

The below data dictionary is for the EA1141 analysis dataset: “ea1141_6month_fup.sas7bdat”.

This dataset contains one record per participant registered, and is unique by SUBJECT_DE. There are a total of **13** variables contained in this dataset.

Variable name	Variable definition	Code Table/Values
		<p>‘Num’ signifies numeric variable</p> <p>‘Char’ signifies character/text variable</p> <p>Otherwise, variables are numeric with coded values as indicated</p>
SUBJECT_DE	De-identified case number (numeric).	Num
FUP_6MO	<p>Was patient follow-up performed at 6 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>NOTE 2: If FUP_6MO in(0,2,3), then FUP_6MO_REASON is populated.</p>	<p>.N=N/A (case did not have any imaging at baseline)</p> <p>.P= N/A (case was diagnosed with cancer following baseline screening)</p> <p>.R= N/A (case withdrew consent prior to 6 months)</p> <p>.F=Forms not yet submitted</p> <p>0=FUP not performed</p> <p>1=Yes: both patient contact and record assessment</p> <p>2=Yes: only patient contact</p> <p>3=Yes: only record assessment</p>
FUP_6MO_REASON	<p>Reason patient follow-up was not performed at 6 months. (numeric, code table)</p> <p>NOTE: This variable has a value of .N if FUP_6MO=1.</p>	<p>.N=N/A (case was diagnosed with cancer following baseline screening, case did not have any imaging at baseline, or case withdrew consent prior to 6 months, or FUP was performed)</p> <p>.F=Forms not yet submitted</p> <p>1=Patient form not submitted</p> <p>2=RA form not submitted</p> <p>3=No attempt to administer FUP form to patient. RA form not submitted/Record assessment not performed.</p> <p>4=No attempt to administer FUP form to patient. Record assessment performed.</p> <p>5=No response after multiple attempts to contact the patient. RA form not submitted/Record assessment not performed.</p>

		<p>6=No response after multiple attempts to contact the patient. Record assessment performed.</p> <p>7= Patient consented to early version of protocol without 6-month contact. RA form not submitted/Record assessment not performed.</p> <p>8= Patient consented to early version of protocol without 6-month contact. Record assessment performed.</p> <p>9=Patient withdrew consent. Record assessment performed (up to date of withdrawal).</p> <p>10=Site error. Patient contact questions not administered. Record assessment performed.</p> <p>11=Participant/proxy refused follow-up form or failed to return follow-up form. Record assessment performed.</p> <p>12=Participant deceased. Record assessment performed.</p>
FUP_6MO_STATUS	<p>Status of patient follow-up at 6 months (<u>numeric, code table</u>).</p> <p>NOTE: This is derived from both the Follow-up Patient Questions and RA Follow-up Records Assessment forms. In instances where the 6-month patient form indicates that follow-up was not done and the 6-month RA form was not submitted (or indicates that record assessment was not done given that date of record assessment is blank), 1 year follow-up forms were checked.</p>	<p>.N=N/A (case was diagnosed with cancer following baseline screening, case did not have any imaging at baseline, or case withdrew consent prior to 6 months)</p> <p>.F=Forms not yet submitted</p> <p>0=Data not available</p> <p>1=Data available based on 6-month FUP: both patient contact and record assessment</p> <p>2=Data available based on 6-month FUP: only patient contact</p> <p>3=Data available based on 6-month FUP: only record assessment</p> <p>4=Data available based on 1-year FUP: both patient contact and record assessment</p> <p>5=Data available based on 1-year FUP: only patient contact</p> <p>6=Data available based on 1-year FUP: only record assessment</p>
FUP_6MO_DATE_YYYY FUP_6MO_DATE_DAYS	<p>Date of follow-up for 6-month patient contact [taken from the FU_DT variable from the Follow-up Patient Questions form in the Follow-up – 6 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>Num</p> <p>.N=N/A</p> <p>.F=Form not yet submitted</p> <p>.M=Data not available</p>

	<p>NOTE 2: If FUP_6MO_STATUS=0 then this variable is .M. If FUP_6MO_STATUS in(3,6) then this variable is .N.</p>	
FUP_6MO_DATERA_YYYY FUP_6MO_DATERA_DAYS	<p>Date of 6-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 – 6 Months folder] (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 FUP_6MO_STATUS=0 then this variable is .M. If FUP_6MO_STATUS in(2,5) then this variable is .N.</p>	Num .N=N/A .F=Form not yet submitted .M=Data not available
FUP_6MO_CANCER	<p>Cancer status at 6 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] (numeric, code table).</p> <p>NOTE: If FUP_6MO_STATUS=0 then this variable is .M, along with the subsequent cancer variables.</p>	.N=N/A (case was diagnosed with cancer following baseline screening, case did not have any imaging at baseline, or case withdrew consent prior to 6 months) .F=Form not yet submitted .M=Data not available 0=No 1=Yes
FUP_6MO_CANCERDATE_YYYY FUP_6MO_CANCERDATE_DAYS	<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] (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 FUP_6MO_CANCER=0 then FUP_6MO_CANCERDATE_YYYY and FUP_6MO_CANCERDATE_DAYS are .N.</p>	Num .N=N/A .F=Form not yet submitted .M=Data not available
FUP_6MO_CANCERDETECT	<p>If cancer, how was the breast cancer detected? [taken from BRST_CNCR_DTCTN from the RA Follow-up Records Assessment form] (numeric, code table).</p>	.N=N/A .F=Form not yet submitted .M=Data not available 1=Patient detected palpable lump 2=Lump found on clinical exam by health care provider

	NOTE: If FUP_6MO_CANCER=0 then FUP_6MO_CANCERDETECT=.N.	3=Not palpable, detected on screening imaging - mammography
		4=Not palpable, detected on screening imaging – breast US
		5=Not palpable, detected on screening imaging – breast MRI
		6=Not palpable, detected on screening imaging – Other
		7=Non-breast imaging test
		8=Unknown
FUP_6MO_CANCERBIOPSY	If cancer, how was the biopsy performed? [taken from BRST_CNCR_BX_PERF from the RA Follow-up Records Assessment form] (numeric, code table). NOTE: If FUP_6MO_CANCER=0 then FUP_6MO_CANCERBIOPSY=.N.	.N=N/A
		.F=Form not yet submitted
		.M=Data not available
		1=Needle biopsy (FNAB or core needle biopsy)
		2=Surgical biopsy
		3=Both needle and surgical biopsy