

The below data dictionary is for the EA1141 analysis dataset: “ea1141_12month_fup.sas7bdat”.

This dataset contains one record per participant registered, and is unique by SUBJECT_DE. There are a total of 29 variables contained in this dataset.

Variable name	Variable definition	Code Table/Values
SUBJECT_DE	De-identified case number (<u>numeric</u>).	Num
TOMO_YR1	<p>Was the Year 1 study screening Tomo performed? [taken from IMAG_COMPL from the Tomosynthesis YR-1 Interpretation form] (<u>numeric, code table</u>).</p> <p>NOTE: Case 4295391 had only 1 scan at baseline, and thus per protocol was not to be screened at year 1, but the second imaging procedure was still performed (protocol deviation). This case is coded TOMO_YR1=1.5.</p>	<p>.N=Case did not receive any imaging at baseline, and thus was taken off-study</p> <p>.O=Case had only 1 scan at baseline, and thus per protocol was not to be screened at year 1</p> <p>.P=Case had screen-detected cancer at baseline or had cancer prior to year 1, and thus was taken off-study</p> <p>.Q=Case died prior to 11 months (330 days)</p> <p>.R=Case withdrew prior to 11 months (330 days)</p> <p>.F=Form not yet submitted</p> <p>0=No</p> <p>1=Yes</p> <p>1.5=Yes (scan done in error as case only had 1 scan done at baseline)</p>
TOMO_YR1_REASON	<p>Reason the Year 1 study screening Tomo was not performed [taken from IMAG_NOT_COMPL from the Tomosynthesis YR-1 Interpretation form] (<u>numeric, code table</u>).</p> <p>NOTE: If TOMO_YR1 in(.N.,O.,P.,Q.,R,1,1.5) then TOMO_YR1_REASON=.N.</p>	<p>.N=N/A (year 1 scan not expected or year 1 scan was performed)</p> <p>.F=Form not yet submitted</p> <p>1=Participant refusal/withdrawal</p> <p>2=Unable to be performed/rescheduled</p> <p>3=Unable to contact patient/Lost to follow-up/Patient moving</p> <p>4=Insurance issue</p> <p>5=Patient felt lump and had a diagnostic mammo/US prior to year 1 time point.</p> <p>6=Patient had a mammo prior to the year 1 time point, and did not wish the repeat the mammo.</p> <p>7=After enrollment, patient saw her PCP for an annual exam the morning of her year 0 imaging. Her PCP</p>

		<p>palpated a concerning area in her left breast and changed the imaging to diagnostic as opposed to screening. Both the year 0 tomo and AB-MRI were completed, but the patient did not receive further study imaging.</p> <p>8=Site did incorrect AB-MR sequence at baseline and mistakenly took the patient off study.</p> <p>9=Patient was admitted to hospital and underwent neurosurgery for metastatic disease to brain</p> <p>10=Patient had imaging done outside of the study.</p> <p>11=Patient had recent rib injury.</p>
TOMO_YR1_REASON_SIMPLE	<p>Reason the Year 1 study screening Tomo was not performed (simplified) [taken from IMAG_NOT_COMPL from the Tomosynthesis YR-1 Interpretation form] (numeric, code table).</p> <p>NOTE: If TOMO_YR1 in(.N.,O.,P.,Q.,R,I,1.5) then TOMO_YR1_REASON_SIMPLE=.N.</p>	<p>.N=N/A (year 1 scan not expected or year 1 scan was performed)</p> <p>.F=Form not yet submitted</p> <p>1=Participant refusal/withdrawal</p> <p>2=Screening unable to be performed/rescheduled</p> <p>3=Medical reason</p> <p>4=Insurance issue</p> <p>5=Imaging was done at an outside institution or outside of the study</p> <p>6=Could not contact patient/patient lost to follow-up</p> <p>7=Site error</p>
TOMO_YR1_DATE_YYYY TOMO_YR1_DATE_DAYS	<p>Date of Year 1 study screening Tomo [taken from IMAG_DT from the Tomosynthesis YR-1 Interpretation form] (numeric, date).</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: If TOMO_YR1 in(.N.,O.,P.,Q.,R,0) then TOMO_YR1_DATE=.N.</p>	<p>Num</p> <p>.N=N/A (year 1 scan not expected or not performed)</p> <p>.F=Form not yet submitted</p>
MRI_YR1	<p>Was the Year 1 study screening MRI performed? [taken from IMAG_COMMENT_YN from the MRI YR-1 Interpretation form] (numeric, code table).</p>	<p>.N=Case did not receive any imaging at baseline, and thus was taken off-study</p> <p>.O=Case had only 1 scan at baseline, and thus per protocol was not to be screened at year 1</p>

