E5508 Primary Analysis Clinical Data Description

This data description is for NCT01107626-D1-Dataset.csv. The data in the spreadsheet are the analysis data for the primary manuscript on NSCLC optimal maintenance therapy analysis results, published in

Ramalingam S.S., Dahlberg S.E., Belani C.P., Saltzman J.N., Pennell N.A., Nambudiri G.S., McCann J.C., Winegarden J.D., Kassem M.A., Mohamed M.K., Rothman J.M., Lyss A.P., Horn L., Stinchcombe T.E., Schiller J.H.. Pemetrexed, Bevacizumab, or the Combination As Maintenance Therapy for Advanced Nonsquamous Non-Small-Cell Lung Cancer: ECOG-ACRIN 5508. J Clin Oncol. 2019 Sep 10;37(26):2360-2367. doi: 10.1200/JCO.19.01006. Epub 2019 Jul 30. PMID: 31361535; PMCID: PMC7001786.

Pemetrexed or bevacizumab is used for maintenance therapy of advanced no squamous non-small cell lung cancer (NSCLC). The combination of bevacizumab and pemetrexed has also demonstrated efficacy. This study contains two step registration, induction therapy step and maintenance therapy. All patients who were registered to at least one of the steps are included.

Data file description

Field	Name	Description	Coding
1	ID	De-identified case ID number	Numeric code, up to 7 digits
2	Gender	Patient's gender	1 = Male 2 = Female
3	Race	Patient's race	1 = White 3 = Black 99 = Other
4	Age	Age at registration	Values in years
5	Ethnicity	Patient's ethnicity	1 = Hispanic 2 = Not Hispanic -1 = Not reported 12 = Unknown
6	Reg_step2	Patient's registration to step 2 status	2 = registered in step 2
7	Treatment	Assigned Treatment Arm at Step 2	A = Bevacizumab alone B = Pemetrexed alone C = Combination of Bevacizumab and Pemetrexed NA = Not applicable or Missing
8	Smoke_history	Patient's smoking history status	1 = Current 2 = Former 3 = Never
9	Histology	Patient's histologic type	1 = Squamous Cell Carcinoma 2 = Adenocarcinoma 3 = Large Cell Undifferentiated

			4 = Bronchoalveolar Carcinoma 5 = Non-small Cell Lung Cancer NOS 6 = Other
10	Stage	Patient's disease stage	1 = IIIB 2= IV M1a 3 = IV M1b 4 = Recurrent
11	PS	ECOG Performance status	0 = Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100) 1 = Restricted in physically strenuous activity but ambulatory (K 70-80) 2 = Ambulatory and capable of all selfcare but unable to carry out any work activities (K 50-60) 3 = Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours (K 30-40) 4 = Completely disabled (K 10-20)
12	Response_step2	Patient's best response for step2	1 = Complete response 2 = Partial response 3 = Stable disease 4 = Progressive disease 99 = Unevaluable -1 = Unknown
13	Response_step1	Patient's best response for step1	1 = Complete response 2 = Partial response 3 = Stable disease 4 = Progressive disease 8 = Unevaluable -1 = Unknown
14	Weight_loss	Weight loss in previous six months	1 =< 5% of body weight 2 = 5-<10% of body weight 3 = 10-<20% of body weight 4 = ≥ 20% of body weight
15	Cva	History of cerebrovascular accident	1 = No 2 = Yes
16	Prior_surgery	Patient's prior surgery status	1 = No 2 = Yes
17	Prior_radiation	Patient's prior radiation therapy status	1 = No 2 = Yes

18	Os_mos_step2	Patient's survival time from random assignment	Values in month
19	Surv_stat	Patient's survival status	0 = Alive 1 = Dead
20	Pfs_mos_step2	Patient's progression free survival time from random assignment	Values in month
21	Pfs_stat_step2	Patient's progression free survival status from random assignment	0 = No progression 1 = Progression/Dead
22	Os_initial	Patient's overall survival time from initial registration	Values in month
23	Os_stat	Patient's survival status from initial registration	0 = Alive 1 = Dead
24	Hilar	Patient's hilar nodes metastatic status	1 = No 2 = Yes
25	Mediastinal	Patient's mediastinal nodes metastatic status	1 = No 2 = Yes
26	Contralateral	Patient's contralateral lung metastatic status	1 = No 2 = Yes
27	Pleura	Patient's pleura metastatic status	1 = No 2 = Yes
28	Brain	Patient's brain metastatic status	1 = No 2 = Yes
29	Skin	Patient's skin metastatic status	1 = No 2 = Yes
30	Adrenal	Patient's adrenal metastatic status	1 = No 2 = Yes
31	Bone	Patient's bone metastatic status	1 = No 2 = Yes
32	Liver	Patient's liver metastatic status	1 = No 2 = Yes
33	Supraclavicular	Patient's Supraclavicular /scalene nodes metastatic status	1 = No 2 = Yes

34	Ipsilateral	Patient's Ipsilateral Lung metastatic status	1 = No 2 = Yes
35	Marrow	Patient's bone marrow metastatic status	1 = No 2 = Yes
36	Other	Patient's other site metastatic status	1 = No 2 = Yes
37	Cycle_numbers	Patient's total cycles of having treatment at step2	Integer
38	Reason_offtx_step1	Patient's off-treatment reason for step 1	1 = Treatment completed per protocol criteria 2 = Disease progression, relapse during active treatment 3 = Adverse event/side effects/complications 4 = Death on study 5 = Patient withdrawal/refusal after beginning protocol therapy 6 = Alternative therapy 7 = Patient off treatment for other complicating disease 99 = Other
39	Reason_offtx_step2	Patient's off-treatment reason for step 2	1 = Treatment completed per protocol criteria 2 = Disease progression, relapse during active treatment 3 = Adverse event/side effects/complications 4 = Death on study 5 = Patient withdrawal/refusal after beginning protocol therapy 6 = Alternative therapy 7 = Patient off treatment for other complicating disease 99 = Other

- Metastasis sites were inadvertently mislabeled in the original analysis dataset. The correct metastasis data were provided in the D1 dataset.

- Missing and not applicable values coded -1 for numeric variables, except where noted otherwise.
- In the analysis, months were calculated as days/30.4375
- Due to data cleaning efforts, data may contain slight discrepancies from that reported in Table 1 and Table 2 in the publication. The number of each metastatic site is incorrect in the publication: The data in this dataset is correct.
- 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).