cetuximab number of doses given (blank when arm_rand=1)	Continuous
40	cetuximab_dose_per_m2	Cetuximab total dose (mg/m2) (blank when arm_rand=1)	Continuous
41	prm_srg	Primary salvage surgery	0=Not operated
			1=Complete resection of all gross disease
			2=Incomplete/partial resection of gross tumor
42	nd_l_srg	Neck dissection (left)	0=Not operated
			1=Complete resection of all gross disease
			2=Incomplete/partial resection of gross tumor
43	nd_r_srg	Neck dissection (right)	0=Not operated
			1=Complete resection of all gross disease

#	Variable	Description	Coding
			2=Incomplete/partial resection of gross tumor
44	survival	Survival status	0=Censored
			1=Event
45	survival_years	Survival time (years)	Continuous
46	include_per_protocol	Include in per protocol sensitivity analysis	1=No
			2=Yes
47	include_all_rand	Include in all randomized sensitivity analysis	1=No
			2=Yes
48	pfs	Progression-free survival status	0=Censored
			1=Event
49	pfs_years	Progression-free survival time	Continuous
50	first_failure_pfs	First failure (PFS)	1.01=Local
			1.02=Regional
			1.03=Local and regional
			1.04=Local and distant
			1.05=Regional and distant
			1.06=Local, regional, and distant
			2.01=Distant
			4.01=Death, COD this disease
			4.02=Death, COD second primary
			4.04=Death, COD other
			4.09=Death, COD unknown
			9=Alive, no failure
51	loc_reg_failure	Local-regional failure status	0=Censored
			1=Event
			2=Competing event
52	loc_reg_failure_years	Local-regional failure time (years)	Continuous
53	distant_mets	Distant metastasis status	0=Censored
			1=Event
			2=Competing event
54	distant_mets_years	Distant metastasis time (years)	Continuous
55	spt	Second primary tumor status [excl. BCC-skin]	0=Censored
			1=Event
			2=Competing event
56	spt_years	Second primary tumor time (years) [excl. BCC-skin]	Continuous
57	include_ae_acute	Include in acute AE analysis	1=No
			2=Yes
58	early_death	Early death	1=No
		(blank when include_ae_acute=1)	2=Yes
59	grd34_acute	Grade 3-4 overall, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
60	grd34_acute_anemia	Grade 3-4 anemia, acute	1=No

#	Variable	Description	Coding
		(blank when include_ae_acute=1)	2=Yes
61	grd34_acute_hearing	Grade 3-4 hearing impaired, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
62	grd23_acute_dry_mouth	Grade 2-3 dry mouth, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
63	grd34_acute_dysphagia	Grade 3-4 dysphagia, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
64	grd34_acute_muc_oral	Grade 3-4 mucositis oral, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
65	grd3_acute_nausea	Grade 3 nausea, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
66	grd34_acute_vomiting	Grade 3-4 vomiting, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
67	grd3_acute_fatigue	Grade 3 fatigue, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
68	grd34_acute_derm_rad	Grade 3-4 dermatitis radiation, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
69	grd34_acute_lymphocytes	Grade 3-4 lymphocyte count decreased, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
70	grd34_acute_neutrophils	Grade 3-4 neutrophil count decreased, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
71	grd3_acute_wt_loss	Grade 3 weight loss, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
72	grd34_acute_wbc	Grade 3-4 white blood cell decreased, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
73	grd34_acute_anorexia	Grade 3-4 anorexia, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
74	grd34_acute_dehydration	Grade 3-4 dehydration, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
75	grd34_acute_hyponatremia	Grade 3-4 hyponatremia, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
76	grd34_acute_kidney	Grade 3-4 acute kidney injury, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
77	grd34_acute_phar_muc	Grade 3-4 pharyngeal mucositis, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
78	grd34_acute_rash	Grade 3-4 rash acneiform, acute	1=No
		(blank when include_ae_acute=1)	2=Yes
79	grd34_acute_pain	Grade 3-4 pain (all terms), acute	1=No
		(blank when include_ae_acute=1)	2=Yes
80	raw_t_score	Raw T-score (blank when include_ae_acute=1)	Continuous
81	include_ae_late	Include in late AE analysis	1=No
			2=Yes

