NRG Oncology/RTOG 0436 Data Dictionary
Dictionary for NCT00655876-D1-Dataset.csv

Note #1: Local failure was estimated by the Kaplan-Meier method (per Section 13.4.1.2 in protocol) and not the cumulative incidence method, which was erroneously printed in the manuscript.

Note #2: Adverse events (AEs) were graded with the Common Terminology Criteria for Adverse Events version 3.0 (CTCAE v3.0).

Note #3: 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).

See also the companion dataset / data dictionary:

- NCT00655876-D2-Dataset.csv / NCT00655876-D2-Data-Dictionary.pdf

#	Variable	Description	Coding for categorical/Min-max for continuous
1	study_no	Study number	Character length 9 [RTOG-0436]
2	cn_deidentified	De-identified patient ID	Length 8
3	rx	Assigned treatment	1 = RT + Chemo + Cetuximab [radiation therapy + paclitaxel + cisplatin + cetuximab] 2 = RT + Chemo [radiation therapy + paclitaxel + cisplatin]
4	case_status	Case Status	1 = Eligible 2 = No protocol treatment 3 = Ineligible
5	reason_for_exclusion	Reason for Exclusion	Character length 100 Reason is not blank (n=16) [analysis_flag_1=1] Reason is blank (n=328) [analysis_flag_1=2]
6	analysis_flag_1	Eligible and evaluable for efficacy endpoints	1=No (n=16) 2=Yes (n=328)
7	analysis_flag_2	Eligible and evaluable for adverse events	1=No (n=25) 2=Yes (n=319)
8	reason_no_treatment	Reason patient did not receive protocol treatment	Character length 100 Reason is not blank (n=9) [case_status=2] Reason is blank (n=335) [case_status=1,3]
9	age	Age (years)	Continuous Min-max = 32-87 . = Not applicable (n=16; analysis_flag_1=1)
10	agefm	Age (years)-Categorized	1 = ≤49 2 = 50-59 3 = 60-69 4 = 70-79 5 = ≥80 . = Not applicable (n=16; analysis_flag_1=1)
11	sex	Sex	1 = Male 2 = Female . = Not applicable (n=16; analysis_flag_1=1)
12	race	Race	1 = American Indian or Alaskan Native 2 = Asian 3 = Black or African American 4 = Native Hawaiian or Other Pacific Islander 5 = White 6 = More than 1 race 9 = Unknown . = Not applicable (n=16; analysis_flag_1=1)

#	Variable	Description	Coding for categorical/Min-max for continuous
13	ethnicity	Ethnicity	1 = Hispanic or Latino 2 = Not Hispanic or Latino 9 = Unknown . = Not applicable (n=16; analysis_flag_1=1)
14	zubrod	Zubrod performance status	Values = 0, 1, 2 . = Not applicable (n=16; analysis_flag_1=1)
15	tstage	T stage (clinical)	1 = T1 2 = T2 3 = T3 4 = T4 . = Not applicable (n=16; analysis_flag_1=1)
16	nstage	N stage (clinical)	1 = N0 2 = N1 . = Not applicable (n=16; analysis_flag_1=1)
17	mstage	M stage (clinical)	1 =M0 2 = M1a . = Not applicable (n=16; analysis_flag_1=1)
18	lesion_size	Cancer lesion size, cm	1 = <5cm 2 = ≥5cm . = Not applicable (n=16; analysis_flag_1=1)
19	histology	Histologic findings	1 = Adenocarcinoma 2 = Squamous cell . = Not applicable (n=16; analysis_flag_1=1)
20	celiac	Celiac nodes status	1 = Present 2 = Absent . = Not applicable (n=16; analysis_flag_1=1)
21	endoscopy_results	Results of the Endoscopic Assessment	1 = Clinical complete response (cCR) (biopsy not required) 2 = Residual disease or suspicion of residual disease and negative biopsy 3 = Residual disease or suspicion of residual disease at the time of endoscopy and positive biopsy 4 = Residual disease or suspicion of residual disease at the time of endoscopy and no biopsy performed to pathologically prove disease 5 = Endoscopy not performed . = Not applicable (n=16; analysis_flag_1=1)
22	ccr	cCR Status	0= Yes, cCR (endoscopy_results = 1) 1= No, residual disease (endoscopy_results = 2,3,4) 999 = Endoscopy not performed (endoscopy_results = 5) . = Not applicable (n=16; analysis_flag_1=1)
23	interim_adeno_flag	Included in the protocol-specified interim cCR analysis of adenocarcinoma patients?	1=No (n=194) 2=Yes (n=150*) **Note: One patient was deemed to be ineligible after this interim analysis so they have analysis_flag_1=1.*
24	ccr_adeno	cCR Status at the interim analysis for adenocarcinoma patients	0= Yes, cCR 1= No, residual disease . = Not applicable (n=194; interim_adeno_flag =1)
25	interim_scc_flag	Included in the protocol-specified interim cCR analysis of Squamous cell	1=No (n=231) 2=Yes (n=113)

