

The below data dictionary is for the EA1141 analysis dataset: “ea1141_year0_screening_derived.sas7bdat”.

This dataset contains one record per participant registered, and is unique by SUBJECT_DE. There are a total of 49 variables contained in this dataset.

Variable name	Variable definition	Code Table/Values
Year 0 image completion variables [16 variables]		
SUBJECT_DE	De-identified case number (numeric).	Num
TOMO_YR0	Was the Year 0 study screening Tomo performed? [taken from IMAG_COMPL from the Tomosynthesis YR-0 Interpretation form] (numeric, code table).	0=No 1=Yes
TOMO_YR0_DATE_YYYY TOMO_YR0_DATE_DAYS	Date of Year 0 study screening Tomo [taken from IMAG_DT from the Tomosynthesis YR-0 Interpretation form] (numeric, date). <i>NOTE: Per HIPAA standards, for each date, the exact date is not given. Instead, two variables are supplied, one giving the year, and one giving days since the baseline date.</i>	Num .N=N/A (Year 0 Tomo not performed)
TOMO_YR0_REASON	Reason Year 0 Tomo not performed (detailed) [taken from IMAG_NOT_COMPL from the Tomosynthesis YR-0 Interpretation form] (numeric, code table).	.N=N/A (Year 0 Tomo performed) 1=Patient refusal/withdrawal 2=Screening unable to be performed/rescheduled 3=Technical failure 4=Subject presented with nipple discharge 5=Subject was found to be ineligible, and site mistakenly did not perform imaging for that reason 6=Physician felt that the patient’s GFR was too low for an elective MRI. As a

		result, neither the Tomo nor the MRI were performed
		7=Patient symptomatic
		8=MRI could not be performed due to IV infiltration. Tomo was not performed either
TOMO_YR0_REASON_SIMPLE	Reason Year 0 Tomo not performed (<u>simplified</u>) [taken from IMAG_NOT_COMPL from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 Tomo performed)
		1=Patient refusal/withdrawal
		2=Screening unable to be performed/rescheduled
		3=Medical reason
		4=Site error
TOMO_YR0_INWINDOW	Was the Year 0 study screening Tomo performed in window per protocol? [taken from TRT_ARM_ASGN_DATE from the Treatment Assignment form and IMAG_DT from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 Tomo not performed)
		0=No (>30 days from study randomization)
		1=Yes (≤30 days from study randomization)
TOMO_YR0_INWINDOW_CAT	Out-of-window categories for Year 0 study screening Tomo [taken from TRT_ARM_ASGN_DATE from the Treatment Assignment form and IMAG_DT from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 Tomo not performed or Year 0 Tomo in window)
		1=31-40 days
		2=41-60 days
		3=>60 days
	NOTE: If TOMO_YR0_INWINDOW=1: Yes, then this variable is set to .N.	
MRI_YR0	Was the Year 0 study abMRI performed? [taken from IMAG_COMMENT_YN from the MRI YR-0 Interpretation form] (<u>numeric, code table</u>).	0=No
		1=Yes
MRI_YR0_DATE_YYYY MRI_YR0_DATE_DAYS	Date of Year 0 study screening abMRI [taken from IMAG_DT from the MRI YR-0 Interpretation form] (<u>numeric, date</u>).	Num
		.N=N/A (Year 0 MRI not performed)
	NOTE: Per HIPAA standards, for each date, the exact date is not given. Instead, two variables are supplied, one giving the year, and one giving days since the baseline date.	
MRI_YR0_REASON	Reason Year 0 abMRI not performed (<u>detailed</u>) [taken from IMAG_NOT_COMMENT from the MRI YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 MRI performed)
		1=Adverse event
		2=Claustrophobia
		3=Injection complication

		4=Equipment failure/error
		5= Patient refusal/withdrawal
		6= Screening unable to be performed/rescheduled
		7=Unknown material of tear duct plug
		8=Subject could not fit in the MRI scanner
		9=Subject presented with breast problem
		10=Subject was found to be ineligible, and site mistakenly did not perform imaging for that reason
		11=Physician felt that the patient's GFR was too low for an elective MRI
		12=Elevated b-HCG
		13=Lack of IV access
		14=Patient had difficulty breathing due to positioning in the MR scanner
		15=Tomo could not be scheduled and performed. As a result, the site did not perform the MRI either.
		16=Patient was symptomatic
		17=Patient was uncomfortable
		18=Subject creatinine did not meet imaging criteria
		19=IV infiltration
		20=Unknown
MRI_YR0_REASON_SIMPLE	Reason Year 0 abMRI not performed (<u>simplified</u>) [taken from IMAG_NOT_COMMEN from the MRI YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 MRI performed)
		1=Patient refusal/withdrawal
		2=Screening unable to be performed/rescheduled
		3=Claustrophobia/Patient uncomfortable in scanner
		4=Medical reason
		5=Site error
		6=Unknown
MRI_YR0_INWINDOW	Was the Year 0 abMRI performed in window per protocol? [taken from TRT_ARM_ASGN_DATE from the Treatment Assignment form and IMAG_DT from the MRI YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 MRI not performed)
		0=No (>30 days from study randomization)
		1=Yes (≤30 days from study randomization)