#	Variable	Description	Coding
82	grd34_late	Grade 3-4 overall, late	1=No
		(blank when include_ae_late=1)	2=Yes
83	grd34_late_hearing	Grade 3-4 hearing impaired, late	1=No
		(blank when include_ae_late=1)	2=Yes
84	grd23_late_dry_mouth	Grade 2-3 dry mouth, late	1=No
		(blank when include_ae_late=1)	2=Yes
85	grd34_late_dysphagia	Grade 3-4 dysphagia, late	1=No
		(blank when include_ae_late=1)	2=Yes
86	grd3_late_wt_loss	Grade 3 weight loss, late	1=No
		(blank when include_ae_late=1)	2=Yes
87	grd34_late_osteonec_jaw	Grade 3-4 osteonecrosis of jaw, late	1=No
		(blank when include_ae_late=1)	2=Yes
88	grd34_late_pain	Grade 3-4 pain (all terms), late	1=No
		(blank when include_ae_late=1)	2=Yes
89	raw_a_score	Raw A-score (blank when include_ae_late=1)	Continuous
90	include_ae_tx	Include in AE analysis, during treatment	1=No
			2=Yes
91	ae_grd34_rel_tx	Treatment-related grade 3-4 AE, during treatment	1=No
		(blank when include_ae_tx=1)	2=Yes
92	include_ae_1mo	Include in AE analysis, 1 month after end of treatment	1=No
			2=Yes
93	ae_grd34_rel_1mo	Treatment-related grade 3-4 AE, 1 month after end of treatment	1=No
		(blank when include_ae_1mo=1)	2=Yes
94	include_ae_3mo	Include in AE analysis, 3 months after end of treatment	1=No
			2=Yes
95	ae_grd34_rel_3mo	Treatment-related grade 3-4 AE, 3 months after end of treatment	1=No
		(blank when include_ae_3mo=1)	2=Yes
96	include_ae_6mo	Include in AE analysis, 6 months after end of treatment	1=No
			2=Yes
97	ae_grd34_rel_6mo	Treatment-related grade 3-4 AE, 6 months after end of treatment	1=No
		(blank when include_ae_6mo=1)	2=Yes
98	include_ae_1yr	Include in AE analysis, 1 year after end of treatment	1=No
			2=Yes
99	ae_grd34_rel_1yr	Treatment-related grade 3-4 AE, 1 year after end of treatment	1=No
		(blank when include_ae_1yr=1)	2=Yes
100	include_ae_2yr	Include in AE analysis, 2 years after end of treatment	1=No
			2=Yes
101	ae_grd34_rel_2yr	Treatment-related grade 3-4 AE, 2 years after end of treatment	1=No
		(blank when include_ae_2yr=1)	2=Yes
102	include_ae_3yr	Include in AE analysis, 3 years after end of treatment	1=No
			2=Yes
103	ae_grd34_rel_3yr	Treatment-related grade 3-4 AE, 3 years after end of treatment	1=No

#	Variable	Description	Coding
		(blank when include_ae_3yr=1)	2=Yes
104	include_ae_4yr	Include in AE analysis, 4 years after end of treatment	1=No
			2=Yes
105	ae_grd34_rel_4yr	Treatment-related grade 3-4 AE, 4 years after end of treatment	1=No
		(blank when include_ae_4yr=1)	2=Yes
106	include_ae_5yr	Include in AE analysis, 5 years after end of treatment	1=No
			2=Yes
107	ae_grd34_rel_5yr	Treatment-related grade 3-4 AE, 5 years after end of treatment	1=No
		(blank when include_ae_5yr=1)	2=Yes
108	include_ft	Include in feeding tube analysis, pretreatment	1=No
			2=Yes
109	feeding_tube	Feeding tube, pretreatment	1=No
		(blank when include_ft=1)	2=Yes
110	include_ft_endtx	Include in feeding tube analysis, end of treatment	1=No
			2=Yes
111	feeding_tube_endtx	Feeding tube, end of treatment	1=No
		(blank when include_ft_endtx=1)	2=Yes
112	include_ft_1mo	Include in feeding tube analysis, 1 month after end of treatment	1=No
			2=Yes
113	feeding_tube_1mo	Feeding tube, 1 month after end of treatment	1=No
		(blank when include_ft_1mo=1)	2=Yes
114	include_ft_3mo	Include in feeding tube analysis, 3 months after end of treatment	1=No
			2=Yes
115	feeding_tube_3mo	Feeding tube, 3 months after end of treatment	1=No
		(blank when include_ft_3mo=1)	2=Yes
116	include_ft_6mo	Include in feeding tube analysis, 6 months after end of treatment	1=No
			2=Yes
117	feeding_tube_6mo	Feeding tube, 6 months after end of treatment	1=No
		(blank when include_ft_6mo=1)	2=Yes
118	include_ft_1yr	Include in feeding tube analysis, 1 year after end of treatment	1=No
			2=Yes
119	feeding_tube_1yr	Feeding tube, 1 year after end of treatment	1=No
		(blank when include_ft_1yr=1)	2=Yes
120	include_ft_2yr	Include in feeding tube analysis, 2 years after end of treatment	1=No
			2=Yes
121	feeding_tube_2yr	Feeding tube, 2 years after end of treatment	1=No
		(blank when include_ft_2yr=1)	2=Yes
122	include_ft_3yr	Include in feeding tube analysis, 3 years after end of treatment	1=No
			2=Yes
123	feeding_tube_3yr	Feeding tube, 3 years after end of treatment	1=No
		(blank when include_ft_3yr=1)	2=Yes
124	include_ft_4yr	Include in feeding tube analysis, 4 years after end of treatment	1=No

