Data Dictionary for SWOG S1007 Toxicity Dataset

Adverse Events Recorded Using CTCAE v4.0 Criteria

(NCT01272037-D2-Dataset.csv)

PubMed ID: 34914339

Variable	Definition	Type	Code	Code Definition
TOXCYC	Treatment cycle number	Num		
TOXNO	Toxicity number; count of how many adverse events the participant has experienced at the time of the current adverse event	Num	Whole numbers, range of 1-15	
TOXCODE	Abbreviated label of adverse event. There is a one-to-one correspondence between TOXCODE and TOXLABEL	Char		
TOXLABEL	Label of adverse event. There is a one-to-one correspondence between TOXLABEL and TOXCODE	Char		
CDELABEL	Label of adverse event, using Common Data Element (CDE) compliant terminology	Char		
TOXCAT	Adverse event category. This is a higher-level categorization than TOXCODE and TOXLABEL	Char		
CTC_CAT	Adverse event category. This is a higher-level categorization than TOXCAT	Char		
TOXDEG	Grade of adverse event	Num	1	Mild
			2	Moderate
			3	Severe
			4	Life-threatening
			5	Death
TXATT	Attribution of adverse event to study treatment	Num	1	Unrelated
			2	Unlikely
			3	Possible
			4	Probable
			5	Definite
ALTPATID	Unique participant identifier	Char		

chemo	Indicator of being randomized to the chemotherapy arm	Num	0	No (equivalent to ARMNAME = 'Endocrine Therapy Alone')
			1	Yes (equivalent to ARMNAME = 'Chemo and Endocrine Therapy')
menop	Menopausal status	Num	0	Premenopausal
			1	Postmenopausal

Note: Only events that had at least one instance of Grade 3 or above, and with TXATT = 3, 4, or 5, were reported in the publication. Only analyzable and AE evaluable patients (include = 1 and CLINTOX = 'Y' from D1) were included in the toxicity analysis.

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).