

NRG Oncology/RTOG-1010 Data Dictionary for NCT01196390-D1-Dataset.csv

Note #1:

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).

Note #2:

Blanks indicate not applicable. Some specific reasons for blanks are described in select variables for added clarity.

Note #3:

Data required for replicating “Table A1: Institutional accrual” are not contained within this data submission due to de-identification procedures.

Note #4:

Adverse events were scored with CTCAE version 4.

See also the companion datasets and data dictionaries:

NCT01196390-D2-Dataset.csv and NCT01196390-D2-Data-Dictionary.pdf

NCT01196390-D3-Dataset.csv and NCT01196390-D3-Data-Dictionary.pdf

#	Variable	Description	Coding
1	study_no	Study number	Character
2	patient_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 <i>consort_rand</i> =2)	Character
5	arm_rand	Assigned treatment (randomization) (blank when <i>consort_rand</i> =1)	1=Chemoradiotherapy plus trastuzumab (CXRT+trastuzumab) 2=Chemoradiotherapy (CXRT)
6	include_in_analysis	Included in primary endpoint analysis (blank when <i>consort_rand</i> =1)	1=No 2=Yes
7	reason_for_exclusion	Reason for exclusion (blank when <i>include_in_analysis</i> =2)	Character
8	reason_ineligible	Reason ineligible (blank when <i>include_in_analysis</i> =2)	Character
9	consort_tx	CONSORT: treatment received	1=Received chemoradiotherapy plus concurrent and maintenance trastuzumab plus surgery 2=Received chemoradiotherapy plus surgery 3=Received chemoradiotherapy plus concurrent and maintenance trastuzumab 4=Received chemoradiotherapy 5=Received chemoradiotherapy plus concurrent trastuzumab plus surgery 6=Received chemoradiotherapy plus maintenance trastuzumab plus surgery

#	Variable	Description	Coding
			7=Received chemoradiotherapy plus concurrent trastuzumab 8=Received chemotherapy only 9=No protocol treatment
10	as_treated_arm	As-treated arm (blank when <i>consort_tx</i> =9)	1=Chemoradiotherapy plus trastuzumab (CXRT+trastuzumab) 2=Chemoradiotherapy (CXRT)
11	consort_lost	CONSORT: lost to follow-up	1=No 2=Yes
12	consort_lost_rsn	CONSORT: reason lost to follow-up (blank when <i>consort_lost</i> =1)	Character
13	consort_disc_rt	CONSORT: discontinued RT	1=No 2=Yes
14	consort_disc_rt_rsn	CONSORT: reason discontinued RT	Character
15	consort_disc_carboplatin	CONSORT: discontinued carboplatin	1=No 2=Yes
16	consort_disc_carboplatin_rsn	CONSORT: reason discontinued carboplatin	Character
17	consort_disc_paclitaxel	CONSORT: discontinued paclitaxel	1=No 2=Yes
18	consort_disc_paclitaxel_rsn	CONSORT: reason discontinued paclitaxel	Character
19	consort_disc_trastuzumab_c	CONSORT: discontinued concurrent trastuzumab	1=No 2=Yes
20	consort_disc_trastuzumab_c_rsn	CONSORT: reason discontinued concurrent trastuzumab	Character
21	consort_disc_trastuzumab_m	CONSORT: discontinued maintenance trastuzumab	1=No 2=Yes
22	consort_disc_trastuzumab_m_rsn	CONSORT: reason discontinued maintenance trastuzumab	Character
23	age	Age (years)	Continuous
24	dage	Age (years) (dichotomized)	1=< 65 2= \geq 65
25	sex	Sex	1=Male 2=Female
26	race	Race	1=American Indian or Alaska Native 2=Asian 3=Black or African American 5=White 9=Unknown
27	ethnicity	Ethnicity	1=Hispanic or Latinx 2=Not Hispanic or Latinx 9=Unknown
28	zubrod	Zubrod performance status	Continuous
29	t_stage_clinical	T stage, clinical, AJCC 7th edition	1=T1

