

NRG Oncology/RTOG-0631 (PMID 37079324) Data Dictionary
NCTN Data Archive
Dictionary for *NCT00922974-D1-Data-Dictionary.csv*

For patients excluded from one or more analyses, (e.g., *nrps_analyzed_m1* = “0=Excluded”, etc.), variables related to those analyses contain missing values (e.g., *nrps_response_m1* = *nrps_change_m1* = *nrps_m1_sensitivity_1* = blank), indicating that the data are not applicable. Other blank values represent missing data.

See also the companion dataset/data dictionaries:

| | |
|----------------------------|------------------------------------|
| NCT00922974-D2-Dataset.csv | NCT00922974-D2-Data-Dictionary.pdf |
| NCT00922974-D3-Dataset.csv | NCT00922974-D3-Data-Dictionary.pdf |
| NCT00922974-D4-Dataset.csv | NCT00922974-D4-Data-Dictionary.pdf |

Please note the following errors in the published manuscript:

- In Table 1, Race:
 - The % of “Other” for the cEBRT group should be 1.5%, not 1.6%
 - The % of “Not reported/unknown” for the cEBRT group should be 3.1%, not 3.0%.
- In Supplemental Table 4, the Cumulative Pain Response for the cEBRT group at 3 months should be 76.3%, not 76.4%
- In Supplemental Table 6A, the number at risk at Month 0 for the cEBRT group should be 130, not 129.
- In Supplemental Table 8, the sample size for the SRS group should be 196, not 202.
- In Supplemental Table 9, the column representing time should be labeled “Month”, not “Year”.

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).

| # | Variable | Description | Format/Coding for categorical data |
|----|--------------------------|---|---|
| 1 | study | Study number | Character length 9 |
| 2 | patient_id | Anonymized Patient ID | Character length 11 |
| 3 | arm | Treatment arm | 1=SRS 2=cEBRT |
| 4 | include_in_analysis | Include in analysis | Yes=Included in analyses No=Excluded from all analyses |
| 5 | age | Age (years) | Continuous; ages ≥ 89 grouped as "89+" per deidentification policies |
| 6 | sex | Sex | Character, maximum length 6 |
| 7 | race | Race | Character, maximum length 25 |
| 8 | ethnicity | Ethnicity | Character, maximum length 22 |
| 9 | zubrod | Zubrod performance status | 0=Zubrod performance status 0 1=Zubrod performance status 1 2=Zubrod performance status 2 |
| 10 | tumor_type | Type of tumor | Character, maximum length 20 |
| 11 | number_of_mets | Number of spine metastases | Character, maximum length 5 |
| 12 | location_of_index_spine | Location of index spine metastasis | Character, maximum length 14 |
| 13 | pain_medication | Pain medication | Yes=Patient was receiving pain medication at the time of study entry No=Patient was not receiving pain medication at the time of study entry |
| 14 | withdrew_consent_study | Withdrew consent to entire study | 0=No 1=Yes |
| 15 | withdrew_consent_qol | Withdrew consent to QOL | 0=No 1=Yes (includes patients who withdrew to entire study) |
| 16 | planned_rt_dose | Intended SRS single-fraction dose | 16=16 Gy 18=18 Gy |
| 17 | received_assigned_rt | Received assigned RT | 0=No 1=Yes |
| 18 | reason_no_assigned_rt | Reason assigned RT not received | Character, maximum length 18 |
| 19 | arm1_dose_delivered | Arm 1 (SRS) RT dose delivered | 16=16 Gy 18=18 Gy <i>Blank for Arm 2 patients and Arm 1 patients not receiving RT.</i> |
| 20 | arm2_srs_dose_delivered | RT dose delivered to Arm 2 (cEBRT) patients who received SRS instead | 16=16 Gy 18=18 Gy <i>Blank for Arm 1 patients and Arm 2 who received cEBRT</i> |
| 21 | nrps_compliance_baseline | Numerical Rating Pain Scale (NRPS) Compliance at Baseline - reason not complete | Character, maximum length 39 |

