

**NRG Oncology/RTOG-0537 Data Dictionary**  
**NCTN Data Archive**

**For patients excluded from analysis (analysis\_inclusion=0), there is no data in variables 6-114.**

**Note:** In result section of the manuscript, there are few typos such as

1. Table 2 Overall score (15 mo) and Table 3 Response at 15 mo: -(n=35) (n=41) should be (n=43) and (n=47)
2. There were no significant differences between the groups with respect to the highest grade of adverse events related to treatment and/or those with any relation to treatment 6 months (instead of 9 months) from randomization.
3. The statement, “Analysis of the data, including imputed item scores, revealed, contrary to the results of the complete data, no significant difference in overall baseline XeQOLS score (P=.12) between the 2 study groups.” should read “Analysis of the data, including imputed item scores, revealed, in agreement to the results of the complete data, a significant difference in overall baseline XeQOLS score (P=.04) between the 2 study groups.”
4. The following statements, “Sixteen patients did not complete either the baseline form (5 patients) or the XeQOLS before treatment (11 patients). Nineteen patients, 13 in the pilocarpine group, failed to complete the XeQOLS or completed the scale outside the planned time frame.” should read as “Eleven patients did not complete the XeQOLS baseline form. Eighteen patients, 12 in the pilocarpine group, failed to complete the XeQOLS at 9 months or completed the scale outside the planned time frame.”

#	Variable	Description	Format/Coding for categorical data
1	study	Study number	Character length 9
2	patid	De-identified patient ID	Character length 11
3	rx	Assigned treatment arm	2=Pilocarpine 3=ALTENS
4	analysis_inclusion	Indicator for inclusion in analysis in general	0=Excluded 1=Included
5	reason_for_exclusion	Reason excluded from analysis in general	Character, maximum length 45 <i>Note: Blank for patients not excluded.</i>
6	Primary_endpoint_analysis_flag	Indicator for inclusion in primary endpoint analysis (Complete Case: 9 Month Endpoint)	0=Excluded 1=Included
7	Imputed_analysis_flag	Indicator for inclusion in primary endpoint analysis (After Imputation: 9 Month Endpoint)	0=Excluded 1=Included
8	has_toxicity	Toxicity information been reported?	1=No 2=Yes
9	age	Age (years)	Continuous <i>Note: variable in Table 1</i>
10	gender	Gender	1=Male 2= Female <i>Note: variable in Table 1</i>
11	race	Race	1=American Indian or Alaska Native 2=Asian 3=Black or African American 4=Native Hawaiian or other Pacific Islander 5=White <i>Note: variable in Table 1</i>
12	white	Race categorized	1=Other Race 2=White
13	ethnicity	Ethnicity	1=Hispanic or Latino 2=Not Hispanic or Latino 9=Unknown <i>Note: variable in Table 1</i>
14	zubrod	Zubrod performance status	0=Fully active, able to carry on all predisease activities without restriction

#	Variable	Description	Format/Coding for categorical data
			1=Restricted in physically strenuous activity but ambulatory and able to carry work of a light or sedentary nature 2= Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours <i>Note: variable in Table 1</i>
15	country	Country of residence	1=United States 2=Canada
16	prior_chemo	Prior Chemotherapy	1=No 2=Yes
17	time_since_prior_rx_cat	Time since RT _ chemotherapy	1=3-6 months ago 2=More than 6 months to 1 year ago 3=1-2 years ago
18	prior_pilocarpine	Prior use of pilocarpine	1=No 2=Yes
19	med_onc_dose	Protocol Specified Dose	1=85-115% 2=< 85%, due to protocol-specified reasons 3=70 - < 85%, due to non-protocol-specified reasons 4=< 70%, due to non-protocol-specified reasons 5=> 115%
20	med_dose_rea	Reason for noncompliant dose	1=Patient refusal 3=Other “ “=Missing (Not Reported) (Applicable if med_onc_dose not equal to 1)
21	has_ae_6mn	Has Adverse events at 6 months?	1=No 2=Yes
22	has_ae_6mn_related	Has Adverse events at 6 months related to treatment?	1=No 2=Yes
23	worst_nonhemato_related_grade	Worst nonhematologic grade: definitely, probably, or possibly related to treatment	0 = grade 0 1 = grade 1 2 = grade 2 3 = grade 3 <i>Note: Applicable if has_toxicity=2</i>
24	grade3_worst_nonhemato_toxicity	Grade 3 Worst nonhematologic Toxicity: definitely, probably, or possibly related to treatment	Character, maximum length 96 <i>Note: Blank for patients =not reported grade 3 worst nonhematologic toxicity related to treatment .</i>
25	has_grade3_worst_nonhemato	Has Grade 3 Worst nonhematologic: definitely, probably, or possibly related to treatment?	1=No 2= Yes <i>Note: Applicable if has_toxicity=2</i>
26	XeQOLS_compliance_baseline	XeQOLS Compliance at Baseline	0=Completed 1=Completed out of time frame 2=Imputed data case 3=Tool not available in patient's language 4=Not completed-other reason 5=Not Received
27	XeQOLS_compliance_mn4	XeQOLS Compliance at 4 months	0=Completed 1=Completed out of time frame 2=Imputed data case 3=Patient withdrew consent 4=Not Received

