

## E1105 Primary Analysis Description for Dataset NCT00520975-D1

The data in Dataset NCT00520975-D1 are the analysis data for the primary manuscript E1105 (PMID: 38967884; PMCID: PMC11297090) published in the following article:

Mezzanotte-Sharpe J, O'Neill 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:

- 999=missing/unknown
- 9999=not applicable
- In the analysis, months were calculated as days/30.4375
- Table 1 in the manuscript: for Prior RT variable was meant to show n=2 missing (code 999) (n=1 in each arm)
- Table 2 in the manuscript: the multivariable 'PFS HR (95% CI), p-value' is a copy of the univariate OS estimates. The PFS multivariable HR (95% CI), p-value estimates were instead meant to be stated as: 0.70 (0.41-1.19), 0.19.
- Reas\_off\_tx variable: patient with reas\_off\_tx code 99 combines the following categories from Figure 1 in the manuscript: death, patient withdrawal, other therapy, other.
- Table 3 in the manuscript summarizes patients with  $\geq$  grade 3 toxicities experienced by  $\geq$  2 patients, with the exception that there is 1 patient listed in Table 3 with a grade 5 'Infection Gr0-2 neut, catheter'. The following statement in the manuscript on page 277 is meant to describe Table 3: "Toxicity incidence, defined as  $\geq$  grade 3 and experienced by  $\geq$  2 patients, occurred in 47% (22/47) of PLAC and 67% (30/45) of BEV patients (Table 3)" was meant to state: "Toxicity incidence, defined as  $\geq$  grade 3 and experienced by  $\geq$  2 patients, occurred in 40.4% (19/47) of PLAC and 62.2% (28/45) of BEV patients (Table 3)". The tox\_incidence variable=1 as indicator for the 19 patients on the PLAC arm and the 28 patients on the BEV arm from Table 3 in the manuscript.
- 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	
e1105rxarm	Treatment assignment	0=Arm A (placebo) 1=Arm B (Bevacizumab)
noprocoltx	Did not start protocol treatment	1=did not start protocol treatment

racecat	Race	1=White 3=Black or African American 4=Asian 5=Native Hawaiian or Other Pacific Islander
age	Age at registration (years)	Continuous variable
menopausalstat	Menopausal status at registration	1=Post menopausal 2=Premenopausal 3=Perimenopausal
ecogps	ECOG Performance Status	0=Fully active 1=Restricted
erstat	Estrogen receptor status	1=negative 2=positive
site_locreg	Involvement at registration: local/regional	1=no 2=yes
site_ipsisup	Involvement at registration: ipsilateral supraclavicular nodes	1=no 2=yes
site_oppbrst	Involvement at registration: opposite breast	1=no 2=yes
site_disnodes	Involvement at registration: distant lymph nodes	1=no 2=yes
site_bone	Involvement at registration: bone	1=no 2=yes
site_bonemar	Involvement at registration: bone marrow	1=no 2=yes
site_lung	Involvement at registration: lung	1=no 2=yes
site_liver	Involvement at registration: liver	1=no 2=yes
site_pleura	Involvement at registration: pleura	1=no 2=yes
site_other	Involvement at registration: other	1=no 2=yes
prior_horm	Prior hormone therapy	1=no 2=yes
hormadj	Prior hormone therapy (in adjuvant setting)	2=yes
hormmet	Prior hormone therapy (in metastatic setting)	2=yes
prior_rt	Prior Radiation Therapy	1=no 2=yes
prior_tax	Prior taxane therapy	1=no 2=yes
prior_dox	Prior doxorubicin therapy	1=no 2=yes
prior_tras	Prior trastuzumab (adjuvant setting)	1=no 2=yes
prior_chemoth	Prior chemotherapy (other than taxane or doxorubicin, adjuvant setting)	1=no 2=yes

carboplat	Carboplatin received	2=yes
cyc_induc	Total number induction cycles	1=6 cycles
cyc_maint	Total number maintenance cycles	Integer
reas_off_tx	Reason off treatment	2=disease progression 3=adverse events 99=death, patient withdrawal, other therapy, other
bestconfresp	Best overall response	1=complete response 2=partial response 3=stable 4=progression 8=unevaluable
stratpriortras	Stratification factor: prior trastuzumab in the adjuvant setting (reported at registration)	1=yes 2=no
stratpriortaxane	Stratification factor: prior taxane in the adjuvant setting (reported at registration)	1=yes 2=no
stratdfi	Stratification factor: disease-free interval (reported at registration)	1= ≤24 months 2= >24 months 3= not stratified on this factor
stratcarboplan	Stratification factor: carboplatin planned (reported at registration)	1=yes 2=no
agedmed	Age categorized at median (used in multivariable PFS and OS Cox models)	0= >55 1= ≤55
erpgrcat	Combined Estrogen and Progesterone Receptor Status (used in multivariable PFS and OS Cox models)	0=estrogen and progesterone negative 1=estrogen or progesterone positive
primsurg2	Most extensive primary surgical procedure prior to registration (used in multivariable PFS and OS Cox models)	0=none 1=biopsy, lumpectomy, partial mastectomy, mastectomy
pfscns	Progression-free survival status	0=censor 1=event
pfs	Progression-free survival time from registration (months)	Continuous variable
oscns	Survival status	0=alive 1=dead
os	Survival time from registration (months)	Continuous variable
facitftinduc	FACIT Fatigue Scale Score (at Cycle 6 of induction)	Integer
factgp5induc	GP5 Question: I am bothered by side effects of treatment (at Cycle 6 of induction)	0=not at all 1=a little bit 2=somewhat 3=quite a bit 4=very much
advevent_none	Patients with no adverse events reported	1=yes
clinchf	Patients with Clinical CHF	1=yes

tox_incidence	The tox_incidence variable=1 as indicator for the 19 patients on the PLAC arm and the 28 patients on the BEV arm from Table 3 in the manuscript who experienced $\geq$ grade 3 toxicities which occurred in 2 or more patients. This variable excludes the 1 patient who experienced the grade 5 ‘Infection Gr0-2 neut, catheter’.	1=yes
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