NRG Oncology/RTOG-1112 Data Dictionary for NCT01730937-D1-Dataset.csv
PMID: 39699905

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:
Blanks indicate not applicable. Some specific reasons for blanks are described in select variables for added clarity.

Note #3:
Specific site and country identifications are not contained within this data submission due to de-identification procedures.

Note #4:
Race categories with 1 patient were grouped into 9=Other/Unknown/Not reported.

Note #5:
The median sorafenib duration for the SBRT and sorafenib group should be 4.9 months not 5.1 months.

Note #6:
The hazard ratio and 95% confidence interval for the association of baseline FACT-Hep total score with overall survival in the manuscript is for a 10-point increase in the baseline FACT-Hep total score.

Adverse events were scored with CTCAE version 4. See also the companion datasets and data dictionaries:
NCT01730937-D2-Dataset.csv and NCT01730937-D2-Data-Dictionary.pdf
NCT01730937-D3-Dataset.csv and NCT01730937-D3-Data-Dictionary.pdf
NCT01730937-D4-Dataset.csv and NCT01730937-D4-Data-Dictionary.pdf
NCT01730937-D5-Dataset.csv and NCT01730937-D5-Data-Dictionary.pdf

#	Variable	Description	Coding
1	study_no	Study number	RTOG-1112
2	deident_subjectid	De-identified patient ID	Character
3	arm_rand	Allocated treatment	1=Sorafenib 2=SBRT and Sorafenib
4	include_in_analysis	Eligible modified intent-to-treat population analyzed for primary end point	1=No 2=Yes
5	reason_for_exclusion	Reason for exclusion (blank when *include_in_analysis*=2)	Character
6	reason_ineligible	Reason ineligible (blank when *include_in_analysis*=2)	Character
7	include_in_ae_analysis	Analyzed for AEs	1=No 2=Yes
8	reason_for_ae_exclusion	Reason for exclusion from AE analysis (blank when *include_in_ae_analysis*=2)	Character
9	age	Age (years)	Continuous
10	sex	Sex	1=Male 2=Female
11	race	Race	2=Asian 3=Black or African American 5=White 9=Other/Unknown/Not reported

#	Variable	Description	Coding
12	zubrod	Zubrod performance status	Continuous
13	t_stage_clinical	Clinical T stage [AJCC 7th edition]	1=T1 2=T2 3=T3a 4=T3b 5=T4
14	n_stage_clinical	Clinical N stage [AJCC 7th edition]	0=N0 1=N1 2=NX
15	m_stage_clinical	Clinical M stage [AJCC 7th edition]	1=M0 2=M1
16	bclc	BCLC stage	1=Intermediate (B) 2=Advanced (C)
17	child_pugh	Child-Pugh score	1=score 5 (Grade A) 2=score 6 (Grade A)
18	platelets	Platelet count $x10^3/\mu l$	Continuous
19	vascular_strat	Macrovascular invasion	1=Vp3, Vp4, or IVC 2=Vp1 or Vp2 3=None
20	alpha_fetoprotein	α-Fetoprotein, ng/mL	1=≤ 400 ng/mL 2=> 400 ng/mL 99=missing
21	num_lesions	>1 Tumor	1=No 2=Yes 999=vascular HCC
22	sum_hcc_diam	Sum of HCC diameter, cm	Continuous, 999=vascular HCC
23	HCCvol_strat	HCC volume/liver volume	1=ratio <10 2=ratio 10-40 3=ratio >40
24	hepatitis_strat	Hepatitis status	1=Hepatitis B or B and C 2=Hepatitis C 3=Other
25	site_strat	Site continent	1=North America 2=Other
26	prior_sorafenib	Prior sorafenib use	1=No 2=Yes 3=Enrolled prior to amendment
27	rt_given	SBRT given	1=Did not receive SBRT 2=Received SBRT (complete) 3=Received SBRT (incomplete-pt refusal) 4=Received SBRT (incomplete-toxic effects)
28	prescribed_dose	Prescribed Dose in Gy (5 fractions)	Continuous
29	received_dose_fxs	Received Dose in Gy (# fractions)	1=50 Gy (5) 2=45 Gy (5) 3=40 Gy (5) 4=35 Gy (5) 5=30 Gy (5) 6=27.5 Gy (5) 7=28 Gy (4)[Pt didn't attend last RT session] 8=24 Gy (4)[due to AEs] 9=21 Gy (3)[due to AEs] 10=20 Gy (2)[due to AEs]

