NRG-HN004 Data Dictionary for NCT03258554-D1-Dataset.csv

Note #1: This is the main dataset for the phase II extended follow-up analysis. There is one record per subject.

Note #2: Data are as of July 31, 2023.

Note #3: Includes phase II subjects.

Note #4: Variables #6-74 are blank when consort_rand=No (variable #3).

Note #5: 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 datasets and data dictionaries:
NCT03258554-D2-Dataset.csv and NCT03258554-D2-Data-Dictionary.pdf
NCT03258554-D3-Dataset.csv and NCT03258554-D3-Data-Dictionary.pdf
NCT03258554-D4-Dataset.csv and NCT03258554-D4-Data-Dictionary.pdf

#	Variable	Description	Coding
1	study_no	Study number	Character
2	deident_subjectid	De-identified subject ID	Character
3	consort_rand	CONSORT: randomized	Character
4	consort_not_rand_rsn	CONSORT: reason not randomized (if #3=No)	Character
5	rx	Assigned treatment	1=RT+Cetuximab
			2=RT+Durvalumab
			8=Pretreatment registration (subjects that were not randomized)
6	consort_tx	CONSORT: treatment received	Character
7	consort_lost	CONSORT: lost to follow-up	Character
8	consort_lost_rsn	CONSORT: reason lost to follow-up (if #7=Yes)	Character
9	consort_disc_rt	CONSORT: discontinued RT (if received RT in #6)	Character
10	consort_disc_rt_rsn	CONSORT: reason discontinued RT (if #9=Yes)	Character
11	consort_disc_drug	CONSORT: discontinued cetuximab/durvalumab (if received cetuximab/durvalumab in #6)	Character
12	consort_disc_drug_rsn	CONSORT: reason discontinued cetuximab/durvalumab (if #11=Yes)	Character
13	consort_include_eff	CONSORT: include in analysis of efficacy	Character

#	Variable	Description	Coding
14	consort_include_ae	CONSORT: include in analysis of adverse events	Character
15	consort_not_include_ae_rsn	CONSORT: reason not included in analysis of adverse events (if #14=No)	Character
16	age_c	Age (years)	Character
17	gender	Gender	1=Male
			2=Female
18	race	Race	1=American Indian or 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
19	ethnicity	Ethnicity	1=Hispanic or Latino
			2=Not Hispanic or Latino
			9=Unknown
20	zubrod	Zubrod performance status	Continuous
21	modified_cci_strat	Modified Charlson Comorbidity Index (CCI)	1=0
			2=1+
22	strat_ps_cci_std	Stratification: Zubrod and modified CCI	1=Zubrod 0 and modified CCI 0
			2=Zubrod 1-2 and/or modified CCI > 0
23	primary_site_p16_grp	Primary site and p16 status	1=Oropharynx, p16-positive
			2=Unknown, p16-positive
			3=Oropharynx, p16-negative
			4=Unknown, p16-negative
			5=Oral cavity
			6=Hypopharynx
			7=Larynx
24	strat_site_p16_std	Stratification: primary site and p16 status	1=p16-positive oropharynx or unknown primary
			2=p16-negative oropharynx or unknown primary, larynx, hypopharynx or oral cavity
25	include_p16_status	Include in analysis of p16	Character
26	p16_status	p16 status (central review) (if #25=Yes)	0=p16-negative