	<p>NOTE: Case 4295391 had only 1 scan at baseline, and thus per protocol was not to be screened at year 1, but the second imaging procedure was still performed (protocol deviation). This case is coded MRI_YR1=1.5.</p>	<p>.P=Case had screen-detected cancer at baseline or had cancer prior to year 1, and thus was taken off-study</p> <p>.Q=Case died prior to 11 months (330 days)</p> <p>.R=Case withdrew prior to 11 months (330 days)</p> <p>.F=Form not yet submitted</p> <p>0=No</p> <p>1=Yes</p> <p>1.5=Yes (scan done in error as case only had 1 scan done at baseline)</p>
<p>MRI_YR1_REASON</p>	<p>Reason the Year 1 study screening MRI was not performed [taken from IMAG_NOT_COMMEN from the MRI YR-1 Interpretation form] (numeric, code table).</p> <p>NOTE: If MRI_YR1 in(.N,.O,.P,.Q,.R,1,1.5) then MRI_YR1_REASON=.N.</p>	<p>.N=N/A (year 1 scan not expected or year 1 scan was performed)</p> <p>.F=Form not yet submitted</p> <p>1=Participant refusal/withdrawal</p> <p>2=Unable to be performed/rescheduled</p> <p>3=Unable to contact patient/Lost to follow-up/Patient moving</p> <p>4=Injection complication</p> <p>5=Claustrophobia</p> <p>6=Adverse event</p> <p>7=After enrollment, patient saw her PCP for an annual exam the morning of her year 0 imaging. Her PCP palpated a concerning area in her left breast and changed the imaging to diagnostic as opposed to screening. Both the year 0 tomo and AB-MRI were completed, but the patient did not receive further study imaging.</p> <p>8=Site did incorrect AB-MR sequence at baseline and mistakenly took the patient off study.</p> <p>9=Insurance issue</p> <p>10=Patient was admitted to hospital and underwent neurosurgery for metastatic disease to brain.</p> <p>11=Patient had recent rib injury and could not tolerate AB-MR.</p> <p>12=Site failure</p> <p>13=Site PI (radiologist) left and no radiologist was authorized to perform the year 1 screen.</p> <p>99=Unknown</p>

MRI_YR1_REASON_SIMPLE	<p>Reason the Year 1 study screening MRI was not performed (simplified) [taken from IMAG_NOT_COMMEN from the MRI YR-1 Interpretation form] (numeric, code table).</p> <p>NOTE: If MRI_YR1 in(.N,.O,.P,.Q,.R,1.1.5) then MRI_YR1_REASON_SIMPLE=.N.</p>	<p>.N=N/A (year 1 scan not expected or year 1 scan was performed)</p> <p>.F=Form not yet submitted</p> <p>1=Participant refusal/withdrawal</p> <p>2=Screening unable to be performed/rescheduled</p> <p>3=Claustrophobia/patient uncomfortable in scanner</p> <p>4=Medical reason</p> <p>5=Insurance issue</p> <p>6=Could not contact patient/patient lost to follow-up</p> <p>7=Site error</p> <p>99=Unknown</p>
MRI_YR1_DATE_YYYY MRI_YR1_DATE_DAYS	<p>Date of Year 1 study screening MRI [taken from IMAG_DT from the MRI YR-1 Interpretation form] (numeric, date).</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: If MRI_YR1 in(.N,.O,.P,.Q,.R,0) then MRI_YR1_DATE=.N.</p>	<p>Num</p> <p>.N=N/A (year 1 scan not expected or not performed)</p> <p>.F=Form not yet submitted</p>
YR1_IMAGING	<p>Combined derived variable of year 1 imaging status (numeric, code table).</p> <p>NOTE: This is derived from TOMO_YR1 and MRI_YR1. The only difference is that the options (.N, .O, .P, .Q, .R) for the TOMO_YR1 and MRI_YR1 variables are set to 0=No for this variable, and 1.5 is set to 1=Yes.</p>	<p>.F= Forms not yet submitted</p> <p>0 = No year 1 imaging</p> <p>0.5 = Only one scan performed at year 1</p> <p>1= Both scans performed at year 1</p>
FUP_12MO	<p>Was patient follow-up performed at 12 months? (numeric, code table).</p> <p>NOTE 1: This is derived from both the Follow-up Patient Questions form and the RA Follow-up Records Assessment form.</p> <p>NOTE2: If FUP_12MO in(0,2,3), then FUP_12MO_REASON is populated.</p>	<p>.N=N/A (case did not have any imaging at baseline)</p> <p>.P= N/A (case had screen-detected cancer at baseline or had cancer prior to year 1, and thus was taken off-study)</p> <p>.Q=N/A (case died prior to 11 months (330 days))</p> <p>.R= N/A (case withdrew consent prior to 11 months (330 days))</p> <p>.F=Forms not yet submitted</p> <p>0=FUP not performed</p>