#	Variable	Description	Format/Coding for categorical data
			5=Missing baseline form
28	XeQOLS_compliance_mn6	XeQOLS Compliance at 6 months	0=Completed 1=Completed out of time frame 2=Imputed data case 3=Patient withdrew consent 4=Not Received 5=Missing baseline form
29	XeQOLS_compliance_mn9	XeQOLS Compliance at 9 months	0=Completed 1=Completed out of time frame 2=Imputed data case 3=Patient withdrew consent 4=Not Received 5=Missing baseline form
30	XeQOLS_compliance_mn15	XeQOLS Compliance at 15 months	0=Completed 1=Completed out of time frame 2=Imputed data case 3=Patient withdrew consent 4=Not Received 5=Missing baseline form
31	baseline_overall_score	XeQOLS Overall score (Complete Case:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline=0</i>
32	baseline_physical	XeQOLS Physical score (Complete Case:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline=0</i>
33	baseline_pain	XeQOLS Pain score (Complete Case:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline=0</i>
34	baseline_personal	XeQOLS Personal score (Complete Case:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline=0</i>
35	baseline_social	XeQOLS Social score (Complete Case:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline=0</i>
36	m4_overall_score	XeQOLS Overall score (Complete Case: 4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
37	m4_physical	XeQOLS Physical score (Complete Case:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
38	m4_pain	XeQOLS Pain score (Complete Case:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
39	m4_personal	XeQOLS Personal score (Complete Case:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
40	m4_social	XeQOLS Social score (Complete Case:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
41	change_m4_overall_score	Change in XeQOLS Overall score (Complete Case: 4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
42	change_m4_physical	Change in XeQOLS Physical score (Complete Case:4 Month)	Continuous <i>Note: Applicable only if</i>

#	Variable	Description	Format/Coding for categorical data
			<i>XeQOLS_compliance_mn4=0</i>
43	change_m4_pain	Change in XeQOLS Pain score (Complete Case:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
44	change_m4_personal	Change in XeQOLS Personal score (Complete Case:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
45	change_m4_social	Change in XeQOLS Social score (Complete Case:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
46	m6_overall_score	XeQOLS Overall score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
47	m6_physical	XeQOLS Physical score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
48	m6_pain	XeQOLS Pain score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
49	m6_personal	XeQOLS Personal score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
50	m6_social	XeQOLS Social score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
51	change_m6_overall_score	Change in XeQOLS Overall score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
52	change_m6_physical	Change in XeQOLS Physical score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
53	change_m6_pain	Change in XeQOLS Pain score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
54	change_m6_personal	Change in XeQOLS Personal score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
55	change_m6_social	Change in XeQOLS Social score (Complete Case:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>
56	m9_overall_score	XeQOLS Overall score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
57	m9_physical	XeQOLS Physical score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
58	m9_pain	XeQOLS Pain score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
59	m9_personal	XeQOLS Personal score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
60	m9_social	XeQOLS Social score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if</i>

#	Variable	Description	Format/Coding for categorical data
			<i>XeQOLS_compliance_mn9=0</i>
61	change_m9_overall_score	Change in XeQOLS Overall score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
62	change_m9_physical	Change in XeQOLS Physical score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
63	change_m9_pain	Change in XeQOLS Pain score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
64	change_m9_personal	Change in XeQOLS Personal score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
65	change_m9_social	Change in XeQOLS Social score (Complete Case:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
66	m15_overall_score	XeQOLS Overall score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
67	m15_physical	XeQOLS Physical score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
68	m15_pain	XeQOLS Pain score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
69	m15_personal	XeQOLS Personal score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
70	m15_social	XeQOLS Social score (Complete Case:15 Social)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
71	change_m15_overall_score	Change in XeQOLS Overall score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
72	change_m15_physical	Change in XeQOLS Physical score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
73	change_m15_pain	Change in XeQOLS Pain score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
74	change_m15_personal	Change in XeQOLS Personal score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
75	change_m15_social	Change in XeQOLS Social score (Complete Case:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
76	responder_4	Responder at 4 Month	0=Nonresponder 1=Responder <i>Note: Applicable only if XeQOLS_compliance_mn4=0</i>
77	responder_6	Responder at 6 Month	0=Nonresponder 1=Responder <i>Note: Applicable only if XeQOLS_compliance_mn6=0</i>

