

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 |
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| SUBJECT_DE | De-identified case number (<u>numeric</u>). | Num |
| FUP_6MO | Was patient follow-up performed at 6 months? (<u>numeric, code table</u>). <i>NOTE 1: This is derived from both the Follow-up Patient Questions form and the RA Follow-up Records Assessment form.</i> <i>NOTE 2: If FUP_6MO in(0,2,3), then FUP_6MO_REASON is populated.</i> | .N=N/A (case did not have any imaging at baseline) .P= N/A (case was diagnosed with cancer following baseline screening) .R= N/A (case withdrew consent prior to 6 months) .F=Forms not yet submitted 0=FUP not performed 1=Yes: both patient contact and record assessment 2=Yes: only patient contact 3=Yes: only record assessment |
| FUP_6MO_REASON | Reason patient follow-up was not performed at 6 months. (<u>numeric, code table</u>) <i>NOTE: This variable has a value of .N if FUP_6MO=1.</i> | .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) .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. |

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| | | 6=No response after multiple attempts to contact the patient. Record assessment performed. |
| | | 7= Patient consented to early version of protocol without 6-month contact. RA form not submitted/Record assessment not performed. |
| | | 8= Patient consented to early version of protocol without 6-month contact. Record assessment performed. |
| | | 9=Patient withdrew consent. Record assessment performed (up to date of withdrawal). |
| | | 10=Site error. Patient contact questions not administered. Record assessment performed. |
| | | 11=Participant/proxy refused follow-up form or failed to return follow-up form. Record assessment performed. |
| | | 12=Participant deceased. Record assessment performed. |
| FUP_6MO_STATUS | <p>Status of patient follow-up at 6 months (<u>numeric, code table</u>).</p> <p><i>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.</i></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><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></p> | <p>Num</p> <p>.N=N/A</p> <p>.F=Form not yet submitted</p> <p>.M=Data not available</p> |

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| | NOTE 2: If FUP_6MO_STATUS=0 then this variable is .M. If FUP_6MO_STATUS in(3,6) then this variable is .N. | |
| FUP_6MO_DATERA_YYYY FUP_6MO_DATERA_DAYS | 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). 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. NOTE 2: If FUP_6MO_STATUS=0 then this variable is .M. If FUP_6MO_STATUS in(2,5) then this variable is .N. | Num .N=N/A .F=Form not yet submitted .M=Data not available |
| FUP_6MO_CANCER | 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). NOTE: If FUP_6MO_STATUS=0 then this variable is .M, along with the subsequent cancer variables. | .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 | 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). 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. NOTE 2: If FUP_6MO_CANCER=0 then FUP_6MO_CANCERDATE_YYYY and FUP_6MO_CANCERDATE_DAYS are .N. | Num .N=N/A .F=Form not yet submitted .M=Data not available |
| FUP_6MO_CANCERDETECT | If cancer, how was the breast cancer detected? [taken from BRST_CNCR_DTCTN from the RA Follow-up Records Assessment form] (numeric, code table). | .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 |

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| | <p>NOTE: If FUP_6MO_CANCER=0 then FUP_6MO_CANCERDETECT=.N.</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> |
| FUP_6MO_CANCERBIOPSY | <p>If cancer, how was the biopsy performed? [taken from BRST_CNCR_BX_PERF from the RA Follow-up Records Assessment form] (numeric, code table).</p> <p>NOTE: If FUP_6MO_CANCER=0 then FUP_6MO_CANCERBIOPSY=.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> |