		1=Yes: both patient contact and record assessment
		2=Yes: only patient contact
		3=Yes: only record assessment
FUP_12MO_REASON	Reason patient follow-up was not performed at 12 months. (numeric, code table) NOTE: This variable has a value of .N if FUP_12MO=1.	.N=N/A (case was diagnosed with cancer following baseline screening, case did not have any imaging at baseline, case withdrew consent prior to 11 months (330 days), case died prior to 11 months (330 days), or FUP was performed)
		.F=Forms not yet submitted
		1=Patient form not submitted
		2=RA form not submitted
		3=No attempt to administer FUP form to patient. RA form not submitted/Record assessment not performed.
		4=No attempt to administer FUP form to patient. Record assessment performed.
		5=No response after multiple attempts to contact the patient. RA form not submitted/Record assessment not performed.
		6=No response after multiple attempts to contact the patient. Record assessment performed.
		7=Patient withdrew consent. RA form not submitted/Record assessment not performed.
		8=Patient withdrew consent. Record assessment performed.
		9=Patient refusal. RA form not submitted/Record assessment not performed.
		10=Patient refusal. Record assessment performed.
		11=Site error. Patient contact questions not administered. Record assessment performed.
		12=After enrollment, patient saw her PCP for an annual exam the morning of her year 0 imaging. Her PCP palpated a concerning area in her left breast and changed the imaging to diagnostic as opposed to screening. Both the year 0 tomo and AB-MRI were completed, but the patient did not receive further study imaging, and the site did not attempt further patient contact. RA form not

		submitted/Record assessment not performed.
		13= Site did incorrect AB-MR sequence at baseline and mistakenly took the patient off study. Record assessment performed.
		14=Could not contact patient as patient was admitted to hospital and underwent neurosurgery for metastatic disease to brain. Record assessment performed.
FUP_12MO_STATUS	Status of patient follow-up at 12 months (<u>numeric, code table</u>). <i>NOTE: This is derived from both the Follow-up Patient Questions and RA Follow-up Records Assessment forms.</i>	.N=N/A (case was diagnosed with cancer following baseline screening, case did not have any imaging at baseline, case withdrew consent prior to 11 months (330 days), or case died prior to 11 months (330 days)) .F=Forms not yet submitted 0=Data not available 1=Data available based on 1-year FUP: both patient contact and record assessment 2=Data available based on 1-year FUP: only patient contact 3=Data available based on 1-year FUP: only record assessment
FUP_12MO_DATE_YYYY FUP_12MO_DATE_DAYS	Date of follow-up for 12-month patient contact [taken from the FU_DT variable from the Follow-up Patient Questions form in the Follow-up – 12 Months folder] (<u>numeric, date</u>). <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: If FUP_12MO_STATUS=0 then this variable is .M. If FUP_12MO_STATUS=3 then this variable is .N.</i>	Num .N=N/A .F=Form not yet submitted .M=Data not available
FUP_12MO_DATERA_YYYY FUP_12MO_DATERA_DAYS	Date of 12-month follow-up record assessment [taken from the FOLLOW_UP_RECS_DT variable from the RA Follow-up Records Assessment form in the Follow-up – 12 Months folder] (<u>numeric, date</u>). <i>NOTE 1: Per HIPAA standards, for each date, the exact date is not given. Instead,</i>	Num .N=N/A .F=Form not yet submitted .M=Data not available

