

NRG Oncology/RTOG-0617 Data Dictionary
NCTN Data Archive
Dictionary for NCT00533949-D1-Data-Dictionary.csv

Data required for replicating Appendix 12 in the primary publication for this trial are not contained within this data submission due to de-identification procedures.

For patients excluded from analysis, there is no data in variables 6-88.

See also the companion dataset/data dictionaries:

- NCT00533949-D2-Dataset.csv NCT00533949-D2-Data-Dictionary.pdf
- NCT00533949-D3-Dataset.csv NCT00533949-D3-Data-Dictionary.pdf

Note: An error in the CONSORT diagram of the primary publication for this trial reports two patients on 74 Gy, no cetuximab as being lost to follow-up. The actual count is one patient.

#	Variable	Description	Format/Coding for categorical data
1	study	Study number	Character length 9
2	patid	De-identified patient ID	Character length 11
3	arm	Assigned treatment arm	1=60 Gy, no cetuximab 2=74 Gy, no cetuximab 3=60 Gy + cetuximab 4=74 Gy + cetuximab <i>Note: Analyses of 60 Gy vs 74 Gy compare arms 1+3 vs 2+4. Analyses of Cetuximab vs No cetuximab compare arms 1+2 vs 3+4.</i>
4	analysis_inclusion	Indicator for inclusion in analysis in general	0=Excluded 1=Included
5	reason_for_exclusion	Reason excluded from analysis in general	Character, maximum length 72 <i>Note: Blank for patients not excluded.</i>
6	analysis_inclusion_rt	Indicator for inclusion in analyses comparing 60 Gy and 74 Gy	0=Excluded 1=Included <i>Note: Excluded are cases enrolled while 74 Gy arms were not open to accrual.</i>
7	analysis_inclusion_cetuximab	Indicator for inclusion in analyses comparing Cetuximab to No cetuximab	0=Excluded 1=Included <i>Note: Excluded are cases enrolled while cetuximab arms were not open to accrual.</i>
8	age	Age at study entry (years)	Continuous
9	gender	Gender	1=Male 2=Female
10	race	Race	1=American Indian/Alaskan Native 2=Asian 3=Black or African American 4=Native Hawaiian/Other Pacific Islander 5=White 9=Unknown
11	ethnicity	Ethnicity	1=Hispanic or Latino 2=Not Hispanic or Latino 9=Unknown

#	Variable	Description	Format/Coding for categorical data
12	zubrod	Zubrod performance status	0=Normal activity 1=Symptoms, but nearly fully ambulatory
13	histology	Histology	1=Squamous cell carcinoma 2=Adenocarcinoma 3=Large cell undifferentiated 5=Non-small cell lung cancer NOS
14	nonsquam_squam	Histology grouped for analyses of non-squamous vs squamous histology	1=Non-squamous histology 2=Squamous histology
15	ajcc_stage_grp	AJCC Stage (6 th edition, 2002)	1=IIIA, or N2 with an undetectable primary 2=IIIB, or N3 with an undetectable primary
16	pet_staging	Use of PET in staging patient	1=No use of PET in staging 2=PET used in staging
17	rt_technique	RT technique used to treat patient	1=3D-CRT 2=IMRT
18	has_egfr_hscore	Indicator for availability of EGFR H-Score	0=No H-Score (no tissue, insufficient tissue) 1=H-Score able to be determined
19	egfr_hscore_200	EGFR H-score dichotomized at 200	1=H-Score < 200 2=H-Score ≥ 200 <i>Note: Blank for patients with has_egfr_hscore = 0</i>
20	smoke_hx	Smoking history	1=Non-smoker (<100 cigarettes in lifetime) 2=Former light smoker (≤10 pack years and quit ≥1 year ago) 3=Former heavy smoker (>10 pack years) 4=Current smoker (quit <1 year ago or currently smoke) 9=Unknown
21	rx_terminated_ae	Treatment terminated due to adverse events (AEs)	0=Not terminated due to AEs 1=Terminated due to AEs
22	received_rt	Did patient receive RT	0=Did not receive RT 1=Received RT
23	rt_dose	Dose of RT received respective to assigned dose	1=Received assigned dose (60 Gy/74 Gy) 2=Received less than assigned dose 3=Received more than assigned dose <i>Note: Blank for patients not receiving RT</i>
24	overall_rt_review	RT review: Overall RT review	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 5=Incomplete RT – Death during RT 6=Incomplete RT – Progression 7=Incomplete RT – Refusal 8=No RT given 9=Not evaluable
25	fractionation_review	RT review: RT Fractionation/Dose	0=Not applicable 1=Per protocol