#	Variable	Description	Format/Coding for categorical data
78	responder_9	Responder at 9 Month	0=Nonresponder 1=Responder <i>Note: Applicable only if XeQOLS_compliance_mn9=0</i>
79	responder_15	Responder at 15 Month	0=Nonresponder 1=Responder <i>Note: Applicable only if XeQOLS_compliance_mn15=0</i>
80	baseline_overall_score_imp	XeQOLS Overall score (Imputed:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline =(0 and 2)</i>
81	baseline_physical_imp	XeQOLS Physical score (Imputed:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline =(0 and 2)</i>
82	baseline_pain_imp	XeQOLS Pain score (Imputed:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline =(0 and 2)</i>
83	baseline_personal_imp	XeQOLS Personal score (Imputed:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline =(0 and 2)</i>
84	baseline_social_imp	XeQOLS Social score (Imputed:Baseline)	Continuous <i>Note: Applicable only if XeQOLS_compliance_baseline =(0 and 2)</i>
85	change_m4_overall_score_imp	Change in XeQOLS Overall score (Imputed: 4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=(0 and 2)</i>
86	change_m4_physical_imp	Change in XeQOLS Physical score (Imputed:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=(0 and 2)</i>
87	change_m4_pain_imp	Change in XeQOLS Pain score (Imputed:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=(0 and 2)</i>
88	change_m4_personal_imp	Change in XeQOLS Personal score (Imputed:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=(0 and 2)</i>
89	change_m4_social_imp	Change in XeQOLS Social score (Imputed:4 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn4=(0 and 2)</i>
90	change_m6_overall_score_imp	Change in XeQOLS Overall score (Imputed:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=(0 and 2)</i>
91	change_m6_physical_imp	Change in XeQOLS Physical score (Imputed:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=(0 and 2)</i>
92	change_m6_pain_imp	Change in XeQOLS Pain score (Imputed:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=(0 and 2)</i>
93	change_m6_personal_imp	Change in XeQOLS Personal score (Imputed:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=(0 and 2)</i>
94	change_m6_social_imp	Change in XeQOLS Social score (Imputed:6 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn6=(0 and 2)</i>
95	change_m9_overall_score_imp	Change in XeQOLS Overall	Continuous

#	Variable	Description	Format/Coding for categorical data
		score (Imputed:9 Month)	<i>Note: Applicable only if XeQOLS_compliance_mn9=(0 and 2)</i>
96	change_m9_physical_imp	Change in XeQOLS Physical score (Imputed:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=(0 and 2)</i>
97	change_m9_pain_imp	Change in XeQOLS Pain score (Imputed:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=(0 and 2)</i>
98	change_m9_personal_imp	Change in XeQOLS Personal score (Imputed:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=(0 and 2)</i>
99	change_m9_social_imp	Change in XeQOLS Social score (Imputed:9 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn9=(0 and 2)</i>
100	change_m15_overall_score_imp	Change in XeQOLS Overall score (Imputed:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=(0 and 2)</i>
101	change_m15_physical_imp	Change in XeQOLS Physical score (Imputed:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=(0 and 2)</i>
102	change_m15_pain_imp	Change in XeQOLS Pain score (Imputed:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=(0 and 2)</i>
103	change_m15_personal_imp	Change in XeQOLS Personal score (Imputed:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=(0 and 2)</i>
104	change_m15_social_imp	Change in XeQOLS Social score (Imputed:15 Month)	Continuous <i>Note: Applicable only if XeQOLS_compliance_mn15=(0 and 2)</i>
105	Unsti_saliva_baseline	Basal whole salivary production: Baseline	Continuous “ “=Missing (Not Reported)
106	Unsti_saliva_mn4	Basal whole salivary production: 4 Month	Continuous “ “=Missing (Not Reported)
107	Unsti_saliva_mn6	Basal whole salivary production: 6 Month	Continuous “ “=Missing (Not Reported)
108	Unsti_saliva_mn9	Basal whole salivary production: 9 Month	Continuous “ “=Missing (Not Reported)
109	Unsti_saliva_mn15	Basal whole salivary production: 15 Month	Continuous “ “=Missing (Not Reported)
110	Sti_saliva_baseline	Stimulated whole salivary production: Baseline	Continuous “ “=Missing (Not Reported)
111	Sti_saliva_mn4	Stimulated whole salivary production: 4 Month	Continuous “ “=Missing (Not Reported)
112	Sti_saliva_mn6	Stimulated whole salivary production: 6 Month	Continuous “ “=Missing (Not Reported)
113	Sti_saliva_mn9	Stimulated whole salivary production: 9 Month	Continuous “ “=Missing (Not Reported)
114	Sti_saliva_mn15	Stimulated whole salivary production: 15 Month	Continuous “ “=Missing (Not Reported)