| # | Variable | Description | Format/Coding for categorical data |
|----|--------------------------|---|--|
| 22 | baseline_nrps | Baseline NRPS | Continuous |
| 23 | baseline_nrps_index | Baseline NRPS at index site | Continuous |
| 24 | nrps_analyzed_m1 | NRPS: Analyzed at Month 1 | 0=Excluded 1=Analyzed |
| 25 | nrps_compliance_m1 | NRPS: Month 1 Compliance | Character, maximum length 39 |
| 26 | nrps_excluded_m1 | NRPS: Month 1 Exclusions for CONSORT diagram | Character, maximum length 24 <i>Blank for ineligible patients and patients with an NRPS; collapses reasons other than "Consent withdrawal" from nrps_compliance_m1 into the "Patient noncompliant" group</i> |
| 27 | nrps_response_m1 | NRPS: Month 1 Response | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m1 is not 1</i> |
| 28 | nrps_change_m1 | NRPS: Month 1 Change at index site (baseline - month 1) | Continuous <i>Blank for patients whose value of nrps_analyzed_m1 is not 1</i> |
| 29 | nrps_m1_sensitivity_1 | NRPS: Month 1 Sensitivity analysis 1: Response using only index site | 0=No response 1=Response |
| 30 | nrps_compliance_m3 | NRPS: Month 3 Compliance | Character, maximum length 39 |
| 31 | nrps_analyzed_m3 | NRPS: Analyzed at Month 3 | 0=Excluded 1=Analyzed |
| 32 | nrps_excluded_m3 | NRPS: Month 3 Exclusions for CONSORT diagram | Character, maximum length 24 <i>Blank for ineligible patients and patients with an NRPS; collapses reasons other than "Consent withdrawal" and "Deceased" from nrps_compliance_m3 into the "Patient noncompliant" group</i> |
| 33 | nrps_response_m3 | NRPS: Month 3 Response (primary endpoint) | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m3 is not 1</i> |
| 34 | nrps_change_m3 | NRPS: Month 3 Change at Index site (baseline - month 3 score) | Continuous <i>Blank for patients whose value of nrps_analyzed_m3 is not 1</i> |
| 35 | nrps_change_m3_secondary | NRPS: Month 3 Change at Secondary site (baseline - month 3 score) | Continuous <i>Blank for patients whose value of nrps_analyzed_m3 is not 1</i> |
| 36 | nrps_m3_sensitivity_1 | NRPS: Month 3 Sensitivity Analysis 1: Response using only index site: | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m3 is not 1</i> |

| # | Variable | Description | Format/Coding for categorical data |
|----|-----------------------|---|---|
| 37 | nrps_m3_sensitivity_2 | NRPS: Month 3 Sensitivity Analysis 2: Assume all patients missing NRPS are responders: | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m3 is blank.</i> |
| 38 | nrps_m3_sensitivity_3 | NRPS: Month 3 Sensitivity Analysis: using 2 point difference from baseline for response instead of 3 points | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m3 is not 1</i> |
| 39 | nrps_m3_sensitivity_4 | NRPS: Month 3 Sensitivity Analysis 4: Assume all patients missing NRPS are non-responders | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m3 is not 1</i> |
| 40 | nrps_compliance_m6 | NRPS: Month 6 Compliance | Character, maximum length 39 |
| 41 | nrps_analyzed_m6 | NRPS: Analyzed at 6 months | 0=Excluded 1=Analyzed |
| 42 | nrps_excluded_m6 | NRPS: Month 6 Exclusions for CONSORT diagram | Character, maximum length 24 <i>Blank for ineligible patients and patients with an NRPS; collapses reasons other than "Consent withdrawal" and "Deceased" from nrps_compliance_m6 into the "Patient noncompliant" group</i> |
| 43 | nrps_response_m6 | NRPS: Month 6 Response | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m6 is not 1</i> |
| 44 | nrps_change_m6 | NRPS: Month 6 Change at Index site (baseline - month 6 score) | Continuous <i>Blank for patients whose value of nrps_analyzed_m6 is not 1</i> |
| 45 | nrps_m6_sensitivity_1 | NRPS: Month 6 Sensitivity Analysis 1: response using only index site | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m6 is not 1</i> |
| 46 | nrps_compliance_m12 | NRPS: Month 12 Compliance | Character, maximum length 39 |
| 47 | nrps_analyzed_m12 | NRPS: Analyzed at 12 months | 0=Excluded 1=Analyzed |
| 48 | nrps_excluded_m12 | NRPS: Month 12 Exclusions for CONSORT diagram | Character, maximum length 24 <i>Blank for ineligible patients and patients with an NRPS; collapses reasons other than "Consent withdrawal" and "Deceased" from nrps_compliance_m12 into the "Patient noncompliant" group</i> |
| 49 | nrps_response_m12 | NRPS: Month 12 Response | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m12 is not 1</i> |
| 50 | nrps_change_m12 | NRPS: Month 12 Change at Index site (baseline - month 12 score) | Continuous <i>Blank for patients whose value of nrps_analyzed_m12 is not 1</i> |