#	Variable	Description	Format/Coding for categorical data
			2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
26	elapsed_days_review	RT review: Elapsed days	0=Not applicable 1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
27	tv_oar_review	RT review: TV/OAR contouring overall	0=Not applicable 1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
28	gtv_review	RT review: GTV contour	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation <i>Note: Blank indicates missing due to lack of contour to review</i>
29	ptv_review	RT review: PTV contour	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: Blank indicates missing due to lack of contour to review</i>
30	ips_lung_review	RT review: Ipsilateral lung contour	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: Blank indicates missing due to lack of contour to review</i>
31	contra_lung_review	RT review: Contralateral lung contour	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: Blank indicates missing due to lack of contour to review</i>
32	spinal_cord_review	RT review: Spinal cord contour	1=Per protocol 2=Acceptable variation 9=Not evaluable <i>Note: Blank indicates missing due to lack of contour to review</i>
33	heart_review	RT review: Heart contour	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: Blank indicates missing due to lack of contour to review</i>
34	esophagus_review	RT review: Esophagus contour	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: Blank indicates missing due to lack of contour to review</i>
35	brachial_plexus_review	RT review: Brachial plexus	1=Per protocol

#	Variable	Description	Format/Coding for categorical data
		contour	2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: Blank indicates missing due to lack of contour to review</i>
36	skin_review	RT review: Skin contour	1=Per protocol 9=Not evaluable <i>Note: Blank indicates missing due to lack of contour to review</i>
37	dva_tv_review	RT review: Tumor volume dose volume analysis	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
38	dva_oar_review	RT review: Organs at risk dose volume analysis	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
39	volume_gtv	Volume of the GTV (cc)	Continuous <i>Note: Blank indicates missing</i>
40	volume_itv	Volume of the ITV (cc)	Continuous <i>Note: Blank indicates missing</i>
41	volume_ptv	Volume of the PTV (cc)	Continuous <i>Note: Blank indicates missing</i>
42	dmax_ptv	Maximum dose to the PTV (Gy)	Continuous <i>Note: Blank indicates missing</i>
43	v100_ptv	Percent of PTV covered by 100% of the prescription dose (%)	Continuous <i>Note: Blank indicates missing</i>
44	v95_ptv	Percent of PTV covered by 95% of the prescription dose (%)	Continuous <i>Note: Blank indicates missing</i>
45	v5_lung	Lung V5 (%)	Continuous <i>Note: Blank indicates missing</i>
46	v20_lung	Lung V20 (%)	Continuous <i>Note: Blank indicates missing</i>
47	dmean_lung	Mean lung dose (Gy)	Continuous <i>Note: Blank indicates missing</i>
48	v5_heart	Heart V5 (%)	Continuous <i>Note: Blank indicates missing</i>
49	v30_heart	Heart V30 (%)	Continuous <i>Note: Blank indicates missing</i>
50	v20_esophagus	Esophagus V20 (%)	Continuous <i>Note: Blank indicates missing</i>
51	v60_esophagus	Esophagus V60 (%)	Continuous <i>Note: Blank indicates missing</i>
52	Dmin_PTV_CTV_MARGIN	Minimum margin between PTV and CTV (mm)	Continuous <i>Note: Blank indicates missing</i>
53	Dmax_PTV_CTV_MARGIN	Maximum margin between PTV and CTV (mm)	Continuous <i>Note: Blank indicates missing</i>
54	Dmean_PTV_CTV_MARGIN	Mean margin between PTV and CTV (mm)	Continuous <i>Note: Blank indicates missing</i>
55	rt_compliance_physician	RT compliance as assessed by physician for subgroup analysis	0=Not compliant 1=Compliant

#	Variable	Description	Format/Coding for categorical data
56	rt_compliance_ptv90	RT compliance as assessed by 90% of PTV covered by 95% of prescription dose for subgroup analysis	0= <90% of PTV covered by at least 95% of prescription dose 1= ≥90% of PTV covered by at least 95% of prescription dose
57	received_conc_chemo	Did patient receive concurrent chemotherapy	0=No 1=Yes
58	received_conc_cetuximab	Did patient receive concurrent cetuximab	0=No 1=Yes <i>Note: Limited to patients assigned to cetuximab arms</i>
59	received_cons_chemo	Did patient receive consolidation chemotherapy	0=No 1=Yes
60	received_cons_cetuximab	Did patient receive consolidation cetuximab	0=No 1=Yes <i>Note: Limited to patients assigned to cetuximab arms</i>
61	conc_cetux_score_overall	Systemic therapy review: Concurrent cetuximab overall review	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: Limited to patients assigned to cetuximab arms</i>
62	conc_chemo_score_overall	Systemic therapy review: Concurrent chemotherapy (paclitaxel/carboplatin) overall review	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
63	conc_cetux_score_dose	Systemic therapy review: Concurrent cetuximab dose review	1= 85-115% of therapy 2= <85% of therapy, per protocol 3= 70-<85% of therapy, not per protocol 4= <70% of therapy, not per protocol <i>Note: Limited to patients assigned to cetuximab arms</i> <i>Note: This will be blank for patients whose value of conc_cetux_score_overall is 9-Not evaluable.</i>
64	conc_chemo_score_dose	Systemic therapy review: Concurrent chemotherapy dose review	1= 85-115% of therapy 2= <85% of therapy, per protocol 3= 70-<85% of therapy, not per protocol 4= <70% of therapy, not per protocol 5= >115% of therapy <i>Note: This will be blank for patients whose value of conc_chemo_score_overall is 9-Not evaluable.</i>
65	conc_cetux_score_delays	Systemic therapy review: Concurrent cetuximab treatment delay review	1= No delays 2= ≤1 week 3= >1 week, per protocol <i>Note: Limited to patients assigned to cetuximab arms</i> <i>Note: This will be blank for patients whose value of conc_cetux_score_overall is 9-Not evaluable.</i>

