E1105 Primary Analysis Description for Dataset NCT00520975-D2

The data in Dataset NCT00520975-D2 are the toxicity data for the primary manuscript E1105 (PMID: 38967884; PMCID: PMC11297090) published in the following article:

> Mezzanotte-Sharpe J, ONeill A, Mayer IA, Arteaga CL, Yang XJ, Wagner LI, Cella D, Meropol NJ, Alpaugh RK, Saphner TJ, Swaney RE, Hoelzer KL, Gradishar WJ, Abramson VG, Sundaram PK, Jilani SZ, Perez EA, Lin NU, Jahanzeb M, Wolff AC, Sledge GW, Reid SA. A randomized phase III double-blind placebo-controlled trial of first-line chemotherapy and trastuzumab with or without bevacizumab for patients with HER2/neu-positive metastatic breast cancer: a trial of the ECOG-ACRIN Cancer Research Group (E1105). Breast Cancer Res Treat. 2024 Sep;207(2):275-282. doi: 10.1007/s10549-024-07417-4. Epub 2024 Jul 5.

Notes:

- Events were classified and graded according to the Common Toxicity Criteria version 3.0 through June 30, 2011 with CTCAE version 4.0 used thereafter.
- For E1105, given the regimen used, ≥ grade 2 adverse events were to be reported only for a select group of non-hematologic events and only ≥ grade 4 hematologic adverse events were to be reported, otherwise, only ≥ grade 3 adverse events were to be reported (≥ grade 2 non-hematologic events to be reported: allergic reaction, cardiac ischemia/infarction, CNS cerebrovascular ischemia, diarrhea, dyspnea, edema (head and neck, limb, trunk/genital, viscera), hemorrhage CNS, left ventricular diastolic dysfunction, left ventricular systolic dysfunction, neuropathy (motor or sensory), thrombosis/thrombus/embolism).
- Those events attributed as possibly, probably, definitely attributed to protocol treatment are included in these data.
- Those events reported in Table 3 in the manuscript are provided in these data. Table 3 in the manuscript summarizes patients with ≥ grade 3 toxicities experienced by ≥ 2 patients, with the exception that there is 1 patient listed in Table 3 with a grade 5 'Infection Gr0-2 neut, catheter'. See Dataset NCT00520975-D1 for tox_incidence variable and more details re: Table 3 in the manuscript.
- Worst grade per patient per type is included in these data.
- To duplicate denominators used for corresponding toxicity rates in Table 3 in the manuscript: use variable advevent_none in Dataset NCT00520975-D1 to remove the patient with no toxicities reported (in addition to also removing patients who did not start protocol treatment (noprotocoltx variable in Dataset NCT00520975-D1)).
- Data provided are able to 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).

Variable Name	Description	Coding
protocol_number	Protocol number	
group_uid	De-identified case id	
toxlabel	Toxicity name	String variable

grade	Maximum grade	3=Grade 3 4=Grade 4 5=Grade 5