#	Variable	Description	Coding
			2=T2 3=T3
30	n_stage_clinical	N stage, clinical, AJCC 7th edition	1=N0 2=N1 3=N2
31	adenopathy	Presence of adenopathy	1=No 2=Yes—coeliac adenopathy absent 3=Yes—coeliac adenopathy present \leq 2 cm
32	her2_determination	HER2-positive determination	1=Positive by immunohistochemistry 2=Positive by fluorescence in-situ hybridisation 3=Positive by both
33	endoscopic_us	Was endoscopic ultrasound done as part of staging?	1=No 2=Yes
34	prim_tum_loc	Primary tumor location	1=Mid esophagus/distal esophagus/esophagogastric junction 2=Mid esophagus/distal esophagus 3=Mid esophagus 4=Mid esophagus/esophagogastric junction 5=Distal esophagus/esophagogastric junction 6=Distal esophagus 7=Esophagogastric junction
35	surg_performed	Underwent surgical resection?	1=No 2=Yes
36	consort_nosurg_rsn	CONSORT: reasons no surgery (when <i>surg_performed</i> =1)	Character
37	surg_type	Type of surgery (when <i>surg_performed</i> =2)	1=Thoracoabdominal esophagectomy 2=Transthoracic (Ivor Lewis) 3=Other
38	weeks_to_surg	Time from end of concurrent treatment to surgery (weeks) (when <i>surg_performed</i> =2)	Continuous
39	nodes_evaluated	Number of nodes resected (when <i>surg_performed</i> =2)	Continuous 9999=Unknown
40	surg_margins	Surgical margin status (when <i>surg_performed</i> =2)	1=Positive 2=Negative
41	resection_class	Resection class (when <i>surg_performed</i> =2)	Character
42	pathologic_CR	Pathologic complete response (when <i>surg_performed</i> =2)	1=No 2=Yes
43	rt_score_tv	RT Review: Tumor volume contouring score (blank when <i>consort_tx</i> =9)	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
44	rt_score_oar	RT Review: Organs at risk contouring score	1=Per protocol

#	Variable	Description	Coding
		(blank when <i>consort_tx</i> =9)	2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
45	rt_score_tv_dva	RT Review: Tumor volume dose volume analysis score (blank when <i>consort_tx</i> =9)	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
46	rt_score_oar_dva	RT Review: Organs at risk dose volume analysis score (blank when <i>consort_tx</i> =9)	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
47	ct_score_overall	Concurrent Paclitaxel + Carboplatin Review score, overall (blank when <i>consort_tx</i> =9)	1=Per protocol 3=Unacceptable deviation
48	ct_score_dose	Concurrent Paclitaxel + Carboplatin Review score, dose (blank when <i>consort_tx</i> =9)	1=85 - 115% 2=< 85%, due to protocol-specified reasons 3=70 - < 85%, due to non-protocol-specified reasons 4=< 70%, due to non-protocol-specified reasons
49	ct_score_delays	Concurrent Paclitaxel + Carboplatin Review score, treatment delays (blank when <i>consort_tx</i> =9)	1=No delays 2= \leq 1 week 3= $>$ 1 week, due to protocol-specified reasons
50	contras_score_overall	Concurrent Trastuzumab Review, overall (blank when <i>consort_tx</i> =9 and <i>arm_rand</i> =2)	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation
51	contras_score_dose	Concurrent Trastuzumab Review score, dose (blank when <i>consort_tx</i> =9 and <i>arm_rand</i> =2)	1=85 - 115% 2=< 85%, due to protocol-specified reasons 3=70 - < 85%, due to non-protocol-specified reasons 4=< 70%, due to non-protocol-specified reasons
52	contras_score_delays	Concurrent Trastuzumab Review score, treatment delays (blank when <i>consort_tx</i> =9 and <i>arm_rand</i> =2)	1=No delays 2= \leq 1 week 3= $>$ 1 week, due to protocol-specified reasons 5= $>$ 2 weeks, due to non-protocol-specified reasons
53	include_maintras_review	Included in Maintenance Trastuzumab Review (blank when <i>consort_tx</i> =9 and <i>arm_rand</i> =2)	2=Yes 9=Not evaluable
54	maintras_score_overall	Maintenance Trastuzumab Review score, overall (blank when <i>include_maintras_review</i> not=2)	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation
55	maintras_score_dose	Maintenance Trastuzumab Review score, dose	1=85 - 115% 2=< 85%, due to protocol-specified reasons 4=< 70%, due to non-protocol-specified reasons
56	maintras_score_delays	Maintenance Trastuzumab Review score,	1=No delays