#	Variable	Description	Format/Coding for categorical data
66	conc_chemo_score_delays	Systemic therapy review: Concurrent chemotherapy treatment delay review	1= No delays 2= ≤1 week 3= >1 week, per protocol 5= >2 weeks, not per protocol <i>Note: This will be blank for patients whose value of conc_chemo_score_overall is 9-Not evaluable.</i>
67	cons_cetux_score_overall	Systemic therapy review: Consolidation cetuximab overall review	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: Limited to patients assigned to cetuximab arms</i>
68	cons_chemo_score_overall	Systemic therapy review: Consolidation chemotherapy overall review	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable <i>Note: There is no score for one patient so this is blank.</i>
69	cons_cetux_score_dose	Systemic therapy review: Consolidation cetuximab dose review	1= 85-115% of therapy 2= <85% of therapy, per protocol 3= 70-<85% of therapy, not per protocol 4= <70% of therapy, not per protocol <i>Note: Limited to patients assigned to cetuximab arms</i> <i>Note: This will be blank for patients whose value of cons_cetux_score_overall is 9-Not evaluable.</i>
70	cons_chemo_score_dose	Systemic therapy review: Consolidation chemotherapy dose review	1= 85-115% of therapy 2= <85% of therapy, per protocol 3= 70-<85% of therapy, not per protocol 4= <70% of therapy, not per protocol 5= >115% of therapy <i>Note: This will be blank for patients whose value of cons_chemo_score_overall is 9-Not evaluable or blank.</i> <i>Note: Two patients have a value for cons_chemo_score_overall but no dose score so this value is blank.</i>
71	cons_cetux_score_delays	Systemic therapy review: Consolidation cetuximab treatment delay review	1= No delays 2= ≤1 week 3= >1 week, per protocol 4= 1-<2 weeks, not per protocol 5= >2 weeks, not per protocol <i>Note: Limited to patients assigned to cetuximab arms</i> <i>Note: This will be blank for patients whose value of cons_cetux_score_overall is 9-Not evaluable.</i>
72	cons_chemo_score_delays	Systemic therapy review:	1= No delays

#	Variable	Description	Format/Coding for categorical data
		Consolidation chemotherapy treatment delay review	2= ≤1 week 3= >1 week, per protocol 4= 1-<2 weeks, not per protocol 5= >2 weeks, not per protocol <i>Note: This will be blank for patients whose value of cons_chemo_score_overall is 9-Not evaluable or blank.</i> <i>Note: Two patients have a value for cons_chemo_score_overall but no delay score so this value is blank.</i>
73	grade3_esophagitis	Grade 3+ treatment-related esophagitis	0=Grade 3+ esophagitis not reported 1=Grade 3+ esophagitis reported
74	grade3_pneumonitis	Grade 3+ treatment-related pneumonitis	0=Grade 3+ pneumonitis not reported 1=Grade 3+ pneumonitis reported
75	grade3_pulmonary	Grade 3+ treatment-related pulmonary AE	0=Grade 3+ pulmonary AE not reported 1=Grade 3+ pulmonary AE reported
76	grade3_toxicity	Grade 3+ treatment-related AE	0=Grade 3+ AE not reported 1=Grade 3+ AE reported
77	grade5_toxicity	Grade 5 treatment-related AE	0=Grade 5 AE not reported 1=Grade 5 AE reported
78	include_in_late_ae	Indicator for inclusion in late AE analyses	0=Exclude (not observed in late period) 1=Include
79	survival_status	Overall survival status	0=Alive 1=Dead
80	survival_months	Time since randomization to death/last follow-up (months)	Continuous
81	cod	Cause of death (site-reported)	1=Lung cancer under study 2=Second primary 3=Protocol treatment 4=Other cause 9=Unknown <i>Note: This will be blank for patients who are alive.</i>
82	local_failure	Local failure status	0=Alive at last follow-up without report of local failure at any time 1=Local failure 2=Dead without report of local failure at any time
83	local_failure_months	Time since randomization to local failure/date of death or last-follow-up if no failure (months)	Continuous
84	distant_failure	Distant failure status	0=Alive at last follow-up without report of distant failure at any time 1=Distant failure 2=Dead without report of distant failure at any time
85	distant_failure_months	Time since randomization to distant failure/date of death or last-follow-up if no failure (months)	Continuous
86	progression free survival	Progression-free survival	0=Alive without progression

#	Variable	Description	Format/Coding for categorical data
		status	1=Progressed or death due to any cause
87	progression_free_survival_months	Time since randomization to progression or date of death, or date of last-follow-up if alive without progression (months)	Continuous
88	lost_to_followup	Indicator for lost to follow-up	0=Not lost to follow-up 1=Lost to follow-up