

NRG-HN004 Data Dictionary for NCT03258554-D2-Dataset.csv

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

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

Note #3: Includes phase II subjects who were randomized, started protocol treatment, and had at least one adverse event reported grade 1-5. See variable `consort_include_ae` in companion dataset NCT03258554-D1-Dataset.csv for a summary of which subjects were included in the analysis of adverse events.

Note #4: 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-D1-Dataset.csv and NCT03258554-D1-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	Comments
1	<code>study_no</code>	Study number	Character	
2	<code>deident_subjectid</code>	De-identified subject ID	Character	
3	<code>rx</code>	Assigned treatment	1=RT+Cetuximab 2=RT+Durvalumab	
4	<code>ctcae_version</code>	CTCAE version	Character	
5	<code>time_point</code>	Time point	Character	
6	<code>ae_term</code>	Adverse event term	Character	
7	<code>ae_grade</code>	Adverse event grade	Continuous	
8	<code>ae_relate</code>	Adverse event relationship to protocol treatment	1=Unrelated 2=Unlikely 3=Possibly 4=Probably 5=Definitely	
9	<code>sae</code>	Serious adverse event (SAE)	1=No 2=Yes	
10	<code>AE_ID</code>	Adverse Event Identifier	Continuous	This variable is intended to provide a unique row key for this dataset