E2112 Primary Analysis Clinical Data Description

The clinicaltrials.gov protocol identifier: NCT02115282
This data dictionary is for the NCT02115282-D1 dataset.

The data in the spreadsheet are the clinical analysis data for the primary manuscript on E2112 results, published in:

> Connolly RM, Zhao F, Miller KD, Lee MJ, Piekarz RL, Smith KL, Brown-Glaberman UA, Winn JS, Faller BA, Onitilo AA, Burkard ME, Budd GT, Levine EG, Royce ME, Kaufman PA, Thomas A, Trepel JB, Wolff AC, Sparano JA. E2112: Randomized phase III trial of endocrine therapy plus entinostat/placebo in hormone receptor-positive advanced breast cancer. A trial of the ECOG-ACRIN Cancer Research Group. J Clin Oncol. 2021 Oct 1;39(28):3171-3181.

This dataset, except for the PFS endpoint, reflects the study database as of May 5, 2020. The PFS endpoint reflects the study database as of September 4, 2018. As defined in the protocol, the final analysis for the PFS endpoint was conducted when 247 PFS events were observed. Therefore, even though central review resulted in a total of 249 PFS events, the PFS data were censored at the time of the 247th event in the analysis.

The records of the 16 patients who were not centrally reviewed (*nocentral* = 1) were reviewed by an independent clinical data review group to determine their PFS status. The data from this independent review are included in the central review PFS variables (*pfs_s* and *pfs_m*).

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, not ECOG case ID
2	first360	Indicator for whether the patient was one of the first 360 patients that were enrolled to the trial	0=no, 1=yes	The primary endpoint PFS was analyzed in the first 360 patients.

Field	Variable Name	Description	Coding	Note
3	nocentral	Indicator for patients who did not have any post-randomization scans and were not centrally reviewed	1=no central review data	PFS endpoint was assessed in the first 360 patients and based on central review. 16 patients didn't have any post-randomization scans and were not centrally reviewed.
4	elig	Met eligibility criteria	0=no, 1=yes	
5	treated	Received protocol therapy	0=no, 1=yes	
6	treat	Treatment arm randomized	A=Arm A, B=Arm B	Arm A=Entinostat+exemestane, Arm B=Placebo+exemestane
7	stra_setting	Stratification factor – setting of progression	1=adjuvant, 2=locally advanced/metastatic	
8	stra_country	Stratification factor – geographic region	1=other country, 2=USA	
9	stra_visceral	Stratification factor – visceral disease	1=no, 2=yes	
10	stra_fulvestrant	Stratification factor- prior fulvestrant use	1=no, 2=yes, 3=no (enrolled prior to Amendment #3)	The prior fulvestrant use stratification factor was added to the protocol in amendment #3. Before amendment #3, only patients without prior fulvestrant use were eligible for the study
11	pfs_s	Progression-free survival (PFS) status based on central review	0=censor, 1=PFS event	As of database on 9/4/2018. The first 360 randomized patients were the primary analysis population for PFS endpoint and had value for this variable
12	pfs_m	PFS time in months based on central review	Continuous variable	As of database on 9/4/2018. The first 360 randomized patients were the primary analysis population for PFS endpoint and had value for this variable
13	pfs_status	PFS status based on local review	0=censor, 1=PFS event	As of database on 5/5/2020

Field	Variable Name	Description	Coding	Note
14	pfs_month	PFS time in months based on local review	Continuous variable	As of database on 5/5/2020
15	surv_s	Overall survival (OS) status	0=censor, 1=died	As of database on 5/5/2020
16	surv_m	OS time in months	Continuous variable	As of database on 5/5/2020
17	ttd_s	Time-to-treatment discontinuation (TTD) status	0=censor, 1=TTD event	As of database on 5/5/2020
18	ttd_m	TTD in months	Continuous variable	As of database on 5/5/2020
19	bestresp	Best response based on local assessment	1=complete response 2=partial response 3=stable disease 4=progressive disease 8=unevaluable disease	As of database on 5/5/2020
20	age	Age at study entry (years)	Continuous variable	
21	gender	Sex	String variable	
22	race	Race	1=White, 2=Black, 3=Asian, 4=unknown	
23	ethn	Ethnicity	1=Non-Hispanic, 2=Hispanic, 3=unknown	
24	ecogps	ECOG performance status	0=0, 1=1	
25	bmi3	Body mass index category	1=BMI <25 Kg/M2 2=BMI 25-30 Kg/M2 3=BMI ≥30 Kg/M2	
26	menopause_stat	Menopausal status	String variable	
27	measurable	Measurable disease at baseline	0=no, 1=yes	

