E2112 Primary Analysis Adverse Events Data Description

The clinicaltrials.gov protocol identifier: NCT02115282
This data dictionary is for the NCT02115282-D2 dataset.

The data in the spreadsheet are the adverse events 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.

The data reflect the study database as of May 5, 2020. Of the 589 patients who started protocol therapy and are in the toxicity analysis population, only the 519 patients who have AEs related to treatment are reported in this dataset.

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	trtm	Treatment arm randomized	A= Arm A, B= Arm B	Arm A=Entinostat+exemestane, Arm B=Placebo+exemestane
3	visit	Assessment time point	String variable	
4	toxlabel	Toxicity name	String variable	per CTCAE v4.0
5	grade	Toxicity grade	1-5	per CTCAE v4.0
6	txrel	Attribution to treatment	3=possibly, 4=probably, 5=definitely	

Notes:

- Unless otherwise specified, blank values indicate missing data
- All treatment-related AEs were included in the database, and only the worst degree was reported in the paper.