MRI_YR0_INWINDOW_CAT	<p>Out-of-window categories for Year 0 abMRI [taken from TRT_ARM_ASGN_DATE from the Treatment Assignment form and IMAG_DT from the MRI YR-0 Interpretation form] (numeric, code table).</p> <p>NOTE: If MRI_YR0_INWINDOW=1:Yes, then this variable is set to .N.</p>	<p>.N=N/A (Year 0 MRI not performed or Year 0 MRI in window)</p> <p>1=31-40 days</p> <p>2=41-60 days</p> <p>3=>60 days</p>
RANDO_ORDER_YR0	<p>Were the Year 0 study scans performed in the correct randomized order per protocol? [taken from the IMAG_DT and IMAG_TIME variables from the Tomosynthesis YR-0 Interpretation form and the MRI YR-0 Interpretation form] (numeric, code table).</p>	<p>.N=N/A (Year 0 Tomo not performed or Year 0 MRI not performed)</p> <p>1=Scans performed <u>out</u> of randomized order</p> <p>2=Scans performed in randomized order (same day)</p> <p>3=Scans performed in randomized order (next day)</p> <p>4=Scans performed in randomized order (>1 day apart)</p>
Year 0 detailed Tomosynthesis screening variables [19 variables]		
TOMO_MANUFACTURER_YR0	<p>Tomo machine manufacturer [taken from MACH_MANU from the Tomosynthesis YR-0 Interpretation form] (numeric, code table).</p>	<p>.N=N/A (Year 0 Tomo not performed)</p> <p>.M=Missing</p> <p>1=Siemens</p> <p>2=GE</p> <p>3=Philips</p> <p>4=Hologic</p>
TOMO_TYPE_YR0	<p>Type of DBT [taken from DBT_TP from the Tomosynthesis YR-0 Interpretation form] (numeric, code table).</p>	<p>.N=N/A (Year 0 Tomo not performed)</p> <p>.M=Missing</p> <p>1=2D CC and MLO views plus CC and MLO Tomo views</p> <p>2=2D CC and MLO views plus MLO Tomo view</p> <p>3=2D CC and MLO views plus CC Tomo view</p> <p>4=CC and MLO Tomo views with synthetic 2D views</p> <p>6=Other</p>

TOMO_TYPE_OTHERSPEC_YR0	<p>Type of DBT, other specify [taken from DBT_TP from the Tomosynthesis YR-0 Interpretation form] (<u>character</u>).</p> <p>NOTE: If TOMO_TYPE_YR0=6:Other, then this variable is populated; otherwise, this variable is set to .N.</p>	<p>Char (\$400.)</p> <p>.N=N/A (Year 0 Tomo not performed, or DBT type is not 6:Other)</p>
<p>TOMO_PRIORMAMMODATE_YR0_YYYY</p> <p>TOMO_PRIORMAMMODATE_YR0_DAYS</p>	<p>Date of most recent prior mammogram [taken from MAMMO_DT from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, date</u>).</p> <p>NOTE 1: Per HIPAA standards, for each date, the exact date is not given. Instead, two variables are supplied, one giving the year, and one giving days since the baseline date.</p> <p>NOTE 2: There were a small number of partial dates. When the year was known, but the exact day was not, TOMO_PRIORMAMMODATE_YR0_YYYY will be populated, but TOMO_PRIORMAMMODATE_YR0_DAYS will be set to .M.</p>	<p>Num</p> <p>.N=N/A (Year 0 Tomo not performed)</p> <p>.M=Missing</p>
TOMO_PRIORUS_YR0	<p>Has the patient had a prior screening ultrasound? [taken from ULTRA_YN from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, code table</u>).</p>	<p>.N=N/A (Year 0 Tomo not performed)</p> <p>.M=Missing</p> <p>0=No</p> <p>1=Yes</p>
<p>TOMO_PRIORUSDATE_YR0_YYYY</p> <p>TOMO_PRIORUSDATE_YR0_DAYS</p>	<p>Date of most recent prior screening ultrasound [taken from ULTRA_DT from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, date</u>).</p> <p>NOTE 1: Per HIPAA standards, for each date, the exact date is not given. Instead, two variables are supplied, one giving the year, and one giving days since the baseline date.</p> <p>NOTE 2: There were a small number of partial dates. When the year was known, but the exact day was not, TOMO_PRIORUSDATE_YR0_YYYY will be populated, but TOMO_PRIORUSDATE_YR0_DAYS will be set to .M.</p> <p>NOTE 3: If TOMO_PRIORUS_YR0=0:No, then this variable is set to .N.</p>	<p>Num</p> <p>.N=N/A (Year 0 Tomo not performed or no prior screening ultrasound)</p> <p>.M=Missing</p>

