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NRG Oncology/RTOG-0415 Data Dictionary NCTN Data Archive

For patients excluded from analysis, there is no data in variables 6-29.

Data required for replicating specific cause of death are not contained within this data submission due to deidentification procedures.

| # | Variable | Description | Format/Coding for categorical data |
|----|----------------------|----------------------------|--|
| 1 | study | Study number | Character length 9 |
| 2 | patid | De-identified patient ID | Character length 11 |
| 3 | arm | Assigned treatment arm | 1=3D-CRT/IMRT 73.8 Gy |
| | | | 2=3D-CRT/IMRT 70 Gy |
| 4 | analysis_inclusion | Indicator for inclusion in | 0=Excluded |
| | | analysis in general | 1=Included |
| 5 | reason_for_exclusion | Reason excluded from | Character, maximum length 45 |
| | | analysis in general | Note: Blank for patients not excluded. |
| 6 | age | Age at study entry (years) | Continuous |
| 7 | age_group | Age at study entry (years) | 1=≤59 |
| | | | 2= 60-69 |
| | | | 3=≥70 |
| 8 | race | Race | 1=American Indian/Alaskan Native |
| | | | 2=Asian |
| | | | 3=Black or African American |
| | | | 4=Native Hawaiian or Other Pacific |
| | | | Islander |
| | | | 5=White |
| | | T2411.14 | 9=Unknown or not reported |
| 9 | ethnicity | Ethnicity | 1=Hispanic or Latino |
| | | | 2=Not Hispanic or Latino 9=Unknown |
| 10 | zubrod | Zubrod performance status | 0=Normal activity |
| 10 | zubrod | Zubrod performance status | 1=Symptoms, but nearly fully |
| | | | ambulatory |
| 11 | psa | PSA at study entry (ng/ml) | Continuous |
| 12 | psa_group | PSA at study entry | 1=<4 ng/ml |
| 12 | psa_group | 1 5A at study Chiry | 2=4 to <10 ng/ml |
| 13 | gleason_group | Gleason | 1=2-4 |
| 13 | gleuson_group | Gleason | 2=5-6 |
| 14 | t_stage | T stage | 1=T1 |
| 1. | t_stage | | 2=T2 |
| 15 | received_rt | Indicator for RT treatment | 0=Did not receive RT |
| | | | 1=Received RT |
| 16 | no_rt_reason | Reason RT was not | 1=Patient refused |
| | | delivered | 2=Other complicating disease |
| | | | 3=Diagnosed with second malignancy |
| | | | 4=Alternate treatment |
| | | | Note: Blank for 1079 patients who |
| | | | received RT |
| 17 | rt_modality | Radiotherapy modality | 1=3D-CRT |
| | | | 2=IMRT |
| | | | Note: Blank for 13 patients not |
| | | | receiving RT |
| 18 | rt_compliance | Compliance with protocol | 1=Per protocol |

Data dictionary: rtog0415.csv

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| # | Variable | Description | Format/Coding for categorical data |
|-----|-----------------------|------------------------------|--|
| | | RT treatment requirements | 2=Acceptable variation |
| | | | 3=Unacceptable deviation |
| | | | 5=Incomplete RT-death |
| | | | 7=Incomplete RT-progression |
| | | | 9=Not evaluable |
| | | | Note: Blank for 13 patients not |
| | | | receiving RT |
| 19 | acute_gi_toxicity | Maximum grade of early | 0=None reported |
| | | (acute) GI toxicity | 1=Grade 1 |
| | | | 2=Grade 2 |
| | | | 3=Grade 3 |
| | | | 4=Grade 4 |
| | | | Note: Blank for 13 patients not |
| | | | receiving RT |
| 20 | acute_gu_toxicity | Maximum grade of early | 0=None reported |
| | | (acute) GU toxicity | 1=Grade 1 |
| | | | 2=Grade 2 |
| | | | 3=Grade 3 |
| | | | Note: Blank for 13 patients not |
| | | | receiving RT |
| 21 | late_gi_toxicity | Maximum grade of late GI | 0=None reported |
| | | toxicity | 1=Grade 1 |
| | | 3 | 2=Grade 2 |
| | | | 3=Grade 3 |
| | | | 4=Grade 4 |
| | | | Note: Blank for 13 patients not |
| | | | receiving RT and 4 patients who died |
| | | | prior to the start of the late toxicity |
| | | | timeframe |
| 22 | late_gu_toxicity | Maximum grade of late GU | 0=None reported |
| | gu | toxicity | 1=Grade 1 |
| | | 133333 | 2=Grade 2 |
| | | | 3=Grade 3 |
| | | | 4=Grade 4 |
| | | | Note: Blank for 13 patients not |
| | | | receiving RT and 4 patients who died |
| | | | prior to the start of the late toxicity |
| | | | timeframe |
| 23 | survival | Overall survival status | 0=Alive |
| 23 | 72744 | O (Orall Sal (1) all Status | 1=Dead |
| 24 | survival_years | Time since randomization | Continuous |
| ~ ' | Jaz vivai_jours | to death/last follow-up | |
| | | (years) | |
| 25 | cod | Cause of death (site- | 1=Due to prostate cancer |
| | | reported) | 2=Due to other reason |
| | | Toponou) | 9=Unknown |
| | | | Note: Specifications of 'other' cause of |
| | | | death are not included due to |
| | | | deidentification procedures. |
| 26 | disease_free_survival | Disease-free survival status | 0=Alive without report of failure |
| 20 | discase_free_survivar | Discase-free survivar status | 1=Failure as defined as the first of the |
| | | | following: local or distant progression, |
| | | | |
| | | | biochemical recurrence per the RTOG |
| | | | Phoenix definition, or death due to any |

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| # | Variable | Description | Format/Coding for categorical data |
|----|---------------------------|---|---|
| | | | cause |
| 27 | disease_free_years | Time since randomization to disease-free survival | Continuous |
| | | failure or last follow-up if no failure (years) | |
| 28 | biochemical_failure | Biochemical failure status | 0=Alive without report of failure |
| | | | 1=Biochemical failure per the RTOG |
| | | | Phoenix definition |
| | | | 2=Dead without report of failure |
| 29 | biochemical_failure_years | Time since randomization | Continuous |
| | | to biochemical failure, or | |
| | | death or last follow-up if no | |
| | | failure (years) | |
| 30 | lost_to_followup | Indicator for whether the | 0=Not lost to follow-up |
| | | patient is lost to follow-up | 1=Lost to follow-up |
| 31 | lost_to_followup_reason | Reason lost to follow-up | 1=Patient withdrew consent |
| | | _ | 2=Patient unable to be contacted for at |
| | | | least 3 years |
| | | | Note: Blank for 1059 patients not lost to |
| | | | follow-up |