# EA1131 Primary Analysis Adverse Events Data Description

This data dictionary is for NCT02445391-D3 dataset.

The data in the spreadsheet are the adverse events analysis data for the primary manuscript on EA1131 results, published in

Mayer IA; Zhao F; Arteaga CL; Symmans WF; Park, Ben H; Burnette, Brian L; Tevaarwerk, Amye J; Garcia, Sofia F; Smith, Karen L; Makower, Della F; Block, Margaret; Morley, Kimberly A; Jani, Chirag R; Mescher, Craig; Dewani, Shabana J; Tawfik, Bernard; Flaum, Lisa E; Mayer, Erica L; Sikov, William M; Rodler, Eve T; Wagner, Lynne I; DeMichele, Angela M; Sparano JA; Wolff AC; Miller KD. Randomized Phase III Postoperative Trial of Platinum-Based Chemotherapy Versus Capecitabine in Patients With Residual Triple-Negative Breast Cancer Following Neoadjuvant Chemotherapy: ECOG-ACRIN EA1131. *J Clin Oncol*. 2021 Aug 10;39(23):2539-2551.

The data reflect the study database as of April 7, 2021. A total of 391 patients started protocol therapy. Only the 382 patients who started protocol therapy and for whom adverse event data were reported as of the data cutoff date are included.

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

| Variable Name | Description | Coding | Note |
|---|---|---|---|
| uid | Patient identifier | | De-identified patient ID, not ECOG case ID<br>Only the 382 patients who were treated and for whom adverse events were reported were included in the database |
| trtm | Treatment arm | B=Arm B (platinum)<br>C=Arm C (capecitabine) | No adverse events data were collected for patients randomized to arm A |
| visit | Assessment time point | String variable | |
| toxlabel | Toxicity name | String variable | per CTCAE v4.0 |
| grade | Toxicity grade | 1-5 | per CTCAE v4.0 |
| txrel | Attribution to treatment | 3=possibly, 4=probably, 5=definitely | |

Note: All treatment-related AEs were included in the database, and only the worst degree was reported in the paper.