

NRG Oncology/RTOG-0534 Data Dictionary for NCT00567580-D4-Dataset.csv

PMID: 35569466

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:

Adverse events (AE) were scored with Common Terminology Criteria for Adverse Events version 3.0 (CTCAE v3.0).

Note #3:

The dataset provides the highest-grade adverse event, by subject and adverse event term, starting or worsening (increased grade) more than 90 days after the end of radiation therapy, restricted to the CTCAE v3.0 categories of “Blood/Bone Marrow”, “Gastrointestinal”, and “Renal/Genitourinary”.

Note #4:

This dataset represents subjects who started protocol radiation therapy and were evaluated for adverse events more than 90 days after the end of protocol radiation therapy. Subjects with no reported adverse events (as defined in Note #3) will not appear in this dataset. The denominator comes from companion dataset NCT00567580-D1-Dataset.csv (has_late_ae_data=1).

See also the companion datasets and data dictionaries:

NCT00567580-D1-Dataset.csv and NCT00567580-D1-Data-Dictionary.pdf

NCT00567580-D2-Dataset.csv and NCT00567580-D2-Data-Dictionary.pdf

NCT00567580-D3-Dataset.csv and NCT00567580-D3-Data-Dictionary.pdf

#	Variable	Description	Coding
1	study	Study number	Character
2	deident_subjectid	De-identified subject ID	Character
3	rx	Assigned treatment arm (randomization)	1=PBRT ¹ Alone 2=PBRT+STADT ² 3=PLNRT ³ +PBRT+STADT
4	ctcae3_category	CTCAE v3.0 category	Character
5	ctcae3_term	CTCAE v3.0 adverse event term	Character
6	grade_max	The subject's highest grade reported for a given adverse event	1= Mild AE 2= Moderate AE 3= Severe AE 4= Life-threatening or disabling AE 5= Death related to AE

¹PBRT= prostate bed radiotherapy

²STADT= short-term androgen deprivation therapy

³PLNRT=pelvic lymph node radiotherapy