#	Variable	Description	Coding
			2=Yes
125	feeding_tube_4yr	Feeding tube, 4 years after end of treatment	1=No
		(blank when include_ft_4yr=1)	2=Yes
126	include_ft_5yr	Include in feeding tube analysis, 5 years after end of treatment	1=No
			2=Yes
127	feeding_tube_5yr	Feeding tube, 5 years after end of treatment	1=No
		(blank when include_ft_5yr=1)	2=Yes
128	include_qlq_1	Include in QLQ-H&N35 analysis, pretreatment	1=No
			2=Yes
129	qlq_hn35_sw_s_1	QLQ-H&N35 swallowing domain score, pretreatment (blank when include_qlq_1=1)	Continuous
130	include_qlq_2	Include in QLQ-H&N35 analysis, end of treatment	1=No
			2=Yes
131	qlq_hn35_sw_s_2	QLQ-H&N35 swallowing domain score, end of treatment (blank when include_qlq_2=1)	Continuous
132	include_qlq_3	Include in QLQ-H&N35 analysis, 3 months after end of treatment	1=No
			2=Yes
133	qlq_hn35_sw_s_3	QLQ-H&N35 swallowing domain score, 3 months after end of treatment (blank when include_qlq_3=1)	Continuous
134	include_qlq_4	Include in QLQ-H&N35 analysis, 6 months after end of treatment	1=No
			2=Yes
135	qlq_hn35_sw_s_4	QLQ-H&N35 swallowing domain score, 6 months after end of treatment (blank when include_qlq_4=1)	Continuous
136	include_qlq_5	Include in QLQ-H&N35 analysis, 12 months after end of treatment	1=No
			2=Yes
137	qlq_hn35_sw_s_5	QLQ-H&N35 swallowing domain score, 12 months after end of treatment (blank when include_qlq_5=1)	Continuous
138	include_qlq_chg_2	Include in QLQ-H&N35 change analysis, end of treatment	1=No
			2=Yes
139	qlq_hn35_sw_s_chg_2	QLQ-H&N35 swallowing domain score, end of treatment, change from pretreatment (blank when include_qlq_chg_2=1)	Continuous
140	include_qlq_chg_3	Include in QLQ-H&N35 change analysis, 3 months after end of treatment	1=No
			2=Yes
141	qlq_hn35_sw_s_chg_3	QLQ-H&N35 swallowing domain score, 3 months after end of treatment, change from pretreatment (blank when include_qlq_chg_3=1)	Continuous
142	include_qlq_chg_4	Include in QLQ-H&N35 change analysis, 6 months after end of treatment	1=No
			2=Yes

#	Variable	Description	Coding
143	qlq_hn35_sw_s_chg_4	QLQ-H&N35 swallowing domain score, 6 months after end of treatment, change from pretreatment (blank when include_qlq_chg_4=1)	Continuous
144	include_qlq_chg_5	Include in QLQ-H&N35 change analysis, 12 months after end of treatment	1=No 2=Yes
145	qlq_hn35_sw_s_chg_5	QLQ-H&N35 swallowing domain score, 12 months after end of treatment, change from pretreatment (blank when include_qlq_chg_5=1)	Continuous
146	include_ging	Include in gingival health analysis, pretreatment	1=No 2=Yes
147	gingival_health	Dental gingival health, pretreatment (blank when include_ging=1)	0=Normal 1=Mild changes/good dental health 2=Moderate/fair dental health 3=Severe changes in dental health
148	include_ging_endtx	Include in gingival health analysis, end of treatment	1=No 2=Yes
149	gingival_health_endtx	Dental gingival health, end of treatment (blank when include_ging_endtx=1)	0=Normal 1=Mild changes/good dental health 2=Moderate/fair dental health 3=Severe changes in dental health
150	include_ging_1mo	Include in gingival health analysis, 1 month after end of treatment	1=No 2=Yes
151	gingival_health_1mo	Dental gingival health, 1 month after end of treatment (blank when include_ging_1mo=1)	0=Normal 1=Mild changes/good dental health 2=Moderate/fair dental health 3=Severe changes in dental health
152	include_ging_3mo	Include in gingival health analysis, 3 months after end of treatment	1=No 2=Yes
153	gingival_health_3mo	Dental gingival health, 3 months after end of treatment (blank when include_ging_3mo=1)	0=Normal 1=Mild changes/good dental health 2=Moderate/fair dental health 3=Severe changes in dental health 4=Life-threatening dental condition
154	include_ging_6mo	Include in gingival health analysis, 6 months after end of treatment	1=No