TOMO_BREAST_DENSITY_YR0	Breast density as reported on Tomo? [taken from BRST_DSTY from the Tomosynthesis YR-0 Interpretation form] (numeric, code table).	.N=N/A (Year 0 Tomo not performed)
		.M=Missing
		1=Almost entirely fat (<25% fibroglandular)
		2=Scattered fibroglandular densities (25%-50% fibroglandular)
		3=Heterogeneously dense (51%-75% fibroglandular)
4=Extremely dense (>75% fibroglandular)		
TOMO_REPEATTECH_YR0	Were repeat or additional views performed for technical reasons? [taken from ADDTL_VIEWS_REAS_YN from the Tomosynthesis YR-0 Interpretation form] (numeric, code table).	.N=N/A (Year 0 Tomo not performed)
		.M=Missing
		0=No 1=Yes
TOMO_REPEATTECH_REASON_YR0	Reason why repeat or additional views were performed? [taken from ADDTL_VIEW_REAS from the Tomosynthesis YR-0 Interpretation form] (numeric, code table). NOTE: If TOMO_REPEATTECH_YR0=0:No, then this variable is set to .N.	.N=N/A (Year 0 Tomo not performed or repeat/additional views not performed)
		.M=Missing
		1=Motion
		2=Artifact
		3=Positioning
4=Exposure		
5=Other		
TOMO_REPEATTECH_REASON_OTH_YR0	Reason why repeat or additional views were performed (Other, specify)? [taken from ADDTL_VIEW_REAS from the Tomosynthesis YR-0 Interpretation form] (character). NOTE 1: If TOMO_REPEATTECH_YR0=0:No, then this variable is set to .N. NOTE 2: If TOMO_REPEATTECH_REASON_YR0=5:Other, then this variable is populated. Otherwise, it is set to .N.	Char (\$400.)
		.N=N/A (Year 0 Tomo not performed or repeat/additional views not performed or reason repeat/additional views performed is not Other) .M=Missing
TOMO_REPEATTECH_NUM_YR0	Number of repeat or additional views [taken from ADDTL_VIEW_NUM from the Tomosynthesis YR-0 Interpretation form] (numeric). NOTE: If TOMO_REPEATTECH_YR0=0:No, then this variable is set to .N.	Num .N=N/A (Year 0 Tomo not performed or repeat/additional views not performed) .M=Missing

TOMO_ADDTLVIEWS_FINDING_YR0	Were additional diagnostic views performed to evaluate a possible finding on the screening views? [taken from ADDTL_VIEW_SCRN_YN from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 Tomo not performed)
		.M=Missing
		0=No
		1=Yes
TOMO_TARGETEDUS_YR0	Was targeted ultrasound performed to evaluate a finding on DBT? [taken from TARG_US_DBT_FIND_YN from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 Tomo not performed)
		.M=Missing
		0=No
		1=Yes
TOMO_CALLBACK_YR0	Was a call back given based on DBT? [taken from a Yes response to either ADDTL_VIEW_SCRN_YN or TARG_US_DBT_FIND_YN from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 Tomo not performed)
		.M=Missing
		0=No
		1=Yes
TOMO_BIRADS_YR0	Final BIRADS from Tomo [taken from BIRADS_1_5 from the Tomosynthesis YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 Tomo not performed)
		1=1:Negative
		2=2:Benign
		3=3:Probably Benign
		4=4:Suspicious Abnormality
		5=5:Highly Suggestive of Malignancy
TOMO_BIRADS_NUM35_YR0	Number of BIRADS 3, 4, or 5 lesions reported on Tomo [taken from BIRADS_3_5_FIND from the Tomosynthesis YR-0 Interpretation form] (<u>numeric</u>). <i>NOTE: If TOMO_BIRADS_YR0 in (1,2), then this variable is set to 0.</i>	Num
		.N=N/A (Year 0 Tomo not performed)
TOMO_SHORTTERMFUP_YR0	Was there short-term FUP based on the DBT? (<u>numeric, code table</u>). <i>NOTE: This is a derived variable, and was defined as at least one lesion rated BI-RADS 3.</i>	.N=N/A (Year 0 Tomo not performed)
		0=No
		1=Yes
Year 0 detailed MRI screening variables [14 variables]		
MRI_MANUFACTURER_YR0	MRI magnet manufacturer [taken from MRI_MAG_MANU from the MRI YR-0 Interpretation form] (<u>numeric, code table</u>).	.N=N/A (Year 0 MRI not performed)
		.M=Missing
		1=GE
		2=Philips
		3=Siemens
		4=Toshiba