	<p><i>two variables are supplied, one giving the year, and one giving days since the baseline date.</i></p> <p>NOTE 2: If FUP_12MO_STATUS=0 then this variable is .M. If FUP_12MO_STATUS=2 then this variable is .N.</p>	
FUP_12MO_330DAYS	<p>Whether or not complete FUP was obtained (330 days) using randomization date (<u>numeric, code table</u>).</p> <p>NOTE: For cases with FUP_12MO_STATUS=1, if either patient contact or record assessment was \geq 330 days from randomization, this is coded as 1.</p>	<p>.N=N/A .F=Forms not yet submitted .M=Data not available 0=FUP < 330 days at 12-month time point 1=FUP \geq 330 days at 12-month time point</p>
FUP_12MO_330DAYSYR0	<p>Whether or not complete FUP was obtained (330 days) using year 0 screening date (<u>numeric, code table</u>).</p> <p>NOTE: For cases with FUP_12MO_STATUS=1, if either patient contact or record assessment was \geq 330 days from year 0 screening, this is coded as 1.</p>	<p>.N=N/A .F=Forms not yet submitted .M=Data not available 0=FUP < 330 days at 12-month time point 1=FUP \geq 330 days at 12-month time point</p>
FUP_12MO_DATELASTRA_YYYY FUP_12MO_DATELASTRA_DAYS	<p>Date of last follow-up timepoint [taken from the FU_DT_PREV and FU_DT_PREV_NA variables from the RA Follow-up Records Assessment form in the Follow-up – 12 Months folder] (<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: If FUP_12MO_STATUS=0 then this variable is .M. If FUP_12MO_STATUS=2 then this variable is .N.</p>	<p>Num</p> <p>.N=N/A .F=Form not yet submitted .O=Site checked “Date of last follow-up timepoint – Not applicable” .M=Data not available</p>
FUP_12MO_CANCER	<p>Cancer status at 12 months: Was the patient diagnosed with breast cancer? [taken from BRST_CNCR_DX across both the Follow-up Patient Questions and RA Follow-up Records Assessment forms] (<u>numeric, code table</u>).</p>	<p>.N=N/A (case was diagnosed with cancer following baseline screening, case did not have any imaging at baseline, or case died prior to 11 months, or case withdrew consent prior to 11 months .F=Form not yet submitted</p>

	<p>NOTE 1: If FUP_12MO_STATUS=0 then this variable is .M, along with the subsequent cancer variables.</p> <p>NOTE 2: In the case where patient contact and record assessment were both done, discordance is checked for. No discordance was observed.</p>	<p>.M=Data not available</p> <p>0=No</p> <p>1=Yes</p>
<p>FUP_12MO_CANCERDATE_YYYY FUP_12MO_CANCERDATE_DAYS</p>	<p>Date of cancer diagnosis [taken from DX_DT from the RA Follow-up Records Assessment form, as the date from medical records will be considered definitive] (<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: If FUP_12MO_CANCER=0 then FUP_12MO_CANCERDATE=.N.</p>	<p>Num</p> <p>.N=N/A</p> <p>.F=Form not yet submitted</p> <p>.M=Data not available</p>
<p>FUP_12MO_CANCERDETECT</p>	<p>If cancer, how was the breast cancer detected? [taken from BRST_CNCR_DTCTN from the RA Follow-up Records Assessment form] (<u>numeric, code table</u>).</p> <p>NOTE: If FUP_12MO_CANCER=0 then FUP_12MO_CANCERDATE=.N.</p>	<p>.N=N/A</p> <p>.F=Form not yet submitted</p> <p>.M=Data not available</p> <p>1=Patient detected palpable lump</p> <p>2=Lump found on clinical exam by health care provider</p> <p>3=Not palpable, detected on screening imaging - mammography</p> <p>4=Not palpable, detected on screening imaging – breast US</p> <p>5=Not palpable, detected on screening imaging – breast MRI</p> <p>6=Not palpable, detected on screening imaging – Other</p> <p>7=Non-breast imaging test</p> <p>8=Unknown</p>
<p>FUP_12MO_CANCERBIOPSY</p>	<p>If cancer, how was the biopsy performed? [taken from BRST_CNCR_BX_PERF from the RA Follow-up Records Assessment form] (<u>numeric, code table</u>).</p> <p>NOTE: If FUP_12MO_CANCER=0 then FUP_12MO_CANCERDATE=.N.</p>	<p>.N=N/A</p> <p>.F=Form not yet submitted</p> <p>.M=Data not available</p> <p>1=Needle biopsy (FNAB or core needle biopsy)</p> <p>2=Surgical biopsy</p> <p>3=Both needle and surgical biopsy</p>

YEAR0_SENSSPEC_REFSTD	<p>Reference standard for cancer (invasive or DCIS) diagnosed through year 1. This variable is needed to estimate the sensitivity and specificity of the year 0 screens. (numeric, code table).</p> <p><i>NOTE: Per consensus from the study team, the reference standard for estimating sensitivity/specificity of the year 0 scans will be defined up to the year 1 imaging. Thus, in addition to year 0 screen-detected cancers, only interval cancers reported during 6-month or 12-month FUP will count. Cancers detected on the year 1 scans, even if done prior to 365 days, will not count.</i></p>	<p>.N=Case did not receive any imaging at baseline, and thus was taken off-study</p> <p>.Q=Case died prior to 11 months</p> <p>.R=Case withdrew prior to 11 months</p> <p>.M=Data unavailable/unresolved/outstanding</p> <p>0=Negative</p> <p>0.5=Negative (no year 1 screening and <11 mos FUP (330 days) from year 0 screen)</p> <p>1=Positive</p>
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