NRG Oncology/RTOG 9804 Data Dictionary NCTN Data Archive

(n=636)

Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients analyzed for the primary endpoint? Started protocol treatment out of patients a	#	Variable	Description	Coding for categorical/Min-max for continuous
Min-max = 1-636	1	study_no	Study number	RTOG-9804
Min-max = 1-636	2	pt id	De-identified patient ID	Continuous
2 = Radiotherapy ± tamoxifen 1 = Eligible 2 = No protocol treatment 3 = Ineligible 4 = Withdrew consent 4 = Withdrew consent 5 analysis_flag 6 reason_for_exclusion 7 reason_for_exclusion 8 treated 8 treated 9 age 9 age 1 Age (years) 10 agefm 10 agefm 11 race 12 tamoxifen_use 12 tamoxifen_use 13 tum_location 14 tum_location 15 mammsize 16 mammsize 16 mammsize 17 Mammographic size of primary tumor, cm 10 margins 10 manuscisc 10 margins 10 margins 10 margins 10 manuscisc 10 margins 10 margins 10 margins 10 manuscisc 10 manuscisc			•	Min-max = 1-636
2 = Radiotherapy ± tamoxifen 4 case_status	3	rx	Assigned treatment	
Case Status				$2 = Radiotherapy \pm tamoxifen$
2 = No protocol treatment 3 = Ineligible 4 = Withdrew consent 5 analysis_flag 2 reason_for_exclusion 3 reason for Exclusion 4 reason for_exclusion 5 reason_for_exclusion 6 reason_for_exclusion 7 analysis_flag_sensitivity 8 reason for Exclusion 7 analysis_flag_sensitivity 8 reason for Exclusion 8 reason for_exclusion 9 reason for_exclusion 1 reace 1 reated 2	4	case status	Case Status	
3 = Ineligible 4 = Withdrew consent				
4 = Withdrew consent				
Analyse_flag				
endpoint? 2 = Yes (n=585) [case status=1,2]	5	analysis flag	Analyzed for the primary	
6 reason_for_exclusion Reason for Exclusion (for incligible/withdrew consent patients) Character variable of length 100 Reason is not blank (n=51) [analysis_flag=1] 7 analysis_flag_sensitivity Randomly allocated with follow-up information? 1 = No (n=7) 2 = Yes (n=629) 8 treated Started protocol treatment out of patients analyzed for the primary endpoint? 1 = No (n=7) 2 = Yes (n=629) 9 age Age (years) Continuous Min-max = 34-85 .= Not applicable (n=51) [analysis_flag_sensitivity=1) 10 agefm Age (years)-Categorized 1 = Xo 2 = Yes (n=579) 11 race Race 1 = Xo 2 = Yes (n=579) 10 agefm Age (years)-Categorized 1 = Xo 2 = Xo 11 race Race 1 = White 2 = Xo 2 = African American 3 = Hispanic 4 = Native Hawaiian or other Pacific Islander 5 = Asian 6 = American Indian or Alaska Native 7 = Other 7 = Other = Not applicable (n=7; analysis_flag_sensitivity=1) 1 = No 12 tamoxifen_use Intention to use tamoxifen? 1 = No 2 = Yes = Not applicable (n=7; analysis_flag_sensitivity=1) <td></td> <td></td> <td></td> <td></td>				
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16 margins Final microscopic margins, $1 = \ge 3 \text{mm} - 9 \text{mm}$				
	16	margins	Final microscopic margins,	