| # | Variable | Description | Format/Coding for categorical data |
|----|------------------------|---|---|
| 51 | nrps_m12_sensitivity_1 | NRPS: Month 12 Sensitivity Analysis 1: response using only index site | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m12 is not 1</i> |
| 52 | nrps_compliance_m24 | NRPS: Month 24 Compliance | Character, maximum length 39 |
| 53 | nrps_analyzed_m24 | NRPS: Analyzed at 24 months | 0=Excluded 1=Analyzed |
| 54 | nrps_excluded_m24 | NRPS: Month 24 Exclusions for CONSORT diagram | Character, maximum length 24 <i>Blank for ineligible patients and patients with an NRPS; collapses reasons other than "Consent withdrawal" and "Deceased" from nrps_compliance_m24 into the "Patient noncompliant" group</i> |
| 55 | nrps_response_m24 | NRPS: Month 24 Response | 0=No response 1=Response <i>Blank for patients whose value of nrps_analyzed_m24 is not 1</i> |
| 56 | nrps_change_wk1 | NRPS Change at Week 1 (baseline - week 1) | Continuous <i>Blank for ineligible and patients who did not complete a week 1 NRPS</i> |
| 57 | nrps_wk1_sensitivity_1 | NRPS: Week 1 Sensitivity Analysis 1: response using only index site | 0=No response 1=Response <i>Blank for ineligible and patients who did not complete a week 1 NRPS</i> |
| 58 | nrps_change_wk2 | NRPS Change at Week 2 (baseline - week 2) | Continuous <i>Blank for ineligible and patients who did not complete a week 2 NRPS</i> |
| 59 | nrps_wk2_sensitivity_1 | NRPS: Week 2 Sensitivity Analysis 2: response using only index site | 0=No response 1=Response <i>Blank for ineligible and patients who did not complete a week 2 NRPS</i> |
| 60 | nrps_change_wk3 | NRPS Change at Week 3 (baseline - week 3) | Continuous <i>Blank for ineligible and patients who did not complete a week 3 NRPS</i> |
| 61 | nrps_wk3_sensitivity_1 | NRPS: Week 3 Sensitivity Analysis 3: response using only index site | 0=No response 1=Response <i>Blank for ineligible and patients who did not complete a week 3 NRPS</i> |
| 62 | fact_analyzed_baseline | FACT: Analyzed at baseline | 0=Not analyzed 1=Analyzed |
| 63 | fact_excluded_baseline | FACT: Reason not analyzed at baseline | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for fact_analyzed_baseline is 1</i> |
| 64 | fact_baseline | FACT: Baseline score | Continuous <i>Blank for patients whose value for fact_analyzed_baseline is not 1</i> |
| 65 | fact_analyzed_m3 | FACT: Analyzed at month 3 | 0=Not analyzed 1=Analyzed |

| # | Variable | Description | Format/Coding for categorical data |
|----|-----------------------|---------------------------------------|--|
| 66 | fact_excluded_m3 | FACT: Reason not analyzed at month 3 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for fact_analyzed_m3 is 1</i> |
| 67 | fact_m3 | FACT: Month 3 score | Continuous <i>Blank for ineligible patients and patients whose value for fact_analyzed_m3 is 0</i> |
| 68 | fact_analyzed_m6 | FACT: Analyzed at month 6 | 0=Not analyzed 1=Analyzed |
| 69 | fact_excluded_m6 | FACT: Reason not analyzed at month 6 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for fact_analyzed_m6 is 1</i> |
| 70 | fact_m6 | FACT: Month 6 score | Continuous <i>Blank for ineligible patients and patients whose value for fact_analyzed_m6 is 0</i> |
| 71 | fact_analyzed_m12 | FACT: Analyzed at month 12 | 0=Not analyzed 1=Analyzed |
| 72 | fact_excluded_m12 | FACT: Reason not analyzed at month 12 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for fact_analyzed_m12 is 1</i> |
| 73 | fact_m12 | FACT: Month 12 score | Continuous <i>Blank for ineligible patients and patients whose value for fact_analyzed_m12 is 0</i> |
| 74 | bpi_analyzed_baseline | BPI: Analyzed at baseline | 0=Not analyzed 1=Analyzed |
| 75 | bpi_excluded_baseline | BPI: Reason not analyzed at baseline | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for bpi_analyzed_baseline is 1</i> |
| 76 | bpi_baseline | BPI: Baseline score | Continuous <i>Blank for patients whose value for bpi_analyzed_baseline is not 1</i> |
| 77 | bpi_analyzed_m3 | BPI: Analyzed at month 3 | 0=Not analyzed 1=Analyzed |
| 78 | bpi_excluded_m3 | BPI: Reason not analyzed at month 3 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for bpi_analyzed_m3 is 1</i> |