#	Variable	Description	Coding for categorical/Min-max for continuous
		patients?	
26	ccr_scc	cCR Status at the interim analysis for squamous cell patients	0= Yes, cCR 1= No, residual disease . = Not applicable (n=231; interim_scc_flag =1)
27	surgery_followup	Surgery in follow-up for recurrent or residual disease?	1=No 2=Yes . = Not applicable (n=16; analysis_flag_1=1)
28	surgery_followup_reason	Reason for surgery in follow-up	1 = Residual disease (n=26) 2 = Recurrent disease (n = 18) 999 = Surgery not performed (n=284; surgery_followup=1) . = Not applicable (n=16; analysis_flag_1=1)
29	tvscore	Tumor volume contouring score	1 = Per protocol 2 = Acceptable variation 3 = Unacceptable variation 9 = Not evaluable . = Not applicable (n=16; analysis_flag_1=1)
30	oarscore	Organs at risk contouring score	1 = Per protocol 2 = Acceptable variation 3 = Unacceptable variation 9 = Not evaluable . = Not applicable (n=16; analysis_flag_1=1)
31	tvscore_dva	Tumor volume dose volume analysis score	1 = Per protocol 2 = Acceptable variation 3 = Unacceptable variation 9 = Not evaluable . = Not applicable (n=16; analysis_flag_1=1)
32	oarscore_dva	Organs at risk dose volume analysis score	1 = Per protocol 2 = Acceptable variation 9 = Not evaluable . = Not applicable (n=16; analysis_flag_1=1)
33	chemo_review	Overall Chemotherapy/ Targeted Agent Review Score	1 = Per protocol 2 = Not per protocol 9 = Not evaluable . = Not applicable (n=16; analysis_flag_1=1)
34	chemo_review_details	Details of Overall Chemotherapy/ Targeted Agent Review Score	1 = Per protocol, no modifications or delays 2 = Per protocol, modifications and/or delays 3 = Not per protocol, modifications and/or delays with ≥ 80% of protocol dose given 4 = Not per protocol, modifications and/or delays with < 80% of protocol dose given 9 = Not evaluable . = Not applicable (n=16; analysis_flag_1=1)
35	chemo_modification_ae	Chemotherapy/ Targeted Agent dose modified/delayed due to AEs	1 = No 2 = Yes . = Not applicable (n=16; analysis_flag_1=1) *Note: This is based on the site's reporting on whether the chemotherapy/targeted agent dose was modified due to AEs. This is not based on the chemotherapy/targeted agent review score.*
36	chemo_termination_ae	Chemotherapy/ Targeted Agent treatment terminated due to	1 = No 2 = Yes . = Not applicable (n=16; analysis_flag_1=1)

#	Variable	Description	Coding for categorical/Min-max for continuous
		AEs	*Note: This is based on the site's reporting on whether the chemotherapy/targeted agent treatment was terminated due to AEs. This is not based on the chemotherapy/targeted agent review score.*
37	local_failure	Local failure status	0 = censored 1 = event 2 = competing event (death) . = Not applicable (n=16; analysis_flag_1=1)
38	local_failure_months	Local failure time (months)	. = Not applicable (n=16; analysis_flag_1=1) *Note: Time from the date of randomization to the date of local failure or last follow-up/death.*
39	survival	Overall survival status	0 = censored 1 = event (death) . = Not applicable (n=16; analysis_flag_1=1)
40	survival_months	Overall survival time (months)	. = Not applicable (n=16; analysis_flag_1=1) *Note: Time from the date of randomization to the date of death or last follow-up.*
41	max_overall_grade	Overall highest treatment-related grade per patient	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5 . = Not applicable (n=25; analysis_flag_2=1)
42	max_gi_grade	Overall highest grade for treatment-related gastrointestinal adverse events	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 . = Not applicable (n=25; analysis_flag_2=1)
43	max_hem_grade	Overall highest grade for treatment-related hematologic adverse events	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 . = Not applicable (n=25; analysis_flag_2=1)
44	max_acne_grade	Overall highest grade for treatment-related acniform rash adverse events	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 . = Not applicable (n=25; analysis_flag_2=1)
45	max_nonhem_grade_90days	Overall highest grade for treatment-related non-hematologic adverse events ≤ 90 days from treatment start	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 4 = grade 4 5 = grade 5 . = Not applicable (n=25; analysis_flag_2=1)