MRI_MAGNET_YR0	MRI magnetic field strength [taken from MAG_FIELD_STRG from the MRI YR-0 Interpretation form] (numeric, code table).	.N=N/A (Year 0 MRI not performed) .M=Missing 1=1.5T 2=3T
MRI_EXAMTIMEL10_YR0	Was the total length of the AB-MR exam less than 10 minutes? [taken from WAS_MR_LESS_10_MIN_YN from the MRI Internal Imaging QC form] (numeric, code table). <i>NOTE: There is an apparent discrepancy with 2 cases (1498354, 231877). On the MRI Internal Imaging QC form, completed by the Imaging Core Lab, these 2 cases answered Yes to whether the scan was <10min, but gave the scan time as exactly 10 mins ('10 00'). Data are kept as is.</i>	.N=N/A (Year 0 MRI not performed) .M=Missing 0=No 1=Yes
MRI_EXAMTIME_YR0	Total recorded length of the AB-MR exam (min) [taken from MR_TIME from the MRI Internal Imaging QC form] (numeric).	Num .N=N/A (Year 0 MRI not performed) .M=Missing
MRI_ULTRAFAST_YR0	Was optional ultrafast imaging performed? [taken from ULTFAST_ADV_IMAG from the MRI Internal Imaging QC form] (numeric, code table).	.N=N/A (Year 0 MRI not performed) .M=Missing 0=No 1=Yes
MRI_PRIORMRI_YR0	Has the patient had any prior breast MRIs? [taken from PRIOR_MRI_YN from the MRI YR-0 Interpretation form] (numeric, code table). <i>NOTE: This question is answered by all cases, even if the baseline (YR-0) MRI was not performed.</i>	0=No 1=Yes 99=Unknown
MRI_PRIORMRIDATE_YR0_YYYY MRI_PRIORMRIDATE_YR0_DAYS	Date of prior breast MRI [taken from MRI_DT from the MRI YR-0 Interpretation form] (numeric, date). <i>NOTE 1: Per HIPAA standards, for each date, the exact date is not given. Instead, two variables are supplied, one giving the year, and one giving days since the baseline date.</i> <i>NOTE 2: This variable will only be populated if MRI_PRIORMRI_YR0=1:Yes; otherwise, it is set to .N.</i>	Num .N=N/A (No prior breast MRI, or unknown)

MRI_MENSTRUALSTATUS_YR0	Menstrual status [taken from MENST_STATUS from the MRI YR-0 Interpretation form] (numeric, code table).	.N=N/A (Year 0 MRI not performed)
		.M=Missing
		1=Pre-menopausal
		2=Peri-menopausal (last menses <1 year ago)
		3=Naturally post-menopausal (last menses >1 year ago)
MRI_BREAST_DENSITY_YR0	Breast density as reported on MRI? [taken from BRST_DSTY from the MRI YR-0 Interpretation form] (numeric, code table).	.N=N/A (Year 0 MRI not performed)
		.M=Missing
		1=Almost entirely fat (<25% fibroglandular)
		2=Scattered fibroglandular densities (25%-50% fibroglandular)
		3=Heterogeneously dense (51%-75% fibroglandular)
MRI_PARENCHYMALENH_YR0	Background parenchymal enhancement as reported on MRI? [taken from DENT_BREAST_PAREN from the MRI YR-0 Interpretation form] (numeric, code table).	.N=N/A (Year 0 MRI not performed)
		.M=Missing
		1=Minimal
		2=Mild
		3=Moderate
MRI_BIRADS_YR0	Final BIRADS from MRI [taken from BIRADS_1_5 from the MRI YR-0 Interpretation form] (numeric, code table).	.N=N/A (Year 0 MRI not performed)
		1=1:Negative
		2=2:Benign
		3=3:Probably Benign
		4=4:Suspicious Abnormality
MRI_BIRADS_NUM35_YR0	Number of BIRADS 3, 4, or 5 lesions reported on MRI [taken from BIRADS_3_5_FIND from the MRI YR-0 Interpretation form] (numeric). <i>NOTE: If MRI_BIRADS_YR0 in (1,2), then this variable is set to 0.</i>	Num
		.N=N/A (Year 0 MRI not performed)

MRI_SHORTTERMFUP_YR0	<p>Was there short-term FUP based on the MRI? (numeric, code table).</p> <p><i>NOTE: This is a derived variable, and was defined as at least one lesion rated BI-RADS 3.</i></p>	<p>.N=N/A (Year 0 MRI not performed)</p> <p>0=No</p> <p>1=Yes</p> <p>1.5=Yes: but single BIRADS 3 lesion that was downgraded, or every BIRADS 3 lesion for the case was downgraded.</p>
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