| # | Variable | Description | Format/Coding for categorical data |
|----|------------------------|--|---|
| 79 | bpi_m3 | BPI: Month 3 score | Continuous <i>Blank for ineligible patients and patients whose value for bpi_analyzed_m3 is 0</i> |
| 80 | bpi_analyzed_m6 | BPI: Analyzed at month 6 | 0=Not analyzed 1=Analyzed |
| 81 | bpi_excluded_m6 | BPI: Reason not analyzed at month 6 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for bpi_analyzed_m6 is 1</i> |
| 82 | bpi_m6 | BPI: Month 6 score | Continuous <i>Blank for ineligible patients and patients whose value for bpi_analyzed_m6 is 0</i> |
| 83 | bpi_analyzed_m12 | BPI: Analyzed at month 12 | 0=Not analyzed 1=Analyzed |
| 84 | bpi_excluded_m12 | BPI: Reason not analyzed at month 12 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for bpi_analyzed_m12 is 1</i> |
| 85 | bpi_m12 | BPI: Month 12 score | Continuous <i>Blank for ineligible patients and patients whose value for bpi_analyzed_m12 is 0</i> |
| 86 | eq5d_analyzed_baseline | EQ-5D: Analyzed at baseline | 0=Not analyzed 1=Analyzed |
| 87 | eq5d_excluded_baseline | EQ-5D: Reason not analyzed at baseline | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for eq5d_analyzed_baseline is 1</i> |
| 88 | eq5d_baseline | EQ-5D: Baseline score | Continuous <i>Blank for patients whose value for eq5d_analyzed_baseline is not 1</i> |
| 89 | eq5d_analyzed_m3 | EQ-5D: Analyzed at month 3 | 0=Not analyzed 1=Analyzed |
| 90 | eq5d_excluded_m3 | EQ-5D: Reason not analyzed at month 3 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for eq5d_analyzed_m3 is 1</i> |
| 91 | eq5d_m3 | EQ-5D: Month 3 score | Continuous <i>Blank for ineligible patients and patients whose value for eq5d_analyzed_m3 is 0</i> |

| # | Variable | Description | Format/Coding for categorical data |
|-----|------------------------|--|--|
| 92 | eq5d_analyzed_m6 | EQ-5D: Analyzed at month 6 | 0=Not analyzed 1=Analyzed |
| 93 | eq5d_excluded_m6 | EQ-5D: Reason not analyzed at month 6 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for eq5d_analyzed_m6 is 1</i> |
| 94 | eq5d_m6 | EQ-5D: Month 6 score | Continuous <i>Blank for ineligible patients and patients whose value for eq5d_analyzed_m6 is 0</i> |
| 95 | eq5d_analyzed_m12 | EQ-5D: Analyzed at month 12 | 0=Not analyzed 1=Analyzed |
| 96 | eq5d_excluded_m12 | EQ-5D: Reason not analyzed at month 12 | Character, maximum length 24 <i>Blank for ineligible patients and patients whose value for eq5d_analyzed_m12 is 1</i> |
| 97 | eq5d_m12 | EQ-5D: Month 12 score | Continuous <i>Blank for ineligible patients and patients whose value for eq5d_analyzed_m12 is 0</i> |
| 98 | include_in_toxicity | Include in analyses of toxicity | 0=No 1=Yes |
| 99 | acute_ae | Any grade acute AEs occurring at 3 months | 0=Did not have any AEs reported 1=Had AEs reported |
| 100 | late_ae | Any grade late AEs occurring after 3 months | 0=Did not have any AEs reported 1=Had AEs reported |
| 101 | survival | Overall survival | 0=Alive 1=Dead |
| 102 | survival_months | Overall survival time since randomization in months to death or last known alive | Continuous |
| 103 | progression_known_mets | Progression of metastases known at baseline | No=No progression of known metastases Yes=Progression of known metastases |
| 104 | appearance_new_mets | Appearance of new metastases | No=No appearance of new metastases Yes=Appearance of new metastases |
| 105 | Compression_fracture | Compression fracture | 0=Alive without compression fracture 1=Compression fracture 2=Died without compression fracture |

| # | Variable | Description | Format/Coding for categorical data |
|-----|-----------------------------|--|---|
| 106 | Compression_fracture_months | Compression fracture time since randomization in months to failure or censoring/competing risk | Continuous |
| 107 | spinal_cord_signal | Spinal cord signal change on MRI | 0=No signal change 1=Signal change 2=Died without signal change |
| 108 | spinal_cord_signal_months | Spinal cord signal change on MRI: Time since randomization to signal change, or censoring/competing risk | Continuous |
| 109 | pain_response | Pain response for analysis of rapidity of pain response | 0=No response 1=Response |
| 110 | pain_response_months | Pain response time since randomization in months | Continuous |
| 111 | pain_relapse | Pain relapse for analysis of duration of pain response (including weeks 1-3) | 0=No pain relapse 1=Pain relapse |
| 112 | pain_relapse_months | Pain relapse time from randomization (or date of death or last known alive if no relapse) | Continuous |