Field	Variable Name	Description	Coding	Note
28	visceral	Visceral disease reported on the study form	0=no, 1=yes	28
29	er_stat	ER status	String variable	
30	erpercent	ER percent	0= ER percent ≥10% 1= ER percent <10%	
31	pgr_stat	PgR status	String variable	
32	numsites	Number of sites involved	integer	
33	prior_rt_yn	Prior radiation therapy	String variable	
34	prior_chemo_yn	Prior chemotherapy	String variable	
35	prior_chemo_setting	Prior chemotherapy setting	String variable	364 patients who received prior chemotherapy had value for this variable
36	prior_cdki_yn	Prior CDK inhibitor therapy	String variable	
37	cdki_type	Type of prior CDK inhibitor	String variable	When prior_cdki_yn=No, blank is N/A
38	prior_everol_yn	Prior everolimus therapy	String variable	
39	prior_fulvest_yn	Prior fulvestrant therapy	String variable	
40	prior_chemo_lines	Total lines of prior chemotherapy	integer	
41	prior_endocrine_lines	Total lines of prior endocrine therapy	integer	
42	offtrt	Indictor for whether patient went off treatment as of the data cutoff date	0=still on treatment, 1=off treatment	589 patients who started protocol therapy had the value for this variable
43	totalcycle	Total number of cycles of protocol treatment received	Integer	583 patients who discontinued therapy as of the data cutoff date had the value for this variable
44	cyclesofar	Total number of cycles of protocol treatment received so far	Continuous variable	6 patients who were still on treatment as of the data cutoff date had value for this variable

Field	Variable Name	Description	Coding	Note
45	off_tx_reas	Reason for discontinuing protocol therapy	2=Disease progression, 3=Adverse events, 4=Death on study, 5=Patient withdrawal, 6=Alternative therapy, 7=Complicating disease, 8=Symptomatic progression/deterioration, 9=Noncompliance, 88=Other	Only the 583 patients who started and discontinued protocol therapy had value for this variable.
46	dosemod	Any dose modification during protocol treatment	0=no, 1=yes	589 patients who started protocol therapy had value for this variable
47	dosered	Any dose reduction during protocol treatment	0=no, 1=yes	589 patients who started protocol therapy had value for this variable
48	acetylation	Indicator for patients with paired lysine acetylation data	1=patients had paired lysine acetylation data	Peripheral blood mononuclear cells (PBMCs) were collected at cycle 1 day 1 (C1D1) and cycle 1 day 15 (C1D15) for these patients.
49	n_cd3_c1d15	fold change in CD3 between C1D1 and C1D15	Continuous variable	397 patients who had paired PBMCs samples at C1D1 and C1D15 had value for this variable
50	n_cd14_c1d15	fold change in CD14 between C1D1 and C1D15	Continuous variable	397 patients who had paired PBMCs samples at C1D1 and C1D15 had value for this variable
51	n_cd19_c1d15	fold change in CD19 between C1D1 and C1D15	Continuous variable	397 patients who had paired PBMCs samples at C1D1 and C1D15 had value for this variable
52	n_cd45_c1d15	fold change in CD45 between C1D1 and C1D15	Continuous variable	397 patients who had paired PBMCs samples at C1D1 and C1D15 had value for this variable

Field	Variable Name	Description	Coding	Note
53	n_cd56_c1d15	fold change in CD56 between C1D1 and C1D15	Continuous variable	397 patients who had paired PBMCs samples at C1D1 and C1D15 had value for this variable
54	fatalAE	Indicator for grade 5 adverse events (AEs)	1=grade 5 AE	All death occurred while on treatment and within 30 days of last protocol therapy were considered grade 5 adverse events

Notes:

- Unless otherwise specified, blank values indicate missing data.
- In the analysis, months were calculated as days/30.4375