#	Variable	Description	Coding
		treatment delays	3=> 1 week, due to protocol-specified reasons
57	surgical_review	Surgical review score	1=Per protocol 2=Acceptable variation 3=Unacceptable deviation 9=Not evaluable
58	surg_review_noteval	Reason surgical review not evaluable	Character
59	survival	Survival status	0=Censored 1=Event
60	survival_months	Survival time (months)	Continuous
61	survival_years	Survival time (years)	Continuous
62	cod	Cause of death	Character
63	disease_free_survival	Disease-free survival status	0=Censored 1=Event
64	disease_free_survival_months	Disease-free survival time (months)	Continuous
65	disease_free_survival_years	Disease-free survival time (years)	Continuous
66	max_grade_all	Overall highest grade for any treatment-related adverse events (blank when <i>consort_tx=9</i>)	1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4 5=Grade 5
67	max_grade_hematologic	Overall highest grade for treatment-related hematologic (haematological)* adverse events (blank when <i>consort_tx=9</i>) *Haematological includes the following CTCAE version 4 terms from the investigations system organ class: CD4 lymphocytes decreased, lymphocyte count decreased, lymphocyte count increased, neutrophil count decreased, platelet count decreased, and white blood cell decreased; and all terms from the system organ class of blood and lymphatic system disorders.	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4
68	max_grade_cardiac	Overall highest grade for treatment-related cardiac adverse events (blank when <i>consort_tx=9</i>)	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4
69	max_grade_sae	Overall highest grade for treatment-related serious adverse events (SAEs) (blank when <i>consort_tx=9</i>)	2=Grade 2 3=Grade 3 4=Grade 4 5=Grade 5
70	grade5_term	Grade 5 CTCAE version 4 term	Character

#	Variable	Description	Coding
71	grade5_days	Days from surgery to grade 5 death	Continuous, 9999=Not applicable (no surgery)
72	grd_any_anemia	Overall highest grade for treatment-related anemia	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4
73	grd_any_neutropenia	Overall highest grade for treatment-related neutropenia	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4
74	grd_any_thrombocytopenia	Overall highest grade for treatment-related thrombocytopenia	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
75	grd_any_febrile_neutropenia	Overall highest grade for treatment-related febrile neutropenia	0=Grade 0 3=Grade 3
76	grd_any_atrial_fibrillation	Overall highest grade for treatment-related atrial fibrillation	0=Grade 0 3=Grade 3 4=Grade 4
77	grd_any_atrial_flutter	Overall highest grade for treatment-related atrial flutter	0=Grade 0 2=Grade 2 3=Grade 3
78	grd_any_cardiac_arrest	Overall highest grade for treatment-related cardiac arrest	0=Grade 0 4=Grade 4
79	grd_any_LV_function	Overall highest grade for treatment-related left ventricular systolic dysfunction	0=Grade 0 3=Grade 3
80	grd_any_sinus_tachycardia	Overall highest grade for treatment-related sinus tachycardia	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
81	grd_any_supra_tachycardia	Overall highest grade for treatment-related supraventricular tachycardia	0=Grade 0 3=Grade 3
82	grd_any_abdominal_pain	Overall highest grade for treatment-related abdominal pain	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
83	grd_any_diarrhea	Overall highest grade for treatment-related diarrhea	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
84	grd_any_dysphagia	Overall highest grade for treatment-related dysphagia	0=Grade 0 1=Grade 1 2=Grade 2

#	Variable	Description	Coding
			3=Grade 3
85	grd_any_esophagitis	Overall highest grade for treatment-related esophagitis (oesophagitis)	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
86	grd_any_nausea	Overall highest grade for treatment-related nausea	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
87	grd_any_vomiting	Overall highest grade for treatment-related vomiting	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
88	LVEF_decline	Percent decline in LVEF from baseline (when <i>max_grade_cardiac</i> =3,4)	Numeric 9999=Not applicable (no decline)