E2108 Primary Analysis Clinical Data Description

The clinicaltrials.gov protocol identifier: NCT01242800
This data dictionary is for the NCT01242800-D2 dataset.

The data in the spreadsheet are the clinical analysis data for the primary manuscript on E2108 results, published in

Khan SA, Zhao F, Goldstein LJ, Cella D, Basik M, Golshan M, Julian TB, Pockaj BA, Lee CA, Razaq W, Sparano JA, Babiera GV, Dy IA, Jain S, Silverman P, Fisher CS, Tevaarwerk AJ, Wagner LI, Sledge GW. Early Local Therapy for the Primary Site in De Novo Stage IV Breast Cancer: Results of a Randomized Clinical Trial (E2108). *J Clin Oncol*. 2022 Mar 20;40(9):978-987.PMCID: PMC8937009.

The data reflect the study database as of December 10, 2019. It includes all patients who were randomized to Step 2 after optimal systemic treatment at Step 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).

Data File Description

Field	Variable Name	Description	Coding	Note
1	uid	Patient identifier		De-identified patient ID
2	elig_step2	Meet eligibility criteria for Step 2	0=No, 1=Yes	
3	trtm	Treatment arm	A= Continued systemic therapy, B= Early local therapy	
4	age2	Age at randomization to Step 2 (years)	Continuous variable	
5	menopausal_stat2	Menopausal status at Step 2	1=Postmenopausal, 2=Premenopausal, 3=Perimenopausal	
6	bmi_grp	Body mass index at Step 2 (Kg/M^2)	0= <25 1= 25-30 2= ≥30	

Field	Variable Name	Description	Coding	Note
7	ps	ECOG performance status	0 = Performance Status 0, 1 = Performance Status 1, 2 = Performance Status 2, 3 = Performance Status 3	
8	metasite2	Metastatic sites at randomization to step 2	1=Visceral only, 2=Bone only, 3=Soft tissue only, 4=Multiple sites, 5=Other single site, 9=No metastatic site	
9	surgery	Received surgery	0=No, 1=Yes	
10	surgery_type	Surgery type	1=Breast conserving surgery, 2=mastectomy	
11	margin	Free margin achieved	1=No, 2=Yes	
12	surgery_time	Surgery time	String variable	Whether a patient received surgery was collected for each reporting period (every 3 months within first 2 years, every 6 months for years 2-5). For example, 03_MO_POST_RAND means 3 months post randomization, ie, whether surgery was performed within 3 months post randomization; 06_MO_POST_RAND means 6 months post randomization, ie, whether surgery was performed between 3 and 6 months post randomization; 12_MO_POST_RAND means 12 months post randomization, ie, whether surgery was performed between 9 and 12 months post randomization.
13	axillary_surgery	Axillary surgery	0=None, 1=Sentinel node biopsy only, 2=Axillary dissection with/without sentinel node biopsy	Only applicable to the 126 patients who reported sentinel node biopsy and/or axillary dissection data. The data in this

				variable are further cleaned since publication.
14	rt	Received radiation therapy	0=No, 1=Yes	
15	rt_time	Radiation time	String variable	Same as surgery_time.
16	rtlocation	Radiation therapy type	1=Locoregional, 2=Metastatic	
17	surv_s2	Overall survival (OS) status	0=Censored, 1=died	As of database on 12/10/2019
18	surv_m2	OS time in months	Continuous variable	As of database on 12/10/2019
19	cod_step2	Cause of death	2=Breast cancer, 3=Other disease, 9=Cause unknown	As of database on 12/10/2019
20	lr_pd_yn	First locoregional recurrence/progression	1=No, 2=Yes	As of database on 12/10/2019
21	status_lr	Status for locoregional recurrence/progression	0=Censored, 1=Locoregional event, 2=Competing risk	As of database on 12/10/2019
22	time_lr	Time to locoregional recurrence/progression in months	Continuous variable	As of database on 12/10/2019

Notes:

- Unless otherwise specified, blank values indicate missing data.
- In the analysis, months were calculated as number of days/30.4375.
- The data in this dataset that are reported in Supplemental Table 1 are further cleaned since publication.