NRG Oncology/RTOG 0522 Data Dictionary for NCT00265941-D2-Dataset.csv

Note #1:
Adverse events were scored with CTCAE version 3.0. All adverse events are CTCAE terms except for skin reaction outside portal, which combines terms pruritus, dermatitis exfoliative NOS, acne NOS, and nail disorder NOS; and skin reaction inside portal, which combines terms radiation dermatitis NOS and radiation recall syndrome.

Note #2:
This dataset is limited to grade 1-4 adverse events that were attributed as definitely, probably, or possibly related to protocol treatment and occurred in at least 10% of patients in either arm. The denominators come from the companion dataset NCT00265941-D1-Dataset.csv (variables include_ae_acute and include_ae_late). In addition, the companion dataset NCT00265941-D1-Dataset.csv includes whether or not a patient experienced a treatment-related grade 5 adverse event (variable grade_5_ae_tx_rel).

Note #3:
The acute and late periods are defined as ≤ 90 and > 90 days, respectively, from the start of radiation therapy.

See also the companion dataset and data dictionary:
NCT00265941-D1-Dataset.csv and NCT00265941-D1-Data-Dictionary.pdf

#	Variable	Description	Coding
1	study_no	Study number	Character
2	pt_id	De-identified patient ID	Character
3	rx	Assigned treatment	1=RT + cisplatin 2=RT + cisplatin + cetuximab
4	adverse_event_time_period	Adverse event time period	1=Acute 2=Late
5	adverse_event	Adverse event	Character
6	adverse_event_grade	Adverse event grade	1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4