#	Variable	Description	Coding
30	reason_not_5fxs	Reason 5 fractions not received	Character
31	rt_dose	Received Dose in Gy	Continuous
32	rt_fxs	# fractions	Continuous
33	rt_score_overall	Overall SBRT Review Score	1=Per protocol 2=Acceptable variation 3=Deviation Unacceptable 4=Incomplete RT – due to AEs
34	reason_unaccept	Reason SBRT review score = Deviation Unacceptable	Character
35	rt_type	Type of SBRT	1=3DCRT 2=IMRT 3=Cyberknife 5=VMAT (Protons were added per journal's request but no patients received them.)
36	rt_motion_m	Method of Motion Management	1=Abdominal compression 2=Gating 3=Automatic breath control (ABC) 4=Real-time tracking 5=No motion management used (ITV approach)
37	rt_motion_a	Method of Motion Assessment	1=Real time fluoroscopy using IGRT system on accelerator table 2=Real time fluoroscopy using the conventional simulator 3=4-D CT scanning 4=Other
38	Liver_volume	*Liver volume (cc)*	Continuous
39	Num_GTVs	*GTV*: Number of GTVs	Continuous
40	GTV_volume	*GTV*: Volume (cc)	Continuous
41	Num_PTVs	*PTV*: Number of PTVs	Continuous
42	Volume_for_PTV_Total_cc_	*PTV*: Volume of total PTV (cc)	Continuous
43	PTV_Total_Mean_Gy_	*PTV*: Mean dose to total PTV (Gy)	Continuous
44	PTV_Total_D95percent_Gy_	*PTV*: Dose to 95% total PTV (Gy)	Continuous
45	Dominant_PTV_Mean_Gy_	*Dominant PTV:* Mean dose (Gy)	Continuous
46	Dominant_PTV_D95percent_Gy_	*Dominant PTV:* Dose to 95% (Gy)	Continuous
47	liver_minus_gtv	*Liver minus GTV*: Volume (cc)	Continuous
48	LIVER_MD	*Liver minus GTV*: Mean dose (Gy)	Continuous
49	D0point5cc_Gy__for_Liver_GTV	*Liver minus GTV*: Maximal dose to 0.5 cc (Gy)	Continuous
50	DV700cc_Gy__to_Liver_GTV	*Liver minus GTV*: Dose to 700 cc spared (Gy)	Continuous
51	D800cc_Gy__Liver_GTV	*Liver minus GTV*: Dose to 800 cc (Gy)	Continuous
52	CV10Gy_cc__for_Liver_GTV	*Liver minus GTV*: Volume receiving < 10 Gy (cc)	Continuous
53	CV15Gy_cc__for_Liver_GTV	*Liver minus GTV*: Volume receiving < 15 Gy (cc)	Continuous
54	STOM_MD	*Luminal GI tissues*: Stomach-Maximum dose to 0.5 cc (Gy)	Continuous
55	D5cc_Gy__to_Stomach	*Luminal GI tissues*: Stomach-Maximal dose to 5 cc (Gy)	Continuous
56	DUOD_MD	*Luminal GI tissues*: Duodenum-Maximum dose to 0.5 cc (Gy)	Continuous
57	D5cc_Gy__to_Duodenum	*Luminal GI tissues*: Duodenum-Maximal dose to 5 cc (Gy)	Continuous
58	SBOW_MD	*Luminal GI tissues*: Small bowel-Maximum dose to 0.5 cc (Gy)	Continuous

#	Variable	Description	Coding
59	D5cc_Gy__to_SmallBowel	*Luminal GI tissues*: Small bowel-Maximal dose to 5 cc (Gy)	Continuous
60	LBOW_MD	*Luminal GI tissues*: Large bowel-Maximum dose to 0.5 cc (Gy)	Continuous
61	D5cc_Gy__to_LargeBowel	*Luminal GI tissues*: Large bowel-Maximal dose to 5 cc (Gy)	Continuous
62	D0point5cc_Gy__to_CommonBileDuct	*Common bile duct*: Maximum dose to 0.5 cc (Gy)	Continuous
63	D0point5cc_Gy__to_GallBladder	*Gallbladder*: Maximum dose to 0.5 cc (Gy)	Continuous
64	KIDNEY_MD_1	*Kidneys*: Mean dose (Gy)	Continuous
65	Dose50percent_Gy__to_Kidneys	*Kidneys*: Median dose (Gy)	Continuous
66	sorafenib_given	Sorafenib given	1=Did not receive sorafenib 2=Received sorafenib
67	soraf_daily_dose	Sorafenib dose per day (mg)	Continuous 9999= Sorafenib received but daily dose unknown
68	soraf_months	Sorafenib duration (months)	Continuous
69	nonprot_sys	*Non-protocol treatment:* Systemic treatment	1=No 2=Yes
70	nonprot_sbrt	*Non-protocol treatment:* SBRT or hepatic palliative radiation	1=No 2=Yes
71	nonprot_rtoth	*Non-protocol treatment:* Radiation to other sites	1=No 2=Yes
72	nonprot_surg	*Non-protocol treatment:* Surgery	1=No 2=Yes
73	nonprot_other	*Non-protocol treatment:* Other non-protocol therapy	1=No 2=Yes
74	survival	Survival status	0=Censored 1=Dead
75	survival_months	Survival time (months)	Continuous
76	cause_of_death	Cause of death	1=Due to disease 4=Due to other cause 9=Unknown
77	pfs	Progression-free survival status	0=Censored 1=Failed
78	pfs_months	Progression-free survival time (months)	Continuous
79	progression_failure	Time-to-Progression status	0=Censored 1=Failed 2=Competing Risk
80	progression_failure_months	Time-to-Progression time (months)	Continuous
81	include_in_vas_analysis	Patients with macrovascular invasion at study entry	1=No 2=Yes
82	best_first_vresponse	Best First Vascular Invasion Response prior to any Progressive Disease	1=PD 2=CR (No PD after CR) 3=PR (No PD after PR) 3.1=PR (PR then PD) 4=SD (No PD after SD) 4.1=SD (SD then PD) 9=Unknown
83	unk_vas_response	Follow-up status for patients with unknown vascular invasion response (where *best_first_vresponse*=9)	1=Died <3 months 2=Died 3 to <6 months 3=Died 6 to <12 months 4=Died ≥ 12 months 5=Alive but withdrew consent <3 months 66=Alive