#	Variable	Description	Coding
			2=Yes
155	gingival_health_6mo	Dental gingival health, 6 months after end of treatment	0=Normal
		(blank when include_ging_6mo=1)	1=Mild changes/good dental health
			2=Moderate/fair dental health
			3=Severe changes in dental health
			4=Life-threatening dental condition
156	include_ging_1yr	Include in gingival health analysis, 1 year after end of treatment	1=No
			2=Yes
157	gingival_health_1yr	Dental gingival health, 1 year after end of treatment	0=Normal
		(blank when include_ging_1yr=1)	1=Mild changes/good dental health
			2=Moderate/fair dental health
			3=Severe changes in dental health
			4=Life-threatening dental condition
158	include_ging_2yr	Include in gingival health analysis, 2 years after end of treatment	1=No
			2=Yes
159	gingival_health_2yr	Dental gingival health, 2 years after end of treatment	0=Normal
		(blank when include_ging_2yr=1)	1=Mild changes/good dental health
			2=Moderate/fair dental health
			3=Severe changes in dental health
			4=Life-threatening dental condition
160	include_ging_3yr	Include in gingival health analysis, 3 years after end of treatment	1=No
			2=Yes
161	gingival_health_3yr	Dental gingival health, 3 years after end of treatment	0=Normal
		(blank when include_ging_3yr=1)	1=Mild changes/good dental health
			2=Moderate/fair dental health
			3=Severe changes in dental health
162	include_ging_4yr	Include in gingival health analysis, 4 years after end of treatment	1=No
			2=Yes
163	gingival_health_4yr	Dental gingival health, 4 years after end of treatment	0=Normal
		(blank when include_ging_4yr=1)	1=Mild changes/good dental health
			2=Moderate/fair dental health
			3=Severe changes in dental health
164	include_ging_5yr	Include in gingival health analysis, 5 years after end of treatment	1=No
			2=Yes
165	gingival_health_5yr	Dental gingival health, 5 years after end of treatment	0=Normal

#	Variable	Description	Coding
		(blank when include_ging_5yr=1)	1=Mild changes/good dental health
			2=Moderate/fair dental health
			3=Severe changes in dental health
166	include_teeth	Include in teeth analysis, pretreatment	1=No
			2=Yes
167	native_teeth_in_place	Native teeth in place, pretreatment (blank when include_teeth=1)	Continuous
168	include_teeth_endtx	Include in teeth analysis, end of treatment	1=No
			2=Yes
169	native_teeth_in_place_endtx	Native teeth in place, end of treatment (blank when include_teeth_endtx=1)	Continuous
170	include_teeth_1mo	Include in teeth analysis, 1 month after end of treatment	1=No
			2=Yes
171	native_teeth_in_place_1mo	Native teeth in place, 1 month after end of treatment (blank when include_teeth_1mo=1)	Continuous
172	include_teeth_3mo	Include in teeth analysis, 3 months after end of treatment	1=No
			2=Yes
173	native_teeth_in_place_3mo	Native teeth in place, 3 months after end of treatment (blank when include_teeth_3mo=1)	Continuous
174	include_teeth_6mo	Include in teeth analysis, 6 months after end of treatment	1=No
			2=Yes
175	native_teeth_in_place_6mo	Native teeth in place, 6 months after end of treatment (blank when include_teeth_6mo=1)	Continuous
176	include_teeth_1yr	Include in teeth analysis, 1 year after end of treatment	1=No
			2=Yes
177	native_teeth_in_place_1yr	Native teeth in place, 1 year after end of treatment (blank when include_teeth_1yr=1)	Continuous
178	include_teeth_2yr	Include in teeth analysis, 2 years after end of treatment	1=No
			2=Yes
179	native_teeth_in_place_2yr	Native teeth in place, 2 years after end of treatment (blank when include_teeth_2yr=1)	Continuous
180	include_teeth_3yr	Include in teeth analysis, 3 years after end of treatment	1=No
			2=Yes
181	native_teeth_in_place_3yr	Native teeth in place, 3 years after end of treatment (blank when include_teeth_3yr=1)	Continuous
182	include_teeth_4yr	Include in teeth analysis, 4 years after end of treatment	1=No
			2=Yes
183	native_teeth_in_place_4yr	Native teeth in place, 4 years after end of treatment (blank when include_teeth_4yr=1)	Continuous
184	include_teeth_5yr	Include in teeth analysis, 5 years after end of treatment	1=No

#	Variable	Description	Coding
			2=Yes
185	native_teeth_in_place_5yr	Native teeth in place, 5 years after end of treatment (blank when include_teeth_5yr=1)	Continuous