#	Variable	Description	Coding for categorical/Min-max for continuous
		•	3 = Negative by negative re-excision
			999 = Missing (n=1)
			. = Not applicable (n=7; analysis_flag_sensitivity=1)
17	pathsize	Largest dimension of DCIS	Continuous
		lesion on pathology	Min-max = 0.0-2.5
		slide, cm	999=Missing (n=2)
			. = Not applicable (n=7; analysis_flag_sensitivity=1)
18	local_failure	Local failure status	0 = censored
			1 = event (defined as biopsy-proven invasive or DCIS
			recurrence)
			2 = competing event (death)
10	1 103	T 10:1	. = Not applicable (n=7; analysis_flag_sensitivity=1)
19	local_failure_years	Local failure time (years)	Time from the date of randomization to the date of local
20	1 1 6 7 1 1 1 1	H 1	failure or last follow-up/death.
20	local_failure_histology	Histology of local failure	0 = No local failure
			1 = Invasive
			2 = Non-invasive
21	survival	Overall survival status	. = Not applicable (n=7; analysis_flag_sensitivity=1) 0 = censored
21	survivai	Overali survivai status	1 = event (death)
22	survival years	Overall survival time (years)	. = Not applicable (n=7; analysis_flag_sensitivity=1) Time from the date of randomization to the date of death or
22	survivar_years	Overall survival time (years)	last follow-up.
23	distant metastasis	Distant metastasis status	0 = censored
23	distant_inctastasis	Distant inclastasis status	1 = event (progression of disease beyond the treated breast
			and regional nodes)
			2 = competing event (death)
			. = Not applicable (n=7; analysis_flag_sensitivity=1)
24	distant metastasis years	Distant metastasis time	Time from the date of randomization to the date of distant
		(years)	metastasis or last follow-up/death.
25	contralateral_failure	Contralateral breast failure	0 = censored
		status	1 = event (contralateral breast failure)
			2 = competing event (death)
			. = Not applicable (n=7; analysis_flag_sensitivity=1)
26	contralateral_failure_years	Contralateral breast failure	Time from the date of randomization to the date of
		time (years)	contralateral breast failure or last follow-up/death.
27	mastectomy_failure	Salvage mastectomy failure	0 = censored
		status	1 = event (defined as removal of the study breast)
			2 = competing event (death)
20	mastastam. Cailum	Caluada mastastama failum	. = Not applicable (n=7; analysis_flag_sensitivity=1)
28	mastectomy_failure_years	Salvage mastectomy failure	Time from the date of randomization to the date of
29	mastactomy type	time (years) Type of salvage mastectomy	mastectomy or last follow-up/death. 0 = No salvage mastectomy
29	mastectomy_type	Type of salvage mastectomy	1 = Ipsilateral
			3 = Bilateral
			9 = Unknown
			. = Not applicable (n=7; analysis flag sensitivity=1)
30	disease_free_survival	Disease-free survival status	0 = censored
			1 = event (death, local failure, contralateral failure,
			distant_metastasis, mastectomy_failure)
			. = Not applicable (n=7; analysis_flag_sensitivity=1)
31	disease free survival years	Disease-free survival time	Time from the date of randomization to the date of
		(years)	failure/death or last follow-up.
32	tamoxifen_given	Tamoxifen received?	$1 = N_0$

#	Variable	Description	Coding for categorical/Min-max for continuous
			2 = Yes
			. = Not applicable (n=7; analysis_flag_sensitivity=1)
33	acute_max_overall_grade	Worst overall grade per	0 = grade 0
		patient for acute treatment	1 = grade 1
		toxicities (≤90 days from	2 = grade 2
		treatment start) [Graded	3 = grade 3
		using National Cancer	4 = grade 4
		Institute Common	. = Not applicable (n=7; analysis_flag_sensitivity=1)
		Terminology Criteria,	
		version 2.0.]	
34	has_late_toxicity	Evaluable for late RT	1 = No
		toxicities?	2 = Yes
			. = Not applicable (n=7; analysis_flag_sensitivity=1)
35	late_max_overall_grade	Worst overall grade per	0 = grade 0
		patient for late radiotherapy	1 = grade 1
		toxicities (> 90 days from	2 = grade 2
		treatment start) [Graded	3 = grade 3
		using the RTOG/European	999 = Did not receive protocol treatment or did not have late
		Organization for Research	RT toxicity information (n=322)
		and Treatment of Cancer	. = Not applicable (n=7; analysis_flag_sensitivity=1)
		Late Radiation Morbidity	
		Scheme.]	