

## Description of NCT00382070-D1 the primary dataset file for NSABP-B-42

**Publication reference:** Mamounas EP, Bandos H, Lembersky BC, Jeong JH, Geyer Jr CE, Rastogi P, Fehrenbacher L, Graham ML, Chia SK, Brufsky AM, Walshe JM, Soori GS, Dakhil SR, Seay TE, Wade III JL, McCarron EC, Paik S, Swain SM, Wickerham DL, and Wolmark N. Use of letrozole after aromatase inhibitor-based therapy in postmenopausal breast cancer (NRG Oncology/NSABP B-42): a randomized, double-blind, placebo-controlled phase 3 trial. *The Lancet Oncology*. 2019; 20: 88-99. PMID: 30509771

Dataset to produce the results in the referenced publication. Additional dataset (NCT00382070-D2) that includes the reported toxicities and used to produce Table 4 of Supplementary appendix is provided separately.

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).

Variable Name	Description	Coding Scheme	Comments
SN_B42	De-identified participant ID		
ATRISK	Inclusion in the analysis status	0 = No 1 = Yes	Those that are not at risk for the primary outcome were not included in the analyses
AGECAP	Age at randomization	In years	= 90 for all patients who are 90 years of age or older
RACE	Race	1 = White 2 = Black or African American 3 = Native Hawaiian or Other Pacific Islander 4 = Asian 5 = American Indian or Alaska Native 6 = Multi-racial 9 = Unknown	
PNODE	Pathologic nodal status	0 = Negative 1 = Positive	
TSCORE	Lowest bone mineral density T score for LS spine, total hip, or femoral neck	0 = $\leq -2.0$ 1 = $> -2.0$	
RECTAMO	Did patient receive tamoxifen as adjuvant therapy	0 = No 1 = Yes	
NOMONHTAM	Number of months for tamoxifen received as adjuvant therapy prior to randomization	0 = 0 months 1 = 1-12 months 2 = 13-24 months 3 = 25-36 months	

Variable Name	Description	Coding Scheme	Comments
AIMONTHS	Number of months for AI received as adjuvant therapy prior to randomization	In months “” = Unknown	
SURG	Surgery Type	1 = Lumpectomy + Axillary Staging + RT 2 = Total Mastectomy + Axillary Staging	
TBCDRAND	Time from breast cancer diagnosis to randomization	In years	
HER2	HER2 status	0 = Negative 1 = Positive 9 = Not done/Unknown	
TRT	Randomized treatment assignment	1 = Placebo 2 = Letrozole	
TRTTIM	Duration of treatment	In months	0 = never started treatment “” = there is no follow-up
REASONTRTENDEDED	Reason Treatment Ended	-1 = Did not start treatment 0 = Unknown 1 = Treatment completed 2 = Declining bone density/Osteoporotic bone fracture 3 = Other adverse event 4 = Patient withdrew/refusal 5 = Disease progress/relapse 6 = Death on study 7 = Alternative therapy 8 = Other disease 9 = Other	
BSPb	Bisphosphonates use at baseline	0 = No 1 = Yes	
CMBisphosCont	Planned to continue bisphosphonates use after randomization	“N” = No “Y” = Yes “” = missing/unknown	
DEATH	Vital status at last follow-up	0 = Alive 1 = Dead	The corresponding time variable is TLFUP
TLFUP	Time from randomization to the last available follow-up	In months 0 = no follow-up	
CODDesc	Description of underlying cause of death	Missing if alive.	Based on the ICD-9 Code

Variable Name	Description	Coding Scheme	Comments
DFS2ndP	Disease-Free survival indicator	0 = Not event 1 = Distant Recurrence 2 = Local-Regional Recurrence 3.1 = Contralateral breast cancer 3.2 = Second non-breast primary cancer 4 = Death	The corresponding time variable is DFSTIM
DFSTIM	Time from randomization to first event	In months 0 = no clinical assessment	For non-events - time from randomization to the last physical contact
DIST	Distant recurrence indicator.	0 = No 1 = Yes	The corresponding time variable is DISTTIM
DISTTIM	Time from randomization to diagnosis of first distant recurrence.	In months 0 = no clinical assessment	For non-events - time from randomization to the last physical contact
SITDISTDESC	Description of site of first distant recurrence	Missing if no event. "Multiple Sites of Recurrence" if more than one ICD9 is associated with the same event	Based on the ICD-9 Code
BCFI	Breast Cancer Free Interval Indicator as first event	0 = Not event 1 = Distant Recurrence 2 = Local-Regional Recurrence 3 = Breast Second Primary Cancer	The corresponding time variable is BCFITIM
BCFITIM	Time from randomization to diagnosis of first breast cancer event	In months 0 = no clinical assessment	Other second primary cancers and death without evidence of recurrence were treated as censored events.
OSTEOP	Osteoporotic bone fracture indicator	0 = No 1 = Yes	The corresponding time variable is OSTEOPTIM
OSTEOPTIM	Time from randomization to diagnosis of first osteoporotic fracture	In months 0 = no clinical assessment	For non-events - time from randomization to the last physical contact
SATE	Serious arterial thrombotic event indicator	0 = No 1 = Yes	The corresponding time variable is SATETIM
SATETIM	Time from randomization to diagnosis of first arterial thrombotic event	In months 0 = no clinical assessment	For non-events - time from randomization to the last physical contact
TOXICITY	Was the toxicity information submitted for the patient?	0 = No 1 = Yes	
SAE1	Serious adverse event	Missing if SAE was not reported	Reported as possibly or probably related to treatment

<b>Variable Name</b>	<b>Description</b>	<b>Coding Scheme</b>	<b>Comments</b>
SAEGrade1	Grade of the SAE1	Missing if SAE was not reported	The highest grade for the reported toxicity
SAE2	Serious adverse event	Missing if SAE was not reported	Reported as possibly or probably related to treatment if more than one was reported
SAEGrade2	Grade of the SAE2	Missing if SAE was not reported	The highest grade for the reported toxicity