

I-SPY 1 TRIAL: ACRIN 6657**Data Dictionary for TCIA Shared Patient Clinical Variables, July 14, 2015**

Data sheet is locked to protect from accidental changes. PW= UCSF6657

Subset of: Data Dictionary for Final, Verified Integrated Data File, March 1, 2011**UPDATES**

April 6, 2016, Replaced Her2CommPos with
Her2MostPos to agree with ACRIN statistical analysis
for primary aim paper.
Changed "ISPY ID" header to "SUBJECTID" for
consistency with training data set in BMMR

Variable Name	Variable Description	Format
SUBJECTID	I-SPY ID de-identifies a patient's CALGB and ACRIN ID	Integer 1001-1239
DataExtractDt	Date clinical data was downloaded from the CALGB database	Date format mm/dd/yyyy
Patient Demographics		
Age	Patient Age	Number
race_id	Patient Race 1=Caucasian 3=African American 4=Asian 5=Native Hawaiian/Pacific Islander 6=American Indian/Alaskan Native 50=Multiple race	Number

On-Study Data (Pre-Treatment)		
ERpos	Estrogen Receptor Status (Allred Score or Community determined), pre-treatment 0=Negative 1=Positive 2=Indeterminate	Number
PgRpos	Progesterone Receptor Status (Allred Score or Community determined), pre-treatment 0=Negative 1=Positive 2=Indeterminate	Number
HR Pos	Hormone Receptor Status, pre-treatment 0=Negative for both ER and PR 1=Positive if either ER or PR was Positive 2=Indeterminate if both ER and PR were Indeterminate	Number
Her2MostPos (replaced Her2CommPos, 4/6/2016)	Her2 Status, pre-treatment, adding in Central Her2 IHC results for missing Community Status 0=Negative 1=Positive Blank= indeterminate or not done	Number
HR_HER2_CATEG ORY	3-level HR/Her2 category pre-treatment 1=HR Positive, Her2 Negative 2=Her2 Positive 3=Triple Negative	Number
HR_HER2_STAT US	3-level HR/Her2 status pre-treatment HRposHER2neg = HR Positive, Her2 Negative HER2pos = Her2 Positive TripleNeg =Triple Negative	Text
BilateralCa	Does the patient have bilateral breast cancer prior to neoadjuvant therapy? 0=No 1=Yes	Number
Laterality	Index Tumor Laterality 1=Left 2=Right	Number

Imaging Data		
MRI LD:	LD spans all disease present (inv & DCIS) even if there is intervening normal tissue, in mm	Number
Baseline	Timepoint 1= baseline	
1-3d AC	Timepoint 2= 1-3days after start of AC	
InterReg	Timepoint 3= Inter-regimen	
PreSurg	Timepoint 4= Pre-Surgery Blank=not available	

***Of Note: Clinical Response & Evaluation is to coincide with MRI schedule.**

T1= Pre-Treatment/Baseline

T2 = Early Treatment Day1, cycle 2

T3= Inter-Regimen

T4= Prior to Surgery for Response evaluation form and sample Post-surgery