#	Variable	Description	Coding
84	qol_consent	Consented to quality-of-life assessments	1=No 2=Yes
85	fact_has_baseline	Has Baseline FACT-Hep: Total Score	1=No 2=Yes
86	fact_has_6month	Has 6-month FACT-Hep: Total Score	1=No 2=Yes
87	fact_has_base_6mo	Has baseline & 6-month FACT-Hep: Total Score	1=No 2=Yes
88	fact_base_score	Baseline FACT-Hep total score	continuous
89	fact_6mo_chg_cat	FACT-Hep Total Score: Change From Baseline to 6 Months *Decline = any decrease of points from baseline; Stable = score increase from baseline of between 0 and 4 points; Improved= score increase of ≥ 5 points from baseline.	1=Improved 2=Stable 3=Decline
90	discontinued_rx_aes	Discontinued treatment due to adverse events	1=No 2=Yes
91	max_grade_all	Overall Highest Grade for any adverse event (regardless of relationship to treatment)	1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4 5=Grade 5
92	max_grade_bloodwork	Overall highest grade for specific BLOODWORK adverse events regardless of relationship to treatment)* *Includes only the following CTCAE version 4 terms from the Investigations system organ class (SOC): alanine aminotransferase increased, aspartate aminotransferase increased, blood bilirubin increased, and platelet count decreased.	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4
93	max_grade_GIbleed	Overall highest grade for specific BLEEDING (GI) adverse events (regardless of relationship to treatment)* *Includes only the following CTCAE version 4 terms from the GASTROINTESTINAL DISORDERS system organ class (SOC): esophageal varices hemorrhage, gastric hemorrhage, upper gastrointestinal hemorrhage, intra-abdominal hemorrhage, and lower gastrointestinal hemorrhage.	0=Grade 0 1=Grade 1 3=Grade 3
94	grade5_term	Grade 5 CTCAE version 4 term (regardless of relationship to treatment)	Character
95	max_grade_related	Overall Highest Grade for any adverse event (Possibly, Probably, or Definitely Related to Treatment)	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4 5=Grade 5

#	Variable	Description	Coding
96	max_grade_bloodwork_related	Overall highest grade for specific BLOODWORK adverse events (Possibly, Probably, or Definitely Related to Treatment)* *Includes only the following CTCAE version 4 terms from the Investigations system organ class (SOC): alanine aminotransferase increased, aspartate aminotransferase increased, blood bilirubin increased, and platelet count decreased.	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3 4=Grade 4
97	max_grade_GIbleed_related	Overall highest grade for specific BLEEDING (GI) adverse events (Possibly, Probably, or Definitely Related to Treatment)* *Includes only the following CTCAE version 4 terms from the GASTROINTESTINAL DISORDERS system organ class (SOC): esophageal varices hemorrhage, gastric hemorrhage, upper gastrointestinal hemorrhage, intra-abdominal hemorrhage, and lower gastrointestinal hemorrhage.	0=Grade 0 3=Grade 3
98	max_GI_grade_related	Overall highest grade for GASTROINTESTINAL adverse events (Possibly, Probably, or Definitely Related to Treatment)	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
99	max_skin_grade_related	Overall highest grade for SKIN adverse events (Possibly, Probably, or Definitely Related to Treatment)	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
100	max_hep_grade_related	Overall highest grade for HEPATOBILIARY adverse events (Possibly, Probably, or Definitely Related to Treatment)	0=Grade 0 3=Grade 3 4=Grade 4 5=Grade 5
101	max_vas_grade_related	Overall highest grade for VASCULAR adverse events (Possibly, Probably, or Definitely Related to Treatment)	0=Grade 0 1=Grade 1 2=Grade 2 3=Grade 3
102	grade5_term_related	Grade 5 CTCAE version 4 term (Possibly, Probably, or Definitely Related to Treatment)	Character