#	Variable	Description	Coding
			1=p16-positive
27	include_pdl1_cps	Include in analysis of PD-L1 combined positive score (CPS)	Character
28	pdl1_cps	PD-L1 CPS (if #27=Yes)	Continuous
29	t_stage_clinical_ajcc8	T stage, clinical (AJCC 8)	Character
30	n_stage_clinical_ajcc8	N stage, clinical (AJCC 8)	Character
31	m_stage_clinical_ajcc8	M stage, clinical (AJCC 8)	Character
32	strat_t_n_std	Stratification: T and N stage	1=T0-3 and N0-2
			2=T4 and/or N3
33	pack_years	Smoking history: pack-years	Continuous
34	comorb_group	Comorbidity group	1=Absolute or relative contraindication to cisplatin
			2=Age >/= 70 with moderate to severe comorbidity or vulnerability to cisplatin
			3=Age < 70 with severe comorbidity or vulnerability to cisplatin
35	comorb_number	Number of comorbidity conditions	Continuous
36	hearing_loss	History of hearing loss	1=No
			2=Yes
37	creatinine_clearance	Creatinine clearance (ml/min)	Continuous
38	periph_neurop_grd1	Pre-existing peripheral neuropathy grade >/= 1	1=No
			2=Yes
39	rt_dose	RT dose (Gy)	Continuous
40	rt_fx	RT fractions	Continuous
41	rt_elapsed_days	RT elapsed days (if #39 > 0)	Continuous
42	rt_type	RT type (if #39 > 0)	Character
43	rt_modality	RT modality (if #39 > 0)	Character
44	include_rt_review_sample	Include in RT review sample	Character
45	rt_score_overall	RT review score, overall (if #44=Yes)	1=Per protocol
			2=Acceptable variation
			3=Unacceptable deviation
			7=Incomplete RT, refusal

#	Variable	Description	Coding
			8=No RT given
46	durvalumab_doses	Durvalumab number of doses given (if #5 = 2)	Continuous
47	durvalumab_dose_mg	Durvalumab total dose (mg) (if #5 = 2)	Continuous
48	cetuximab_doses	Cetuximab number of doses given (if #5 = 1)	Continuous
49	cetuximab_dose_per_m2	Cetuximab total dose (mg/m2) (if #5 =1)	Continuous
50	ct_score_overall	Chemotherapy review score, overall	1=Per protocol
			2=Acceptable variation
			3=Unacceptable deviation
			4=Not evaluable
51	survival	Survival status	0=Censored
			1=Event
52	survival_days	Survival time (days)	Continuous
53	survival_years	Survival time (years)	Continuous
54	cause_of_death	Cause of death (if #51=1)	1=Due to this disease
			2=Due to second primary or other malignancy
			3=Due to protocol treatment
			4=Due to other cause
			9=Unknown
55	progression	Progression	1=No
			2=Yes
56	progression_site	Progression sites of first failure (if #55=Yes)	D=distant
			L=local
			LD=local and distant
			LR=local and regional
			LRD=local, regional, and distant
			R=regional
57	progression_site_distant	Progression sites of first distant failure (if #56=D, LD, or LRD)	Character
58	pfs	Progression-free survival status	0=Censored
			1=Event
59	pfs_years	Progression-free survival time	Continuous

#	Variable	Description	Coding
60	first_failure_pfs	First failure for progression-free survival	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
			4.03=Death, COD protocol treatment
			4.04=Death, COD other
			4.09=Death, COD unknown
			9=Alive, no failure
61	loc_reg_failure	Local-regional failure status	0=Censored
			1=Event
			2=Competing event
62	loc_reg_failure_years	Local-regional failure time (years)	Continuous
63	loc_reg_failure_sens	Local-regional failure status (sensitivity analysis)	0=Censored
			1=Event
			2=Competing event
64	distant_mets	Distant metastasis status	0=Censored
			1=Event
			2=Competing event
65	distant_mets_years	Distant metastasis time (years)	Continuous
66	comp_mort	Competing mortality status	0=Censored
			1=Event
			2=Competing event
67	comp_mort_years	Competing mortality time (years)	Continuous
68	comp_mort_sens	Competing mortality status (sensitivity analysis)	0=Censored
			1=Event
			2=Competing event
69	response_4mo_text	Response at 4 months	CR=complete response

#	Variable	Description	Coding
			NE=not evaluable
			PD=progressive disease
			PR=partial response
			SD=stable disease
70	response_4mo_method	Response at 4 months method of assessment (if #69=CR, PR, SD, or PD)	Character
71	response_4mo_days_rt_end	Response at 4 months days from end of RT (if #69=CR, PR, SD, or PD)	Continuous
72	include_feeding_tube_1yr	Include in analysis of feeding tube at 1 year	Character
73	feeding_tube_1yr	Feeding tube at 1 year from end of RT (+/- 8 weeks) (if #72=Yes)	Character
74	non_prot_treat	Non-protocol treatment in patients with progression (if #55=Yes)	Character